SUBJECTIVE NURSING ASSESSMENT OF COUGH EFFORT

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BY

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Date

To the Associate Vice President for Research
and Dean of the Graduate School:

I am submitting herewith a thesis written by Huberta T. Cozart entitled "Subjective Nursing Assessment of Cough Effort." I have examined the final copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science, with a major in Nursing.

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DEDICATION

This academic pursuit is lovingly dedicated to the memory of
my mother, Mrs. Camila Apiado Thiam,
who provided me an exemplary model of faith,
integrity, hard work, and determination.

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SUBJECTIVE NURSING ASSESSMENT
OF COUGH EFFORT

ABSTRACT

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Decisions to wean patients from mechanical ventilation (MV) often are based on nurses' bedside assessment of cough effort intensity (CEI). A repeated measures correlational design was used. For equivalence and stability reliabilities, three nurses ($\underline{N}$ = 243) subjectively rated the MV patient's ($\underline{N}$ = 62) CEI twice on 3 days. For construct validity, the patient's average CEI was correlated with each day's vital capacity (VC) and negative inspiratory pressure (NIP) measured by respirometers and negative inspiratory force meters. Using percentage agreement (H_1) and Spearman rho correlation coefficients (H_2, H_3, H_4), results failed to demonstrate adequate reliability and validity of CEI. Critical care and intermediate care nurses' subjective assessment of CEI in MV and post-extubated patients did not meet established criteria for equivalence and stability reliability. CEI was poorly correlated with VC and NIP.

Findings suggest subjective nursing assessments of cough effort should not be used as indicators of patient readiness to wean from MV.

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CHAPTER 1

INTRODUCTION

Cough is a captivating subject for many researchers; it has been referred to in a plethora of ways. The Arabic physician Maimonides, in 1190, alluded to cough's protection action of "cleansing of the lungs" (Muntner, 1963, p. xiv). Hippocrates offered an acoustical description of cough as "the voice of the lung" (Braga, Legnani, & Allegra, 1989, p. 97). Others have referred to cough as a "two-edged sword," meaning that cough serves normal and pathological functions (Young, Bitsakou, Caric, & McHardy, 1991, p. 7); "watchdog of the lungs" (Korpas & Tomori, 1979, p. 135); an "uncommon cause of suffering" (Hagen, 1991, p. 190; "a strong Valsalva maneuver" (Leith, 1977, p. 569); a "reflex" (Guyton, 1986, p. 475); and a "respiratory act" (Braga et al., 1989, p. v). In contrast to such metaphorical and functional descriptions of cough, Hanneman (1994) described cough as an "effort that shakes the body and tenses the neck, facial, and abdominal muscles" (p. 6).

From the above characterizations of cough effort intensity, it is clear that the authors observed and interpreted cough effort intensity subjectively from

different perceptual foci (Spodick, 1975; Woolf & Rosenberg, 1962). Ways in which multiobserver variability affect the measurement of a variable have generated numerous investigations of the reliability and validity of subjective and objective measurements (Cary, Huseby, Culver, & Kosanke, 1979; Gjorup, Bugge, & Jensen, 1984; Godfrey, Edwards, Campbell, Armitage, & Oppenheimer, 1969; Smyllie, Blendis, & Armitage, 1965; Spodick, 1975; Thurlbeck et al., 1969). These investigations have demonstrated problems with reliability and validity of both subjective and objective assessment parameters.

Despite a long and sustained interest in the subject of cough, research has been limited to the inducement of cough, with various stimuli and under various conditions, and the treatment of cough. Because of the importance of cough in health and illness, it is curious that so little attention has been given to development of objective measures for cough assessment (Cox et al., 1984; Hanneman, 1994; Yang, 1992).

The actual execution of a cough is dependent on inspiration of a large volume of air and the subsequent contraction of thoraco-abdominal muscles (Cox et al., 1984; Guyton, 1986). Thus, intensity of cough effort theoretically should correlate with vital capacity, the

maximum amount of air a person can breathe out after the deepest possible breath in, and with negative inspiratory pressure, the most negative pressure produced when a person contracts thoraco-abdominal musculature to breathe in against an occluded airway (Yang, 1992; Yang & Tobin, 1991). The correlation between cough effort intensity and vital capacity, and likewise between cough effort intensity and negative inspiratory pressure, should be linear and positive (Hanneman, 1994; Multz et al., 1990; Yang, 1992).

Although cough is an objective sign that can be observed, the designation of intensity of cough is subjective (Woolf & Rosenberg, 1962). Determination of cough effort intensity is made individually by the person assessing the cough effort. Intensity of cough effort has the potential to be a valuable assessment tool for changes in certain conditions, such as increasing muscle weakness in Guillian-Barre syndrome. However, using cough effort intensity as an indicator of deterioration or improvement in health and illness states may be meaningless if reliability of the subjective assessment of cough effort is not ascertained (Cox et al., 1984; Braga et al., 1989; Woolf & Rosenberg, 1962).

In two studies, cough effort was markedly different in cardiac surgery patients who were and were not able to

complete weaning from mechanical ventilation early in the postoperative period (Hanneman, 1994; Hilberman et al., 1976). Hanneman suggested that this subjective, yet simple, bedside criterion may have good prognostic ability as a determinant of weaning outcome. However, prior to testing the predictive performance of cough effort, it is necessary to establish the basis for adequate psychometric properties of the subjective assessment of cough effort in mechanically ventilated patients.

Problem of Study

The purpose of this study was to determine the extent to which nurses' subjective assessment of cough effort intensity in mechanically ventilated patients and post-extubated patients is reliable and valid.

Rationale for Study

Hanneman, Ingersoll et al. (1994) recommended that frequently used subjective indicators of patient readiness to wean from mechanical ventilation be tested and compared with more objective measures for their predictive ability. Even though the clinical indicator of cough effort intensity (CEI) has not been tested psychometrically, clinicians continue to rely on this subjective assessment for decision

making. The equivalence of subjective and objective measures of CEI has not been addressed in the literature.

Cough is the most recognizable index of an underlying disorder in the pulmonary system, and it is a common response elicited by clinicians from the client on physical examination. Literature abounds on the dynamics of cough in health and illness (Korpas & Widdicombe, 1991; Langlands, 1967); cough induced by various stimuli (Pounsford, Birch, & Saunders, 1985); and cough therapy (Braga et al., 1989; Fuller, 1990; Irwin & Curley, 1991). However, no research was found on the assessment of cough effort intensity.

Investigation of nurses' assessment of cough effort is needed to determine the extent to which this frequent assessment is performed accurately and consistently. Because cough is a common sign that may suggest underlying pathology, assessment of cough by the same and different practitioners should reflect true changes in cough and not variability in the measurement technique. Reliable and valid nurse assessment of cough effort intensity would provide the foundation for future research to test patient CEI as a reliable and legitimate assessment of weaning readiness for mechanically ventilated patients. In light of current concerns for cost containment and quality of patient care, using CEI to assess weaning readiness would offer

major advantages to the objective and invasive assessments currently used.

Theoretical Framework

Effective nursing interventions are predicated on accurate assessments performed by the practitioner. The foundation of practice is derived from scientific principles in the biological and social sciences. This study was based on the conceptual model of weaning advanced by the American Association of Critical Care Nurses' (AACN) National Study Group on Weaning from Mechanical Ventilation (Knebel et al., 1994) and the laws of pulmonary physiology (Guyton, 1986).

The AACN Third National Study Group on Weaning from Mechanical Ventilation developed a model for weaning from mechanical ventilation that involves three phases: (a) preweaning, (b) weaning process, and (c) weaning outcome (Knebel et al., 1994). In this model, weaning is described as a patient-supported process toward the goal of spontaneous ventilation without assistive devices. The preweaning phase is the period before actual withdrawal of ventilator support takes place, when essential data are accumulated and analyzed by practitioners to best manage the patient's adjustment from mechanically supported breathing to spontaneous breathing. Decisions about appropriate weaning protocols and the physiologic parameters that need

to be monitored are made. In the preweaning phase, clinicians judge the patient's readiness to wean. This research was designed to test: (a) both equivalence and stability reliability of qualitative nurse ratings of CEI and (b) the relationship between the bedside nurse's qualitative evaluation of CEI and lung volume, as measured by vital capacity in milliliters, and respiratory muscle strength, as measured by negative inspiratory pressure in centimeters of water pressure.

Approaches to assessment of patient readiness to wean from mechanical ventilation are diverse and vary from unstructured personal preference to structured multidisciplinary collaborative protocols (Burns, Burns, & Truwit, 1994; Knebel et al., 1994). Common practice in the clinical setting is for recovery room nurses and physicians to elicit a cough effort from the intubated patient when they are evaluating the patient's potential for weaning several hours after a surgical procedure. This subjective assessment is done in the preweaning phase along with objective parameters of arterial blood gas values, vital capacity, and negative inspiratory pressure. The assumptions underlying this study are that: (a) cough effort intensity during the preweaning phase influences decisions about readiness to wean, (b) cough effort assessment is

clearly within the domain of practice of the bedside nurse, (c) instruments that measure lung volume reliably produce valid measures of forced expiration during cough effort, and (d) instruments that measure maximum inspiratory pressure reliably produce valid measures of respiratory muscle excursion during cough effort.

According to Cox et al. (1984), the mechanism of cough is the intraabdominal muscle contraction "against a closed glottis that produces the sudden, rapid airflow through the bronchial tree" (p. 381). And, as Floyd and Silver (1950) and Strohl, Mead, Banzett, Loring, and Kosch (1981) have indicated, the contraction of lateral abdominal muscles, the external obliques, provides the major force of the cough effort.

Cough is vagally-mediated, resulting from stimulation of sensory nerve endings located in the upper and lower respiratory pathways. Irwin, Rosen, and Braman (1977) grouped the cough receptors according to their nervous origins. These groups are: (a) glossopharyngeal, (b) phrenic, (c) trigeminal, (d) vagus, and (e) cortical cough receptors. When various stimuli, for example, mechanical or chemical (Adcock, 1991; Fuller, 1990), thermal (Braman & Corrao, 1985), or even psychogenic (Godfrey, 1980), such as nervous cough in boring lectures or

symphonies, irritate the receptors, the impulse generated travels via the afferent nerve endings to the cough center, located in the medulla and pons (Hagen, 1991). Then the cough impulse travels down the expiratory muscles via the efferent nerve endings.

Guyton (1986) described four sequential events in order for a cough to occur. Initially, inspiration of approximately 2.5 liters of atmospheric air enters the pulmonary airways. Closure of the epiglottis and vocal cords follows. Then contraction of the abdominal musculature ensues which pushes against the diaphragm and causes the internal intercostals to contract in return. Thus, the pulmonary pressure surges to 100 mm Hg or more. Finally, sudden opening of the vocal cords and epiglottis releases the trapped gas from the pleural cavity with a velocity as high as 75 to 100 miles an hour. Because of lung compression that occurs earlier, the tracheo-bronchial components constrict and the expelled air gushes forth through the "bronchial and tracheal slits" (Guyton, 1986, p. 475).

Gas laws underlying pulmonary mechanics are integral to this research. The following gaseous principles (Levitsky, 1986; Levitsky, Cairo, & Hall, 1990) are applicable to the variables under scrutiny:

1. Gas diffusion occurs "when there is a net movement of molecules from an area in which [the] . . . gas exerts a high partial pressure to an area in which it exerts a lower partial pressure" (Levitsky et al., 1990, p. 125).

2. Boyle's law, which applies to the mechanics of breathing, states that during negative-pressure breathing, alveolar pressure is made lower than atmospheric pressure.

Vital capacity in milliliters is defined as the maximum amount of air that an individual can eject from the airways after maximum lung inhalation (Guyton, 1986). Negative inspiratory pressure is defined as "the measure of the output of the inspiratory muscles against a maximum stimulus, provided either by total occlusion of the airway or by preventing inspiratory gas flow, as measured in cm H_20 negative pressure" (Scanlan, Spearman, & Sheldon, 1990, p. 999). These two objective measures of readiness to wean from mechanical ventilation are most commonly used by clinicians (Aloi & Burns, 1995; Hanneman, Ingersoll et al., 1994). Thus, vital capacity and negative inspiratory force were used in this study to test construct validity of cough effort intensity.

Hypotheses

Four hypotheses were tested. Two hypotheses specified a priori evidence of reliability of cough effort

intensity and two specified a priori evidence of construct validity.

H1. There will be evidence of adequate equivalence reliability ($r \geq .80$; Nunnally & Bernstein, 1994) of cough effort in mechanically ventilated patients and post-extubated patients, as assessed by multiple nurses simultaneously.

H2. There will be evidence of adequate stability reliability ($r \geq .80$; Nunnally & Bernstein, 1994) of cough effort in mechanically ventilated patients and post-extubated patients, as measured by test-retest assessment by the same nurse within a 3-minute time interval.

H3. There will be adequate evidence of construct validity of nurses' subjective ratings of cough effort intensity in mechanically ventilated patients and post-extubated patients, as determined by a positive correlation ($r \geq .70$; Munro & Page, 1993) between cough effort intensity and vital capacity.

H4. There will be adequate evidence of construct validity of nurses' subjective ratings of cough effort intensity in mechanically ventilated patients and post-extubated patients, as determined by a positive correlation

($r \geq .70$; Munro & Page, 1993) between cough effort intensity and negative inspiratory pressure.

Definition of Terms

Construct validity was conceptually defined as "the degree to which an instrument measures the construct under investigation" (Polit & Hungler, 1991, p. 642). Construct validity was operationally defined as a correlation of $r \geq .70$ (Munro & Page, 1993) between cough effort and vital capacity, and between cough effort and negative inspiratory pressure.

Cough effort intensity was conceptually defined as a purposeful act that is "initiated voluntarily without the presence of irritating stimuli" (Scanlan et al., 1990, p. 667) that causes contraction of the external oblique muscles, with forceful air expulsion from the lungs. Cough effort intensity was operationally defined as the nurses' subjective rating of cough effort as weak, moderate, or strong.

Equivalence reliability was conceptually defined as the consistency of classifications of cough effort intensity for the same patient by more than one nurse, also termed interrater agreement (Waltz, Strickland, & Lenz, 1991). Operationally, equivalence reliability was defined as agreement of $r \geq 80\%$ (Nunnally & Bernstein, 1994) among

cough effort assessments performed by three nurses simultaneously for the same patient.

Negative inspiratory pressure was conceptually defined as the maximum negative pressure generated against a closed airway (Wilkins, Sheldon, & Krider, 1990). Negative inspiratory pressure was operationally defined as the maximum negative pressure generated against an occluded airway over 15 seconds (Truwit & Marini, 1992) using a portable water pressure meter with the patient in the semi-recumbent position (Hanneman, Lindley, Kehr, & Witherspoon, 1994).

Stability reliability was conceptually defined as the consistency of classification of cough effort for the same patient by the same nurse on two occasions, also termed intrarater agreement (Waltz et al., 1991). Operationally, stability reliability was defined as a correlation $r \geq .80$ (Nunnally & Bernstein, 1994) between two cough effort assessments performed by one nurse on the same patient within a 3-minute period of time.

Vital capacity was conceptually defined as the maximum volume of air expired after a maximum inspiration (Wilkins et al., 1990). Vital capacity was operationally defined as the best of three consecutive maximal expirations obtained

by a portable spirometer with the patient in the semi-recumbent position (Hanneman, Lindley et al., 1994).

Limitations

This study has three limitations. First, the generalizability of study findings are limited to nurses and adult patients in the study units. Second, the findings are limited to patients who are sufficiently alert and oriented to cooperate with the effort-dependent measures of vital capacity and cough effort. Finally, the cough effort classifications to be tested are ordinal level data and may demonstrate reduced variability compared to classifications constructed on an interval or ratio level.

Summary

Cough is a normal airway defense mechanism and also a sign of localized pulmonary or systemic pathology. Despite abundant literature on cough dynamics, inducement, and therapy, there is little evidence of research on cough assessment. Research on predictors of weaning outcome from mechanical ventilation has suggested that subjective assessment of cough may be a meaningful predictor. This notion, however, cannot be tested until the psychometric properties of cough effort measurement have been evaluated. Thus, the purpose of this study was to determine the extent

to which the subjective assessment of cough effort intensity in mechanically ventilated patients and post-extubated patients is reliable and valid when performed by nurses. This study was designed to test the evidence for equivalence and stability reliability of nurse assessment of cough effort intensity and the construct validity of cough effort intensity with vital capacity and negative inspiratory pressure.

The theoretical framework that guided this study is comprised of (a) the conceptual model of weaning developed by a group of nurse scientists and clinicians, and (b) laws of pulmonary physiology that govern volume and pressure mechanics. The four directional hypotheses are related to adequate evidence of reliability and validity of cough effort assessment in mechanically ventilated patients and post-extubated patients. Limitations of this study include convenience sampling and ordinal level classifications of cough effort intensity.

CHAPTER 2

REVIEW OF THE LITERATURE

The purpose of this chapter is to present an overview of the literature on cough that is relevant to this study. The following areas are reviewed: (a) the anatomy and physiology of cough, (b) experimental studies of cough, (c) cough and mechanical ventilation, and (d) the relationships among cough, vital capacity, and negative inspiratory pressure.

Anatomy and Physiology of Cough

Cough is a protective mechanism, a component of the mucociliary process of cleansing the tracheobronchial tree of pulmonary debris. However, investigators have alluded to the autonomy of cough as a clearance mechanism by itself. Cough has been identified as a physiologic reflex, with its own center in the central nervous system, and with its own special receptors.

Cough is vagally-mediated. Its major function is to protect the airways from foreign body invasion. The cough center involves the medullary portion of the brain. Cough is produced by various inflammatory, chemical, mechanical,

thermal, otic or tactile stimuli in the ear canal otherwise known as Arnold's nerve response, and psychogenic stimuli (Wilkins, Sheldon, & Krider, 1990). These stimuli create the afferent impulses that traverse the respiratory passages by way of the vagus nerve to the medulla.

Cough involves four phases of events: (a) inspiratory, (b) compressive, (c) expiratory, and (d) cessation (Leith, 1985). Cox et al. (1984) described these phases of cough as air inhalation, contraction of expiratory muscles, and expulsion of the intrapulmonic air characterized by an exploding sound thereafter into the outside environment.

Guyton (1986) described the systematic physiological sequence of the cough reflex. It starts with the inhalation of atmospheric air (2.5 liters) into the airways that closes off the epiglottis and the vocal cords. Contraction of external abdominal muscles and the intercostals builds up intrathoracic pressure to as high as 300 mm Hg (Irwin, Rosen, & Braman, 1977). Hagen (1991) compared the contraction of respiratory muscles against a closed glottis as analogous to a valsalva maneuver, a major motor element of cough. Then, the sudden outward gush of the entrapped pleural air opens up the glottis and vocal cords along with the expulsion of a sound recognized and identified as a cough.

Experimental Studies on Cough

Cough has been the subject of experimental studies using animal and human subjects. Animal experimentation to produce involuntary cough has involved induction of various elements. Examples cited by Bickerman and Rodgers (1980) included: (a) chemical (e.g., sulfuric and citric inhalation in pigs and dogs studied by Winter and Flataker in 1954); (b) mechanical (e.g., metal slug insertion in dogs done by Tedeschi et al. in 1959); and (c) electrical stimulation, done by Stefko and Benson in 1953.

Human subjects experimentation to induce involuntary cough has included use of several different agents. Examples of these agents include: (a) chemical aerosol induction, such as citric acid inhalation (Barros, Zammattio, & Rees, 1989; Bickerman & Barach, 1954; Pounsford, Birch, & Saunders, 1985); (b) methacholine inhalation (Corrao, Braman, & Irwin, 1979); (c) nebulized distilled water (Higenbottam, 1984); capsaicin (Collier & Fuller, 1984); (d) histamine (Rees & Clark, 1984); and (e) prostaglandin (Costello, Dunlop, & Gardiner, 1985).

The clinical picture of cough encountered in the hospital setting has been analyzed qualitatively in a number of ways: productive and/or unproductive, wet (Braman & Corrao, 1985) and/or dry (Korpas & Tomori, 1979), barking

cough, "smoker's" cough, nervous, painful, hacking, debilitating, cancerous, persistent, and so forth. The cough which is characterized as psychogenic, termed "habit cough" by Miller (1987), is diagnosed usually in the adolescent and childhood stages. This type of cough is identified by its "harsh, barking, and disturbing" attributes as well as its day-only-occurrence (Miller, 1987, p. 209).

Time of cough occurrence has been ascribed to morning, afternoon, evening (Wilkins et al., 1990), or nocturnal. Even body positioning has been implicated in cough production, for example, chronic postnasal drip (Wilkins et al., 1990). Activities of daily living like eating or drinking, and sometimes laughing, have been associated with cough (Widdicombe, 1989; Wilkins et al., 1990). Other authors have described cough quantitatively, using frequencies such as periodic, limited, "in fits," "bouts," or "paroxysmal." Still others characterized cough as to its strength or intensity, such as strong, moderate, or weak (Hanneman, 1994); high or low, two-tone, effective or ineffective; as to its time or duration (e.g., acute or chronic) and seasonal (winter or spring).

Empey (1980) and Irwin et al. (1977) described cough as voluntary or involuntary. Findings from studies have

demonstrated the feasibility of measuring spontaneous voluntary coughing with the electromyogram (Cox et al., 1984). Spontaneous coughing bouts have been scored over a period of time (Loudon & Romans, 1967). Quantitative estimations of spontaneous cough frequency have been made (Braga & Allegra, 1989; Field, 1974; Woolf & Rosenberg, 1962). Inclusive in these studies, the investigators have identified essential conditions for the production of effective cough. These conditions are: (a) presence of patent airway; (b) normal airway structures and mechanics; (c) viable receptors; (d) normally-functioning mucociliary process; (e) intact spinal cord and vagus nerve; (f) sound respiratory center, cough center, and intact cranial nerves #9 through #12; (g) healthy chest wall musculature; (h) well-conditioned abdominal muscles; and (i) disease-free diaphragm (Empey, 1980; Langlands, 1967; Leith, 1985; Widdicombe, 1980). Of major significance is that there is no standard coding for cough at the present time (Braga, Legnani, & Allegra, 1989). Therefore, liberal interpretations of cough prevail.

Woolf and Rosenberg (1962) used a tape recording system to objectively investigate assessment of cough suppressants under clinical conditions. Although many other researchers have incorporated subjective measurements, such as patients'

self-reported impressions of cough frequency, these researchers believed that objective measurements, such as counted coughs from tape-recordings, would be more reliable.

Wall-mounted microphones were connected to a sound-activated tape recording system which had a speaking clock that recorded the number of hours. Each patient with chronic cough was assigned to a single room for 4 study days. The first day was designated as a control day with no cough medication; the second and third days were designated placebo treatment days; and on the fourth day, the patient was administered the antitussive drug. The number of clearly distinguishable coughs were totalled for each day and used to construct a cough curve for each patient. Coughs produced on day 4 for 2 hours after each medication dose were compared with those produced during the other three days--control and placebo days (Woolf & Rosenberg, 1962).

No significant observer error was found between the two investigators who counted the recorded coughs. The researchers reported that this objective, cough-counting technique provided viable information that supported the use of the antitussive medication. The results of Woolf and Rosenberg's (1962) study help support the decision that objective, rather than only subjective, methods should be employed in documenting cough intensity.

In a study by Bickerman and Itkin (1960), a cough challenge device was used to induce cough effort via aerosolized inhalation. A pneumotachograph equipped with a transducer and a condenser microphone was installed to count number of coughs demonstrated, mean flow rates, air volume, as well as cough sounds. As a result of their findings, these investigators recommended that objective measures should be employed rather than subjective measures to determine cough intensity and/or frequency.

Cox et al. (1984) studied the abdominal electromyographic (EMG) method to objectively assess the intensity of cough, which "correlates well with the volume, airflow and noise produced in different coughs" (p. 377). An assumption underlying their research was that the EMG reflects the abdominal muscle activity generated during a coughing episode. These investigators also used a Bruel and Kjaer sound level meter to measure the sound of cough.

Mossberg and Camner (1980) and Rees and Clark (1984) investigated the effect of voluntary coughing in human subjects by measuring the effectiveness of clearance mechanisms of the airways. In their aerosol inhalation study, Mossberg and Camner found great variability in cough effort effectiveness due to different precipitation of the aerosol particles in the larger or smaller airways, whereby

the best clearance effected by cough effort was produced from the proximal and larger bronchi.

Rees and Clark (1984) studied cough effort intensity, measuring cough effort with deep inspiration and cough effort without initial inhalation. The results showed a reduction of airway conductance in the latter. The researchers concluded that the inhalation phase of cough effort intensity affected the smooth muscle resistance and conductance of secretions in the airway. Furthermore, Rees and Clark recommended that, to ensure reliable results, respiratory maneuvers be measured at 1-minute or greater intervals following a cough effort.

Gravenstein, Devloo, and Beecher (1954) quantified cough intensity by noise measurement using substances such as ammonia, citric acid, and intravenous paraldehyde on human subjects for 3 days to induce cough responses. These investigators used a recording device called an Albert Grass sound recorder that captured the amplitudes of the cough responses and recorded them on ink paper as the control for the experiment. They also assigned one person to actually record cough sounds from outside the patient's room. Additionally, the investigators asked the subjects to respond to a questionnaire asking them about their cough frequency, with the following options: less frequent, same,

or more frequent. Comparative estimations for both methods were thus measured. Although these investigators reported finding significant differences in the subjective measurement of cough frequency and no significant differences in the objective measurement of cough frequency, no numerical values were stated.

The repeatability of a measure of cough was tested by Pounsford et al. (1985) in their two-group study using normal and asthmatic patients. These researchers tested both groups with a baseline citric acid aerosol inhalation of varying concentrations of 0.5%, 1%, 2%, 4%, 8%, 16%, and 32%. These dosages were administered at 4-minute time intervals to induce a cough response. Also, two broncho-dilators of various increments were administered to subjects for 4 experimental days at the same time each day to induce the cough response. One-half hour after each drug or placebo testing, serial citric acid inhalations were administered and differences of cough responses were recorded, respectively. Thus, four randomized experiments were repeated conducted by administering two drugs and a placebo on different days. Cough recording done by the researchers consisted of attaching a mercury strain gauge, sensitive to thyroid cartilage motion, around subjects' necks to measure their cough response. Likewise, a Medelec

fibroptic recorder was used to measure airway flow, cough movements, and valve opening. Data showed no significant effect of the bronchodilators and the citric acid in normal subjects. However, there was significant cough reduction effected by the bronchodilators in asthmatic subjects.

Mossberg and Camner (1980) assessed the reproducibility of cough in persons with obstructive lung disease. They investigated mucociliary transport and cough as clearance mechanisms by using an inhalation test aerosol of teflon particles. Subjects were tested twice for 2 consecutive days. Data showed that for an effective cough to occur, hypersecretion of tracheobronchial materials should occur to move particles out of the airways. Likewise, in patients with effective cough, there was a significant correlation between amount cleared by cough found on the 2 test days.

Findings from previous studies provided evidence that frequency and intensity of cough have been investigated; however, these researchers used methods to measure cough that are impractical to use at the bedside. Many of the methods rely on acoustic measures of cough, which are not applicable to patients with artificial airways.

Cough and Mechanical Ventilation

Cough, as discussed, is the most efficacious mechanism for clearing the pulmonary airways. However, the cough

reflex can be blocked by anesthesia and analgesia (Miller, 1987). Cough requires an open glottis to be effective. When a patient undergoes intubation, the endotracheal tube rests within the glottis. The vocal cords are open to accommodate the artificial airway. Cough is impaired, albeit not sufficiently to totally obliterate the cough effort. Even with the vocal cords open, the expiratory muscles are powerful enough to produce increased intrapulmonary pressures (Guyton, 1986). Langlands (1967) documented that cough production was possible even when the glottis failed to close between coughing episodes. Widdicombe (1980) reinforced this concept by stating that tracheotomized patients "can mimic an efficient cough if their respiratory muscles are optimal" (p. 13).

Mead, Turner, and Macklem (1967) reported the concept of equal pressure point which compared coughing at different pleural volumes. Coughing episodes at high lung volumes produce contraction of larger airways (i.e., bronchi and trachea), whereas coughing bouts at lower pulmonary volumes constrict smaller airways (i.e., respiratory bronchioles).

Cough has been documented to have an effective functional role in elimination of increased secretions in the presence of endotracheal tube and mechanical ventilation (Dilworth & Pounsford, 1991). However, reduction in lung

volume due to the presence of artificial airway means decreased inspiratory flow rates, thereby reducing the intensity of cough (Dilworth & Pounsford, 1991).

Cough, Vital Capacity, and Negative Inspiratory Pressure

Vital capacity and negative inspiratory pressure are two objective assessments that reflect a picture of a patient's respiratory reserve. They are easily measured at the bedside. Measurement of vital capacity is preceded by maximal inspiration followed by maximal expiration. In similar fashion, as cited by various authors (Guyton, 1986; Irwin et al., 1977; Leith, 1985), the genesis of cough begins with inhalation of atmospheric gas. A volume of twice the normal tidal volume is essential for cough production for clearance purposes (Pilbeam, 1992). A patient's vital capacity usually falls in the range of 65 to 75 mg/kg of body weight. Values less than 15 mg/kg are determined to be insufficient for an adequate cough production (Pilbeam, 1992).

Negative inspiratory pressure (NIP) reflects respiratory muscle strength. NIP measurement with a one-way valve allows exhalation but precludes inspiration, thereby maximizing diaphragmatic muscle activity at decreased lung volumes (Pilbeam, 1992). A NIP of -80 cm H_2O or less is

considered normal. Measurements between 0 and -20 cm H_2O are considered insufficient for the production of an effective and efficient cough (Pilbeam, 1992).

Summary

Literature on cough from several perspectives was reviewed. Experimental research using animal as well as human subjects has been conducted on both voluntary and involuntary cough effort. Quantitative cough measurement (i.e., counting the frequency) has received more attention than qualitative evaluation of cough effort intensity.

Changes in cough physiology resulting from intubation and mechanical ventilation were reviewed. Although intensity of cough is reduced with an artificial airway, the ability to produce a cough effort is preserved as long as vagal trajectories are intact.

Finally, the relationships among cough, vital capacity, and negative inspiratory pressure were explored. Vital capacity indicates the patient's capacity to exhale following a deep breath. Negative inspiratory pressure measures a patient's respiratory muscle strength. These two parameters are considered valid assessments of the mechanical capacitance of the patient to push air in and out of the airways, yielding an adequate cough effort.

CHAPTER 3

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

This chapter presents the study design, procedures for data collection, and the data analysis plan. The purpose of this study was to determine the extent to which the subjective evaluation of cough effort is reliable and valid. The research design was correlational (Polit & Hungler, 1991) with repeated measures (Pedhazur & Schmelkin, 1991). The study was designed to explore the relationships among the variables of interest: (a) cough effort intensity, (b) vital capacity, and (c) negative inspiratory pressure. The degree of agreement among three nurses of cough effort intensity for the same patient was determined. In addition, the correlation between repeated assessments of cough effort for the same patient made by the same nurse within a 3-minute interval of time was determined. Cough effort intensity was correlated with vital capacity and negative inspiratory pressure. Assessments of reproducibility of nurse ratings of cough effort intensity, vital capacity, and negative inspiratory pressure were done on 3 days for each patient. A repeated measures design was appropriate for this study to control for intrasubject variability while

identifying interindividual patterns of intrasubject change (Pedhazur & Schmelkin, 1991).

Medical and surgical patients on mechanical ventilation were studied on Day 1 of data collection. The same patients were studied again on Day 2 and Day 3. When the patients were extubated prior to study completion, measurements were done in the extubated state. The three measurement times varied for each patient population.

On each day of measurement, three staff nurses were asked to rank the patient's cough effort as strong, moderate, or weak. Three minutes later, the procedure was repeated. Then, the investigator measured vital capacity and negative inspiratory pressure. Three nurses were selected for interrater (equivalence) reliability to reflect the typical number of nurses who care for a patient within a 24-hour period and the number of cough effort assessments most likely to be compared clinically. Test-retest measurement intervals were limited to 3 minutes to reduce the chance of changes in patient status (e.g., change in level of consciousness, secretions, etc.).

Setting

The setting for this study was a large, tertiary, 656-bed teaching hospital licensed to care for acute and chronic medical and surgical patients and located in a

metropolitan southwestern area of the United States. Data were collected in 6 adult critical care units, 3 adult intermediate care (stepdown) units, and 6 medical and surgical floors. Diversity of study units resulted from patient transfers based on acuity over the 3 days of data collection.

Population and Sample

Two populations were relevant to this study: patients and nurses. Both populations were from the same setting.

Patient Population and Sample

The patient population was adult, critically ill, medical and surgical patients who were receiving mechanical ventilation at the beginning of the study. Criteria for patient selection were: (a) 18 years of age or older; (b) on mechanical ventilation; (c) good understanding of English language; (d) absence of contraindications to coughing (e.g., elevated intracranial pressure); and (e) alert, cooperative, and able to follow commands. No exclusions were made on gender or race. Factors that were not controlled for included pain medications, time of day of data collection, co-morbidities, and presence or absence of significant others during data collection.

The six critical care study units admit from 20 to 120 patients per month; however, the number of patients who met eligibility criteria for study participation was unknown. Thus, convenience sampling was used to assure completion of data collection within a 6-month period of time. Within the broad convenience sampling technique, proportional stratified sampling (Talbot, 1995) was used to ensure that the sample was representative of the target population. Proportional sampling determinations were based on the average monthly admissions for each critical care unit. Fourteen patients were studied from the medical intensive care unit (ICU), 3 from the coronary care unit, 14 from the trauma ICU, 7 from the neurological ICU, 21 from the cardiovascular ICU, and 3 from the transplant critical care unit. The total sample of 62 patients included 24 medical patients and 38 surgical patients.

Sample size was estimated from Cohen's (1988, p. 102) table for the Pearson product-moment correlation coefficient, using the following parameters: (a) two-tailed test, (b) alpha of .05, (c) power of .95, and (d) moderate to large effect size. The large effect size was justified based on the research findings of Multz, Aldrich, Prezant, Karpel, and Hendler (1990). Multz et al. found a nearly threefold increase in the variability of negative

inspiratory pressure (NIP) when performed by different raters (coefficient of variation = 32%) compared to repeated measures by one rater (coefficient of variation = 12%). However, the restriction of range inherent in the ordinal level rankings of cough effort intensity were considered to mediate the expected variability in NIP.

Nurse Population and Sample

The nurse population was nurse clinicians who practiced in adult medical and surgical units. The target populations varied from 8 to 33 nurses, based on study unit size. Criteria for nurse subject inclusion were: (a) registered nurse, and (b) on staff in one of the study units. No exclusions were made based on gender or race. Convenience sampling was used with the nurse subjects.

Nurses who were assigned in the study units were recruited per their availability and convenience on the day of study. A total of 279 nurses were asked to participate in the study; 243 actually participated in data collection. Of the 279 nurses, 36 refused to participate: 2 outright refused; 16 could not participate because of acuity of patient load, such as a code blue situation; 6 were on patient rounds at the time of data collection; 5 were called to the phone; and 7 had to go for their lunch break when the investigator was finally able to assemble a triad. The

study nurses varied for daily measurements, but the same triad was used for the two sets of measurements on a given day. Factors not controlled for in this study included individual perceptions of what constituted a strong, moderate, or weak cough effort and nurse workload at the time of data collection.

Protection of Human Subjects

Study approval was obtained from the institutional review boards of Texas Woman's University and the clinical agency (Appendix A). Support of the study was obtained from the medical directors and nurse managers from all the study units. Waiver of written consent was granted by both institutional review boards. Verbal consents were obtained from nurse subjects. Because all patient subjects were intubated on the first day of the study, their consents were provided by nonverbal communication (i.e., blinking eyes twice to indicate "yes"). Patient consent to continue study participation was obtained again on day 2 and day 3 of data collection. When extubated, patients gave verbal consent. The principal investigator explained the study and the procedures for data collection at recruitment time according to the study protocol.

Patient Subjects

Potential risks to patient subjects included: (1) anxiety or frustration with regard to understanding the study protocol; (2) fatigue from performing the cough effort twice; (3) discomfort from performing the cough effort, particularly in postoperative surgical patients with thoracic or abdominal incisions; (4) loss of confidentiality; (5) hemodynamic compromise, manifested by increased or decreased arterial blood pressure and heart rate, during vital capacity and negative inspiratory pressure measurements (Hanneman, Lindley, Kehr, & Witherspoon, 1994); and (6) arterial desaturation during vital capacity and negative inspiratory pressure measurements (Hanneman, Lindley et al., 1994).

Steps to reduce the risks to patients were taken. To reduce anxiety or frustration, adequate time was provided for explanation of the study protocol. The principal investigator taught the patient how to cough, demonstrated the cough effort, and asked the patient to do a return demonstration of the cough effort. These steps were repeated upon patient request. The investigator remained with the patient during implementation of the study protocol. To reduce fatigue, the patient was permitted a 3-minute rest period between repeated cough efforts. A

longer rest period, of up to 5 minutes, was granted upon patient request. To reduce the risk of discomfort, the patient was placed in the semi-recumbent position to promote descent of the diaphragm, and a pillow was placed over the anterior thoraco-abdominal area for splinting benefit. To reduce the chances of loss of confidentiality, study code numbers were used on all data collection forms and the study findings were reported in the aggregate, without specific identifying information.

Because the physiologic mechanism underlying hemodynamic compromise during vital capacity (VC) and negative inspiratory pressure (NIP) measurements was not clear, no particular steps were taken to reduce the potential risk. However, every patient who was mechanically ventilated in the critical care units had continuous heart rate monitoring, and most had continuous arterial blood pressure monitoring. The investigator positioned herself at the patient's bedside facing the monitor so that increases or decreases in heart rate and/or blood pressure were immediately detected. Measurements would have been aborted for clinically significant changes in hemodynamic status, which were determined a priori with the unit staff and typically were a change in either direction of approximately 20% or more. Hanneman, Lindley et al. (1994) reported that

hemodynamic compromise or arterial desaturation occurred in 13% of the MICU patient population and that abortion of the measurement resulted in rapid return of hemodynamic or saturation status to baseline values. Hemodynamic compromise was not observed in cardiovascular surgical patients in a previous study using measurements similar to those that were used in this study (Hanneman, 1994). To reduce the risk of arterial desaturation, the investigator positioned herself so that the pulse oximeter digital readout was observable. Measurements would have been aborted for arterial desaturation to 85% or less. In addition, the vital capacity measurements were done with entrainment of supplemental oxygen to reduce the risk of desaturation during this measurement. None of the potential risks occurred during data collection.

Nurse Subjects

Potential risks to the nurse subjects included: (1) anxiety, irritation, or frustration with regard to the study protocol, (2) disruption of the usual nursing daily routine for data collection, and (3) loss of confidentiality. Steps to reduce the aforementioned risks to the nurse subjects included: (1) provision of adequate explanation to the nurses in the hospital units, along with the opportunity to ask questions and seek clarification;

(2) immediate discontinuance of the procedure in the event the nurse needed to attend to assigned patients; and (3) use of coded aggregate data only, without the possibility of identification of individuals.

Instruments

Five instruments were used for this study: (1) a patient demographic form, (2) a nurse demographic data form, (3) a nurse rating form, (4) a portable spirometer, and (5) a portable inspiratory force meter. Each is discussed respectively.

The patient demographic form (Appendix B) contains three sections: (a) patient demographics, (b) construct validity measurements, and (c) nurse codes. Patient demographics were obtained from the patient's medical records. To facilitate accurate data collection, patient study code number and date and time of measurements were included in the patient demographic section. Patient demographics include: study unit (nominal level datum); age (interval level datum); gender and race (nominal level data); height, weight, and artificial airway size (interval level data); and ventilator mode, primary diagnosis, and secondary diagnosis (nominal level data).

Age, race, gender, and diagnoses were used to describe the sample. Height and weight were used to determine

obesity. Obesity has been shown to affect pulmonary mechanics performance (Naimark & Cherniack, 1960); thus, potentially affecting the two measures that were used to determine evidence of construct validity. Size of artificial airway can affect VC, NIP, and cough effort. Work of breathing is increased from airflow resistance through small diameter artificial airways (Shapiro, Wilson, Casa, Bloom, & Teague, 1986).

Ventilator mode was used as an indicator of patient acuity. For example, patients on assist-control or intermittent mandatory ventilation modes at the time of initial assessment might be more acutely ill than patients who are on a spontaneous breathing mode (e.g., continuous positive airway pressure or T-piece).

The construct validity section of the demographic form includes nurse cough effort ratings (ordinal level data) for 3 consecutive days as well as vital capacity and negative inspiratory pressure measurements (interval level data) obtained for 3 consecutive days. These data were used to determine construct validity of nurses' subjective ratings of cough effort intensity. The nurse ratings of cough effort intensity were transcribed from the raw data rating forms to the demographic form for ease of data entry.

The third section of the patient demographic form contains the nurse code numbers for each day of data collection. This section was added to enhance accuracy and ease of data entry.

The nurse demographic form (Appendix C) includes: study unit (nominal level datum); age (interval level datum); educational preparation (nominal level datum); years in nursing, ICU, and study unit (interval level data); and RN patient assignment (nominal level datum). RN patient assignment and years in practice, in ICU, and in the study unit were of interest because Benner (1984) suggested that the perceptual ability of nurses increases with nursing practice experience. The other data were collected for purposes of describing the sample.

The nurse rating form (Appendix D) contained the three classifications of cough effort intensity: weak, moderate, and strong. The nurses were instructed to observe the cough effort and then to mark the one classification that best described the cough effort intensity. The form was cut in half for each day of data collection. The top half was used for the first cough effort, and the bottom half was used for the second cough effort.

The Wright Mark 20 respirometer (Ferrais Medical Inc., Holland, NY) was used to measure vital capacity. The Mark

20 is a portable mechanical respirometer for measuring expiratory volume. It has a slide type on/off switch, push button reset, and two concentric outer dials. One dial records volume of 0-1 liter; the other records volume of 0-100 liters. The respirometer is accurate for vital capacity ±2% for continuous flows of ≤16 liters per minute (LPM) and ±5% for continuous flows up to 60 LPM. The Wright Mark 20 respirometer was calibrated according to manufacturer's specifications by the biomedical engineering department at the hospital prior to use in the study. Vital capacity was measured according to the study protocol in Appendix E.

The Boehringer Model #4103 inspiratory force meter (Boehringer Laboratory, Norristown, PA) was used to measure negative inspiratory pressure. It is a portable manometer equipped with an adapter for connection to the artificial airway. The manometer is equipped with a memory pointer that captures the highest inspiratory or expiratory pressure up to ±150 cm H_2O. The manometer was attached and completely blocked for a period of 15 seconds while the inspiratory efforts of the patient were noted (Truwit & Marini, 1992). Negative inspiratory pressure was measured according to the study protocol in Appendix D.

Data Collection

The investigator approached the nursing personnel in all of the study units and requested their input on mechanically ventilated patients who were conscious, cooperative, and hemodynamically stable. Using this input, the investigator selected patients to approach about study participation.

Convenience sampling of nurse subjects was used based on availability of nurses due to the hectic and unpredictable nature of patient activity in the areas of study. Verbal nurse consent was obtained and the study protocol was subsequently explained and followed.

Patients were initially recruited while on mechanical ventilation and two cough efforts were evaluated independently by three nurses. Each patient was followed for 3 days even if they were extubated prior to completion of data collection. At each of the three measurement times, the full study protocol was followed. The general steps included:

1. Obtain consent
2. Prepare bedside and equipment
3. Collect demographic data
4. Teach patient how to cough
5. Assemble three nurses at the patient's bedside

6. Instruct nurses to rate the patient's cough effort independently, using the Nurse Rating Form
7. Instruct patient to cough
8. Provide a 3-minute rest interval
9. Again instruct nurses to independently rate the cough effort, using the rating form
10. Instruct patient to cough a second time
11. Measure the patient's vital capacity three consecutive times and record the best of the three efforts
12. Measure the patient's negative inspiratory pressure and record the most negative reading over a 15-second period of measurement
13. Clean up and verify forms are completed accurately

The three measurement times were variable within each study unit, according to nurse availability and patient stability. In most cases, data were collected after the shift changes and initial patient assessments were completed. Medical patients usually were studied early in the day, prior to the initiation of daily activities and diagnostic testing. Surgical patients were usually admitted to the critical care unit in the midday or early afternoon; these patients were then studied between 6:00 P.M. and 10:00 P.M., when they were hemodynamically stable, or between 05:00 A.M. and 08:00 A.M. just prior to extubation.

A pilot study was conducted with the initial nine patients to test the study protocol and overall methodology. No major problems were identified in the pilot study; thus, these measurements were included with the data for the major study.

Treatment of Data

Height and weight, regardless of measurement unit recorded, were converted to centimeters and kilograms, respectively. Primary and secondary diagnoses were assigned a numerical code. All data were entered into the VAX 6360 mainframe computer, using the Statistical Package for Social Sciences (SPSSX, 1986), at Texas Woman's University and checked for accuracy. Descriptive statistics were used to describe the samples and subsamples. Inferential statistics were used to test the hypotheses.

Description of Samples

Patient demographics were analyzed for the total sample and for medical and surgical subsamples. Interval level data were analyzed with frequency distributions and all measures of central tendency and variability. The *t* test for independent samples was used to compare interval level data for the medical and surgical subsamples. Nominal level data were analyzed with frequency distributions and mode;

comparative analyses used chi-square. Nurse demographics were analyzed for the total sample and for medical and surgical subsamples, as described for patient demographics according to the level of data.

Testing of Hypotheses

Hypotheses 1--evidence of adequate equivalence reliability ($\underline{r} \leq .80$; Nunnally & Bernstein, 1994) of cough effort intensity in mechanically ventilated patients and post extubated patients, as assessed by multiple nurses simultaneously was tested with the calculation of percentage agreement. Findings were reported in tabular format.

It was originally proposed that the Pearson product-moment correlation coefficient be used to test Hypotheses 2, 3, and 4. However, the data did not meet the assumptions underlying parametric statistics. Therefore, the Spearman rho correlation coefficient, with an alpha of .05 for all analyses, was used to test: Hypothesis 2--evidence of adequate stability reliability ($\underline{r} \geq .80$; Nunnally & Bernstein, 1994) of cough effort intensity in mechanically ventilated patients and post-extubated patients, as measured by test-retest assessment by the same nurse within a 3-minute time interval; Hypothesis 3--evidence of construct validity of nurses' subjective ratings of intensity as a measure of cough effort in mechanically ventilated patients

and post-extubated patients, as measured by a positive correlation ($r \geq .70$; Munro & Page, 1993) between cough effort intensity and vital capacity, and Hypothesis 4--evidence of construct validity of nurses' subjective ratings of cough effort intensity in mechanically ventilated patients and post-extubated patients, as determined by a positive correlation ($r \geq .70$; Munro & Page, 1993) between cough effort intensity and negative inspiratory pressure.

Summary

This correlational study with repeated measures was designed to explore relationships among the variables of cough effort intensity, vital capacity, and negative inspiratory pressure. The samples were medical and surgical patients ($N = 62$) and nurses ($N = 243$) from selected units in one large hospital. The setting, populations and methods of sample selection of patient and nurse samples, steps taken for protection of human subjects, instruments used, data collection procedures, and treatment of data were described. Hypothesis 1, concerning equivalence of nurse rankings of cough effort intensity, was tested by calculating the percentage of agreement. Data analyses were completed using Spearman rho correlation coefficients to test Hypotheses 2, concerning stability reliability of nurse rankings of cough effort intensity, as well as Hypotheses 3

and 4, concerning strength of relationships between cough effort intensity and vital capacity and negative inspiratory pressure.

CHAPTER 4

ANALYSIS OF DATA

A correlational (Polit & Hungler, 1991) design with repeated measures (Pedhazur & Schmelkin, 1991) was used to test four hypotheses of relationships among the variables of interest: (a) cough effort intensity, (b) vital capacity, and (c) negative inspiratory pressure. Cough effort intensity was assessed twice by the same individual nurse and a triad of nurses. Measurements were repeated on 3 consecutive days in each of 62 patients. This chapter includes the description of the patient and nurse samples as well as the results of data analysis. A summary of findings concludes the chapter.

Description of the Sample

This study had two samples: patients and nurses. All of the subjects, both patients and nurses, were conveniently recruited from a large, tertiary teaching hospital in a metropolitan southwestern area of the United States. Sixty-two patients and 243 nurses participated in the study between August, 1995 and November, 1995. A description of the patient sample precedes that of the nurse sample.

Patient Sample

Medical and surgical patients were recruited from all adult critical care areas of the hospital, except the Post Anesthesia Care Unit (i.e., recovery room), while receiving mechanical ventilation. Ninety-two patients, or their family members, were approached for study participation. Of these, 12 declined participation. The attrition rate for the 80 patients (or family members) participating in the study was 23% (n = 18). Two patients were transferred to another hospital prior to completion of data collection, 3 were dropped by the investigator due to deterioration of medical status and 2 due to methicillin-resistant staphylococcus aureus, 4 were unable to cooperate with study procedures, 2 were discharged prior to completion of data collection, and 5 were extubated before the triad of nurses could be assembled at the bedside for testing. The final sample of 62 patients was comprised of 24 (39%) medical patients and 38 (61%) surgical patients.

The patient demographics of age, height, and weight are shown in Table 1 for the entire sample and for medical and surgical subsamples. Surgical patients, on average, were 4 years older than medical patients; however, the difference was not significant (t = -1.02, df = 60, p = .31). Although height was the same in both groups, on average the surgical

patients weighed more than the medical patients. However, the differences were not significant (t = 1.45, df = 60, p = .15).

Table 1

Patient Demographic Data of Age, Height, and Weight for Total Sample and for Medical and Surgical Subsamples

Variables	Total Sample (N = 62)	Medical Subsample (n = 24)	Surgical Subsample (n = 38)
Age			
Mean	55	53	57
Median	56	53	58
SD	16	16	16
Height in Inches			
Mean	66	66	66
Median	66	66	66
SD	4	4	4
Weight in Pounds			
Mean	181	169	189
Median	174	154	184
SD	53	47	55

Patient demographics of gender and race are shown in Table 2. Patients were evenly distributed by gender, with slightly more males in the medical group and more females in the surgical group. These differences in subsample gender were not significant (X^2 = .27, df = 1, p = .60). The majority of patients in both groups were Caucasian, with

approximately equal numbers of African-American and Hispanic patients in the subsamples (X^2 = .50, df = 2, p = .78).

Table 2

Patient Demographic Data of Gender and Race for Total Sample and for Medical and Surgical Subsamples

Variables	Total Sample (N = 62)		Medical Subsample (n = 24)		Surgical Subsample (n = 38)	
	f	%	f	%	f	%
Gender						
Male	31	50	13	54	18	47
Female	31	50	11	46	20	53
Race						
Caucasian	37	60	13	54	24	63
African-American	16	26	7	29	9	24
Hispanic	9	14	4	17	5	13

Primary diagnoses of the medical group consisted predominantly of cardiopulmonary problems (e.g., acute respiratory failure, pulmonary edema, acute respiratory distress syndrome), followed by neurologic problems (e.g., epidural hematoma, cerebral hemorrhage). Primary diagnoses in the surgical group consisted predominantly of cardiac surgery and abdominal surgery. The diagnoses for each subsample are shown in Table 3.

Table 3

Major Categories of Diagnoses for Medical and Surgical Subsamples (N = 62)

Subsample	Diagnoses			
	Primary		Secondary	
	f	%	f	%
Medical Subsample (n = 24)				
Cardiopulmonary Conditions	13	54	11	46
Nervous System Conditions	5	21	5	21
Other Body System Conditions: Renal, Gastrointestinal, Lymphatic, Gynecological	6	25	8	33
Surgical Subsample (n = 38)				
Cardiopulmonary Conditions	22	58	21	56
Musculoskeletal Conditions	5	13	3	8
Gastrointestinal Conditions	7	18	7	18
Other Body System Conditions: Neurologic, Gynecological, Renal, and Miscellaneous	4	11	7	18

All 62 patients were intubated and receiving mechanical ventilation on the first day of data collection. The endotracheal and tracheostomy tubes varied from size 6.0 mm to size 8.5 mm (M = 7.84, mode = 8.00, SD = 0.46, and range = 2.5). The other mechanical ventilation-related data are shown in Table 4. Differences in the mode of ventilation were significant between medical and surgical subsamples (X^2 = 30.1, df = 6, p = .00004). Most of the

medical patients were on the assist-control mode and the surgical patients were on either a continuous positive airway pressure (CPAP) or synchronized intermittent mandatory ventilation (SIMV) mode of ventilation. Testing was done in head-elevated positions for 95% of the subjects.

Table 4

Mechanical Ventilation (MV) Related Data (N = 62)

Variables	f	%
Ventilator Mode		
Intermittent Mandatory Ventilation/Synchronized Intermittent Mandatory Ventilation (IMV/SIMV)	17	27
Assist Control Ventilation (AC)	10	16
Continuous Positive Airway Pressure Ventilation (CPAP)	24	39
Tracheostomy Tube Ventilation (T-Piece)	1	2
Pressure Support Ventilation (PS)	3	5
Mandatory Minute Ventilation (MMV)	2	3
Synchronized Intermittent Mandatory Ventilation Plus Pressure Support Ventilation (SIMV+PS)	5	8
Body Position on Mechanical Ventilation		
Flat	3	5
15-degree	22	35
30-degree	27	44
45-degree	8	13
60-degree	2	3

The mean values for vital capacity (VC) and negative inspiratory pressure (NIP) were compared between the medical and surgical subsamples for all 3 days of data collection. VC on the first day was higher in the surgical subsample

(*M* = 1,250 ml, *SD* = 696) than in the medical subsample (*M* = 840 ml, *SD* = 604). This difference was significant (*t* = 2.58, *df* = 60, *p* = .02); there were no significant differences in the other mean values.

Nurse Sample

For every patient, nurses assigned to the intensive care units assessed cough effort intensity on the first day of data collection. When the patient was transferred from the critical care unit to another area of the hospital, the nurses assigned to the new area assessed cough effort intensity. Of the 279 nurses asked to participated in the study, 252 agreed with 243 completing the study. The attrition rate was 3%; 9 nurses were unavailable at the time of data collection.

The nurse demographic data of age and length of experience which included years in study unit, years in critical care nursing and years in nursing are shown in Table 5 for the total sample and for the medical and surgical subsamples. In the total nurse sample, ages varied from 23 to 68 years, with a mean age of 37 years. Surgical nurses, on average, were 3 years older than medical nurses; the difference was significant (*t* = -2.65, *df* = 241, *p* = .009).

Table 5

Nurse Demographic Data of Age and Length of Experience, Including Years in Study Unit, in Critical Care Nursing, and in Nursing, for Total Sample and for Medical and Surgical Subsamples

Variables	Total Sample (N = 243)	Medical Subsample (n = 72)	Surgical Subsample (n = 171)
Age			
Mean	37	35	38
Median	36	35	37
SD	8	7	8
Range	45	30	45
Length of Experience			
Years in Study Unit			
Mean	4	4	4
Median	3	3	4
SD	4	4	4
Range	21	20	21
Years in Critical Care Nursing			
Mean	6	6	5
Median	4	4	4
SD	6	5	6
Range	25	20	25
Years in Nursing			
Mean	12	10	13
Median	10	9	11
SD	8	7	8
Range	32	28	31

Gender and race variables were considered irrelevant to the study findings by the Institutional Review Board of the study hospital; hence, these data are not reported. The mean length of nursing experience was 11.5 years, with 9.6 years in the medical subsample and 12.5 years in the surgical subsample (t = -2.64, df = 241, p = .009). There were no significant differences in length of critical care experience or in length of study unit experience between medical and surgical nurses.

In terms of educational preparation, as shown in Table 6, the majority of nurse subjects (N = 144; 57%) had a baccalaureate degree; the education listed by the remaining nurses was diploma, associate degree, master's degree, doctor's degree, and other. The other category included 1 nurse in the medical subsample who was a respiratory therapist and 2 nurses in the surgical subsample who were licensed vocational nurses.

Findings

The data were tested for the assumptions underlying use of the Pearson product-moment correlation coefficient (Munro & Page, 1993). The data did not demonstrate linear relationships between cough effort intensity and VC and between cough effort intensity and NIP. The VC and NIP values were abnormally distributed, even when outliers were

Table 6

Nurse Demographic Data of Education for Total Sample and for Medical and Surgical Subsamples

Variables	Total Sample (N = 243)		Medical Subsample (n = 72)		Surgical Subsample (n = 171)	
	f	%	f	%	f	%
Education						
Diploma	19	8	3	4	16	9
Associate Degree (AD)	73	30	27	38	46	27
Bachelor's Degree (BS)	137	56	37	51	100	58
Master's Degree (MS)	10	4	4	6	6	4
Doctor's Degree (PhD)	1	1	0	0	1	1
Other	3	1	1	1	2	1

systematically removed. Further, the assumption of homoscedasticity was not met. Thus, nonparametric statistics were used in lieu of the Pearson product-moment correlation coefficient.

To test Hypothesis 1, equivalence reliability ≥ .80 (Nunnally & Bernstein, 1994) of cough effort intensity as assessed by multiple nurses simultaneously, interrater agreement was calculated according to the method described by Waltz, Strickland, and Lenz (1991). For each triad of cough effort intensity rankings, the percentage of agreement was calculated as follows. If all 3 rankings were the same,

the agreement was scored as 100%. If 2 of the 3 rankings were the same, the agreement was scored as 67%. If none of the rankings were the same, agreement was scored as 0%. The interrater agreement, or interrater reliability (IRR), for all nurse triads for the first and second testings on each of the 3 days varied from .72 to .80. The overall IRR for all testings combined was .76. The IRRs for each testing period are shown for the total sample and for the medical and surgical subsamples in Table 7. The overall IRR and the IRRs for most of the testing periods were lower than .80.

Table 7

Interrater Reliabilities for the Total Sample and the Medical and Surgical Subsamples

Variables	Total Sample (N = 62) r	Medical Subsample (n = 24) r	Surgical Subsample (n = 38) r
Day 1			
1st Cough Effort	.72	.75	.69
2nd Cough Effort	.76	.81	.73
Day 2			
1st Cough Effort	.76	.81	.73
2nd Cough Effort	.80	.89	.74
Day 3			
1st Cough Effort	.79	.78	.80
2nd Cough Effort	.74	.78	.72
Mean IRR	.76	.80	.74

Hypothesis 2, stability reliability ≥ .80 (Nunnally & Bernstein, 1994) assessed by rankings on the same patient by the same nurse 3 to 5 minutes apart, was tested with the two-tailed Spearman rho correlation coefficient. The average correlations of test-retest nurse rankings varied from .49 to .77 for the total sample. The overall mean correlation was .65. Stability correlation coefficients for the total sample and for the medical and surgical subsamples are shown in Table 8. The mean correlation for the medical subsample was higher than that for the surgical subsample.

Table 8

Test-Retest Correlation Coefficients for the Total Sample and the Medical and Surgical Subsamples

Variables	Total Sample (N = 62) r	Medical Subsample (n = 24) r	Surgical Subsample (n = 38) r
Day 1			
1st Nurse	.72	.62	.79
2nd Nurse	.56	.49	.60
3rd Nurse	.64	.72	.57
Day 2			
1st Nurse	.73	.94	.54
2nd Nurse	.64	.68	.68
3rd Nurse	.71	.76	.67
Day 3			
1st Nurse	.77	.76	.76
2nd Nurse	.62	.72	.62
3rd Nurse	.49	.57	.43
Mean r	.65	.70	.62

The Spearman rho correlation coefficient was used to test Hypothesis 3, construct validity of cough effort intensity with vital capacity determined by a correlation of $r \geq .70$ (Munro & Page, 1993). For each day of testing, the best (i.e., highest) of the three vital capacity measures was calculated. For each day of testing, the average of the three nurse rankings for the first cough effort was calculated. These values were correlated with the two-tailed Spearman rho. The correlations for the total sample and for each subsample are shown in Table 9. In the medical subsample, the correlation was stronger with each subsequent day of data collection. In contrast, the correlation was weaker with each subsequent day of data collection in the surgical subsample.

Table 9

Validity Correlation Coefficients for Best Vital Capacity Effort and Average Cough Effort Intensity for the Total Sample and the Medical and Surgical Subsamples

Variables	Total Sample (N = 62) r	Medical Subsample (n = 24) r	Surgical Subsample (n = 38) r
Day 1	.17	.01	.36*
Day 2	.32	.35	.30
Day 3	.35	.47*	.29

*$p < .05$ (two-tailed Spearman rho)

The two-tailed Spearman rho correlation coefficient was used to test Hypothesis 4, construct validity of cough effort intensity with negative inspiratory pressure determined by a correlation of $r \geq .70$ (Munro & Page, 1993). For each day of testing, the average of the three nurse rankings for the first cough effort was correlated with NIP. The correlations for the total sample and for each subsample are shown in Table 10.

Table 10

Validity Correlation Coefficients for Negative Inspiratory Pressure and Average Cough Effort Intensity for the Total Sample and the Medical and Surgical Subsamples

Variables	Total Sample (N = 62) r	Medical Subsample (n = 24) r	Surgical Subsample (n = 38) r
Day 1	.12	.23	.09
Day 2	.28*	.24	.32*
Day 3	.22	.22	.21

*$p < .05$ (two-tailed Spearman rho)

Summary of Findings

In this chapter, descriptive and correlational statistical analyses of the data were reported. The patient sample consisted of 62 medical and surgical subjects, while

the nurse sample numbered 243. Convenience sampling was used for both patient and nurse samples.

Percentage agreement was used to test Hypothesis 1 (equivalence reliability). With the exception of interrater reliability for medical nurses, the IRRs were less than .80. The Spearman rho correlation coefficient was used to test Hypothesis 2 (stability reliability). Likewise, the test-retest correlation coefficients were < .80. Hypotheses 3 and 4 specified construct validity for cough effort intensity, assessed with vital capacity and negative inspiratory pressure, respectively. Using the Spearman rho correlation coefficient, construct validity was not supported as hypothesized. The relationships between cough effort intensity (CEI) and vital capacity and between CEI and NIP were weak to moderate.

CHAPTER 5

SUMMARY OF THE STUDY

A summary of the study is presented in this chapter. The findings are discussed in relationship to findings reported in the literature by other investigators. The specific focus of this chapter is to present conceptual elements of the literature and their relationships to the conclusions. Recommendations for future studies are also included.

Summary

The purpose of this study was to test the subjective nursing assessment of cough effort by nurse clinicians and to test the correlation of cough effort intensity with vital capacity and negative inspiratory pressure. Four hypotheses were tested. The first two hypotheses tested evidence of adequate equivalence reliability and stability reliability of subjective cough effort ratings of medical and surgical patients by critical care and acute care nurses. The last two hypotheses tested the relationships between cough effort intensity and vital capacity and negative inspiratory pressure. The conceptual model of weaning developed by the

AACN Third National Study Group on Weaning from Mechanical Ventilation (Knebel et al., 1994) and laws of pulmonary physiology (Guyton, 1986) comprised the conceptual framework used for this study.

This study had a correlational design with repeated measurements. The study was conducted at a tertiary, nonprofit, teaching hospital in a large urban southwestern city in the United States. The sample consisted of 62 medical and surgical patients and 243 critical care and acute care nurses, conveniently sampled. The patient sample was asked to participate in the study voluntarily with body language consent while on mechanical ventilation in the critical care units. The nurse sample was also asked to voluntarily participate with verbal consent. Signed consents were waived by the institutional review boards of Texas Woman's University and the hospital.

The investigator completed the demographic forms for both the patient and nurse samples. The nurses were requested to evaluate intensity of cough effort by placing a mark or check on a nurse rating form provided by the investigator. Cough effort intensity (CEI) was rated as weak, moderate, or strong. Construct validity data consisted of vital capacity and negative inspiratory pressure readings obtained by the investigator with the use

of bedside portable respirometer (for VC) and portable inspiratory force meter (for NIP).

Descriptive and inferential statistics were used to analyze the data. Percentage agreement was used to test interrater reliability of CEI, and the Spearman rho correlation coefficient was used to test stability reliability of CEI. The Spearman rho correlation coefficient was used to test the relationships of the three study variables. Neither the reliability coefficients nor the validity coefficients met the a priori criteria for evidence of adequate reliability and validity in the total sample. The medical subsample, however, did meet the criterion ($\underline{r} \geq .80$) for interrater reliability.

Discussion of Findings

The results of the study must be evaluated within the context of several limitations. The limitations include convenience sampling technique, a posteriori designation of subsamples, and a large number of nurses for interrater reliability testing.

Convenience sampling was less of a problem in this study because of the homogeneity existing within the study subjects, critical care patients and critical care nurses. According to Polit and Hungler (1991), there is minimal bias when the phenomena under investigation are fairly

homogeneous within the population. Furthermore, the investigator used proportional stratified sampling (Talbot, 1995) to obtain a patient sample representative of the target population. The investigator obtained the number of admissions per month in the critical care units from unit managers and then determined the number of patients to be studied from each unit. The a posteriori designation of the two subsamples, medical and surgical, was employed to help explain the findings and to compare the findings of this study to a previous study by Hanneman (1994) on weaning predictors in surgical patients. Recruitment of a large number of nurses for equivalence and stability reliability was executed to mimic the reality of clinical practice where different clinicians routinely assess cough effort intensity (CEI).

Cough effort intensity assessment is subjective. Yet assessments of the same effort by multiple nurses should be similar if comparisons of documented CEI in the patient medical record are to be made among shifts or days of patient hospital stay. Analysis of data from the 243 nurses' subjective assessment of CEI revealed wide discrepancies of agreement in their rankings. Cough may be a sign of cardiopulmonary disease (as discussed in Chapter 2). As pointed out by Smyllie, Blendis, and Armitage

(1965), "the value of a sign as an index of a disease process depends mainly on its ability to discriminate between diseases [its validity] and the consistency with which it can be repeated [its observer variation]" (p. 412). The investigators studied 20 respiratory signs in 20 patients as assessed by 9 observers using standard deviation agreement index. Smyllie et al. found that interrater reliability of the pulmonary physical signs resulted "midway between chance and complete agreement" (p. 413).

According to Smyllie et al. (1965), in the 1951 history-taking, unpublished study by Cochrane et al., cough was one of the four respiratory signs and symptoms investigated. The findings noted "considerable interobserver and intra-observer error" (p. 413) in history taking on the sign of cough as rated by multiple observers.

Findings from these studies validate the results of this study and imply wide variability of multiple observer agreement. Individual subjective evaluation of any sign or symptom involves two elements that interplay with each other, namely, the individual's perception of an event (e.g., CEI) and the individual's interpretation of the event (e.g., CEI rating as strong, moderate, or weak). These elements have been cited by Spodick (1975) to impact "perceptual differences within a group of recognized

experts" (p. 594) and, interestingly, within the subjects as well.

The average nurse who participated in this study was experienced, with approximately 12 years of nursing practice experience. Therefore, the evidence for inadequate reliabilities for cough effort assessment cannot be explained by nurse experience. The findings of inadequate equivalence reliability and inadequate stability reliability suggest that substantial error is introduced into CEI assessment and that this error, in contrast to valid changes in patient effort, may be reflected in nursing documentation. According to Woolf and Rosenberg (1962), "any subjective evaluation is apt to be highly variable and with an unacceptable margin of error" (p. 95).

Due to patient acuity and nurse workload, it is possible that the nurses in this study did not devote full attention to differentiation of cough effort intensity. Observer fatigue could have impacted the CEI assessment results, as nurses in the critical care areas were working 12 to 16 hour shifts. In addition, no observer training was provided to the 243 nurses before or during this study. In contrast, in the study by Hanneman (1994), rater training was done with two observers, with a reported IRR $\geq$ .95.

Another explanation for the low reliabilities may be the restricted range of ranking choices for CEI. In other words, the three categories of qualitative descriptors (weak, moderate, and strong) may not be sufficient to capture the variability in cough effort intensity. In their study, Thurlbeck et al. (1969), using three categories to rate assessment of emphysema (mild, moderate, and severe), also reported wide discrepancies in the scores. Variability enhances reliability (Nunnally & Bernstein, 1994), and perhaps more options for CEI description would have increased interrater reliability in this study. Nevertheless, in clinical practice, cough effort is almost exclusively documented as weak, moderate, or strong.

Variability in CEI rankings, however, would not be expected to improve stability, or test-retest, reliability. If raters cannot select the same category from three options, they are unlikely to select the same ranking when more options exist. Although the retest occurred within 3 to 5 minutes of the first assessment, it is possible that patient cough effort varied in intensity between the two measurement times. Again, however, this possibility would pose problems for clinical assessment of cough effort on a periodic basis.

Data collection time spent in a particular area could have affected the study results. The medical subsample had higher interrater reliability than the surgical subsample. The investigator spent 2 to 3 months in the medical intensive care unit for the first 19 patient subjects. The medical intensive care nurses became familiar with the study protocol. Consequently, the nurses were readily available for data collection. In contrast, the investigator spent a shorter duration of time in the surgical units, and the surgical nurses were impatient to complete the study.

Classical measurement theory was used as the psychometric framework. Generalizability theory might yield different results because formulas are available within that psychometric framework for multiple raters ranking one observation of an ordinal level nature. The theoretical and technical aspects of generalizability theory are beyond the scope of this investigator, but they may be useful for a secondary analysis of these data.

On study day 1, every patient was on mechanical ventilation. Study results suggest that CEI is unlikely to be a useful indicator of weaning readiness. Both medical and surgical subsamples showed low reliabilities on day 1.

The presence of an endotracheal tube and mechanical ventilation prevents the production of cough sound. Thus,

these factors could have affected nurse assessment of cough effort intensity due to the absence of the sound of cough. It is possible that some nurses rated cough effort as nonexistent or weak due to the absence of cough sound alone (Cox et al., 1984; Gravenstein, Devloo, & Beecher, 1954; Hagen, 1991). Other nurses might have rated the cough by looking at other cough effort intensity indicators, such as contraction of abdominal and intercostal musculature (Irwin, Rosen, & Braman, 1977) or triggering of the ventilator alarm. Interestingly, data collected by Cox et al. (1984), using the electromyographic (EMG) method (objective instrument) to measure cough intensity and cough flow volume indicated a significant positive correlation between integrated EMG and cough noise. However, as shown in Table 7, interrater reliabilities were neither materially nor consistently improved during days 2 and 3 when most patients were extubated and able to produce cough sound.

The correlations between vital capacity and cough effort intensity were weak to moderate. Because vital capacity maneuvers are effort-dependent, the investigator collected the best of three vital capacity readings. Thus, fatigue may have been a factor. Although vital capacity was measured within 10 minutes of CEI assessment, the patient had produced several maximum cough efforts, including those

during the return demonstration. Unwillingness or inability to extend full cooperation influences reproducibility and contributes to variability of VC measurements (Yang, 1992).

The correlation between cough effort intensity and negative inspiratory pressure was weak. Again, patient fatigue could have affected the results. In a related study done by Multz et al. (1990), three NIP measurements performed by one rater on one patient on one day were reproducible; measurements by different raters and on different days were not.

Conclusions

Based on the findings of this study, the following conclusions were drawn:

1. Cough effort intensity assessment by multiple nurses is not a reliable measure.
2. Cough effort intensity assessment by medical and surgical nurses is not stable, even when a short period of time exists between repeatability measurements.
3. Subjective nursing assessment of cough effort intensity has a weak to moderate positive relationship with vital capacity.
4. Subjective nursing assessment of cough effort intensity has a weak to moderate relationship with negative inspiratory pressure.

Implications

The purpose of this study was to assess the reliability of subjective assessment of CEI; to determine if CEI was a valid indicator of vital capacity and NIP, and to examine the stability of CEI. Multiple nurses were used to mimic actual hospital conditions.

Current practices of using subjective CEI assessment as a weaning readiness parameter should be discontinued. Potentially, reliability of the CEI could be enhanced if appropriate instruction were used to teach nurses correct methods for assessing CEI in clinical situations. The amount of training and expertise has direct ramification in the critical thinking abilities employed by clinicians which affect clinical decisions and the quality of patient care rendered at the bedside (Benner, 1984).

The repeatability measurement of CEI should be tested by a different mechanism than was used in this study. For example, a video or film recording of one actual cough event of the patient could be rated by the same nurse once and then again a week later. The objective recording will uphold the stability reliability of CEI.

Evidence of a weak positive relationship was found between CEI and VC and CEI with NIP as well. However, the use of machines like VC and NIP meters provide easy

accessibility and objectivity of results that are obtainable quickly at the bedside without lengthy patient preparation and waiting time for results. Poor reproducibility of VC and NIP measurements by various investigators would warrant further investigation.

Recommendations for Further Study

In view of the findings of this study and the importance of cough effort intensity as a clinical assessment parameter, further research on cough effort is needed. The following recommendations are made for future research on cough effort intensity:

1. A similar study should be undertaken using specific descriptors for cough effort intensity rankings, such as those used in Hanneman's (1994) study.
2. A secondary analysis of these data should be done using techniques from generalizability theory.
3. Further research should be conducted on the objective measures of vital capacity and negative inspiratory pressure to validate the problems with reliability found in the studies by Multz et al. (1990) and Yang (1992).
4. Further research is recommended to determine whether differences in equivalence reliability between medical

and surgical nurses found in this study exist under conditions of an a priori comparative design.

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APPENDIX A

AGENCY APPROVALS

9203 Burger Lane
Houston, Texas 77040
July 6, 1995

CPHS Committee
UTHSC & Hermann Hospital
6431 Fannin
John Freeman Building, Suite G - 700
Houston, Texas 77030

Dear CPHS Committee:

My name is Huberta (Bette) Cozart, a graduate student enrolled at Texas Woman's University under the tutelage of Dr. Sandra K. Hanneman. I am respectfully submitting a research application for your approval entitled, **"Subjective Nursing Assessment of Cough Effort".** I have included additional pages which are **5a, 6a, 7a,** and **8a** for **Nurse Subjects** information. May I please request the CPHS Committee to waive written consent for nurse subjects due to minimal risks to the participants? I have included, however, a written consent for nurse subjects in this application.

I sincerely hope for your kind consideration and assistance in my pursuit of a master's degree.

Very truly yours,

Huberta T. Cozart
Huberta (Bette) T. Cozart, RN, BSN

TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

HUMAN SUBJECTS REVIEW COMMITTEE
1130 M D Anderson Blvd., Houston Texas 77030 713/794-2114

MEMORANDUM

TO: Huberta Cozart

FROM: HSRC

DATE October 11, 1995

SUBJECT HSRC Application

Proposal Title: Subjective Nursing Assessment of Cough Effort

Your changes to your application to the HSRC have been reviewed and approved

REMEMBER TO PROVIDE COPIES OF THE SIGNED INFORMED CONSENT TO ME WHEN THE STUDY HAS BEEN COMPLETED. GRADUATION MAY BE BLOCKED UNLESS CONSENTS ARE RETURNED.

Thank you for your patience in awaiting the committee's decision The committee extends its best wishes for a productive and very successful project. Should you have any further questions about your application please contact me at 794-2114

Doris E Wright

Doris E Wright Ph D
Chairperson

THE UNIVERSITY OF TEXAS
HOUSTON
HEALTH SCIENCE CENTER

The Committee for the
Protection of Human Subjects

NOTICE OF APPROVAL TO BEGIN RESEARCH August 4, 1995

HSC-O-TWU-95-011 - "Subjective Nursing Assessment of Cough Effort"
P.I.: Huberta Cozart, MSN Student

PROVISIONS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consent, etc.

APPROVED: At a Convened Meeting

APPROVAL DATE: July 21, 1995 EXPIRATION DATE: June 30, 1996

CHAIRPERSON: Alan C. Swann, M.D.

Subject to any provisions noted above, you may now begin this research.

CHANGES - The P.I. must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.

INFORMED CONSENT - Informed consent must be obtained by the P.I. or designee using the format and procedures approved by the CPHS. The P.I. must instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document.

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS - The P.I. will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS - The P.I. will maintain adequate records, including signed consent documents if required, in a manner which ensures confidentiality.

HERMANN

C.P.H.S. Number: HSC-O-TWU-95-011

Notification of C.P.H.S. Approval: 8/9/95

Title: "Subjective Nursing Assessment of Cough Effort"

P.I.: Huberta T. Cozart, MSN Student

Thank you for choosing Hermann Hospital to participate in this research project. Approval is hereby granted by Hermann Hospital Administration to initiate this research project involving Hermann Hospital patients, staff or facilities.

This approval is subject to the investigator's acceptance of the following stipulations

Changes — Changes to a study, including change of principal investigator, changes in services involved, or changes in budget or funding will require a new Hermann Hospital approval.

Education — The P.I. will provide inservice education to all personnel affected by the research study.

Records — All in-patients on any research protocol will have in their hospital medical record a copy of the signed informed consent document. A research identification sticker will be placed on the outside of the chart (Stickers are enclosed.).

Patient Enrollment — The P.I. will register all Hermann Hospital patients in this study via the enclosed Research Patient Registration Log. The log should be faxed to Special Billing at 704-4257 (or mailed to Special Billing, 6424 Fannin, Houston, TX 77030). Timely, written notification of Patient enrollment is a requirement for Hermann's continued support of your research.

Billing — There are no research related charges attached to this study. However, the Investigator agrees to forward a copy of the study results to the Hermann Research Office.

Please sign and return a copy of this letter to Special Billing, Hermann Administrative Annex (or FAX #704-4257), to indicate your acceptance of our terms and policies.

If you have any questions, or need additional information, please contact the Hermann Hospital Research Office at 704-4255

Hermann Hospital Approval: _____ DATE

P.I. Acceptance: _____ DATE

copy Sandra Hanneman, RN, PhD
Special Billing
CPHS

Hermann Hospital
Texas Medical Center

APPENDIX B

PATIENT DEMOGRAPHIC DATA FORM

PATIENT DEMOGRAPHIC DATA FORM

Subjective Nursing Assessment of Cough Effort
PI: BETTE T. COZART, RN, BSN

A. **Patient Demographics**

Patient Code #_____
Unit _____ (1=MICU; 2 = CCU; 3-3CULLEN; 4=4CULLEN/CIMU; 5=CVTU; 6=STICU; 7=NICU; 8= JONES; 9=6JONES; 10=SIMU; 11=OTHER)

Dates of Study: (month/day/year/time)
Day 1: ___/___/___/___:___
Day 2: ___/___/___/___:___
Day 3: ___/___/___/___:___

Age: _____
Gender:_____ (1 = MALE; 2 = FEMALE)
Race:_____ (1=CAUCASIAN; 2=BLACK; 3=HISPANIC; 4=ASIAN/ORIENTAL; 5=OTHER)
Height:_____
Weight:_____
ETT Size:_____
Ventilator Mode:____ (1=IMV/SIMV; 2=A/C; 3=CPAP; 4=T-PIECE; 5=PS; 6=IMV+PS; 7=MMV; 8=OTHER)
Primary Diagnosis:_____
Secondary Diagnosis:_____

B. **Construct Validity Measurements**

Day 1: Date:_____ MV__(1=Yes; 2=No) Position__(1=30; 2=45; 3=90)

	Rater 1	Rater 2	Rater 3	VC (1)_____	NIP_____
(1st)	CE___	CE___	CE___	(2)_____	
(2nd)	CE___	CE___	CE___	(3)_____	

Day 2: Date:_____ MV__(1=Yes; 2=No) Position__(1=30; 2=45; 3=90)

	Rater 1	Rater 2	Rater 3	VC (1)_____	NIP_____
(1st)	CE___	CE___	CE___	(2)_____	
(2nd)	CE___	CE___	CE___	(3)_____	

Day 3: Date:_____ MV__(1=Yes; 2=No) Position__(1=30; 2=45; 3=90)

	Rater 1	Rater 2	Rater 3	VC (1)_____	NIP_____
(1st)	CE___	CE___	CE___	(2)_____	
(2nd)	CE___	CE___	CE___	(3)_____	

PATIENT DEMOGRAPHIC DATA FORM

Patient Code #_____

C. **Nurse Codes**

Day 1
- Nurse 1 Code #_____
- Nurse 2 Code #_____
- Nurse 3 Code #_____

Day 2
- Nurse 1 Code #_____
- Nurse 2 Code #_____
- Nurse 3 Code #_____

Day 3
- Nurse 1 Code #_____
- Nurse 2 Code #_____
- Nurse 3 Code #_____

APPENDIX C

NURSE DEMOGRAPHIC FORM

NURSE DEMOGRAPHIC FORM

Subjective Nursing Assessment of Cough Effort
PI: BETTE T. COZART, RN, BSN

Unit (1=MICU; 2 = CCU; 3-3CULLEN; 4=4CULLEN/CIMU; 5=CVTU; 6=STICU; 7=NICU; 8= JONES; 9=6JONES; 10=SIMU; 11=OTHER)

Education (1=DIPLOMA; 2=ADN; 3=BACHELOR'S; 4=MASTER'S; 5=PhD; 6=OTHER)

Patient's Assigned RN (1=YES; 2=NO)

Nurse Code #____ Unit__ Age___ Education___ Yrs in Nursing__
Yrs in ICU____ Yrs in Study Unit____ Patient's Assigned RN__

Nurse Code #____ Unit__ Age___ Education___ Yrs in Nursing__
Yrs in ICU____ Yrs in Study Unit____ Patient's Assigned RN__

Nurse Code #____ Unit__ Age___ Education___ Yrs in Nursing__
Yrs in ICU____ Yrs in Study Unit____ Patient's Assigned RN__

Nurse Code #____ Unit__ Age___ Education___ Yrs in Nursing__
Yrs in ICU____ Yrs in Study Unit____ Patient's Assigned RN__

Nurse Code #____ Unit__ Age___ Education___ Yrs in Nursing__
Yrs in ICU____ Yrs in Study Unit____ Patient's Assigned RN__

Nurse Code #____ Unit__ Age___ Education___ Yrs in Nursing__
Yrs in ICU____ Yrs in Study Unit____ Patient's Assigned RN__

Nurse Code #____ Unit__ Age___ Education___ Yrs in Nursing__
Yrs in ICU____ Yrs in Study Unit____ Patient's Assigned RN__

Nurse Code #____ Unit__ Age___ Education___ Yrs in Nursing__
Yrs in ICU____ Yrs in Study Unit____ Patient's Assigned RN__

APPENDIX D

NURSE RATING FORM

NURSE RATING FORM

Subjective Nursing Assessment of Cough Effort
PI: BETTE T. COZART, RN, BSN

Patient Code #_____

Nurse Code #_____

Day #____ (1=Day One, 2=Day Two, 3=Day Three)

Direction: Please check **One Choice Only!**

Initial Cough Effort:

____ Weak

____ Moderate

____ Strong

(Cut here)

NURSE RATING FORM

Subjective Nursing Assessment of Cough Effort
PI: BETTE T. COZART, RN, BSN

Patient Code #_____

Nurse Code #_____

Day #____ (1=Day One, 2=Day Two, 3=Day Three)

Direction: Please check **One Choice Only!**

Second Cough Effort:

____ Weak

____ Moderate

____ Strong

APPENDIX E

STUDY PROTOCOL

STUDY PROTOCOL

Subjective Nursing Assessment of Cough Effort

PI: Bette T. Cozart. RN. BSN

Consent

1. Approach patient and/or next of kin (legally authorized representative) about patient participation in the study.

   (a) explain study to patient and/or next of kin: state the purpose and describe the procedure.

   (b) If patient/next of kin wishes to participate. obtain verbal consent.

   (c) Obtain a green research sticker from the envelope marked "Research Stickers" and put on the patient's medical record.

Equipment Preparation

1. Bring the study respirometer and the study negative inspiratory pressure (NIP) meter and all the necessary attachments to the approved research units.

2. Place the following equipment at the patient's bedside:

   2.1 One 22 mm OD/15 ID adapter

   2.2 Bacterial filter

   2.3 One 6-inch wide bore tubing

   2.4 Wright respirometer.

   2.5 Boehringer NIP meter.

3. Assemble equipment.

   (WRIGHT METER)

3.1 Attach the white larger end of bacterial filter to the inlet at a right-angle of the Wright respirometer (other end of filter attaches to patient's endotracheal tube).

3.2 For extubated patients, attach the 22 mm OD/15 mm ID adapter to the bacterial filter which is connected to the inlet of the Wright meter.

(BOEHRINGER METER)

3.3 Attach a white 3/4 inch adapter to the bottom steel part of the Boehringer meter.

3.4 Hook/shove a transparent 1-inch adapter to one end of blue-colored tubing where a caramel-colored seal/barrier underside is visually seen. The opposing end will have the other caramel-colored seal closing off the opening.

3.5 Attach a 4-6 inch straw-sized transparent tubing to the end of the 1-inch adapter above.

3.6 Close off the two smaller ports of the blue-colored tubing, one port located on top and the other port located in front of the tubing.

3.7 One port of the blue-colored tubing is left open for connection to the patient.

4. Label a zip-lock plastic bag with the patient's name, unit, bed number, and study code #.

5. Have a pillow (regular hospital pillow for medical patients and red heart pillow for surgical patients) ready for splinting.

Bedside Preparation

1. Write the patient's name and bed number on the Research Patient Registration Log (master roster).

2. Take three (3) Patient Demographic Data forms and three (3) nurse rating forms from the envelope marked "Data Collection Forms". Cut each nurse rating form in half.

3. Write the subject number from next to the patient's name on the master roster onto the forms in the slots "Patient Code #".

4. Assess patient for baseline vital signs, arterial saturation, and level of consciousness.

4.1 Patient able to follow commands.

4.2 Stable vital signs.

4.3 Pulse oximeter oxygen saturation ≥95%.

Procedures for Data Collection

1. Complete the patient demographics section of Patient Demographic Data Form.

1.1 Age (in years) - obtain from the patient's medical record.

1.2 Height (in.) - obtain from the patient's medical record. If unavailable, obtain from patient/next of kin.

1.3 Weight (lb.) - obtain from the patient's medical record. If unavailable, obtain from patient/next of kin.

1.4 Gender - obtain from the patient's medical record.

1.5 Race - obtain from the patient's medical record.

1.6 Primary diagnosis - obtain from the patient's medical record.

1.7 Secondary diagnosis - obtain from the patient's medical record.

1.8 ETT/TR - obtain from the patient's medical record.

1.9 Ventilator mode - obtain from the patient's respiratory care record.

2. Patient Teaching

2.1 Place patient in the semi-recumbent position if there are no contraindications.

2.2 Teach patient how to perform cough effort using one pillow held firmly over the anterior thoraco-abdominal area by the principal investigator.

2.3 Demonstrate maximal effort cough.

2.4 Have patient do a return demonstration.

3. Complete the nurse demographic form.

3.1 Age - ask the individual nurse subject.

3.2 Education - ask the individual nurse subject.

3.3 Work experience in three areas: (1) Study Unit, (2) Critical Care, and (3) Nursing - ask the individual nurse subject.

3.4 Patient's assigned RN - ask nurse subject if assigned to care for study patient.

4. Reliability assessment.

4.1 Assemble three (3) nurses at patient's bedside, at least 3 feet apart.

4.2. Give each nurse a rating sheet.

4.3 Explain that each nurse should watch the patient cough and then immediately check the best descriptor of cough effort. Pick only one of the three cough effort rankings and make a "check" or "X" mark in front of the choice.

4.4 Instruct patient to cough as hard as possible while holding pillow over anterior thoraco-abdominal area.

4.5 Collect the rating sheets and put in envelope.

4.6 Wait 1-3 minutes. Instruct nurses not to discuss patient cough or ratings.

4.7 Give each nurse a rating sheet.

4.8 Same as 4.3.

4.9 Same as 4.4

4.10 Collect the rating sheets and thank the nurses for their help.

5. Validity Assessment

5.1 Wash hands and don nonsterile gloves.

5.2 As appropriate, remove the patient from the ventilator and allow a minute or so for the patient to develop his or her own spontaneous ventilation. If the patient should become hypoxic (pulse oximetry saturation $\leq$ 92 %), return the patient to the ventilator.

5.3 Measure vital capacity.

5.3.1 Explain to the patient that the purpose of this procedure is to test the maximum amount of air the patient can breathe out after the deepest breath in possible.

5.3.2 Attach adapter to endotracheal or tracheostomy tube or mouthpiece.

5.3.3 Attach a noseclip to the extubated patient's nose before measuring the vital capacity.

5.3.4 Instruct the patient to breathe in as deeply as possible.

5.3.5 Turn Wright on. Instruct the patient to breathe out slowly and as completely as possible.

5.3.6 Turn off the Wright at the end of exhalation.

5.3.7 Repeat steps 5.3.4 through 5.3.6.

5.3.8 Repeat steps 5.3.4 through 5.3.6.

5.3.9 Disconnect adapter and place patient back on ventilator, as appropriate.

5.3.10 Record best effort (highest value) of the three VC measurements.

5.4 Measure negative inspiratory pressure.

5.4.1 Explain to the patient that the purpose of this procedure is to test the strength of the muscles. Tell the patient that this procedure may cause breathlessness but it will last less than 15 seconds.

5.4.2 Attach the Boehringer one-way valve to the endotracheal or tracheostomy tube or mouthpiece.

5.4.3 Attach a noseclip to the extubated patient's nose before NIP measurement.

5.4.4 Instruct the patient to try as hard as possible to breathe in for 15 seconds by the clock (Truwit & Marini, 1992).

5.4.5 Disconnect the Boehringer and place patient back on ventilator, as appropriate.

5.4.6 Record the most negative reading during the 15 second measurement.

6. Clean up.

6.1 Place disposable equipment in plastic bag and seal.

6.2 Remove gloves and wash hands.

6.3 Verify that all demographic data collection forms and nurse rating sheets are correctly coded.

6.4 Staple together the two rating sheets for each nurse subject with the demographic data for the patient.

6.5 Paper clip together the nurse data in a brown envelope and store in secure place.

6.6 Thank patient for participation and, if Day 1 or 2, remind patient that the same procedure will be repeated the next day or two more days.