ABSTRACT

Angela Ohlhaut.  Effects of Instruction Method on Vital Capacity and Maximum Sustained Phonation in Adult Female Controls  (Under the direction of Kathleen T. Cox, Ph.D.)  Department of Communication Sciences and Disorders, May 2012.

The collection of aerodynamic measurements including vital capacity and maximum sustained phonation is common practice in Speech-Language Pathology to aid in the assessment and treatment of vocal dysfunction.  Current research lacks information regarding the ideal instructions to be given to a patient about how to exhale for vital capacity or what type of feedback is reasonable to provide to a patient during maximum sustained phonation collection.  The purpose of this study is to determine the effect of instruction and visual feedback during the collection of vital capacity and maximum sustained phonation tasks, respectively.

Fifty female participants were included in this study.  Each participant performed a total of 12 maximum sustained phonation tasks.  6 trials were conducted while sustaining the vowel /i/, and 6 trials during the vowel /a/.  For each vowel sound /i/ and /a/, 3 trials received visual feedback from the examiner during collection and 3 did not.  Each participant also performed 6 vital capacity tasks. Participants were instructed to exhale utilizing a “slow” exhalation for half the trials (8-10 seconds) and a “fast” exhalation (3-6 seconds) for the other half.  The order of maximum sustained phonation and vital capacity tasks was randomized for each patient.

Descriptive analyses of the data revealed that instruction and visual feedback provided no practical significance in predicting length of maximum sustained phonation or amount of air exhaled during vital capacity collection.
EFFECTS OF INSTRUCTION METHOD ON VITAL CAPACITY AND MAXIMUM SUSTAINED PHONATION IN ADULT FEMALE CONTROLS

A Thesis

Presented to

the Faculty of the Department of Communication Sciences and Disorders

East Carolina University

In Partial Fulfillment

of the Requirements for the Degree

Master of Science in Communication Sciences and Disorders

By

Angela Ohlhaut

May 2012
EFFECTS OF INSTRUCTION METHOD ON VITAL CAPACITY AND MAXIMUM SUSTAINED PHONATION IN ADULT FEMALE CONTROLS

by

Angela Ohlhaut

APPROVED BY:

DIRECTOR OF THESIS

Kathleen T. Cox, Ph.D.

COMMITTEE MEMBER

Laura Ball, Ph.D.

COMMITTEE MEMBER

Suzanne Hudson, Ph.D.

COMMITTEE MEMBER

Walter E. Pofahl, M.D.

CHAIR OF THE DEPARTMENT OF COMMUNICATION SCIENCES AND DISORDERS

Gregg Givens, Ph.D.

DEAN OF GRADUATE STUDIES

Paul Gemperline, Ph.D.
DEDICATION

To my family:

Thank you for all the wonderful memories from 2909. Thank you for your never-ending love and support throughout my entire life. Thank you especially Mom and Dad for always believing in me and providing endless encouragement and wisdom.

Love,

Angela
ACKNOWLEDGEMENTS

I would like to thank Dr. Cox for sharing her support and vast knowledge of the field throughout this project.

I would like to thank the members of my committee, Dr. Walter Pofahl, Dr. Suzanne Hudson and Dr. Laura Ball, for their guidance and help with this project.
# Table of Contents

LIST OF TABLES......................................................................................................................... ix

I. REVIEW OF THE LITERATURE

Introduction ................................................................................................................................. 1
Vital Capacity ............................................................................................................................ 3
Maximum Sustained Phonation ............................................................................................... 6
Research Questions ................................................................................................................. 9

II. METHODOLOGY

Selection of Participants ............................................................................................................ 12
Operational Definitions ........................................................................................................... 13
Procedures ............................................................................................................................... 14
Specific Instructions for Vital Capacity .................................................................................... 15
Specific Instructions for Maximum Sustained Phonation ....................................................... 16
Data Analysis .......................................................................................................................... 16

III. DEPENDENT AND INDEPENDENT VARIABLES AND STATISTICAL TREATMENT OF THE DATA

Participants .............................................................................................................................. 18
Vital Capacity ........................................................................................................................ 19
Maximum Sustained Phonation ............................................................................................... 21
IV. DISCUSSION

Vital Capacity...........................................................................................................25

Maximum Sustained Phonation...............................................................................25

General Discussions and Clinical Implications.......................................................26

Limitations of the Study.............................................................................................27

Implications for Future Research............................................................................27

Summary and Conclusions.......................................................................................28
LIST OF TABLES

1. Normal Values for Vital Capacity Measurements ............................................. 11
2. Normal Values for Maximum Sustained Phonation ........................................ 11
3. Demographic Information of Female Participants ......................................... 18
4. Variables Collected for Vital Capacity .......................................................... 19
5. Paired Samples T-Test For Vital Capacity ....................................................... 20
6. Means for Maximum Sustained Phonation With and Without Visual Feedback ... 22
7. Paired Samples T-Test For Maximum Sustained Phonation ............................ 22
8. Maximum Sustained Phonation Measurements ............................................... 24
LIST OF FIGURES

1. Vital Capacity Volume ................................................................. 20
2. Maximum Sustained Phonation Time ........................................... 23
CHAPTER I

REVIEW OF THE LITERATURE

Aerodynamics is the study of the motion of air particles. In the realm of speech-language pathology (SLP), aerodynamic analysis of phonation refers to the study of airflow and pressure produced during voicing, and yields indirect physiologic information (Sapienza & Hoffman-Ruddy, 2009; Zraick, Smith-Olinde & Shotts, 2011). Common aerodynamic measures include lung volume and capacities, subglottal air pressure, laryngeal airflow, laryngeal resistance, maximum phonation duration and s/z ratio (Zraick et al, 2011, Stemple, Weinrich & Brehm, 2008; Netsell, Lotz & Shaughnessy, 1984). These measures, in combination with clinician and patient perception, laryngeal imaging, and speech acoustics, provide speech-language pathologists (SLPs) information regarding a client’s vocal quality and can be monitored at an initial evaluation, continuing through voice therapy intervention (Zraick et al. 2011). Yiu’s (2004) research found when 5 trials were conducted per measure, voice condition was reliably predicted up to 91% with aerodynamic measures (Yie, Yuen, Whitehall & Winkworth, 2004). This suggests that voice integrity, potentially related to the overall health of an individual, is closely associated with aerodynamic measures. Many aeroacoustic models exist which relate to the relationship between airflow, pressure, vocal fold vibration, and the acoustic output of the voice. Most systems designed for the collection of aerodynamic analysis consist of a hardware and software system designed to measure airflow and air pressure during voicing (Sapienza et al. 2009).

When one reviews the current literature, though, it is easily seen that there is a lack of specific direction on how aerodynamic measurements should be collected by the SLP. Few
articles can be located that describe in detail the instructions given to a patient about how to exhale for vital capacity (VC) or what type of feedback is reasonable to provide to a patient during these types of vocal tasks. Noting that examiner effects are always a possibility when conducting tests on humans, it is important to document the most appropriate methods of eliciting tasks from patients to ensure validity and reliability of the data. This is especially true for commonly collected measures that clinicians across the profession of SLP utilize on a daily basis. These measures can be found in many evaluation reports, clinical (SOAP) notes, and the criteria may be used for discharge decisions. Thus, it is important that highly utilized measures are scrutinized so that a clinician is fully aware of how to minimize confounding effects to increase validity and reliability. Tests such as VC and Maximum Sustained Phonation (MSP) are common measurements used routinely and documented in protocols such as the Dysphonia Severity Index (Wuyts, F.L., De Bodt, M.S. & Molenberghs, G. et al., 2000).

Two such measures include vital capacity (VC) and maximum sustained phonation (MSP). Defined more specifically later in this paper, VC is the volume of air collected on an exhale and MSP is the length of phonation during a sustained phonation task (Miller, M.R. & Hankinson, J, 2005; Stemple et al., 2008). MSP can also be used to capture acoustic or duration (seconds) data as well. Because VC is related to phonation volume (Kent, 1987), collecting and comparing both is common in the clinic. VC and MSP are commonly used by clinicians to make judgments about breath support and the potential for the pulmonary system to support a good voice quality. While the definition of breath support can be debated (Sapienza & Ruddy, 2009), it is well known that SLPs utilize the term breath support to teach patients how to increase the reservoir of air provided in the lungs as well as for valving and control at the level of the vocal folds. VC is a measure that provides an objective measure of lung volume, while MSP
helps determine how air is being valved by the vocal folds. A large VC paired with a low MSP could indicate that the patient is unable to use all of the air provided by the lungs during a sustained vowel task, for example. Thus, ensuring that these two measures are collected in a manner that increases validity and reliability is of the utmost importance to the voice clinician.

**Vital Capacity**

1. **Definition of vital capacity**
   
   a. Vital capacity is the total amount of air that can be exhaled after a maximum inspiration (Sapienza et al., 2009).
   
   b. VC refers to the max amount of air available for respiration or phonation (Stemple et al., 2008)
   
   c. VC is one of the volumes in the lungs. Other lung volumes include Total Lung Capacity (TLC), Residual Volume (RV), Total Lung Capacity (TLC) (Barreiro, T.J. & Perillo, I., 2004)

**Importance to SLP**

VC, being a test of maximum performance, elicits productions of respiratory volume beyond those used in everyday speech/voice situations. However, reduced capability in performing these tests relates to a possible underlying deficit of the speech system, especially when used extensively or under stressful conditions. VC is of clinical interest for patients experiencing difficulty with adequate respiratory volume who need to produce speech tasks of a more effortful nature such as lecturing, singing, and extensive talking. Improvement of VC may indicate that an individual possesses a larger volume of air from which increased speaking demands may draw upon. This increased “gasoline” for the phonatory system helps the patient
maintain good vocal quality in vocally demanding situations such as lecturing. In addition, VC is helpful in determining if MSP is within normal limits, aerodynamically. It is well documented that the volume of air produced during MSP should be at least 80% of the VC value (Solomon, N.P., Garlitz, S.J., and Milbrath, R.L., 2000; Kent et al., 1987). One popular and highly effective treatment for individuals with dysphonia is the Vocal Function Exercises program (Stemple, J.C., Lee, L., D’Amico, B., Pickup, B, 1994). This program requires adequate performance of MSP, which will thus rely heavily on a good VC. Thus, VC can help predict the effectiveness of VFE (Stemple, J.C., et al., 1994, Sapienza et al, 2009).

Normal VC

In the normal population, VC can be predicted from an individual’s age, sex, and height (Kent et al., 1987; Sapienza et al., 2009). There are numerous studies in the literature which provide normative data for both men and women (Yiu et al., 2004; Kent et al., 1987; Zraick et al, 2011). In one recent study utilizing a newer instrument, the Phonatory Aerodynamic System (PAS) (Stemple et al., 2008), Zraik, et al., (2011) found that 2.87 liters (l) was the mean expiratory volume for females ages 18-39, 2.85 l was the mean expiratory volume for females ages 40-59 and 2.09 l for ages 60-89. For males, they found the norms to be 4.14 l for ages 18-38; 4.19 for ages 40-59, and 3.09 for ages 60-89. (Zraick et al., 2011, p. 10). Table 1 provides data from several studies which documented normal VC values. In addition, the literature also describes abnormal VC values found in certain populations. In 2007, Shaheen et al. found the mean VC of nonsmokers to be significantly greater than that of smokers, in his study of 45 female nonsmokers and 30 female smokers ages 18-30 (p. 629).

Impairment of VC
It is important, too, to clearly document what can impair VC or result in abnormal values during assessment. It is clear that smoking decreases VC as do numerous other pulmonary conditions (Awan, S. & Alphonso, V., 2007). Approximately 15% of cigarette smokers have a declined maximum amount of air exhaled in the first second following a maximal inhalation (forced expiratory volume in one second). This condition is associated with airflow obstruction and possible decreased life expectancy due to chronic obstructive pulmonary disease (Crapo, R., 1994). Awan et al.’s 2007 findings show that decreases in respiratory capacity and control occur in relatively young smokers, who have only smoked for a short time. In addition, examiner influences must be considered carefully as the instructions provided to the patient will likely affect the outcome of a performance based task (Yiu et al., 2004). The effort the patient provides is also likely to influence the outcome of VC. Often collected on individuals with breathing disorders, it is not uncommon to find these individuals are highly fatigued due to their chronic breathing difficulties. Effort may be reduced to generalized fatigue. As decreased VC is often used to predict other measures, it is critical that this measure is collected in the most valid and reliable manner (Evans et al., 2003, Crapo, 1994).

**Methods of Collecting Vital Capacity**

In the pulmonary literature, there is ample definition of various lung volumes and Pulmonary Function Tests (PFTs) used in pulmonary assessment. For example, Forced expiratory volume (FEV) is often discussed in terms of 1 second or 5 seconds. (Crapo, 1994; Miller et al, 2005; Solomon et al., 2000). This is not true for VC, likely because the definition is of a complete exhalation. One would imagine it is more critical to get all the air out, than to get it out in a certain time frame. However, it is possible that duration of exhalation of VC could have
an effect on its value and a recommended exhalation length should be determined for this very important task.

As stated earlier, there is clear documentation of normal values of VC in the literature. Few of these studies, though, report the exact manner in which VC was collected. While nearly all of them indicate that VC was collected on an exhale, few indicate the duration of the exhale. Zraik, et al. (2011) described that the mean expiratory airflow duration of their participants was 3.75. However, it is not clear if they were given instructions to maintain the exhale at this duration or if told to exhale for less than 5 seconds for example. Zraick’s 2011 research article suggests that no such timing restrictions were considered. Participants were instructed to inhale maximally, and exhale into the facemask, with no consideration of the duration of the exhale. Miller et al. (2005) mentions that when collecting vital capacity the exhalation should not be excessively slow in order to avoid obtaining a vital capacity that is less than the person’s true measurement. However, no criterion is provided to define what is considered excessively slow. He suggests that in healthy individuals, 5-6 seconds is an appropriate amount of time to collect vital capacity. Thus, it is clear that more explanation of the duration of exhalation during VC tasks is necessary.

**Maximum Sustained Phonation (MSP)**

Maximum Sustained Phonation (MSP) is the longest amount of time which phonation can be sustained on a vowel sound, most typically /a/, though /i/ and /u/ are also used (Kent, 1987). Sustaining the phonemes /s/ and /z/ for as long as possible is also a MSP task (Treole & Trudeau, 1997; Kent et al. 1987; Zraick et al. 2011; Solomon et al. 2000). MSP is also referred to as Maximum Phonation Duration. MSP is a universally accepted clinical task in SLP for the
assessment of the respiratory and phonatory systems (Schmidt, P., Klingholz, F. & Martin, P., 1988; Solomon et al., 2000; Kent, 1987). It is considered a maximum performance task in that it measures a person’s ability to efficiently manage an adequate air supply during phonation. Frequency, sound pressure level, and airflow measurements can be obtained during a sustained vowel (Stemple, et al. 2008). An individual’s MSP length is supported by an increased vital capacity measurement.

**Importance to SLP**

MSP is a helpful clinical tool because it is simple to obtain in a clinical setting, yet it provides an estimate of vocal proficiency (Treole, et al. 1997, Schmidt et al., 1988). Schmidt et al. (1988) cites several clinical observations which found a correlation between MSP value and organic and functional voice disorders. Solomon et al. (2000) note that MSP has been found to be inversely related to the severity of a disorder. Information obtained from an MSP task relates to vocal fold function, respiratory support and is useful in pre/post therapeutic measures (Stemple et al., 2008).

**Normal MSP**

The mean value in seconds for MSP in normal populations has been well documented. Table 2 provides a sample of these data. Most recently, Zraick et al., (2011) found that normal values for 18-39 year olds was 17.69 seconds, with a standard deviation of 5.81. Kent et al.’s (1987) study summarized various normative data studies regarding MSP which show variability in outcomes, however; duration for male performance was consistently longer than female. There are many influences on MSP, including: age, sex, stature, physical characteristics of the respiratory system, glottal conditions, pitch, loudness, vowel quality, breath control, voice
training and emotional state (Schmidt et al., 1988; Kent et al., 1987; Treole et al., 1997, Crapo, 1994; Zraick, 2011).

**Impairment of MSP**

MSP is an important health indicator because it aids in quantifying how the respiratory system coordinates with the phonatory system (Awan et al., 2007). Awan et al.’s 2007 research found nonsmokers produced significantly longer phonation times as well as a lower rate of airflow than nonsmokers during controlled maximum phonation task. Additionally, the overall mean MSP for smokers fell below the normal mean, as previously defined in this article as well as several others.

**Methods of Collecting MSP**

When collecting MSP, the person is instructed to inhale as much as possible, choose a comfortable level of voice sound pressure and pitch, and sustain the target phoneme for as long as possible (until there is no air left in the lungs) (Kent et al., 1987, Schmidt et al., 1988, Solomon et al., 2000, Treole et al., 1999, Zraick et al., 2011). Sometimes the patient is given a pitch to match, but often the patient self-selects the fundamental frequency after being told to produce a comfortable pitch. The maximum duration is obtained over several trials and compared to normative data, yielding an approximation of respiratory and phonatory function (Solomon et al., 2000).

Solomon et al. (2000) observes that due to the heavy reliance on client performance, the validity of MSP as a reliable clinical assessment task has been challenged. Treole et al. (1997) states that the information gained with MSP only shows what a person is capable of at a given moment, and cautions the use of MSP tasks. However, Finnegan (1984) found that MSP is
enhanced by the use of visual feedback. This suggests that visual feedback has the effect of increasing length of phonation. It is not plausible to accurately measure the level of client effort, however, the use of visual feedback has the possibility to encourage clients to perform to their maximum ability and alleviate varying client effort levels. Miller et al.’s 2005 (Miller, M.R. & Hankinson, J., 2005) study suggests that the most important aspect in proper collection of pulmonary function testing is the enthusiasm and motivation of the collector. It is plausible that clients do now perform to their maximum ability, but with a desire to perform better, improve their performance (Kent et al., 1987).

The KayPENTAX Phonatory Aerodynamic System (PAS) has the capability to obtain phonatory acoustic and aerodynamic measurements. It consists of a hardware and software system. Results obtained can be analyzed to monitor phonatory function during speech. Through the use of a pneumotachograph facemask, oral airflow is collected at the mouth and sound distortion is minimized along with and loss of high frequency fidelity. This information is then measured and analyzed by the software system. Possible data collection measurements include frequency, sound pressure, airflow and air pressure (Sapienza et al., 2009; Stemple et al., 2008; Zraick et al., 2011)

**Research Questions**

It is thus clear that the methods of collecting VC and MSP need continued investigation to ensure that SLP professionals are obtaining the most reliable and valid data during patient assessments. Therefore, the following research questions will be investigated:

1. Does method of instruction have an effect on vital capacity?
a. It is predicted that VC collected in a fast method (shorter duration) will correlate better with normative data than vital capacity collected in a slow method (longer duration).

2. Does the presence of visual feedback have an effect on maximum sustained phonation?
   a. MSP collected with visual feedback will exceed MSP collected without visual feedback.
   b. There will be no difference in MSP /a/ compared to MSP /i/ for either condition, visual feedback or no visual feedback.
### Table 1

*Normal Values for Vital Capacity Measurements*

<table>
<thead>
<tr>
<th>Study</th>
<th>Female VC (18-39 years)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awan, et al. (2007)</td>
<td>3.35 liters</td>
<td>Results are average of 3 trials of females between 18-30</td>
</tr>
<tr>
<td>Zraik, et al., (2011)</td>
<td>2.87 liters</td>
<td>Females between 18-39</td>
</tr>
</tbody>
</table>

### Table 2

*Normal Values for Maximum Sustained Phonation*

<table>
<thead>
<tr>
<th>Study</th>
<th>Female MSP (18-39 years)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awan, et al. (2007)</td>
<td>21.49 seconds</td>
<td>Results are average of 3 trials of females between 18-30</td>
</tr>
<tr>
<td>Zraik, et al., (2011)</td>
<td>17.69 seconds</td>
<td>Females between 18-39</td>
</tr>
</tbody>
</table>
CHAPTER II

METHODOLOGY

This chapter will provide information on the participant selection procedures used to evaluate different methods for collecting vital capacity and mean phonation duration.

Selection of Participants

Fifty female participants, ages 18-39, were recruited for this study. This age group was chosen to be able to compare to a recently published normative study (Zraick, Smith-Olinde, & Shotts, 2011). Participants were recruited through email advertisements across East Carolina University, classroom announcements in the Department of Communication Sciences and Disorders and through flyers hung throughout the Health Sciences Building, East Carolina University. Eligibility requirements included the following: participants had to have no previous diagnoses of laryngeal/voice disorders, respiratory/lung disorder, or neurological disorders. Smoking status was not an exclusionary criteria, however, those with respiratory/lung disorders were not eligible. Participants needed to report feeling healthy on the day of the testing with no illness such as an upper respiratory infection or cough. Additionally, pregnant women, children and prisoners were not eligible.

Advertising instructed the participants to contact either Dr. Kathleen T. Cox or Angela Ohlhaut to discuss participation. During this phone call or email exchange, the participant was given an explanation of the study and if via email, a copy of the informed consent form was emailed to the potential participant. Phone contacts were asked if an email could be used to send an informed consent form. This was done if the participant agreed. The informed consent form was sent to as many potential participants as possible. During this initial contact, participants
were asked if there was a history of voice/laryngeal, respiratory/lung, or neurological disorders. These diagnoses, along with the possibility of pregnancy, were discussed and the participant was enrolled if none of these issues were affirmed. The participants were then given an appointment at their convenience to come to the Voice & Swallowing Lab of the Department of Communication Sciences and Disorders (Health Sciences Bldg, Suite 2310J).

During this appointment, all appropriate informed consent procedures were completed and participants were asked to sign an informed consent document (Appendix A) and were given a copy. Testing (described in a later section) began after the participant had ample time to read, review, and sign the informed consent form and ask questions. The total time present in the testing session averaged 30-45 minutes per participant. All IRB guidelines were adhered to throughout the course of this study.

**Operational Definitions**

For the purposes of this study, **aerodynamic analysis** refers to the measurement of the airflow stream produced during voicing or breathing. This is done by collecting a voice or breathing sample through a facemask which is designed to capture the air stream out of the nose and mouth. These signals are measured through a computerized system that produces an output (i.e., printout) with numerical data representing an analysis of the components of the airflow signal. The tool used was the Phonatory Aerodynamic System (PAS) (KayPentax, Inc., Lincoln Park, NJ). See photograph in Appendix B.

**Vital capacity (VC)** is defined as the volume of air completely exhaled after a maximal inhalation (Ruppel, 1998). It is routinely defined as a slow, complete exhalation (Crapo, 1994;
Zraick 2011). Current literature (Yiu et al., 2004; Kent et al., 1987; Zraick et al, 2011) indicates a normal range for this age group to be 2.5-4 liters.

**Force vital capacity (FVC)** is defined as exhalation as forcefully and quickly as possible following a maximal inhalation (Ruppel, 1998). For the purposes of this study, FVC was not performed and if a participant produced a VC task that was too forced, the trial was not counted and the participant was reinstructed in the VC procedures.

**Maximum sustained phonation (MSP)** is defined as phonation on a vowel sound (/a/ or /i/) for as long as possible following a maximal inhalation. Current literature (Kent, 1987; Zraick, 2011) indicates a normal range for this age group to be greater than 15 seconds.

**Procedures**

The Phonatory Aerodynamic System (PAS) – The PAS (KayPentax, Inc., Lincoln Park, NJ) provides data about the aerodynamic functions of the larynx (voice box) during voicing and breathing. PAS is capable of calculating aerodynamic measurements such as vital capacity, phonatory flow rate, sound pressure level, fundamental frequency (Fo), glottal resistance, subglottal pressure and efficiency measurement. A more descriptive explanation of the PAS is eloquently provided in Zraick, et al., 2011. All measurements are collected as the participant holds a facemask to the nose and mouth. This mask is removed in between tasks or when the participant requires a break. After appropriate training and explanation the participant performs several tasks, including the following:

a. 3 trials of vital capacity (VC) using the “short” method of instruction (VCS)

b. 3 trials of VC using the “long” method of instruction (VCL)

c. 3 trials of maximally sustained /a/ with no visual feedback (NVFa)
d. 3 trials of maximally sustained /a/ with visual feedback (VFa)
e. 3 trials of maximally sustained /i/ with no visual feedback (NVFi)
f. 3 trials of maximally sustained /i/ with visual feedback (VFı)

All trials were completed in a randomized order to control for order effects. All tasks were trained prior to the collection of data. The examiner modeled the tasks for the participant and the participant then produced the training trials. The participant was asked to hold the facemask up to the mouth and nose during production of the aforementioned tasks and was able to remove it at will at any time. The participant was able to inhale and exhale through the facemask, but most patients removed the facemask during breaks and in between tasks. The facemask is hand-held and the participant is in total control of its placement. The air tight seal around the facemask where it makes contact with the skin was check prior to each task and the examiner continued to monitor this during tasks.

**Specific Instructions for Vital Capacity Tasks**

There were two methods of collecting vital capacity: fast and slow. In the SLOW (VCS) method, the participant was asked to fully inhale, place the facemask up to the face, and exhale completely for as close to 10 seconds as possible. For this trial to be accepted, the participant had to exceed 7 seconds and was encouraged to exhale towards 10 seconds. If the participant exceeded 10 seconds, that was acceptable. Trials that were less than 7 seconds were eliminated and the participant was reinstructed in the slow method. In the FAST (VCF) method, the participant was asked to fully inhale, place the facemask up to the face, and exhale completely within 5 seconds. The participant was instructed to take longer than 2 seconds, but
not to exceed 5 seconds. Trials that were less than 2 seconds were eliminated and the participant was reinstructed in the fast method. Time was monitored by both participant and examiner via the PAS system output monitor. For either method, the examiner did not provide any feedback during exhalation. Data collected for vital capacity tasks was volume in liters, duration in seconds, and peak expiratory flow in liters/second.

**Specific Instructions for Maximum Sustained Phonation**

There were two methods of collecting MSP: visual feedback and no visual feedback. In the visual feedback method (VFA for the /a/ vowel and VFI for the /i/ vowel) the participant was instructed to inhale maximally, place the facemask to the face, and produce an /a/ vowel at a self-selected pitch and decibel level. The examiner used a hand signal visual input (a hand pulling towards the examiner to indicate, “more, more” so to speak) to encourage the participant to continue phonating for as long as possible. The examiner did not speak at all during this production. In the no visual feedback method, the procedures were exactly the same as the visual feedback method except the examiner did not provide the hand gesture. The examiner sat still observing the screen of the PAS instead. Data collected during these tasks included duration in seconds, mean sound pressure level in dB, mean expiratory airflow in liters/second, and mean fundamental frequency in Hz (cycles/second).

**Statistical Analyses**

Descriptive statistics and significance studies were used to describe the participant pool and the overall nature of the data. Means and standard deviations were calculated when appropriate. T-tests were used to determine if a statistical difference existed between the relationship between length of phonation time and presence of visual feedback as well as the
relationship between volume of air exhaled and length of exhalation. *P*-values were used to determine significance in the means for the two conditions at the point 0.05 level.
CHAPTER III

DEPENDENT AND INDEPENDENT VARIABLE AND STATISTICAL TREATMENT OF THE DATA

The present study examined the influence of timing factors on the collection of vital capacity measurements. It also examined the influence of visual feedback for collecting maximum sustained phonation. Descriptive statistics and significance tests were used to examine the relationship between the response and explanatory variables. Dependent variables were the volume of air exhaled for vital capacity tasks and the length of phonation for maximum sustained phonation. Every participant completed three trials per variable in the study. These three trials were then averaged together in order to obtain a mean. The means were used in the statistical analysis. Paired sample t-tests were used to determine if there were statistically significant differences in the means of the response variables under the different conditions.

There were 50 participants total, between the ages of 19 and 38. The average age of participants was 23. The average height of participants was 64.98 inches, with a standard deviation of 2.3 inches.

Table 3

Demographic Information of Female Participants

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>64.978 inches</td>
</tr>
<tr>
<td>Age</td>
<td>23 years</td>
</tr>
</tbody>
</table>
**Vital Capacity**

Table 4 illustrates the data for the two conditions for vital capacity: fast and slow exhalation. The mean volume for the fast exhalation was 2.82 liters (L) with a standard deviation of 0.8751 liters. The mean for the slow exhalation was 2.821 L with a standard deviation of 0.8732 L. Figure 1 illustrates the data for vital capacity, showing the sample minimum, first quartile, median, third quartile, maximum. The outliers are indicated as points above or below the boxplot. The highest volume collected under the fast condition was 4.9 L, and the lowest volume was 0.93 L. The highest volume collected for the slow exhalation was 4.69 L, and 0.77 L was the lowest volume collected. Table 5 shows the results of the paired samples t-test. The numbers shown represent the difference between the average volume for the two conditions, fast and slow. The $P$-value, 0.987, is given in the final column. The $P$-value is large which indicates that there is not a statistically significant difference in the mean vital capacities under the two conditions.

Table 4

*Variables Collected for Vital Capacity*

<table>
<thead>
<tr>
<th>Condition</th>
<th>Mean (in Liters)</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast Exhalation</td>
<td>2.82</td>
<td>0.8751</td>
</tr>
<tr>
<td>Slow Exhalation</td>
<td>2.821</td>
<td>0.8732</td>
</tr>
<tr>
<td>Difference in Means (Fast minus Slow)</td>
<td>-0.010</td>
<td>0.4390</td>
</tr>
</tbody>
</table>
Table 5

Paired Samples T-Test For Vital Capacity

<table>
<thead>
<tr>
<th>Pair</th>
<th>VCFVolume</th>
<th>VCSVolume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paired Differences</td>
<td>Mean</td>
<td>Std. Deviation</td>
</tr>
<tr>
<td>VCFVolume - VCSVolume</td>
<td>-0.00103</td>
<td>0.4390</td>
</tr>
</tbody>
</table>

Figure 1

Vital Capacity Volume
**Maximum Sustained Phonation**

Each participant performed 12 maximum sustained phonation task in total. Six trials were performed sustaining the vowel /i/, 3 trials with visual feedback and 3 trials without visual feedback. Six trials were performed sustaining the vowel /a/, 3 trials with visual feedback and 3 trials without visual feedback. Table 6 shows the findings for the two conditions under which maximum sustained phonation was collected (with and without visual feedback) for vowel sounds /i/ and /a/. For the /i/ vowel, the average phonation time without visual feedback was 17.971 seconds, and the average phonation time with visual feedback was 18.436 seconds. For the /a/ vowel, the average phonation time without visual feedback was 18.779 seconds, and the average phonation time with visual feedback was 18.803 seconds. Figure 2 shows the sample minimum, first quartile, median, third quartile, maximum for maximum sustained phonation findings. The longest finding for the /i/ sound with visual feedback was 27.18 seconds and 7.84 seconds was the shortest time found. For the /i/ sounds without visual feedback, 7.26 seconds was the shortest time, and 27.34 seconds was the longest time found. For the /a/ sound with visual feedback, 7.59 seconds was the shortest duration and 28.99 seconds was the longest. For the /a/ sound without visual feedback, 28.98 seconds was the longest and 8.73 seconds was the shortest time found.

Table 7 shows the results of paired samples tests for the two vowels /i/ and /a/ with and without visual feedback. The numbers shown represent the differences in the means for the conditions. The $P$-values in the last column, 0.127 for /i/ and 0.929 for /a/, show that differences in the means for two conditions are not statistically significant at the 0.05 level.
Table 6

**Means for Maximum Sustained Phonation With and Without Visual Feedback**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Mean (in seconds)</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>/i/ without Visual Feedback</td>
<td>17.971</td>
<td>4.687</td>
</tr>
<tr>
<td>/i/ with Visual Feedback</td>
<td>18.436</td>
<td>4.944</td>
</tr>
<tr>
<td>Difference in Mean (/i/ with and without visual feedback)</td>
<td>0.465</td>
<td>2.117</td>
</tr>
<tr>
<td>/a/ without Visual Feedback</td>
<td>18.779</td>
<td>4.919</td>
</tr>
<tr>
<td>/a/ with Visual Feedback</td>
<td>18.803</td>
<td>4.836</td>
</tr>
<tr>
<td>Difference in Mean (/a/ with and without visual feedback)</td>
<td>0.025</td>
<td>1.942</td>
</tr>
</tbody>
</table>

Table 7

**Paired Samples T-Test For Maximum Sustained Phonation**

<table>
<thead>
<tr>
<th>Pair</th>
<th>Paired Differences</th>
<th>Std. Deviation</th>
<th>Mean</th>
<th>Std. Error</th>
<th>95% Confidence Interval of the Difference</th>
<th>t</th>
<th>df</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pair 1 MSiVFTime - MSiTime</td>
<td>.46460</td>
<td>2.11661</td>
<td>.29933</td>
<td>-.13693</td>
<td>1.06613</td>
<td>1.552</td>
<td>49</td>
<td>.127</td>
</tr>
<tr>
<td>Pair 2 MSaVFTime - MSaTime</td>
<td>.02460</td>
<td>1.94204</td>
<td>.27465</td>
<td>-.52732</td>
<td>.57652</td>
<td>.090</td>
<td>49</td>
<td>.929</td>
</tr>
</tbody>
</table>
Table 3 shows the results of the difference in the means for sound pressure level, sound pressure level during voicing, pitch and airflow. Sound pressure is the magnitude of change in the atmospheric pressure caused by the vibration of the sound source. Pitch is dependent on the frequency of sound and allows sounds to be placed on a scale from low to high (Emanuel et al. 2009). Airflow refers to the average airflow produced during sustained vowel production; this provides a general idea of laryngeal function (Sapienza et al. 2009)
Table 8

*Maximum Sustained Phonation Measurements*

<table>
<thead>
<tr>
<th>Condition (with minus without visual feedback)</th>
<th>Sound pressure level (Decibel)</th>
<th>Sound pressure level during voicing (Decibel)</th>
<th>Pitch (Hertz)</th>
<th>Airflow (Liters/Second)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference in Means for /i/</td>
<td>-0.337</td>
<td>0.212</td>
<td>0.588</td>
<td>-0.005</td>
</tr>
<tr>
<td>Difference in Means for /a/</td>
<td>0.642</td>
<td>-0.086</td>
<td>1.971</td>
<td>-0.056</td>
</tr>
<tr>
<td>Difference in Standard Deviation for /i/</td>
<td>14.903</td>
<td>1.362</td>
<td>9.382</td>
<td>0.685</td>
</tr>
<tr>
<td>Difference in Standard Deviation for /a/</td>
<td>13.948</td>
<td>8.044</td>
<td>11.631</td>
<td>0.472</td>
</tr>
</tbody>
</table>
Chapter IV

DISCUSSION

The purpose of the present study was to determine the effect of timing components and visual feedback in healthy adult females for vital capacity and maximum sustained phonation tasks, respectively. Prior to data collection, the investigators formed several hypotheses. The first research question was to determine if the length of exhalation during the collection of vital capacity tasks affected the amount of air exhaled. The second question was developed to determine if the presence of visual feedback affected the duration of a sustained vowel sound during maximum sustained phonation tasks.

**Vital Capacity**

We collected vital capacity under two conditions: fast and slow exhalation. Zraick’s 2011 research found the mean vital capacity for females age 18-39 to be 2.87 liters. In the current study, the average amount of air collected under the fast condition, defined as an exhalation lasting between 3-5 seconds was 2.773 liters. The slow condition, defined as an exhalation lasting between 8-10 seconds had an average of 2.73 liters. The difference in the amount of air exhaled under each condition does not demonstrate statistical significance.

**Maximum Sustained Phonation**

A total of 12 maximum sustained phonation trials were performed. 6 trials were performed on the vowel /a/, and 6 trials on /i/. For each vowel sound, the examiner provided visual feedback for 3 trials and did not provide visual feedback for 3 trials. In 2011 Zraick et al. found the mean maximum sustained phonation time for females between the ages of 18-39 to be
17.69 seconds. This study found the mean time for the vowel /i/ without visual feedback to be 18.171, and the mean time for /i/ with visual feedback to be 18.656. For the vowel /a/, the mean time without visual feedback was 19.046 seconds, and the mean time with visual feedback was 18.985 seconds. The difference between these times for both vowels /a/ and /i/ does not demonstrate statistical significance.

**General Discussions and Clinical Implications**

As previously discussed, both maximum sustained phonation tasks and vital capacity measures are an important aspect of the practice of Speech-Language Pathology. The accuracy and reliability of these measures is therefore crucial. The findings from this study suggest that method of instruction and visual feedback do not significantly impact results.

Clinicians can apply the findings from this study into their everyday clinical tasks. When collecting vital capacity, clinicians should encourage patients to exhale for a duration that is best suited for that individual. Other aspects of this clinical task should be of a higher priority than the length of the exhalation. Clinicians should focus on the patient’s comprehension of the importance of inhaling to full capacity and releasing all air from the lungs, rather than the length of the exhalation. Clinicians can use these findings to their advantage by individualizing task instruction.

Our findings imply that the collection of maximum sustained phonation is not affected by a clinician’s use of visual feedback, which means the presence of visual feedback will neither increase nor decrease a patient’s phonation length. When collecting maximum sustained phonation, clinicians should use their clinical judgment regarding the use of visual feedback. This study only examined the effect visual feedback has on phonation length, it is possible that
visual feedback affects other aspects besides phonation length. Perhaps in some instances the clinician might chose to provide visual feedback to a patient who seems to be having difficulty comprehending the task.

**Limitations of the Study**

The limitations of this study need to be addressed before replication is considered. Many of the participants in the study were Speech-Language Pathology graduate or undergraduate students. It is possible that a familiarity with aerodynamic testing affected outcomes.

For maximum sustained phonation, it is possible that visual feedback did not significantly affect phonation time because the participants were fully aware of the importance of putting forth a maximum effort, and did require visual feedback to do so. It is possible that visual feedback provided to a population less familiar with maximum sustained phonation measurements would have an effect on phonation length.

Regarding vital capacity, it is possible that participants’ knowledge of the collection of vital capacity influenced results. Although instructed to exhale for either a “fast” or “slow” time, it is possible that participants’ knowledge of the task influenced the amount of air exhaled under these two conditions. For those who are less familiar with vital capacity measurements, perhaps timing components would have a greater influence of the amount of air exhaled.

**Implications for Future Research**

Compared to the current literature, this research offered insight into the collection methods of maximum sustained phonation and vital capacity.
The effect of visual feedback on length of phonation was the only aspect considered in this study. Future research should investigate the influence of visual feedback on other aspects of maximum sustained phonation. As mentioned previously, it is possible that visual feedback influences patient comprehension of task. It is also possible that visual feedback increases a patient’s overall comfort with the task.

The current study examined the use of visual feedback. Future research should investigate verbal feedback, and a combination of both visual and verbal feedback. Finnegan’s 1984 research found that visual feedback did increase the length of phonation. The effect of both verbal and visual, or verbal feedback alone on phonation length should be investigated.

Regarding vital capacity, future research may consider adjusting the defined parameters of “fast” and “slow”. Research which investigates these numbers using a different time frame to describe the two parameters may find timing aspects have an influence of amount of air exhaled.

**Summary and Conclusions**

Data analysis demonstrated that the variables investigated in the current study did not demonstrate statistical significance in either the length of maximum sustained phonation tasks or the amount of air exhaled during the collection of vital capacity. Although these findings were not statistically significant, the knowledge gained from this study may still be applicable to clinical application during the collection of aerodynamic measurements.
REFERENCES


TO: Kathleen T. Cox, PhD, Department of CSDI, ECU, Mailstop #668

FROM: UMCIRB

DATE: June 23, 2011

RE: Expedited Category Research Study

TITLE: “Effects of instruction on phonatory aerodynamic values”

UMCIRB #11-0385

This research study has undergone review and approval using expedited review on 6/22/11. This research study is eligible for review under an expedited category number 4 & 6 where this is a collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, retinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. Also, this is a collection of data from voice, video, digital, or image recordings made for research purposes. 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 6/22/11 to 6/21/12. The approval includes the following items:

- Internal Processing Form (dated 5/25/11, received 6/7/11)
- Informed consent (dated 6/6/11)
- COI disclosure form (dated 6/6/11)
- Recruitment flyer

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.
Informed Consent to Participate in Research
Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: Effects of instruction on phonatory aerodynamic values

Principal Investigator: Kathleen T. Cox, PhD, CCC-SLP
Institution/Department or Division: East Carolina University, Department of Communication Sciences & Disorders
Address: Health Sciences Bldg, Suite 3310, Mailstop 668, Greenville, NC 27858
Telephone #: 252-744-6085

Researchers at East Carolina University (ECU) study problems in society, health problems, environmental problems, behavior problems and the human condition. Our goal is to try to find ways to improve the lives of you and others. To do this, we need the help of volunteers who are willing to take part in research.

Why is this research being done?
The purpose of this research is to study how changes in methods of instruction affect the amount of air a person can exhale when breathing or talking. The decision to take part in this research is yours to make. By doing this research, we hope to learn the most effective way to collect lung volumes in respiratory and voice testing situations.

Why am I being invited to take part in this research?
You are being invited to take part in this research because you are a healthy volunteer. If you volunteer to take part in this research, you will be one of about 100 people to do so.

Are there reasons I should not take part in this research?
You should not take part in this research if you have a known voice, breathing or neurological disorder or are pregnant.

What other choices do I have if I do not take part in this research?
You can choose not to participate. Participation or choosing not to participate in this study does not affect your work, education, or patient care at East Carolina University.

Where is the research going to take place and how long will it last?
The research procedures will be conducted in Room 2310J of the Health Sciences Building on the Health Sciences Campus of East Carolina University. You will need to come to testing only one time during the study. The total amount of time you will be asked to volunteer for this study is approximately 30 minutes on one day.

What will I be asked to do?
You are being asked to do the following: First, you will be asked to consent to the research study and will sign informed consent forms. Testing then will consist of you holding a face mask up to your nose and mouth. This mask is removable by you at any time. You can breathe and talk with the mask on. You will be asked to perform several

UMCIRB Number: 11-0385

Consent Version 6/6/2011
UMCIRB Version 2010.05.01

FROM TO__

UMCIRB APPROVED

Participant's Initials
Title of Study: Effects of Instruction on Phonatory Aerodynamic Values

tasks including exhaling completely at a fast rate, a slow rate and exhaling while producing three sounds /a, s, eee/. You will be shown how to produce these tasks and will be given time to practice and answer questions. You will perform each task 3 times after practice and questions. Your lung volume (air during exhalation) will be measured by a computer during the tasks.

What possible harms or discomforts might I experience if I take part in the research?
It has been determined that the risks associated with this research are no more than what you would experience in everyday life.

What are the possible benefits I may experience from taking part in this research?
We do not know if you will get any benefits by taking part in this study. This research might help us learn more about the best ways to collect breathing data from patients with lung disorders and voice disorders. There may be no personal benefit from your participation but the information gained by doing this research may help others in the future.

Will I be paid for taking part in this research?
No, we will be unable to pay you for your participation.

What will it cost me to take part in this research?
It will not cost you any money to be part of the research.

Who will know that I took part in this research and learn personal information about me?
To do this research, ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- Any agency of the federal, state, or local government that regulates human research. This includes the Department of Health and Human Services (DHHS), the North Carolina Department of Health, and the Office for Human Research Protections
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff, who have responsibility for overseeing your welfare during this research, and other ECU staff who oversee this research.

How will you keep the information you collect about me secure? How long will you keep it?
All data will be housed on the computer in the testing room, but your name will not be in this computer. A participant number will be in the computer along with your data. Your name and the participant number will be linked on a list kept in the office of Dr. Kathleen T. Cox. Once data has been analyzed statistically (approximately January, 2012), the list of participants’ names and numbers will be shredded. The actual data from the computer will be unable to be linked back to your name.

What if I decide I do not want to continue in this research?
If you decide you no longer want to be in this research after it has already started, you may stop at any time. You will not be penalized or criticized for stopping. You will not lose any benefits that you should normally receive.

Who should I contact if I have questions?
The people conducting this study will be available to answer any questions concerning this research, now or in the future. You may contact the Principal Investigator at 252-744-6085 (days, between 9:00 AM – 5:00 PM)
If you have questions about your rights as someone taking part in research, you may call the Office for Human Research Integrity (OHRI) at phone number 252-744-2914 (days, 8:00 am-5:00 pm). If you would like to report a complaint or concern about this research study, you may call the Director of the OHRI, at 252-744-1971

Is there anything else I should know?
You are welcome to request a drink of water at any time during the testing and also may request a break, such as for the restroom. Testing can take longer than 30 minutes if you would prefer breaks.

I have decided I want to take part in this research. What should I do now?
The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

<table>
<thead>
<tr>
<th>Participant's Name (PRINT)</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

Person Obtaining Informed Consent: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person’s questions about the research.

<table>
<thead>
<tr>
<th>Person Obtaining Consent (PRINT)</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>
IMPORTANT INFORMATION

Continuing and Final Review Obligations

As Principal Investigator, you are required to submit a continuing or final review form to the Office for Human Research Integrity for IRB review. This is a federal requirement to continue or close your research study before the date of expiration as noted on the attached approval letter. This information is required to summarize the research activities since it was last approved. The regulations do not permit any research activity outside of the IRB approval period. Additionally, the regulations do not permit the UMCIRB to provide a retrospective approval during a period of lapse.

You must submit this form even if there has been no activity, no participants enrolled or you do not wish to continue the activity any longer. Research studies that are allowed to be expired will be reported to the Vice Chancellor for Research and Graduate Studies, along with relevant other administration within the institution. The continuing or final review form is located on our website at http://www.ecu.edu/rgs/irb/ along with our meeting submission deadlines. Please contact the UMCIRB office at 252-744-2914 if you have any questions regarding your role or requirements with continuing review.

Required Approval for Any Changes to IRB-Approved Research

As Principal Investigator, you are required, prior to making any changes in your research study must have those changes reviewed and approved by the IRB. The only exception is when those changes are to eliminate an immediate apparent hazard to the participant. In the case when changes must be immediately undertaken to prevent a hazard to the participant and there is no opportunity to obtain prior IRB approval, the IRB must be informed of the changes as soon as possible via a protocol deviation form.

Reporting Unanticipated Problems to the IRB that Affect Participants or Others

As Principal Investigator, you are required to report to the IRB all unanticipated problems that have occurred in your research within the time frame specified in the UMCIRB rule for reporting Unanticipated Problems Involving Risks to Participants or Others.