

**A STUDY OF ANXIETY AND AGITATION EVENTS IN MECHANICALLY
VENTILATED PATIENTS**

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Anxiety and agitation are experienced by critically ill patients frequently and produce management challenges for clinicians. The purpose of this study was to describe critically ill patients' behaviors classified as "anxious or agitated", clinician interpretation of these behavioral cues, and choice of interventions based on those interpretations. This qualitative secondary analysis used existing longitudinal data (observations, interviews, and medical records) from an ethnographic study of 30 critically ill patients who were weaning from prolonged mechanical ventilation, patient families and clinicians who cared for them. Each event of anxiety or agitation was analyzed using dimensional analysis techniques.

Exploration of relationships of resulting themes and patterns using graphic displays led to development of the Anxiety–Agitation in Critical Illness Model which describes patient physiological, behavioral and psychological responses to stimuli of anxiety and agitation; clinician assessment of symptoms of anxiety and agitation, and management strategies chosen by clinicians. Interaction was identified as the core process in which patients appraised the threat of stimuli. Clinician assessment of patient interaction guided assessment and management of anxiety and agitation. Clinicians observed and interpreted patient responses to stimuli using "knowing the patient" and attributions about anxiety and agitation. Two opposing or dialectic

attributions were revealed: discrimination vs. generalization and anxiety as an expected response vs. a character flaw.

Interventions were designed to modify the stimulus of anxiety or agitation and included physical comfort measures, distraction, supportive verbal strategies, and music. Withholding presence and withholding information was described by clinicians as strategies used when patient anxiety was associated with ventilator weaning. These interventions were called “out of sight, out of mind” and “sneaking the wean”. These were new and unexpected psychosocial interactions not described previously in the literature. Sedation was used to modify appraisal of or response to the stimulus. Sedation management was inconsistent and variable especially when anxiety was associated with ventilator weaning.

This study provides a foundation for practice improvement by offering a comprehensive model and alternative considerations for interpretation and management of symptoms in the ICU. It suggests areas for additional study, specifically, social support, sedation and withholding information or presence.

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PREFACE

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and gives me a role model to emulate. And because I can call her “friend”, makes her that much more special in my life.

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Finally, I am grateful to my parents who gave me the wonderful gifts of curiosity, acceptance and honor. While they did not live to see me finish this work, I know they are always with me.

1.0 INTRODUCTION

An important therapeutic goal in critical care is promoting patient comfort and well being, while maintaining patient safety. Occurrence of numerous uncomfortable symptoms particularly anxiety and agitation are well established (Nelson et al., 2001). Interpreting and treating patient symptoms are integral components of critical care nursing practice (Bergbom-Engberg & Haljamae, 1989; Chlan, 2003; Gries & Fernsler, 1988; Logan & Jenny, 1997; Rotondi et al., 2002) In a survey of 783 members of the American Association of Critical Care Nurses (Frazier et al., 2003), 71.3% reported that anxiety assessment was very important, yet ICU clinicians use inconsistent and variable terms to describe psychological symptoms (Broyles, L., Colbert, A., Tate, J., Swigart, V., & Happ, M. B., 2008; Egerod, 2002). Little is known about how critical care clinicians (nurses, physicians, and respiratory therapists) interpret or distinguish among different psychological symptoms and the strategies that critical care clinicians employ to manage psychological symptoms.

1.1 PURPOSE

The purpose of this study is to describe critically ill patients' behaviors classified as "anxious or agitated", clinician interpretation of these behavioral cues, and choice of interventions based on those interpretations.

1.2 SPECIFIC AIMS

The specific aims of this study are to describe:

1. critically ill patients' psychological symptoms classified as "anxious or agitated"
2. clinician interpretation of psychological symptoms and behavioral signs
3. clinician choice of interventions and
4. factors influencing clinician interpretation and management strategies.

1.3 RESEARCH QUESTIONS

Research Questions (RQ) to be addressed by this study are:

1. What are the defining characteristics and cues of psychological symptoms exhibited by patients who are experiencing prolonged critical illness?

2. How are these characteristics and cues interpreted as behavioral signs by clinicians? b) How do clinicians discriminate between various psychological symptoms and behavioral signs?
3. What therapeutic strategies (e.g., medications, non-pharmacologic methods) do clinicians undertake in response to patients' psychological symptoms and behavioral signs?
4. How do physiologic, social and behavioral characteristics of the patient influence psychological symptoms and behavioral signs the clinician's use to interpret and manage those symptoms?

1.4 OPERATIONAL DEFINITIONS

Agitation – psychomotor excitement, tumultuous behavior, excessive motor activity, usually non-purposeful, associated with internal tension (Crippen, 1999)

Anxiety - feeling of dread, fear, lack of control; perceived threat to homeostasis (Bay & Algase, 1999)

Behavioral Signs- information utilized by the clinician, in absence of verbal input from the patient that the clinician uses to base action

Behaviors – actions by the patient that are observed by the clinician

Clinician - Professional critical care staff with responsibilities for care of the patient; includes physicians, registered nurses and respiratory therapists.

Interventions – actions taken by the clinician to overcome a problem

Prolonged mechanical ventilation - ≥ 4 days on mechanical ventilation with at least one failed wean attempt

Sign – Abnormality indicative of disease, detectable by another person and sometimes the patient (Anonymous, 1994)

Symptom – Subjective experience reflecting changes in a person's biopsychosocial function, sensation or cognition (Anonymous, 1994)

1.5 BACKGROUND AND SIGNIFICANCE

Mechanical ventilation is frequently employed to support patients with life-threatening physiologic dysfunctions. While most patients require mechanical ventilation for only a few days, the greatest burden in terms of the cost of critical illness and patient experience is incurred by the relatively small number of patients who require prolonged mechanical ventilation (Holcomb, Wheeler, & Ely, 2001). Strategies to reduce the duration of ventilatory support are important because of the increased morbidity and mortality associated with prolonged mechanical ventilation (≥ 7 days) (Kollef et al., 1998).

Sedation and analgesia are often prescribed to achieve optimal comfort, reduce the physiologic stress response, improve ventilatory control, and facilitate nursing care of patients being mechanically ventilated (Holcomb, et al., 2001). Inadequate sedation can lead to agitation, ventilator asynchrony, treatment disruption, or myocardial ischemia (Weinert, Chlan, & Gross, 2001). Even optimally sedated patients may experience untoward effects of mechanical ventilation due to immobility, altered levels of consciousness and loss of protective reflexes (Sessler et al., 2001). Excessive or prolonged sedation may prolong ventilatory dependence,

predisposing the patient to ventilator associated pneumonia (Heyland, Cook, Griffith, Keenan, & Brun-Buisson, 1999), ventilator associated lung injury, malnutrition, and polyneuropathy of critical illness. Prolonged or over-sedation of critically ill patients has also been associated with long term negative psychiatric outcomes, such as depression and post-traumatic stress disorder (Jones, Griffiths, Humphris, & Skirrow, 2001; Nelson, Weinert, Bury, Marinelli, & Gross, 2000).

Clinicians assess and manage patient psychological symptoms and behavioral signs with a great degree of variability (Bair et al., 2000). While efforts to standardize sedation assessment and management through the use of protocols have been described (Jacobi et al., 2002), there is no universally accepted method to assess and maintain optimal sedation and analgesia (De Jonghe et al., 2000; Jacobi, et al., 2002; Ostermann, Keenan, Seiferling, & Sibbald, 2000)

The presence of psychological symptoms such as anxiety is typically validated by a verbal statement from the person. However, most critically ill patients are unable to verbalize their feelings due to endotracheal intubation and mechanical ventilation. Therefore, clinicians must rely on other behavioral cues to diagnosis and treat psychological symptoms. The accuracy of interpretation of these cues is clouded by the similarity among behavioral manifestations of anxiety and agitation and other commonly encountered conditions such as pain, delirium or frustration with communication difficulty.

While the etiology of anxiety and agitation may be unclear, the potential negative outcomes of prolonged anxiety and agitation are device disruption, increased oxygen consumption, and iatrogenic complications associated with treatment (Campbell & Happ, 2010; Nelson et al., 2004; Nelson et al., 2001) Yet, common interventions to treat anxiety and agitation such as sedation or physical restraints are not without risk. Inconsistent description of behavioral cues (Egerod, 2002; Weinert, et al., 2001) and unpredictable management strategies for

psychological symptoms (Bair, et al., 2000) are recognized as important clinical problems in the critical care population. Although there have been descriptive and correlational studies of psychological symptoms, behavioral signs and their treatment in critically ill patients (Bergbom-Engberg & Haljamae, 1989; Chlan, Savik, & Weinert, 2003; Chlan, 2003, 2004; Claesson, Mattson, & Idvall, 2005; Frazier, et al., 2003; Nelson, et al., 2001; Rincon et al., 2001; Rotondi, et al., 2002; Rundshagen, Schnabel, Standl, & Schulte am Esch, 1999), there have been no studies that described clinician's interpretations of psychological symptoms or actions that clinicians take based on behavioral signs exhibited by patients. This study is unique in that it used longitudinal descriptive case studies and examined observational and interview data with clinical record data to describe the patients' psychological symptoms, behavioral signs, interpretations, and interventions undertaken by critical care clinicians.

1.5.1 Current state of knowledge about anxiety and agitation in critical illness

The literature was reviewed to identify current state of the science and gaps in knowledge regarding anxiety and agitation in critical illness. Computerized searches were conducted using the following databases: CINAHL, Medline, PsychInfo, and Dissertations Abstracts. Keywords included agitation, anxiety, critical care, intensive care, patient, patient experience, measure, scale, management, and nurse. Because multiple disciplines have responsibilities for assessment and management of psychobehavioral symptoms in the ICU, literature from nursing, medicine, pharmacology and psychology formed the basis for this literature review. Research, theoretical and review articles from 1980 through 2007 were included as well as older seminal articles. Reference lists from articles and tables of content from critical care specialty journals were used to identify additional articles for consideration.

This literature review includes descriptions of patients' experiences during episodes of critical illness to confirm that anxiety is a common occurrence. Investigations describing the experience of critical illness were included first to determine occurrence of anxiety. Also, studies were included that described stressors that might contribute to the development of anxiety (See Table 1). Since agitation is a common behavioral manifestation of anxiety, literature about agitation was also reviewed (See Table 2). Given the wide variability in interpretation of behaviors, studies that investigated the assessment and treatment of psychobehavioral symptoms were included in the review. A review of current neurocognitive measures used during critical illness was also conducted.

The literature review is organized by studies of 1) anxiety; 2) methodologic challenges with studies of anxiety and agitation; 3) agitation 4) state measurement, assessment and management; and 5) sedation guidelines.

1.5.2 Anxiety as a patient experience

In these studies, patient responses were examined using a variety of approaches. Anxiety is a common and universal human experience when one encounters a perceived threat (Bone et al., 1995). Historically, the origin of the word "anxiety" can be related to respiratory events such as choking or squeezing (Stone, 1997), intriguing since most critically ill patients are mechanically ventilated (Angus et al., 2006; Behrendt, 2000; Carson, 2006; Carson et al., 2006; Cox et al., 2007) and respiratory events and sensations are common (Bergbom-Engberg & Haljamae, 1989; Claesson, et al., 2005; Green, 1996; Gries & Fernsler, 1988; Jablonski, 1994; Johnson & Sexton, 1990; Johnson, St John, & Moyle, 2006; Logan & Jenny, 1997; Nelson, et al., 2001; Novaes et al., 1999; Pennock, Crawshaw, Maher, Price, & Kaplan, 1994; Roberts et al., 2007; Rotondi, et

al., 2002; Samuelson, Lundberg, & Fridlund, 2007). Anxiety has been defined as “subjective energy” (Peplau, 1952) transformed into “relief behavior” with subjective categories including feelings of uncertainty, dread, brooding, fear, doubt, apprehension, helplessness, powerlessness and tension (Whitley, 1992). Unlike fear, anxiety results in increased motor activity such as vigilance, pacing, or cardiovascular excitation (Bay & Algase, 1999).

Generally, anxiety precedes a physiologic response which manifests as a number of behavioral signs. Patients experiencing anxiety have manifestations in a number of spheres including affective, cognitive, physical, and behavioral. Examples of effects in the affective sphere are feeling tense, edgy or fearful. Anxiety may have an impact on the patient’s cognition by decreasing the ability to concentrate or creating confusion. Increases in sympathetic activity associated with anxiety can cause elevations in vital signs or tremors. Finally, patients undertake behaviors to remove the threatening stimulus (Bone, et al., 1995).

Critically ill patients encounter stress from both internal and external sources. Internally, patients experience life threatening physiologic changes with accompanying acute stress responses. Discomfort is present to varying degrees during the patient’s stay and may be the result of interventions to treat acute physiologic dysfunction. Making sense of these sensations is difficult due to the unfamiliar environment, distorted perceptions, communication impairment, and fear (Bone, et al., 1995).

1.5.3 Patient / family perspectives

One study (Novaes, et al., 1999) offered evidence that patients, families and nurses have different ideas about intensity of stressors experienced during critical illness. In this study, 50 patients, their families and caregivers completed the Intensive Care Unit Environmental Stressor

Scale (ICUESS) and assigned a rank to stressors from most to least stressful. Families and caregivers were instructed to complete the scale from the “patient’s point of view”. All three groups ranked “being in pain” as the most stressful experience. However, patients ranked ‘having no control over oneself’, ‘being unable to move hands or arms’, and ‘not knowing when things are going to be done to me’ as very stressful; these stressors were ranked much lower by caregivers. The total mean scores on the ICUESS of the patients and caregivers differed significantly ($p = .0018$) with the caregivers assigning more total stress than patients. This study was performed while patients were in the ICU so patients’ perspectives were in real time rather than retrospective (Novaes, et al., 1999). This study is important as it illustrates a potential mismatch in perception of the nature of patient’s stressors by caregivers. Greater perceptions of stress or discomfort by caregivers could lead to over-treatment or inappropriate treatment.

1.5.4 Methods measurement and timing

In these studies patient responses were examined using a variety of approaches. A number of studies of patients’ ICU experiences found anxiety as a component of the critically ill patient’s experience (Adamson et al., 2004; Bergbom-Engberg & Haljamae, 1989; Claesson, et al., 2005; Green, 1996; Gries & Fernsler, 1988; Hupcey & Zimmerman, 2000; Jablonski, 1994; Johnson & Sexton, 1990; Johnson, et al., 2006; Logan & Jenny, 1997; Lusardi & Schwartz-Barcott, 1996; Novaes, et al., 1999; Papathanassoglou, 2003; Pochard et al., 1995; Rundshagen, Schnabel, Wegner, & am Esch, 2002; Russell, 1999; Wunderlich, Perry, Lavin, & Katz, 1999). These studies used a variety of designs, including descriptive, exploratory and correlational, and enrolled samples ranging in size from 6 to 289 patients). Several studies utilized structured interviews. In addition, a variety of instruments with validated psychometrics were used to

determine the prevalence of symptoms during the ICU stay, including anxiety (Chlan, 2003, 2004), anxiety and depression (Rattray, Johnston, & Wildsmith, 2005; Rincon, et al., 2001), stressors (Novaes, et al., 1999; Rotondi, et al., 2002), symptoms in critically ill patients with cancer (Nelson, et al., 2001), symptoms in chronic critical illness (Nelson, et al., 2004) and symptom clusters (Li & Puntillo, 2006). Several studies used non-validated questionnaires and retrospective chart review. Semantic differential scales and Likert –type scales were used to explore uncertainty and stress (Wunderlich 1999 and questionnaires were used to document the presence of stressful events (Pennock, et al., 1994) and psychiatric symptoms (Pochard, et al., 1995).

The timing of the interviews and data collection varied. Several studies were conducted while the patient was in the ICU (Chlan, 2003, 2004; Hupcey & Zimmerman, 2000; Logan & Jenny, 1997; Lusardi & Schwartz-Barcott, 1996; Nelson, et al., 2001; Novaes, et al., 1999; Pochard, et al., 1995; Rincon, et al., 2001; Rotondi, et al., 2002) while others were conducted after ICU discharge but while the patient remained in the acute care setting (Green, 1996; Pennock, et al., 1994; Pochard, et al., 1995). When studies were conducted during the ICU admission, the goals were to assess the presence of symptoms during the ICU stay. None of these studies attempted to incorporate information about caregivers' assessment and management of the symptoms.

1.5.5 Studies conducted during ICU admission

Chlan (2003) administered the Spielberger State Anxiety Inventory (SSAI) to 200 mechanically ventilated ICU patients. The majority (77%) rated anxiety as moderate or high, regardless of gender, ethnicity, time on mechanical ventilation or medical diagnosis. The highest anxiety

levels were reported by patients who had been mechanically ventilated for greater than 22 days, with patients who received ventilatory support prior to the current hospitalization reporting lower anxiety levels (Chlan, 2003). This study had several limitations. The SSAI indicates the presence of anxiety, but does not provide for description of anxiety producing events or conditions and was administered only once during the patient's stay. Data were not collected about medications administered within 8 hours of conducting the anxiety inventory.

In a second study, Chlan (2004) measured anxiety of 200 mechanically ventilated patients using both the Speilberger State Anxiety Inventory and the Visual Analog Scale – Anxiety. The two instruments were found to correlate significantly ($r=.50$, $p=.01$) (Chlan, 2004). Although there was variability in the patient's anxiety ratings on both scales, the mean state of anxiety was in the moderate range. As in Chlan's earlier study, this sample was restricted to patients who were alert and decisionally capable and, therefore, was not reflective of the general population of critically ill patients. The patients' level of anxiety could have been affected by various medications or other stress-producing events. Patients were not excluded if they had received medications for anxiety within 8 hours of the testing. In the proposed study, medication administration is a key variable. While determining the presence of anxiety during critical illness is important, the proposed study will extend Chlan's (2003, 2004) findings by describing clinician's interpretation and treatment of anxiety in critically ill patients.

A prospective study conducted in Columbia (Rincon, et al., 2001) revealed the presence of psychiatric diagnosis such as depression, anxiety or delirium in 29.2% of all patients ($n=96$) admitted to a CCU. Although 58% of these patients were treated for some type of psychiatric diagnosis during their stay, there was great variability between the diagnoses and treatments made by independent psychiatric raters and those made by CCU staff. The importance of this

study was to highlight the inconsistency of screening and management of psychiatric symptomatology in a critical care unit.

1.5.6 Studies conducted following ICU discharge

Several studies were conducted after discharge from the ICU with a range of time after discharge from 48 hours to 6 years (Adamson, et al., 2004; Bergbom-Engberg & Haljamae, 1989; Claesson, et al., 2005; Gries & Fernsler, 1988; Jablonski, 1994; Johnson & Sexton, 1990; Papathanassoglou, 2003; Rundshagen, et al., 2002; Russell, 1999; Wunderlich, et al., 1999). Rationale for choice of delayed data collection included stabilization of physical and psychologic stress, providing a time period enabling patients to “make sense” of their experiences or to determine actual memories. Lack of recall was common in these studies. Sources of patient stress related to mechanical ventilation were endotracheal tube discomfort and suctioning. Other sources of stress were inability to communicate, immobility, difficulty sleeping, lack of control, lack of privacy, dry mouth, and thirst. Disturbances from vivid dreams or hallucinations were described in several studies.

Patients who were interviewed after discharge from ICU described anxiety and fear that they had experienced during mechanical ventilation in the ICU (Jablonski, 1994). Patients’ attempts at communication were often misinterpreted and acted upon by clinicians. Often, according to these patients, physical restraint was applied or sedation was administered as a “pharmacologic restraint” to control attempts at treatment disruption (Jablonski, 1994).

1.5.7 Summary

While these studies provide important insight into the patient's experience, results may be influenced by inaccurate representation of their overall experience because of disturbed memories, perceptual distortions or delirium that often accompany critical illness. However, information and patient descriptions about the experience of being critically ill has been relatively consistent over the last 20 years. Patients experience discomfort related to mechanical ventilation and immobility. They are distressed by the inability to communicate, difficulty sleeping, and disturbed perceptions. Clinicians often misinterpret patient's behaviors and communication attempts and act upon those interpretations. This body of literature is limited to survivors of critical illness who are cognitively intact and able to communicate about and reflect on their ICU experience. One in five critically ill patients do not survive (Angus et al., 2004) and many of those who survive are unable to communicate their feelings or to recall their experiences (Jones, et al., 2001; Roberts, et al., 2007; Rotondi, et al., 2002; Samuelson, Lundberg, & Fridlund, 2006; Samuelson, et al., 2007; Weinert, Sprenkle, Weinert, & Sprenkle, 2008)

The proposed study will extend prior work by examining psychological symptoms and clinicians' responses to those symptoms. This study differs from previous work about psychological symptoms in that it includes multiple perspectives (patients, families and clinicians), includes both observational and interview data as well as medical record data. In addition to patient's concurrent accounts of their experience during weaning from prolonged mechanical ventilation in the ICU, the dataset included survivors (n=25) and non-survivors (n=5) of critical illness.

Table 1 Literature related to anxiety in critically ill patients

Author	Sample	Sample mechanically ventilated?	Method/Design	Timing	Findings/Patient Experience
Gries & Fernsler, 1988	9	Yes	Exploratory Interview fixed alternative and open ended questions	1-7 days after extubation Unknown	Intrapersonal Inactivity and immobility Gagging Lack of information Inability to cope with MV Vivid dreams Interpersonal Inability to communicate Lack of information Extrapersonal ETT Suctioning Extubation
Bergbom-Engberg & Haljame, 1989	158	Yes	Correlational Phone interviews using standardized questionnaires	2 months after discharge Recall in late post-treatment period	Anxiety//Fear Related to: Agony/Panic Insecurity Inability to communicate Difficulty sleeping or resting Suctioning

Table 1 (continued)

Johnson & Sexton, 1990	14	Yes	Descriptive exploratory Interviews	1-6 months following weaning; 3 patients receiving nocturnal ventilation unknown	Mild to extreme distress Inability to speak ETT or trach discomfort Suctioning Time disorientation Noise Fear
Jablonski, 1994	12	Yes	Semi-structured interviews by phone or in home	After discharge from ICU	Inability to communicate – helplessness, frustration Misinterpretation of communication seen as “apprehension” by clinicians and action taken based on those misinterpretations
Pennock, Crawshaw, Maher, Price & Kaplan, 1994	127 post operative OHS	Yes	Descriptive cross sectional survey Questionnaire – 25 item Likert scale	48 hours after discharge from ICU Allowed physical and mental adjustment	ETT discomfort Inability to talk Confusion Sleeplessness

Table 1 (continued)

Pochard, Lanore, Bellivier, Ferrand, Mira, Belghith, Brunet, & Dhainaut, 1995	43	Yes	Prospective descriptive 32 item questionnaire Visual analog scale	48-96 hours after weaning from mechanical ventilation Detection of psychiatric disorders	Pain Inability to communicate Noise Dreams, nightmares and sleep disorders Diffuse anxiety and fear of dying Physical depression, intellectual depression Delirium
Green, 1996	26	62% of sample	Descriptive Thematic content analysis of focused interviews	48 hours after discharge from ICU Captured feelings about transfer to general ward	92% of sample remembered ICU stay Pain, discomfort Presence of tubes Feelings of panic, fear Dreams and hallucinations
Lusardi & Schwartz-Barcott, 1996	9	Unknown	Direct observation Interview	During ICU stay and 24 hours after transfer from ICU Observations of level of consciousness and communication	Swings in level of consciousness due to acuity and sedation, most notably within 48 hours of admission

Table 1 (continued)

Logan & Jenny, 1997	20	Yes	Grounded theory Interviews	Following transfer from ICU to acute care Unknown	Anxiety encountered during weaning from MV A great deal of cognitive activity unrecognized by staff Supportive activities by nurses described
Novaes, Knobel, Bork, Pavao, Nogueira-Martins et al., 1999	50	Yes	Cross-sectional analytical survey Intensive Care Unit Environmental Stressor Scale ICU-ESS	During ICU stay Comparison of stressors perceived by patient, RN and family	Pain Lack of control Unable to move Uncertainty
Russell, 1999	298	Yes	Qualitative analysis of structured personal interviews, semi-structured phone interviews, written questionnaires	6 months following critical illness Effect of memories on recovery	Voicelessness Physically Endotracheal tube Psychologically Fear Lack of knowledge Language barriers Lack of power Lack of privacy Lack of communication Fear Pain Discomfort Vivid disturbing dreams

Table 1 (continued)

Wunderlich, Perry, Lavin, & Katz, 1999	19	Yes	Exploratory retrospective Structured interviews	48h – 3 months following extubation To maximize subject recall	Uncertainty and stress ETT discomfort Vulnerability when restrained Inability to communicate Fear related to lack of knowledge Communication and information from nurses decreased amount of uncertainty and stress
Hupcey & Zimmerman, 2000	14	Yes – 50% of sample	Grounded theory Interviews	During ICU stay when condition stabilized or after transfer to regular unit Unknown	Patients needed to know Confused perceptions
Jones, Griffiths, Humphries, & Skirrow, 2001	45	Yes		2 and 8 weeks post discharge from ICU	
Rincon, Granados, Unutzer, Gomex, Duran, et al., 2001	96	No	Prospective cohort descriptive Medical Record Review Hospital Anxiety and Depression Scale Confusion Assessment Method	During ICU stay Presence of psych disorders during ICU stay	29.2% patients had depression, anxiety, or delirium Variability in screening for and treatment of psychiatric disorders

Table 1 (continued)

Nelson, Meier, Oei, Nierman, Senzel, et al., 2001	50 ICU patients with cancer	Yes	Prospective descriptive Edmonton Symptom Assessment Scale	During ICU stay Symptoms experienced; predicted 50% death rate	Pain, Discomfort, Sleep Disturbances, Anxiety 63% reported moderate to severe anxiety
Granberg-Axell, Malmros, Bergbom & Lundberg, 2002	19 ICU patients	Yes	Observation Retrospective chart review	After discharge	Delirium classified based on behavior Restlessness, fear – moderate delirium Agitation, “out of control” or bizarre thinking – severe delirium
Rotondi, Chelluri, Sirio, Mendelsohn, Schulz, et al., 2002	100	Yes	Prospective cohort Intensive Care Unit Stressful Experiences Questionnaire – ICU-SEQ	Prior to discharge Recollection of MV	Of those who remembered ETT Inability to speak Pain Anxiety Difficulty with ETT associated with: Difficulty sleeping Spells of terror Fear of being alone Overall Trouble Speaking Thirst Tension Being out of Control Difficulty swallowing

Table 1 (continued)

Rundshagen, Scnabel, Wegner, & amEsch, 2002	289 Critically Ill patients	Yes	Prospective Structured Interview	After discharge Unknown	21.1% dreams 6.6% hallucinations
Papathanassaglou & Patiraki, 2003	8 Critically ill adults	Unknown	Phenomenology Interview, dream recall	1-6 years after discharge Long term effects	Alteration in perception of mind, lived body, time and space Isolation Death and Rebirth
Chlan, 2003	200 ICU patients	Yes	Secondary analysis of descriptive Spielberger State Anxiety Inventory	During ICU stay Presence of anxiety in ICU	Anxiety rated high in 154 patients
Adamson, Murgo, Boyle, Kerr, Crawford, & Elliott, 2004	6	Unknown	Interview	6 months post ICU Impact of ICU stay on recovery	Dreams and nightmares Pain
Chlan, 2004	200 ICU patients	Yes	Correlational Spielberger State Anxiety Inventory and Visual Analog Scale - Anxiety	During ICU stay Presence of anxiety during ICU stay	Great variability in anxiety measured by SSAI and VAS Mean state of anxiety moderate
Nelson, Meier, Litke, Natale, Siegel, & Morrison, 2004	50 chronically critically ill patients	Yes	Condensed form Memorial Symptom Assessment Scale, ventilator outcomes, vital signs, functional status	At discharge from ICU, 3 and 6 months post discharge to respiratory care unit for weaning	44% pain 60% psychosocial symptoms 90% distress with communication ability

Table 1 (continued)

Claesson, Matttson & Idvall, 2005	8 patients who had 2-3 week ICU stays	Yes	Semi-structured, open-ended interviews	6-12 weeks post ICU stay Memories	Suffocating, anxiety and panic Dreams, nightmares and hallucinations
Rattray, Johnsston, & Wildsmith, 2005	80	Unknown	Prospective longitudinal Hospital Anxiety and Depression Scale Impact of Events Scale Intensive Care Experience Questionnaire	Hospital discharge, 6 and 12 months post discharge Outcomes	Adverse perceptions of ICU experiences (measured by ICE/Q at discharge) associated with negative emotional outcome (anxiety/depression, PTSD)
Johnson, St. John, & Moyle, 2006	9	Long term mechanical ventilation	Qualitative analysis of semi-structured home interviews	2 weeks to 2 months following discharge Unknown	Fluctuating levels of consciousness Sensations unfamiliar result of critical illness and technology ETT discomfort, suctioning Communication difficulties caused anxiety, fear and uncertainty

Table 1 (continued)

Li & Puntillo, 2006	15 surgical	Yes	Descriptive pilot study Symptom scale	During ICU admission Presence of symptoms	Dyspnea reported by 100% of patients Significant correlations between: Tiredness – thirst, anxiety, discomfort - strong Thirst – hunger, anxiety, discomfort- moderate Moderate correlation between dyspnea and depressed feelings
Roberts, Rickard, Rajbhandari, & Reynolds, 2007	41	Unknown	Prospective cohort mixed method Telephone interview Questionnaire – PTSD symptoms on Likert scale	18-24 months post hospital discharge Relationship of behaviors in ICU to outcomes (PTSD)	83% sample had factual recall Presence of delirium affected factual recall ETT discomfort Related presence of delirium to symptoms of PTSD 2 years post discharge

Table 1 (continued)

<p>Samuelson, Lundberg, & Fridlund, 2007</p>	<p>206</p>	<p>Yes</p>	<p>Descriptive cohort correlational ICU – SEQ ICU Memory Tool CAM-ICU MAAS Medical Record review Interview Multivariate analysis</p>	<p>5 days after discharge from ICU Unknown</p>	<p>ETT discomfort Inability to speak Restrictions from tubes and lines Terror or panic Nightmares</p>
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1.5.8 Agitation as a patient experience

Compared to anxiety, agitation is considered more severe and dangerous (Szokol & Vender, 2001). Agitation is often considered the extreme manifestation of anxiety. Agitation has been observed in up to 72% of critically ill patients (Fraser, Prato, Riker, Berthiaume, & Wilkins, 2000). Agitation is defined as “tumultuous behavior” and “extreme emotional disturbance”, (<http://dictionary.reference.com/browse/agitation>) and can be viewed as increased intensity in both physical and psychological spheres (Chevrolet & Jolliet, 2007). Examples of behavioral symptoms that typify agitation in the critically ill might be fidgeting, restlessness, thrashing, picking at bed sheets, or pulling at lines or tubes (Cohen et al., 2002; Fraser, et al., 2000). Agitated patients may be partially or completely disoriented and unable to follow verbal commands. Vital signs such as blood pressure and heart rate may be elevated. Respiratory rate elevation may interfere with ventilator synchronization leading to inadequate ventilation and exacerbating conditions that contribute to agitation (Cohen, et al., 2002).

Agitation is a visible cue that occurs when a strong sensory stimulus accompanies brain dysfunction (Crippen & Ermakov, 1992). Causes of agitation are complex, multi-factorial and begin with physiologic processes, hemodynamic or metabolic, that contribute to brain dysfunction (Crippen & Ermakov, 1992). Some of the predisposing factors include: pain, delirium, hypoxemia, brain hypoperfusion, disruption of sleep-wake cycle, ventilator discomfort, medication effects and withdrawal from drugs or alcohol (Cammarano, Pittet, Weitz, Schlobohm, & Marks, 1998; Crippen, Levy, Truog, Whetstine, & Luce, 2000; Fraser, et al., 2000; Looper, 2007; Peterson et al., 2006; Puntillo, 1990; Szokol & Vender, 2001). Other contributing factors include physical restraints, environmental irritants, inability to communicate,

immobility, dry mouth, or thirst (Cohen et al., 2005; Martin et al., 2006). For example, patients report that noise levels in the ICU are distressing. Unfortunately, because of their critical illness, patients are unable to effectively process and to make sense of this stimulus. They may react by becoming restless or agitated because they are unable to communicate effectively.

Although variable over time and often mixed with degrees of calm or sedated states (Peterson, et al., 2006; Tate et al., 2005, May), agitated patients have longer ICU stays and longer and higher risk of treatment disruption (Jaber et al., 2005; Woods et al., 2004). When asked about assessment of anxiety, 783 critical care nurses rated agitation as their most important clinical indicator of anxiety (Frazier et al., 2002).

1.5.9 Incidence of agitation

The reported incidence of agitation is highly variable. In three studies, the incidence of agitation in critically ill patients ranged from 16-71% (Fraser & Riker, 2001; Jaber, et al., 2005; Woods, et al., 2004). The substantial variability in reported incidence likely results from the varying definitions of agitation used in these studies. Woods et al (2004) included patients who were dangerously hyperactive and received higher than guideline recommended doses for sedation and/or analgesia. Fraser and Riker (2000) included patients whose behavior was described by caregivers as “excessive motor activity associated with internal tension” and reported a lower incidence. Finally, Jaber, et al (2005) included patients who moved their heads or extremities and “bucked the ventilator” despite staff attempts to calm the patient. Woods, et al (2004) identified an occurrence of only 16% likely due to stricter inclusion criterion, while the latter studies identified higher rates of agitation. None of the units studied utilized delirium assessment and only one setting (Woods, et al., 2004) utilized a sedation protocol.

1.5.10 Contribution of agitation studies to this study

The contribution of these three studies to the proposed investigation lies in several areas. First, the list of behavioral descriptors used by Fraser and Riker (2001) formed the basis for descriptors that were used to analyze narrative data from the chart and observational records by identifying agitation events. (See Table 3). Definitions by Woods, et al (2004) and Jaber, et al (2005) were considered as cues for documentation of agitated behavior. Fraser and Riker (2001) applied sedation scales to descriptions of behaviors in medical charts, a similar technique that will be utilized in this investigation. Medication records were reviewed for dosages of sedation and analgesia. Cases of doses outside recommended guidelines formed examples of “extreme cases” to be explored.

Table 2 Studies related to agitation in critically ill patients

Author	Sample	Methodology	Variables	Findings
Fraser, Prato, Riker, Berthiaume, & Wilkins (2000)	130 ICU patients	Retrospective chart review	SAS SAAs	Occurred in 70.8% patients. Severe agitation occurring at least once in 46.1% patients. Occurred on average 2.4 days after admission with the duration of severe agitation 3.2 days. Severe agitation weakly correlated with longer ICU stay. Age did not influence occurrence or severity of agitation. Causes anxiety, delirium, medication effects or pain
Woods., Mion, Connor, Viray, Jahan, et al (2004)	143 MICU patients	Descriptive; prospective	MAAS - agitation measure; also doses of SAAs higher than recommended guideline dosages	23 (16.1%) agitated Younger, admitted from outside hospital, lower pH, and hypoxemic. Agitated patients had longer ICU LOS, more vent days, likely to self-extubate; benzos, narcotics and neuroM Blocking agents more frequently and at higher dosages Haldol used in only 4% - sedation protocol in place

Table 2 (continued)

<p>Jaber, Chanques, Altairac, Sebbane, Vergne, et al (2005)</p>	<p>182 MICU and SICU patients</p>	<p>Observational, prospective</p>	<p>Modified Ramsay Medical record review</p>	<p>No difference between agitated and not based on age, gender or time of day. Independent predictors - sepsis, alcohol abuse, use of sedatives, fever, dysnatremias, use of psychoactive drugs. Occurred early in the patient's ICU stay (< 3-5 days) and lasted approximately 4 days Associated with a prolonged ICU stay. Complications in agitated group -nosocomial infection, rupture of anastomotic sutures, and treatment interference (e.g. unplanned extubations and central venous catheter removal). No significant difference in mortality.</p>
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Table 3 Terms used to describe agitation (Fraser, et al, 2000)

Agitation Behaviors	Pain, discomfort without agitation
Restless Thrashing Anxious Disoriented Delirious Visibly agitated Pulling tubes Pulling restraints Attempting self-extubation Agitated Picking Resists Screaming Bucking ventilator Incoherent Uncooperative Very confused	Combative Frightened Kicking Paranoid Fidgeting Terrified Flailing Striking out at staff Withdrawal symptoms Protesting loudly Biting endotracheal tube Threatening All over bed Attempts to adjust ventilator Tries to sit up Constant motion Getting out of bed Wild when awake

1.5.11 State measurement

Despite its high incidence and potential negative impact on care, standards for defining, assessing and treating anxiety and agitation does not exist. In a study of agitation using chart review, Fraser et al (2000), used a list of 31 different terms when searching narrative descriptions of agitation and 13 terms associated with pain or discomfort without agitation. The responsibility for evaluating anxiety and agitation, determining when thresholds of behavior are potentially dangerous and administering appropriate treatment belongs to the bedside nurse

(Gehlbach & Kress, 2002). Unfortunately, without an objective measure or verbal clarification from the patient, assessment of anxiety and agitation is highly variable and changes over time (Chase, Starfinger, Lam, Agogue, & Shaw, 2004).

1.5.11.1 Assessment

Accurately assessing anxiety and agitation symptoms require patient confirmation of symptom quality or intensity. In patients who are mechanically ventilated, verbal confirmation from the patient is impossible and characterizing the qualitative components is difficult at best. In a study by Aslan, Badir & Selimen (2003), questionnaires were administered to 91 critical care nurses to determine how they approach pain assessment in nonverbal critically ill patients. Nearly 40% of those sampled indicated that they did not know how to assess symptoms of pain in these patients and 37.4% scrutinized patient behaviors or signs to determine pain level (Aslan, Badir, & Selimen, 2003). This study typifies the use of behavioral cues to determine a patient state (pain). The process of assessing these symptoms via behavioral sign is similar (and similarly variable) for determining psychological symptoms such as anxiety and agitation.

1.5.11.2 Management

Psychological symptoms and behavioral signs are managed in several different ways. Sedation is planned and ordered usually by the physician and is administered and managed at the discretion of the bedside nurse. In a survey of 783 critical care nurses (Frazier, et al., 2003), most (74.1%) felt that anxiety was a potentially harmful condition and that anxiety management was important and beneficial to critically ill patients. The most frequent intervention was pharmacologic; however, non-pharmacologic strategies were also disclosed such as family presences, controlling environmental stressors, reassurance, information sharing and touch. This

study was hampered by a low response rate (31.6%) and the possibility of selection bias related to the use of active members of the American Association of Critical Care Nurses who may have practice patterns different from those nurses who are not active members.

In order to better understand nurses attitudes, beliefs and behaviors related to sedation, Weinert & Gross (2001) utilized focus groups to interview 34 critical care nurses who worked in either a medical or surgical ICU in an academic medical center. The nurses indicated 3 major goals for sedating patients: comfort, amnesia, and safety. Nurses justified their own sedation practices by indicating the lack of scientific evidence to support one practice over another, commenting that protocols would not be helpful given the wide variation of patients' sedation requirements. Despite expending a great deal of time and effort, nurses reported that patient responses to questions about their needs were either not given or not useful. In absence of direct answers to questions, the nurses responded to patients' motor movements and level of consciousness as indicative of sedation level. Under-sedation was determined via large muscle movement, ventilator asynchrony, changes in vital signs, or unsafe actions such as pulling at lines and tubes or striking out at caregivers. On the other hand, lacks of responsiveness, decreased blood pressure or absence of spontaneous breathing were described as indicating over sedation. Nurses reported that systems issues such as work load might affect their decision to medicate a patient while many based their decision to sedate (or not sedate) upon family requests. While acknowledging that there are non-pharmacologic strategies to alleviate anxiety , the nurses admitted that they do not use non-pharmacologic strategies because they are time-consuming and largely ineffective (Weinert, et al., 2001). Use of focus group strategy might have influenced less vocal members from making substantive contributions based on the organizational climate of the medical center. There may be a gap between what the nurses

described in the focus groups in order to be seen in a more positive light and what their actual sedation practices might include.

Several rating scales have been constructed to assess psychobehavioral symptoms commonly addressed by critical care clinicians. Such scales address single items, such as level of consciousness, or a combination of items such as level of consciousness and response to verbal, tactile or therapeutic stimuli (Olson, Thoyre, & Auyong, 2007). Use of these scales in combination with a sedation protocol has been associated with improved patient outcomes such as decreased hospital and ICU length of stay and decreased length of mechanical ventilation (Brook et al., 1999). A standardized sedation scale permits clinicians to systematically detect and quantify agitation and guide initiation and evaluation of treatment (Sessler & Varney, 2008).

Prior studies indicated that sedation scales are used in less than 50% of ICU's (Payen, Chanques, Mantz, Hercule, Auriant, Leguillou, Binhas, Genty, Rolland, Bosson, et al., 2007). The reasons for resistance to use are unclear as they have been shown to be easy to use, effective in assessing levels of quiet and sedate behaviors as well as levels of restlessness and agitation, capable of measuring distinct levels of behavior, useful in diverse patient populations, and valid and reliable (Cohen, et al., 2002; Fraser & Riker, 2001; Hansen-Flaschen, Cowen, & Polomano, 1994; Sessler, 2004; Sessler & Varney, 2008; Watson & Kane-Gill, 2004). The most common constructs evaluated in these scales are level of consciousness and behavior (See Table 4). Additional constructs may include ventilator synchrony (Ambuel, Hamlett, Marx, & Blumer, 1992; Curley et al., 2006; De Jong et al., 2005; De Jonghe et al., 2003); pain (Ambuel, et al., 1992); anxiety (De Jong, et al., 2005; Ramsay, Savege, Simpson, & Goodwin, 1974); muscle tone (Ambuel, et al., 1992); sleep (De Jong, et al., 2005); facial expression (De Jonghe,

et al., 2003); tolerance to care (Curley, et al., 2006). Two scales were designed specifically for use in pediatric critical care (Ambuel, et al., 1992; Curley, et al., 2006).

Most scales test level of consciousness first by observation. If no response is solicited, auditory and tactile stimuli are applied. In two scales, (RASS, ATICE) ability to follow commands is tested (De Jonghe, et al., 2003; Sessler et al., 2002). Agitation is graded in severity in SAS, MAAS, RASS, and ATICE (De Jonghe, et al., 2003; Devlin et al., 1999; Riker et al., 1994; Sessler, et al., 2002). The MAAS scale (Devlin, et al., 1999) and the SAS (Riker, et al., 1994) are unique in that they can be retrospectively applied to observations described in clinician progress notes. In this study, the MAAS scale was applied to descriptions of behavioral signs described in medical records.

Grap, Borchers, Munro, Elswick & Sessler (2005) applied wrist actigraphy monitors to determine the correlation between wrist and ankle movement, heart rate and blood pressure with observational scales of sedation in 20 critically ill patients. Wrist actigraphy was moderately correlated with the Richmond Agitation-Sedation Scale ($r=.58$) and the Comfort Scale ($r=.62$) although weakly correlated with vital signs (Grap, Borchers, Munro, Elswick, & Sessler, 2005). Wrist and ankle actigraphy were correlated significantly ($r=0.69$, $p< 0.001$). Highly agitated patients showed decrease in movement only in the presence of wrist restraints. These findings would be difficult to generalize due to the small sample size. This study did not determine whether any information from the sedation scales, vital signs or actigraphy triggered a response from the nurse caregivers.

In a second study, Weinert and McFarland (2004) tested the Minnesota Sedation Assessment Tool (MSAT) in 94 intubated patients and 93 nurses in both medical and surgical ICU's. The MSAT demonstrated good reliability between raters, kappa = .72- .85 on the motor

and arousal subscales respectively. Correlation between the MSAT and a visual analog scale was good but demonstrated a weaker correlation with valid sedation instrument, the Vancouver Interaction and Calmness Scale, likely due to divergent constructs. The researchers compared actual and hypothetical MSAT subscale scores to sedation administration. The MSAT arousal scale was more predictive of sedation administration than the motor scale indicating that arousal was the more significant factor when nurses make decisions about whether or not to intervene (Weinert & McFarland, 2004).

Table 4 Sedation scales - symptoms observed

Author	Instrument/scale	Consciousness	Agitation	Pain	Ventilator Synchrony	Other	Physiologic Parameters
Ramsay (1974)	Ramsay Scale	x	X			Anxiety	
Ambuel (1992)	Comfort Scale	X	X	x	x	Muscle tone	
Riker (1994)	Sedation Agitation Scale SAS	x	X				
Devlin (1999)	Motor Activity Assessment Scale, MAAS	x	X				
Sessler (2002)	Richmond Agitation and Sedation Scale RASS	x	x				
DeJonghe (2003)	ATICE	x	x		x	Comprehension Facial Expression	
Weinert (2004)	Minnesota Sedation Assessment Tool MSAT	X				Spontaneous muscle activity	
DeJong (2005)	American Association of Critical Care Nurses (AACN) Sedation Assessment Scale for Critically Ill Patients	x	x		x	Anxiety	Sleep
Curley (2006)	State Behavioral Scale	x	x		x	Consolability Tolerance to care Attentiveness	Vital Signs

1.5.11.3 Sedation guidelines

Because nurses are directly responsible for titrating sedation according to patient need, it is important that symptoms are accurately and consistently interpreted. There is, however, no definition of “adequate sedation”. Nurses’ interpretation of patients’ behavior to determine sedation adequacy was compared with a standardized sedation rating (Weinert & Calvin, 2007). Numeric ratings on the Minnesota Sedation and Agitation Tool (MSAT), rating of adequate sedation (over, under or adequately sedated), sedation therapy and behavior over time were recorded every 4 hours. In this study, patients were five times more likely to be judged as under-sedated as over-sedated. Patients were minimally arousable in 32% and motionless in 21% of the assessments despite an over-sedation rating recorded in <3% of the assessments. Patients were significantly more likely to be rated as under-sedated if they were older, the amount of sedation administered within the previous four hours and time of day. Patients were more likely to be rated as under-sedated on the night shift despite lack of variation in level of consciousness or drug dose over a 24 hour period. Nurses’ perceptions of patients’ sedation level differed significantly depending on the time of day.

Even when guidelines for sedation management are introduced, there is a great deal of variability in the acceptance of and adherence to those guidelines (Bair, et al., 2000). In one institution, specific medication guidelines were introduced to assist clinicians in the management of pain, delirium, anxiety and sleep deprivation as well as restlessness and agitation. During a four month introductory period, physicians and nurses were given educational sessions and reminder cards. However, criterion for determining differential diagnoses of anxiety, delirium or pain was not presented to the staff. A prospective study of 100 Medical ICU patients and their medical records was conducted. Physician adherence to the prescriptive portion of the guidelines

and nurse adherence to the medication administration portion of the guidelines were determined via medical record review. In 58% of the cases, adherence either partially or totally to the guidelines was achieved. During interviews, physicians reported that they deviated from the guidelines based on individual patient need. However, the patients in the non-adherent group had slightly more hospital acquired complications, had received more classes of medications and were more likely to be physically restrained. Moreover, patients who had received medications adherent to the guidelines were more acutely ill and less likely to survive their ICU stays. The four month window of implementation may not have given the guidelines enough time to become routine within the unit. Physician medication preference may have had an impact on the results. This again illustrates inconsistencies in physician prescriptive practices and nurse adherence to guidelines by recognizing the impact of individual clinician choice and response to symptoms at the bedside. Although a sedation protocol was not in place during the proposed study, individual clinician practices will be explored.

There is also evidence that differences between nurse and physician description and interpretation of psychobehavioral symptoms may result in inconsistency in achieving treatment goals. Using case study method, direct observation, and semi-structured interviews, Egerod (2002) determined differences between nurses and physicians in describing indications for sedation. Formal interviews were conducted with 8 key informants. In addition, the researcher observed 145 nurses in the field, clarifying and validating through informal interviews about sedation practice. Medical record review revealed inconsistencies in interpreting psychobehavioral symptoms that necessitated sedation intervention (Egerod, 2002). Utilizing a framework that included indication, interventions, expectations and outcomes to analyze the data, the researcher concluded that there were no clear common indications for sedation nor were

there common definitions of terms between two groups of clinicians, physicians and RN's. The study demonstrated that differences in terminology may affect the intervention chosen. For example, "patient ventilator asynchrony" was interpreted as the machine not meeting the patient's ventilatory needs, necessitating a change in ventilator settings while "not following the ventilator" was interpreted as patient controlled etiology and treated with sedation. This study illustrates the impact of inconsistent language used to describe symptoms by nurses and physicians on choice of interventions and on outcomes. The proposed study will extend these findings by examining through case analysis new and existing patterns in the identification and management of anxiety and agitation.

1.5.11.4 Summary

Critical illness presents clinicians with identification and management challenges when trying to interpret competing physiologic and psychological states that often change rapidly. Agitation has a negative impact on patient outcomes in terms of length of stay and duration of mechanical ventilation. Measurement of sedation levels in critically ill adults is important in order to titrate medications to the desired individual level of sedation while maintaining a margin of safety. Clinicians often rely on non-specific signs of distress such as grimacing or elevated vital signs to approximate the sedation level of patients (Fraser, et al., 2000). This review illustrates issues related to bedside evaluation and management of psychological symptoms and behavioral signs. Nurses manage these symptoms with three goals in mind: comfort, amnesia, and safety (Weinert, et al., 2001). The proposed study explored both clinician identification of and responses to symptoms and rationales for choosing these responses.

1.6 PRELIMINARY STUDIES

1.6.1 Preliminary Study #1

Exploring the Relationship Between Anxiety and Weaning from Long-Term Mechanical Ventilation (LTMV) Using Mixed Methods (Tate et al., 2005)

Purpose: To describe nurse (RN) and respiratory therapist (RT) assessment and management of patient behaviors described as anxiety and to explore the relationship between patient behaviors and daily weaning trial duration.

Methods/Design: Mixed methods event analysis was conducted on data (interviews, observations, clinical record documentation of ventilator weaning events) from a larger ethnographic study of weaning from LTMV. Textual data were analyzed using qualitative coding and constant comparison. Motor Activity Assessment Scale (MAAS) scores, derived from clinical record and observational data, were categorized as sedated, fluctuating, agitated, or calm and were analyzed in relationship to daily wean trial duration (hours) and the patient's weaning pattern (progressive, inconsistent, plateau, or terminal). The relationship between MAAS categories and weaning duration was examined by repeated measures analysis using marginal modeling with model parameters estimated using generalized estimating equations.

Findings: Psychological symptoms, behavioral signs, and physiologic changes during weaning events were most frequently described by RNs/RTs as “anxiety” and treated with sedation. RN/RT assessment of psychological symptoms rarely differentiated symptoms such as psychomotor agitation and confusion from “anxiety.” No patterns were discerned with respect to identification of the psychological symptoms. No sedation scoring system was in place so the potential for variability in clinician interpretation of psychological symptoms and behavioral

signs exist. Patients with MAAS ratings categorized as sedated or fluctuating (intermittently agitated and sedated) weaned for significantly less time per day ($p < .01$) than those consistently classified as calm or agitated. No significant relationship was found between percentage of days in a particular MAAS category and weaning patterns.

Implications of findings to the proposed study: This study established the importance of anxiety as a psychological symptom potentially impacting ventilator weaning progress and outcomes. These numeric values are overly restrictive and reveal little about the context, course or outcome of each occurrence of psychological symptoms. The proposed study seeks to more fully explicate the clinical phenomena of psychological symptoms.

1.6.2 Preliminary Study #2

Clinicians' Evaluation and Management of Mental Health, Substance Abuse, and Chronic Pain Conditions in the Intensive Care Unit (Broyles, L., et al., 2008)

Purpose: To describe clinicians' evaluation and management of co-existing mental health, substance abuse (MHSA) and chronic pain (CP) conditions in patients with prolonged critical illness.

Methods: This was a longitudinal qualitative description of a sub-group of patients ($n=11$) with co-existing MHSA and/or CP conditions who were weaning from LTMV. Within this subset of the original, "parent study" data, researchers more closely examined (1) the identification, assessment, and management of pre-existing MHSA-CP conditions; and (2) the relationship between MHSA-CP and weaning outcomes (days to wean, daily wean times).

Findings: Patients' pre-existing conditions and medications were not valued as integral to the overall treatment plan in patients weaning from long term mechanical ventilation.

Caregivers resorted to cognitive shortcuts resulting in conflict and tension between caregivers and patients. Assumptions were made without careful evaluation of the meaning of symptoms exhibited by these patients.

Implications of findings to the proposed study: Patient's pre-existing MHSA and CP conditions will be considered during analysis of the data in the proposed study. The methods and analysis techniques used in the proposed study will be similar particularly related to pattern identification and display of sedation/analgesic administration. However, the proposed study used the full 30 patient dataset, and offers analysis of the event of psychological symptoms with full description of contextual factors and clinician management.

1.6.3 Additional Experiences

I served as project director on two NIH funded studies, "Ventilator Weaning: Processes of Care and Communication" (RO1-NR07973) and "Improving Communication in Non-Speaking ICU Patients" (RO1-HD043988) which contribute to my development as a researcher. In my role for the ventilator weaning study, I conducted nearly half of the field observations and most formal interviews. I have firsthand knowledge of the data and methods. I led analysis sessions to merge the qualitative and quantitative data to answer the original research questions related to the processes of care and communication in ventilator weaning. The field experiences as well as the analysis session provided the basis for my interest in psychological symptoms and behavioral signs. Given these experiences, I was able to analyze qualitative and quantitative data.

In addition, I have also served as a co-investigator on two additional NIH funded studies "Provider and Organizational Norms of Treatment for Seriously Ill Elders (PONCEL)" (R21-NR0102650) and "Apolipoprotein E, Inflammatory Markers and Delirium in ICU Patients

(GOOD)” (R03NR011052). Both of these studies were conducted in the ICU. In my role as Co-Investigator for PONCEL, I conducted field observations and interviews related to clinician decision-making practices regarding life-sustaining treatments for critically ill elders. I also analyzed the qualitative data for this study and assisted with dissemination of results. My responsibilities further my skill as an ethnographic researcher. My role as Co-Investigator on the GOOD study enhances my skills using neurocognitive measures.

I also serve as a Co-Investigator on “SPEACS-2: Improving Communication and Quality Outcomes in the ICU” an Interdisciplinary Nursing Quality Research Initiative (INQRI) grant funded by the Robert Wood Johnson Foundation. I assisted with grant preparation and now assist with operational management and data analysis.

Experiences as a result of my role in the above studies include:

Consenting participants

Collect qualitative data including participant observation and interview data on participants including critically ill, non-speaking patient participants.

Collection of demographic and clinical data.

Performing neurocognitive, sedation and communication measures

Database Management.

Data Analysis

Writing for scientific journals

Presentation of research findings

1.7 RESEARCH METHODS AND DESIGN

1.7.1 Design

The study used a descriptive longitudinal multiple case study design with event analysis. According to Yin (2003), features of this inquiry meet the technical definition of case study methodology. First, the problem is real-life, contemporary rather than historical, and exists within an environment where rich context and phenomenon are inextricably linked. Case study methods require analysis of multiple sources of data including both qualitative and quantitative evidence as well as evidence drawn from detailed observation or existing sources (Yin, 2003). In addition, a longitudinal multiple case study design provided the investigator the ability to examine patterns and trends over time (Yin, 2003). A final justification for choosing case study over other methods is under conditions where the researcher has little control over the context (Hentz, 2007).

The objectives for multiple case study design are to draw inferences from a number of cases and is used to confirm an explanation about a phenomenon given examination of that phenomenon in a number of cases (Mariano, 2001; Yin, 2003). Multiple embedded case study design examines subunits of the phenomenon, allows for more complex analyses to be performed and offers greater understanding of each case (Yin, 2003). Full explication of multiple cases enabled the investigator to develop a rich theoretical framework that states the conditions under which the phenomenon is found and those conditions when it is less likely to be found (Yin, 2003).

This exploratory longitudinal investigation used existing data from an ethnographic study of 30 critically ill patients. Observational, interview, and medical record data were available for

this 30 patient cohort whose lengths of observation ranged from 3-65 days with a total of 655 days in the total dataset.

The strategy for qualitative analysis of case studies involved developing thick description of each case using reflection, constant comparison and creativity (Mariano, 2001). Once descriptions for several cases were conducted, cross-case analysis compared explanations to determine a more general explanation. The entire dataset was examined for patterns in both the qualitative and quantitative evidence (Mariano, 2001; Yin, 2003). In order to decrease bias, the investigator attempted to identify and relinquish (bracket) any preconceived notions about the phenomenon.

This investigation also utilized event analysis to examine key aspects of psychological symptoms (anxiety and agitation) in critically ill patients during the period of weaning from long term mechanical ventilation. Event analysis is used to describe and analyze events significant to an inquiry (Kayser-Jones, 2002). This technique is useful when the objective is to investigate complex clinical phenomena in rich detail integrating multiple facets of the event such as antecedents, consequences, and relationships among key variables that have an impact on the event itself (Happ, Swigart, Tate, & Crighton, 2004). In this study, psychological symptoms (anxiety/agitation) and behavioral signs were the events of interest. Events were treated as non-independent of the case. This investigation used both quantitative and qualitative data from a variety of sources to develop a complete description of the presentation, course, characteristics and outcomes of the events.

The units of analysis were phrases and sentences describing each event of anxiety and agitation. Descriptions of each episode were explored from clinical progress notes, data collector observation notes, and formal interviews from patients, families and clinicians. In

addition, numerical data from the medical record were available and includes vital signs, lab data, ventilator settings and daily wean times as well as demographic, medication administration, retrospectively applied Motor Activity Assessment Scale (MAAS) (Devlin, et al., 1999) and other therapeutic records. All records were de-identified. The investigator was open to the discovery of additional subunits as this phenomenon was explored.

This dataset was extensive representing a large investment of time and intellectual effort therefore qualitative secondary analysis (QSA) was proposed. The investigator utilized an *analytic expansion* and extension of questions that arose during the analysis of the original dataset (Thorne, 1998b). The use of this dataset for this study was a logical step based on the investigator's relationship with the parent study. The investigator was one of the primary data collectors on the parent study. This removed the potential limitation of QSA in that this investigator has knowledge of the significant attributes of the context and particular nuances of the original research design or methods (Thorne, 1994). Interviews with patients, families and clinicians provided insight into the critical illness experience. Further confirmatory interviews of clinicians provided more focused data about management of psychological symptoms and behavioral signs from the perspective of ICU clinicians.

A strength of this study design was that the analysis did not rely on interview data alone but included additional forms of information. This investigator also conducted a large percentage of observations which are recorded in the form of field notes describing not only visible data but data collected via other senses. Artifacts in the form of written clinical records provided "real time" descriptions by clinicians. The depth and breadth of data drawn from a variety of sources enabled a more robust inquiry (Sandelowski, 2002).

1.7.2 Clinical Setting

The setting was a 28-bed medical and step-down ICU in a large urban medical center. This research was conducted within the context (ICU) that the phenomenon (psychological symptoms or behavioral signs) occurs. Long term contact within the ICU enhanced the potential to achieve a thorough understanding of the phenomenon (Lincoln & Guba, 1985; Mariano, 2001; Yin, 2003). Further, the research questions in this investigation arose from the observation of clinical practice; therefore it was appropriate to study them within the context of the clinical setting (Miller & Crabtree, 2005).

1.7.3 Sample

The original dataset was from a micro-level ethnography (Fetterman, 1998) which involved a longitudinal study of 30 patients weaning from LTMV (> 4 days). Patients were purposively selected to represent variability in age, gender, ethnicity, diagnosis, and severity of illness (APACHE III). (See Appendix 5).

1.7.4 Recruitment

Participants were recruited for the original study (RO1-NR07973, PI Mary Beth Happ, PhD, RN) by study personnel to reflect variability in important clinical criteria as indicated in relevant literature about weaning from long term mechanical ventilation, a companion clinical trial and ongoing analysis. Daily rounds and discussions with nursing personnel provided information about potential study participants. Patient and family participants were approached by bedside

nurses to gain permission for study personnel to speak with them about participation in a research study. Proxy consent was obtained for those patients who were decisionally impaired. Clinician participants were approached for consent to participate if they were actively involved in the care of one of the study patients. The study was approved by the Institutional Review Board.

1.7.5 Data collection

Qualitative and quantitative data elements were defined and collected from multiple sources. See Table 4 for a summary of those elements.

Data collection included sustained field observations, interviews with patients, family members and clinicians, and clinical record review. Field observation conducted over a 16 month period represents 655 days of weaning from (LTMV) in 16 women and 14 men, aged 59.5 ± 17.6 years (range 25-87 years) with 4 African-American patients (13%) represented. Interviews were conducted with 31 family members about their perceptions of the experience of weaning from LTMV both from their own and from the patient's perspective. Eighteen patients were interviewed about their experiences. Both family and patient interviews included descriptions about feelings, worries, and symptoms. Formal meetings between family members and staff (n=11) were observed and recorded. Clinicians who were actively involved in the care of these 30 patients were interviewed both formally and informally and represent a cross section of disciplines including 11 physicians, 10 nurses, 7 respiratory therapists, 3 others. All narrative clinical documents with descriptions recorded by direct caregivers were available for the period of weaning (range 3-65 days) for each study patient. There were over 1100 source documents

available. Additional interviews with five clinicians were conducted to expand and/or confirm description of the phenomenon.

Table 5 Data elements

Concepts	Measure or definition	Source
Patient Characteristics		
Medical diagnosis		Medical Record
Hospital Length of Stay		Medical Record
ICU Length of Stay		Medical Record
Post –ICU disposition		Medical Record
Sociodemographic	Age, sex, marital status	Medical Record
Communication method		Medical Record, Fieldnotes
Clinical Characteristics		
Severity of Illness	APACHE III - a validated severity of illness scale that ranges from 0 (not ill) to 299 (extremely ill).	Calculated from medical record data on day of admission and first day of ventilator weaning
Level of consciousness	Glasgow Coma Scale Patient is assessed against the criteria in three spheres (eye opening, verbal and motor responses); score is totaled; lower scores reflect deeper levels of unconsciousness; total of 15 reflects fully awake	Medical Record
Wean time	Length of time within a 24-hour period that the patient is able to breathe with either partial or no ventilatory assistance recorded in hours and fractions of hours	Medical Record
Ventilator settings	FiO ₂ , CPAP, - changes and trends in ventilator settings	Medical Record Recorded when they coincide with event of anxiety or agitation; can be used as antecedent or intervention to an event

Table 5 (continued)

Physiologic Variables		
Vital Signs	Temperature, Heart rate, Respiratory rate both with and without full ventilatory support	Medical Record Comparison with anxiety and agitation events May be seen as antecedent or indicative of events
Gas exchange	Arterial blood Gases, Hemoglobin/Hematocrit	Medical Record Comparison with anxiety and agitation events May be used as contextual factors of event
Activity	Bathing, chair sitting, PT.OT procedures, Chest tubes, Airway type, dialysis	Medical Record Comparison with anxiety and agitation events May be used as antecedent or contextual factor of event
Medication Profile		
	Sedative, analgesics	Medical Record All sedatives and analgesics will be recorded hourly for entire study period Used to determine intervention or occurrence of event
Social Context		
	Family presence at bedside, family behaviors	Medical Record Fieldnotes

1.8 DATA ANALYSIS PLAN

In this study, the events of interest were the occurrence of psychological symptoms and behavioral signs indicative of anxiety or agitation. Specifically, the data set was reviewed for evidence of each occurrence of the following psychological symptoms and behavioral signs: anxiety, restlessness, agitation.

In the initial phase of the study, all documents were imported into Atlas.TI version 5.2, a qualitative software program that allows for efficient management of documents and qualitative coding and analysis. Existing coding from the parent study was removed and clean copy of text was used for analysis.

A list of keywords was developed from a review of the literature (Fraser, et al., 2000; Fraser & Riker, 2001; Jaber, et al., 2005; Woods, et al., 2004) and through discussion with clinical experts. Sedation and analgesic administration were used to identify instances of anxiety or agitation. Concurrent contextual and symptom information was recorded. Each incident (event) was read and questions were raised such as “What is going on here?” “With whom?” “What are the circumstances?” Each event was analyzed using dimensional analysis techniques to identify properties and dimensions of causal conditions, patient responses, clinician actions and strategies, intervening conditions, consequences and context (Kools, McCarthy, Durham, & Robrecht, 1996). Memos that characterized contextual features, antecedents, consequences, language usage were recorded. The social and environmental dimensions of these symptoms were explored. All events were compared within and between cases (Strauss, 1990) for patterns using constant comparative analysis. This allowed for collapsing of codes into themes or categories.

Narrative data were merged with quantitative data (i.e., vital signs, medication dosages, sedation scale ratings and ventilator settings) into a metamatrix (Miles, 1994) which was constructed and analyzed with thematic lines tailored to meet the research aims using “events” of anxiety or agitation as the unit of analysis. This analytic approach provided description of context and clinician actions including pharmacologic and non-pharmacologic interventions implemented to manage these symptoms. Eventually, meta-matrix construction allowed for data to be displayed and relationships more easily discerned. Further work on confirmation of patterns was performed using graphical data display. For instance, medication administration was re-displayed in a graphic with an overlay of descriptions of psychological symptoms and behavioral signs. Assumptions about associations were supported or refuted (Happ, et al., 2004). Diagramming main concepts and the relationships between concepts resulted in the development of a model depicting these complex, multi-dimensional features of anxiety and agitation symptom identification and management.

In this study, methodologic rigor or trustworthiness was maintained in four ways outlined by Lincoln and Guba (1985), Sandelowski (1986) and Morse and Field (1995). These procedures were maintained throughout the data collection, analysis and dissemination phases of this study as described by Morse, et al (2002). First, an audit trail of methodologic notes and analytic memos were recorded systematically to detail thoughts and establish *dependability* (Morse & Field 1995; Sandelowski, 1986). This enabled review of the decision plan for consistent and stable conclusions. Multiple data sources (medical record data, study observation notes and interview with patients, families and clinicians) were cross-checked or triangulated to support *confirmability*. *Credibility* was established through consultation with colleagues and experts as necessary to determine if the analysis reflected critical care practice accurately. Specifically, weekly analysis meetings between the investigator and the advisor provided

credibility and fittingness of findings (Morse & Field 1995). Meetings with the advisor to review and critique analytic lines were conducted more frequently during the final analysis and often included an additional committee member with qualitative expertise. The sample was pre-selected to support a wide range of critically ill patients with variability in age, sex, race, and medical diagnosis. This purposive sample as well as thick descriptive data and rich description of context established *transferability*.

1.8.1 Considerations for data analysis approach

QSA offered several advantages. First there was an existing longitudinal dataset of thirty critically ill patients' experiences of care in the ICU. This was a convenient and cost-effective source of information (Szabo & Strang, 1997). It also eliminated a source of respondent burden to critically ill patients who are already at risk and vulnerable (Szabo & Strang, 1997). The proximity to the original research team and data sources offered a source of validation for both the narrative and quantitative data and eliminated the risk of misinterpretation of context. This investigator maintained a continued engagement in the field with the ICU clinicians, patients and care environment.

1.9 LIMITATIONS

This study design had several limitations. One disadvantage of this methodology was that data were collected with a focus on the weaning event not the psycho-behavioral symptom experience. Purposive selection was conducted to theoretically saturate based on analysis of weaning from LTMV rather than anxiety and agitation. In the current study, the analytic lens

was re-focused on the psycho-behavioral symptom identification and management. Because the phenomenon of interest was different from the original focus of data collection, additional data in the form of clinician interviews were undertaken to achieve theoretical saturation.

While primarily a strength in QSA, the PI's relationship with the original dataset could potentially risk premature closure to new insights. However, acknowledgement and bracketing this potential bias, the use of critical care experts to validate and close mentoring in the analysis reduced this potential limitation.

1.10 HUMAN SUBJECTS

This study was approved by the University of Pittsburgh Institutional Review Board (IRB). This investigator was a co-investigator on the original study and was involved in all phases of planning; participant recruitment; data collection, security, management and analysis; and contributed to dissemination of findings collaboratively and independently. The current study questions developed from intense contact with the study participants and unit as well as from the parent study analysis. It extended the original research questions related to the processes of care and communication in patients who are weaning from LTMV. A modification reflecting addition research questions to the original protocol was approved by the University of Pittsburgh, IRB on April 14, 2007. The IRB approved all subsequent annual renewals.

Written informed consent was obtained prior to observations and interviews from patient participants and their families. Proxy consent was obtained from surrogates for those patients who were unable to demonstrate decisional capability. Clinicians were informed of and assented

to observations during patient care and informed consent obtained prior to formal interviews. Human subject rights were explained to each participant.

1.10.1 Potential risks to participants

There were no physical risks associated with this study. Potential breaches to confidentiality were addressed by limiting access of study records to study personnel only. All records were stored in a locked file cabinet in a locked office or in a password protected file on a computer. All records were de-identified. The qualitative database and quantitative spreadsheets were controlled by the principal investigator.

Because observations of clinical care were recorded, a risk existed should study records be subpoenaed for litigation or requested by an insurer. A Certificate of Confidentiality was granted by the NIH to protect patients, their families and clinicians from exposure due to their participation in the parent study.

1.10.2 Procedures to minimize risks

The research team maintained confidentiality of research records by assigning pseudonyms to participants and places. All participants were assigned a code number known only to the PI and Co-PI. All records linking the identity of research participants to their study codes were password protected and all data was stored in locked files in locked offices.

1.10.3 Potential benefit

Participants were unlikely to gain any direct benefits from their involvement in this study. However, their contributions could lead to improved identification and management of anxiety and agitation that is experienced by critically ill patients in the future.

1.10.4 Importance of the knowledge gained

The results of this study contribute to improved critical care practice and address the American Association of Critical Care Nurses' research priority area of **symptom management** by pinpointing issues crucial to reliable interpretation and management of psychological symptoms and behavioral signs. Moreover, this study addresses the National Institute of Nursing Research areas of research opportunity which includes managing symptoms in acute illness (Buerhaus, 2006). Additionally, this study and the resulting model of Anxiety and Agitation in Critical Illness serve as a basis for development and testing of interventions to improve the identification and management of psychological symptoms.

1.10.5 Data safety and monitoring plan

The Data Safety and Monitoring plan was ongoing and assured that the team maintained the confidentiality and security of all study records. Regular review for consistency with study protocol was conducted weekly with study personnel. There were no breaches of confidentiality and security of study records was maintained. Annual reports to the IRB were sent throughout the study period.

1.10.6 Inclusion of women and minorities

In the parent study, there were no exclusion criteria based on sex or race. Every attempt was made to enroll a sample that reflected variability in patient characteristics consistent with relevant criteria reported in the literature. Women represented 53% (16/30) of the sample. African Americans made up 13% (4/30) of the sample which is consistent with local geographic demographics. Children younger than age 21 were not enrolled in this study as is consistent with the population demographics of this unit.

2.0 MANUSCRIPT 1 - METHODS

The methods used in this study are described in greater detail with particular focus on qualitative secondary analysis in manuscript 1 located in section 2.2.

2.1 LETTER TO THE EDITOR

May 30, 2010

Judith Gedney Baggs, PhD, RN, FAAN
Editor-in-Chief, Research in Nursing & Health
Elizabeth N. Gray Distinguished Professor
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Dear Dr. Baggs;

Please find the enclosed manuscript entitled “Qualitative Secondary Analysis: A Case Exemplar” for your consideration for publication in *Research in Nursing and Health*. This paper describes a commonly used, yet rarely reported analytic technique for qualitative data. We provide a review of qualitative secondary analysis and illustrate its utility through an exemplar. Nursing studies that used qualitative secondary analysis are reviewed to illustrate a variety of approaches, purposes, and modes of data sharing. This paper should be useful to many of your readers including experienced researchers and students as qualitative secondary analysis has not been addressed extensively in the nursing literature.

The authors have made contributions to preparing this manuscript and no others have made significant contributions. All authors read and reviewed this manuscript. We appreciate your effort and the effort of our peer reviewers. This paper has not been published before and is not being considered for publication elsewhere. Please feel free to contact me with any questions. I look forward to your comments.

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2.2 MANUSCRIPT 1: QUALITATIVE SECONDARY ANALYSIS: A CASE EXEMPLAR

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Conflict of interest and disclosures:

There are not conflicts of interest or disclosures associated with this manuscript.

2.3 ABSTRACT

Abstract: Qualitative secondary analysis (QSA) is the use of qualitative data collected by someone else or to answer a different research question. Researchers often seek to maximize data utility by undertaking a secondary analysis, yet QSA is seldom reported explicitly. In this paper, we describe methodologic considerations using a case exemplar to illustrate challenges and strategies to overcome them. In addition, we review QSA found in nursing literature emphasizing purposes, methods of data sharing and approaches.

2.4 BACKGROUND

Health care research requires significant time and resources. Secondary analysis of existing data provides an efficient alternative to collecting data from new groups or the same subjects. Secondary analysis, defined as the reuse of existing data to investigate a different research question (Heaton, 2004), has a similar purpose whether the data are quantitative and qualitative. Common goals include (1) to perform additional analyses on the original dataset, (2) to analyze a subset of the original data, (3) to apply a new perspective or focus to the original data or (4) to validate or expand findings from the original analysis (Hinds, Vogel, & Clarke-Steffen, 1997). Synthesis of knowledge from meta-analysis or aggregation may be viewed as an additional, although controversial, purpose of secondary analysis (Heaton, 2004).

Qualitative studies utilize a number of different data sources such as interviews, observations, field notes, archival meeting minutes or clinical record notes to produce rich descriptions of human experiences within a social context. The work entailed requires a significant outlay of resources for data collection and analysis. When feasible, qualitative secondary analysis (QSA) can be a useful and cost-effective alternative to designing and conducting redundant primary studies. With advances in computerized data storage and analysis programs, sharing qualitative datasets has become easier. However, little guidance is available for conducting, structuring procedures, or evaluating QSA (Szabo & Strang, 1997).

QSA has been described as “an almost invisible enterprise in social research” (Fielding, 2004). Primary data is often re-used; however, descriptions of this practice are embedded within the methods section of qualitative research reports. Studies using QSA may not be explicitly

identified as such. Searching or classifying reports as QSA is difficult because many researchers refrain from identifying their work as secondary analyses (Hinds, et al., 1997; Thorne, 1998a).

In this paper, we provide an overview of QSA and a selective review of QSA in nursing research to exemplify the variety of purposes, modes of data sharing and approaches that can be utilized. A unique, expanded approach to QSA is presented as a methodological exemplar to illustrate issues to consider when undertaking QSA.

2.4.1 QSA Typology

In a review of QSA from social science and health literature, Heaton (2004) classified QSA studies based on the relationship between the secondary and primary questions and the scope of data analyzed. The several types of QSA identified included studies that (1) investigated questions entirely different from the primary study, (2) applied a unique theoretical perspective or (3) extended the primary work by elaborating on findings or exploring a concept that emerged from the primary study. Heaton found that most studies investigated questions that were unique or additional to the primary study (Heaton, 2004). The studies also varied in the choice of data used. Some utilized an entire dataset, while others examined selected portions or combinations of datasets.

While Heaton based her classifications on a review of empirical studies, Thorne developed a similar classification system derived theoretically (Heaton, 2004; Thorne, 1994, 1998a) Like Heaton, Thorne classified studies based on the relationship of the secondary questions to the primary study and the range of data used in the secondary study. However, Thorne included the relationship of the secondary researcher to the primary study as an important

factor in the classification system. Comparison of these two classification systems can be found in Table 6.

Table 6 Comparison of Thorne and Heaton's classification of QSA

QSA Relationship to Primary Question	Relationship of Primary Investigators to QSA Investigators	Thorne's classification	Heaton's classification
Entirely new empirical, methodological, or theoretical	Different	Armchair Induction	Supra-analysis
	Same	Not classified	
Extension of primary study to concepts revealed but not fully investigated in primary study	Different	Retrospective interpretation	Supplementary
	Same	Analytic expansion	
Validation of primary findings by QSA	Different or Same	Not classified	Re-analysis
Combination of two distinct datasets; can be different samples or pooled data to examine mutual and/or contradictory themes	Different or Same	Amplified sampling	Amplified analysis
Combination of one original primary dataset with a new primary dataset	Different or Same	Cross-validation	Assorted analysis

2.4.2 Modes of data sharing

There are several ways that researchers can access existing qualitative datasets for QSA. Heaton (2004) identified three modes of data sharing: (1) formal, (2) informal and (3) auto-data. Formal data sharing involves accessing and analyzing deposited or archived qualitative data by an independent group of researchers. Historical research often uses formal data sharing. Informal data sharing refers to requests for direct access to an investigator's data for use alone or to pool with other data, usually as a result of informal networking. In some instances, the primary

researchers may be invited to collaborate. The most common mode of data sharing is auto-data, defined as further exploration of a qualitative data set by the primary research team. Due to the iterative nature of qualitative research, when using auto-data, it may be difficult to determine where the original study questions end and discrete, distinct analysis begins (Heaton, 1998).

To illustrate the variety of QSA in nursing published since Heaton's review, a focused literature review of QSA studies was conducted. A search of the electronic literature database, MEDLINE was undertaken using keywords: secondary, qualitative, secondary analysis, nursing. A hand search of reference lists from articles was also conducted to identify additional articles for consideration. Table 2 illustrates the purposes of the primary and secondary studies, approach, mode of data sharing, typology, and benefits of each QSA. Heaton's typology and classification of modes of data sharing were used in this review as the methods and selection of exemplars closely resembled her review.

Table 7 Selected review of qualitative secondary analyses in nursing

Authors of QSA	Purpose of primary study(s)	Primary study data collection methods	Purpose of QSA	Mode of data sharing*	Analysis methods of QSA	Typology of QSA *	Benefit of QSA
Deatrick, Angst, & Moore (2002)	Describe parents' end of life decision making for children with cancer	Combined retrospective interview and questionnaire with prospective interviews	Describe parents' perception of participating in Phase I clinical trials for their children who had cancer Combined two existing datasets, purposively sampled for decisions to participate in Phase I clinical trial	Informal	Descriptive cross-sectional	Supra-analysis Maximized use to existing data to answer different research question	Decreased respondent burden.
Hutchinson (1990)	Describe unprofessional behavior in nurses	Participant observation In depth interviews	To explain how nurses "bent the rules" to benefit the patient	Autodata	Grounded theory	Assorted Combined original data with new interview data	Used primary data which addressed a sensitive topic

Table 7 (continued)

<p>Johnson, Bottorff, Moffat, Ratner, Shoveller, & Lovato (2003)</p>	<p>Explore adolescents' perspectives on tobacco dependence and culturally patterned beliefs</p>	<p>Structured and unstructured interviews Open card sort of key phrases</p>	<p>Explore attitudes toward smoking and personal experiences with smoking Develop contract and structural questions used in subsequent primary data collection to elicit description of organization of adolescent cultural knowledge of tobacco dependence</p>	<p>Autodata</p>	<p>Ethnography, content analysis, and thematic analysis</p>	<p>Assorted Utilized secondary analysis of primary dataset to construct questions used in second and third phases of study</p>	<p>Unique technique to identify language used by adolescents</p>
<p>Matzanoukas & Jasper (2008)</p>	<p>Describe the practice reality of nurses</p>	<p>Ethnography Semi-structured interviews</p>	<p>To identify the types of nursing knowledge used to guide care of hospitalized patients</p>	<p>Autodata</p>	<p>Thematic analysis</p>	<p>Supplementary Utilized theoretical typology of nursing knowledge to identify types of knowledge utilized by practicing nurses</p>	<p>Maximized use of data</p>

Table 7 (continued)

Morse & Pooler (2002)	Describe patterns of comfort used by nurses caring for trauma patients	Videotaped observation	Describe responses of families and interactions between nurses and families in the trauma room	Autodata	Ethogram	Supra-analysis Examined a subset of data using the Model of Suffering framework applied to family members	Maximized use of video data
Norton, Tilden, Tolle, Nelson, & Eggman (2003)	Assess family stress related to withdrawal of life support Identify phases of decision making families go through to withdraw life sustaining treatment	Individual, semi-structured interviews	Describe communication needs of family members who experienced conflict with clinicians during decision to withdraw life support	Autodata	Qualitative descriptive analysis	Supplementary Logical extension of original work Utilized subset of original sample to examine questions that emerged during primary data analysis	Decreased respondent burden of vulnerable group

Table 7 (continued)

<p>Olliffe & Thorne (2007)</p>	<p>Explore men with prostate cancer's experiences of helpful and unhelpful cancer communication</p> <p>Describe connections between masculinity and men's experiences of prostate cancer across the illness trajectory</p>	<p>Individual, in-depth, semi-structured interviews</p>	<p>Describe how interactions and patterns of communication between prostate cancer patients and male physicians are informed and influenced by masculinity</p>	<p>Informal</p>		<p>Amplified analysis</p> <p>Combined datasets</p> <p>Strong fit between the data sets, QSA research questions and nature of data</p> <p>Theoretically representative data bases?</p>	<p>Avoided challenge of recruiting men to participate in qualitative interview-based studies about health and illness.</p> <p>Maximized use of qualitative databases to answer additional research questions</p>
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Table 7 (continued)

<p>Pickens (1999)</p>	<p>Describe perceptions of self-care abilities and limitations in patients hospitalized with serious mental illness</p> <p>Describe interaction between formal and informal social networks of patients with mental illness</p>	<p>Structured and semi-structured interviews</p>	<p>Identify use of self care actions to support and maintain normalcy using pre-determined themes</p>	<p>Autodata</p>	<p>Content analysis, thematic analysis</p>	<p>Amplified</p> <p>Utilized two different datasets drawn from patients with similar diagnoses to determine relationships between the desire for normalcy and self-care activities</p>	<p>Re-used data drawn from a population that is difficult to access for research</p>
<p>Radina & Armer (2004)</p>	<p>Explore quality of life experiences of women who experience post-mastectomy lymphedema focused on the context of family and social roles</p>	<p>Ethnography</p> <p>In depth semi-structured interviews</p> <p>In depth unstructured interviews</p> <p>Observations</p>	<p>Determine the effect of the onset of post-mastectomy lymphedema and related stressors on women and their families</p>	<p>Informal</p>	<p>Template analysis using resiliency model</p>	<p>Supplementary</p> <p>Applied template of resiliency model to answer secondary question</p>	<p>Used small but theoretically saturated sample</p>

Table 7 (continued)

Santacroce, Deatrck, & Ledlie (2002)	Develop theory of disclosure of diagnosis to children with perinatally acquired HIV infection by their parental care providers	Interviews, fieldnotes	Describe management of children's' treatment for HIV infection by seropositive mothers.	Informal	Applied Family Management Style Model to data, Symbolic interaction	Supplementary Added a new expert in qualitative methods to guide re-examination of data with a focus on treatment, a concept that arose during the primary analysis	Decreased respondent burden of vulnerable population Saved time
Seymour, Ingleton, Payne & Beddow (2003)	Evaluate patients' perceptions of palliative care services	Interviews	Describe patients' expectations and experiences of palliative care	Autodata	Evaluation methodology	Amplified analysis Synthesized evaluation data from three studies of palliative care services	Demonstrated applicability of findings beyond the local and limited contexts

Table 7 (continued)

Szabo & Strang (1999)	Explore how family caregivers of patients with dementia experience respite	Semi-structured interviews, fieldnotes	Describe and explain the experience of control of family caregivers of patients with dementia	Autodata	Grounded theory	Supplementary Examined concept imbedded within original study Logical extension guided by literature	Maximized use of dataset with vulnerable population
Thorne, Hislop, Armstrong, & Oglov (2008)	Describe cancer patients' perceptions of helpful and unhelpful communication	Interviews, focus groups	Examine belief of cancer patients that communication by providers is associated with disease outcomes	Autodata	Qualitative interpretive description	Supplementary Re-examined a subset of patients who believed that communication affected their cancer outcomes	
Thorne, Nyhlin, & Paterson (2000)	Describe chronic illness self-management techniques	Intensive interview and think aloud decision making recordings	Describe the barriers in health care relationships experienced by individuals with chronic health problems	Autodata	Triangulation	Amplified Provided evidence of similar themes despite differences in diagnostic categories and culture	Used similar approach but with different population

Table 7 (continued)

Thorne, Oglov, Armstrong, & Hislop (2007)	Describe patient perspectives of helpful and unhelpful communication with providers during chronic illness and cancer	Interviews Focus groups Longitudinal	Explore interpretation of prognostic communication between provider and patients with chronic illness or cancer.	Autodata	Qualitative interpretive description	Amplified Capitalized on methodologic similarity between studies, frequently occurring phenomenon in both primary studies. Common qualitative software used in both studies permitted efficient access, recoding and analysis	Maximized use of large dataset
Williams & Collins (2002)	Grounded theory exploration of the subjective experience of schizophrenia	Interviews	Describe social construction of disability	Autodata	Editing approach to data reduction using a literature derived conceptual framework	Supra-analysis Re-examined existing dataset using a social construction of disability	Provided access to population that may be reluctant to discuss their illness experience

* Mode of data sharing and QSA classification per Heaton (2004)

2.4.3 An Exemplar QSA

Below we describe a QSA exemplar conducted by the primary author of this paper (JT), a member of the original research team, who used a supplementary approach to examine concepts revealed but not fully investigated in the primary study. First, we describe an overview of the original study on which the QSA was based. Then, the exemplar QSA is presented to illustrate: (1) the use of auto-data when the new research questions are closely related to or extend the original study aims, (2) the collection of additional clinical record data to supplement the original dataset and (3) the performance of separate member checking in the form of expert review and opinion. Considerations and recommendations for use of QSA are reviewed with illustrations taken from the exemplar study. Finally, discussion of conclusions and implications is included to assist with planning and implementation of QSA studies.

2.4.4 The Primary Study

The original study was a micro-level ethnography designed to describe the processes of care and communication with patients weaning from long term mechanical ventilation (LTMV). Table 5 presents the research questions addressed by the primary study.

Table 8 Research question comparison

Primary study

QSA

What is the process of care and communication in weaning LTMV patients from mechanical ventilation?

⇒ What are the defining characteristics and cues of psychological symptoms such as anxiety and agitation exhibited by patients who are experiencing prolonged critical illness?

What interpersonal interactions (communication contacts, extent and content of communications) contribute to weaning success or are associated with inconsistent/plateau weaning patterns?

⇒ How are these characteristics and cues interpreted as -behavioral signs by clinicians? b) How do clinicians discriminate between various psychological symptoms and behavioral signs?

What therapeutic strategies (e.g., medications/nutrients, use of instruction or comfort measures, rehabilitative treatments) contribute to weaning success or are associated with inconsistent/plateau weaning patterns?

⇒ What therapeutic strategies (e.g., medications, non-pharmacologic methods) do clinicians undertake in response to patients' anxiety and agitation?

What social (patient, family, clinician characteristics) and environmental factors (noise, lighting, room size/arrangement, work pattern, workload) contribute to weaning success or are associated with inconsistent/plateau weaning patterns?

⇒ How do physiologic, social and behavioral characteristics of the patient influence the clinician's interpretation and management of anxiety and agitation?
What contextual factors influence interpretation and management of psychological symptoms and behavioral signs?

The original dataset included 30 patients in a 28-bed medical and step-down ICU in a large urban medical center observed over a 14 month period. Data were collected by two experienced investigators and JT, the primary investigator for the QSA. Data sources included sustained field observations, interviews with patients, family members and clinicians, and clinical record review, including all narrative clinical documentation recorded by direct caregivers.

During the conduct of the original study, it became apparent that anxiety and agitation had a direct effect on patients' daily wean time, an observation that helped to formulate the questions for the QSA. In addition to being an important phenomenon that had an impact on weaning, anxiety and agitation were frequently occurring phenomena in observations at the bedside and during interviews with clinicians. The focus of the QSA therefore became anxiety and agitation in critically ill patients. Descriptions of cues that clinicians used to identify anxiety and agitation in critically ill patients, the strategies they used to manage these symptoms and the contextual factors that influenced clinicians' choices emerged as important areas that were related to weaning from LTMV. Thus, the secondary topic was closely aligned as an important facet of the primary phenomenon. In fact, during the exemplar QSA, periods of weaning were found to be antecedent to some, but not all, episodes of anxiety and agitation. The close, natural relationship between the primary and QSA research questions is demonstrated in the side-by-side comparison in Table 3.

2.4.5 The QSA

The purpose of the exemplar QSA was to describe critically ill patients classified as "anxious or agitated" and clinician interpretation and management of these psychological symptoms and

behavioral signs. The occurrence of numerous uncomfortable symptoms during mechanical ventilation in the ICU are well established (Nelson, et al., 2001). Interpreting and treating anxiety and agitation are integral components of critical care nursing practice (Bergbom-Engberg & Haljamae, 1989; Chlan, 2003; Gries & Fernsler, 1988; Logan & Jenny, 1997; Rotondi, et al., 2002). Little is known about how critical care clinicians (nurses, physicians, and respiratory therapists) interpret different psychological symptoms like anxiety and agitation or the strategies they employ to manage such symptoms. This QSA focused on new questions which extended the focus of the original study to recognition and management of anxiety or agitation, behaviors that often accompany mechanical ventilation and weaning but occur throughout the trajectory of critical illness and recovery.

2.4.6 Considerations when Undertaking QSA

2.4.6.1 Practical Advantages

A key practical advantage of QSA is maximizing use of existing data. Data collection efforts represent a significant percentage of the research budget in terms of cost and labor (Coyer & Gallo, 2005; Rew, Koniak-Griffin, Lewis, Miles, & O'Sullivan, 2000). This is particularly important in view of the competition for research funding. Planning and implementing a qualitative study involves considerable time and expertise not only for data collecting (e.g., interviews, participant observation or focus group), but in establishing access, credibility and relationships (Thorne, 1994). The cost of QSA is often seen as negligible since the outlay of resources for data collection is assumed by the original study. However, QSA incurs costs related to storage, researcher's effort for review of existing data, analysis, and any further data collection that may be necessary. In this QSA exemplar, we capitalized on an existing

longitudinal dataset of 30 critically ill patients' experiences of care in the ICU, a convenient and cost-effective source of information (Szabo & Strang, 1997). However, the new line of inquiry required additional time, space and effort not part of the original study budget. Data files had to be stored and maintained and the analysis required computer software and hardware upgrades. New personnel were hired to assist with the analysis. Funds were received from the Association of Critical Care Nurses to support database construction, analysis and consultation by proficient critical care nurses. In spite of these expenses, QSA permitted us to conduct the study for far less cost than undertaking a new inquiry.

Another advantage of QSA is access to data from an assembled cohort. In conducting original primary research, practical concerns arise when participants are difficult to locate or reluctant to divulge sensitive details to a researcher. In the case of vulnerable critically ill patients, participation in research may seem an unnecessary burden to family members who may be unwilling to provide proxy consent (Fielding, 2004). QSA permits new questions to be asked of data collected previously from these vulnerable groups (Rew, et al., 2000). It also allows questions to be asked of data collected on groups or events that occur with scarcity (Thorne, 1994). QSA prevents additional respondent burden for vulnerable groups such as the mentally ill (Pickens, 1999; Williams & Collins, 2002), patients with cancer (Radina & Armer, 2004; Seymour, et al., 2003; Thorne, et al., 2007), family caregivers (Deatrck, et al., 2002; Szabo & Strang, 1999) critically ill, elderly, or trauma patients and their families (Morse & Pooler, 2002). Access to patients can be difficult particularly when the topic of the study is sensitive such as adolescent sexuality (Rew, et al., 2000), life support withdrawal (Norton, et al., 2003), HIV status (Santacroce, Deatrck, & Ledlie, 2000) or communication about masculinity (Oliffe & Thorne, 2007). Participants' time and effort in the primary study therefore becomes more

worthwhile. In fact, it is recommended that data already collected from existing studies of vulnerable populations or about sensitive topics be analyzed prior to engaging new participants. In this way, QSA becomes a cumulative rather than a repetitive process (Fielding, 2004).

QSA for research with critically ill patients is advantageous because patients are at risk with physical conditions that wax and wane, their families experience a particularly stressful time and clinicians need to attend to care demands. Access to this population can be affected by efforts of caregivers to protect patients, e.g., professional territoriality. Furthermore, the process of gaining trust and entre into the critical care setting takes time. In the exemplar QSA, the professional credibility of researchers established during the primary study facilitated entre later when we returned to conduct the QSA. The QSA reduced respondent burden for vulnerable critically ill patients and their caregivers, thus maximizing participants' investment of time and expertise(Szabo & Strang, 1997).

2.4.6.2 Suitability of Original Dataset

Several characteristics of QSA make this methodology challenging. The first question should consider whether it is possible to conduct the desired analysis(Heaton, 1998). Many procedures necessary for strict adherence to the requirements of a particular methodology cannot be fulfilled using QSA (Rew, et al., 2000; Szabo & Strang, 1997). For example, some methods are not readily combined based on differences in philosophical or conceptual perspectives (Coyer & Gallo, 2005). Although research questions may be related, datasets derived from diverse theoretical vantage points are different(Thorne, 1994). In this exemplar, micro-ethnography, examination of in-depth case description and event analysis were utilized in both the primary and secondary analyses. A strength of this study design was that the analysis did not rely on interview data alone but also included additional information, such as participant observations,

medical record data and event analysis of each instance of anxiety or agitation during the patient's illness experience.

2.4.6.3 Data Adequacy and Congruency

Secondary researchers must determine that the primary data set meets the needs of the QSA. Data may be insufficient to answer a new question or the focus of the QSA may be so different as to render the pursuit of a QSA impossible (Heaton, 1998). The underlying assumptions, sampling plan, research questions, and conceptual framework selected to answer the original study question may not fit the question posed during QSA (Coyer & Gallo, 2005). The researchers of the primary study may have selectively sampled participants and analyzed the resulting data in a manner that produced a narrow or uneven scope of data (Hinds, et al., 1997). Thus, the data needed to fully answer questions posed by the QSA may be inadequately addressed in the primary study. A critical review of the existing dataset is an important first step in determining whether the primary data fits the secondary questions (Hinds, et al., 1997).

2.4.6.4 Passage of Time

The timing of the QSA is an important consideration. If the primary study and secondary study are performed sequentially, findings of the original study may influence the secondary study. On the other hand, studies performed concurrently offer the benefit of access to both the primary research team and participants member checking (Hinds, et al., 1997).

The passage of time since the primary study was conducted can also have a distinct impact on the usefulness of the primary dataset. Data may be outdated or contain a historical bias(Coyer & Gallo, 2005). Since context changes over time, characteristics of the phenomena of interest may have changed. Analysis of older datasets may not illuminate the phenomena as they

exist today.(Hinds, et al., 1997) Even if participants could be re-contacted, their perspectives, memories and experiences change. The passage of time also has an impact on the relationship of the primary researchers to the data – so auto-data may be interpreted differently by the same researcher with the passage of time. Data are bound by time and history, therefore, may be a threat to internal validity unless a new investigator is able to account for these effects when interpreting data(Rew, et al., 2000).

This exemplar QSA was undertaken several years after the primary data were analyzed. During this time, critical care practice evolved including the development of clinical practice guidelines and research findings were published on topics relating to anxiety, agitation and sedation. Initially, it was not clear whether these events would outdate potential contributions of data from the primary study. Historic effects were addressed by the investigator's ongoing role from the original study and subsequent studies in critical care. Observations of clinical practice indicated that implementation of recommendations from professional organizations and evidence from research findings have not been consistently codified at the institutional level nor applied at the bedside. Variability in implementation of sedation protocols which include assessment and management of anxiety and agitation is not unique to the local institution as evidenced by recent reports in the literature (Aitken, Marshall, Elliott, & McKinley, 2009; Patel et al., 2009; Shehabi et al., 2008; Tanios, de Wit, Epstein, & Devlin, 2009; Weinert & Calvin, 2007).

2.4.6.5 Researcher stance/Context involvement

Issues related to context are a major source of criticism of QSA for some authors (Gladstone, Volpe, & Boydell, 2007; Heaton, 2004; Mauthner, Parry, & Milburn, 1998) although others have less concern (Fielding, 2004). One of the hallmarks of qualitative research is the relationship of the researcher to the participants. It can be argued that removing active contact with participants

violates this premise. Tacit understandings developed in the field may be difficult or impossible to reconstruct (Thorne, 1994). Qualitative fieldworkers often react and redirect the data collection focus based on a growing knowledge of the setting. The setting may change as a result of external or internal factors. Because the context in which the data were originally produced cannot be recovered, the ability of the researcher to react to the lived experience may be curtailed (Gladstone, et al., 2007; Heaton, 2004; Mauthner, et al., 1998). Researchers utilize a number of tactics to filter and prioritize what to include as data that may not be apparent in either the written or spoken records of those events (Thorne, 1994). Interpretation of researchers as unique participants in a unique time and social context may be impossible to, re-construct even if the secondary researchers were members of the primary team (Mauthner, et al., 1998).

There are steps to overcome this criticism. On one hand, reflexivity between the researcher, participants and setting is impossible to recreate when pre-existing data are examined. While this QSA investigator performed many observations, debriefings and interviews in the original study, the focus was on the weaning process, not on anxiety or agitation. However because management of anxiety and agitation was such an important part of weaning management, we asked questions during interviews and recorded many observations of restless or agitated behavior with de-briefing at the bedside following these events. Medical record data presented additional description of anxiety and agitation of sufficient volume to fully explore the phenomenon.

2.4.6.6 Relationship of QSA Researcher to Primary Study

The relationship of the QSA researcher to the primary study is an important consideration. When the QSA researcher is not part of the original study team, contractual arrangements detailing access to data, its format, access to the original team, and authorship should be agreed upon

(Hinds, et al., 1997). The QSA researcher should assess the condition of the data, documents including transcripts, memos and notes, and the clarity and flow of interactions (Hinds, et al., 1997). An outline of the original study and data collection procedures should be reviewed critically (Heaton, 1998). If the secondary researcher is a member of the original study team, direct access to the original investigative team for the purpose of ongoing clarification is essential (Hinds, et al., 1997).

There is also the potential that membership on the original study team may offer the secondary researcher little advantage over someone independent of the team. For instance, members of the primary research team may have had varying degrees of contact with the data, thus conferring varied levels of knowledge of the original dataset depending on their roles in the primary research study (Fielding, 2004; Heaton, 2004). Some research team members may have been responsible for only one type of data collection such as field work or interviews. There may be differences among team members with their degree of involvement with analysis of the primary data.

In the exemplar QSA, the principal investigator (MBH) was readily accessible. Questions about the data could be answered with ease. Contact with additional informants and additional primary data collection was facilitated by ongoing presence in the clinical setting. As a member of the primary team, JT was responsible for the full scope of data collection including participant observation and formal and informal interviews of patients, families and clinicians. Gaps in data related to anxiety and agitation derived from the original dataset were assessed routinely and additional data compiled from available clinical records from the original study and from other sources.

2.4.6.7 Informed Consent of Participants

Thorne raised the issue of whether data collected for one study purpose can be ethically re-examined to answer another question without participants' consent (Thorne, 1998a). Many institutional review boards permit consent forms to include verbiage about the possibility of future use of existing data. While this mechanism is becoming routine and welcomed by researchers, concerns have been raised that a generic consent cannot possibly address all future secondary questions and may violate the principle of full informed consent (Gladstone, et al., 2007; Parry & Mauthner, 2004). Because the study of agitation-anxiety was an extension of the original question to describe the processes of care and communication during weaning from LTMV, exploration of the "sub process" of management of agitation-anxiety was covered in the broad language of the original consent. Moreover, given the frequency of the phenomenon of anxiety and agitation observed and recorded in the original study and the frequency with which participants described their anxiety experiences during interviews, we felt obligated to further explore what was clearly an important aspect of patients' families' and clinicians' experience of critical illness.

2.4.6.8 Rigor of QSA

The primary standards for evaluating rigor of qualitative studies are trustworthiness (logical relationship between the data and the analytic claims), fit (the context within which the findings are applicable), transferability (the overall generalizability of the claims) and auditability (the transparency of the procedural steps and the analytic moves processes) (Lincoln & Guba, 1985). Thorne suggests that standard procedures for assuring rigor can be modified for QSA (Thorne, 1994). For instance, the original researchers may be viewed as sources of confirmation while new informants, other related datasets and validation by clinical experts are sources of

triangulation that may overcome the lack of access to primary subjects (Heaton, 2004; Thorne, 1994).

In this exemplar QSA study, methodologic rigor or trustworthiness was achieved in four ways. First, an audit trail of methodologic notes and analytic memos was recorded systematically to detail thoughts of researchers and establish dependability (Morse & Field 1995). This enabled other researchers to review the analytic decisions that led to consistent and stable conclusions (Sandelowski, 1986). Second, multiple data sources were cross-checked or triangulated to provide confirmability. Third, credibility was established through consultation with colleagues and experts to ensure that the analysis reflected critical care practice accurately. Finally, periodic analysis meetings were held to establish credibility and fittingness of findings (Morse & Field 1995). The patient sample was evaluated for appropriateness to answer the new research questions. The sample included a wide range of critically ill patients with variability in age, sex, race, and medical diagnosis. This sample also included thick descriptive contextual data from families, clinicians, field notes and clinical records supported transferability.

2.4.7 Conclusion and Implications

These observations derived from the experience of posing a new question to be answered by existing qualitative data collected on a vulnerable sample of critically ill patients can serve as a template for researchers considering QSA. Consideration relating to the quality, availability and appropriateness of existing data are of primary importance. A realistic plan for collecting additional data to answer questions posed in QSA should consider burden and resources of time for data collection and analysis and efforts to store and maintain data. Local variations in study approval practices by institutional review boards may impact the ability of researchers to conduct

a QSA. Researchers should consider context as a potential limitation to new analyses. Finally, the cost of QSA is often minimized and should be fully evaluated prior to making a decision to pursue QSA.

3.0 SUMMARY OF STUDY

The purpose of this study was to describe critically ill patients' behaviors classified as "anxious or agitated", clinician interpretation of these behavioral cues, and choice of interventions based on those interpretations. The specific aims were addressed in three manuscripts. The first manuscript, *Qualitative Secondary Analysis: a Case Exemplar*, discussed methods for accomplishing a qualitative secondary analysis and is presented in section 3.0. It is currently in review by *Research in Nursing and Health*. In the second manuscript, anxiety and agitation during critical illness were described in regard to their prevalence, assessment, attributions and the interventions/strategies used in response to these occurrences. A manuscript, *Anxiety and agitation in critically ill patients*, intended for submission to *Qualitative Health Research* was developed from the synthesized findings and can be found in section 4.0. The third manuscript, *Recognition and management of anxiety in patients weaning from prolonged mechanical ventilation*, intended for submission to *Critical Care Medicine* presents findings that relate specifically to anxiety events during weaning from prolonged mechanical ventilation and can be found in section 5.0.

Data collection followed the process outlined in the Overview document with minimal variation. The major difficulty (and change) arose when attempting to apply MAAS scores to the events of anxiety and agitation as there was insufficient data to calculate MAAS scores for each event. Previously MAAS scores were retrospectively applied to behavioral descriptions

from the clinical record. However, in the current study, descriptions of motor activity was inadequate for application of the score to each anxiety or agitation event. This calculation was therefore omitted.

The study led to development of a model for recognition and management of anxiety and agitation in critical illness. The model is consistent with Lazarus and Folkman's Transactional Model of Stress and Coping but is specific to the ICU context. It includes clinician responses to anxiety and agitation interaction between patient, clinician, and technology and consideration of physiological responses to experiences common in critical illness. Discussion of this model can be found in Manuscripts 2 and 3.

Research Question #1 (*What are the defining characteristics and cues of psychological symptoms exhibited by patients who are experiencing prolonged critical illness?*) was addressed by both results papers, manuscripts 2 and 3. Terminology from the literature and physiologic signs were used to indicate events of anxiety and agitation. Interaction was the core process enabling patients to appraise the threat of stimuli and guiding assessment and management of anxiety and agitation. Stimuli of anxiety and agitation were described by participants and included care activities such as bathing, position changes and suctioning. Patients indicated that they developed anxiety when they were left alone providing a clearer link between isolation and anxiety. Participants indicated that ventilator weaning stimulated anxiety. Physical sensations that contributed to the development of anxiety or agitation during mechanical ventilation and ventilator weaning were air hunger, breathlessness and endotracheal tube discomfort.

Research Question #2 (*How are these characteristics and cues interpreted as behavioral signs by clinicians? and How do clinicians discriminate between various psychological symptoms and behavioral signs?*) was addressed by both results papers,

manuscripts 2 and 3. Interaction was identified as the core process and patient movement was an important characteristic of interaction that enabled clinicians to identify and manage anxiety and agitation. Dialectics showed the tension innate in assessing anxiety and agitation in the context of critical illness where patients are unable to communicate their feelings and emotions. Two opposing attributions were revealed: discrimination vs. generalization and anxiety as an expected response vs. a character flaw. “Anxiety” may have been used as a catch-all, general term because it is understandable and a condition that can be treated. Conversely the data also showed instances where clinicians’ attempt to differentiate anxiety from other conditions (pain, dyspnea, etc). Anxiety was viewed as an expected appropriate response to stimuli by some clinicians. On the other hand, clinicians viewed anxiety as a response patients could control and viewed those patients weak or having a character flaw that contributed to their inability to control anxiety. Assessment required “knowing the patient”. This personal knowledge came in three dimensions, (1) continuity, (2) transfer of care information, and (3) patient history.

Research Question #3 (*What therapeutic strategies (e.g., medications, non-pharmacologic methods do clinicians undertake in response to patients psychological symptoms and behavioral signs?*) was addressed by both results papers, manuscripts 2 and 3. Interventions were designed to modify the stimulus whether it was physical or psychological. Clinicians provided physical comfort measures when they determined that a physical stimulus resulted in anxiety or agitation. Supportive verbal strategies were used even when patients’ ability to process and respond was limited. Music provided for patients by family members created a calming environment in an individualized way.

Sedation management was a challenge as the competing clinical goals of awake yet calm created tension between clinicians. Sedation was ordered by physicians and administered by

nurses for patient comfort and safety. In addition, nurses administered sedation to control behaviors considered unsafe such as disrupting important medical devices, striking out or trying to get out of bed. Sedation management was inconsistent and variable especially when anxiety was associated with ventilator weaning.

A process of withholding presence or withholding information was described by clinicians when anxiety was associated with ventilator weaning. These interventions were called “out of sight, out of mind” and “sneaking the wean”. While most weaning trials were structured to actively include the patient, sometimes clinicians deliberately did not include them to prevent anxiety. These were new and unexpected findings not described extensively in the literature.

Research Question #4 (How do physiologic, social and behavioral characteristics of the patient influence psychological symptoms and behavioral signs clinicians use to interpret and manage those symptoms?) was addressed by results papers, manuscripts 2 and 3. Clinicians relied on their knowledge of patients’ previous responses or prior history to direct management of anxiety or agitation.

Research Question #5 (*What contextual factors influence interpretation and management of symptoms?*) was addressed by both results papers, manuscripts 2 and 3. Weaning from prolonged mechanical ventilation contributed to a conditioned anxiety response. Clinician attributions influenced both interpretation and management of anxiety and agitation.

There are several limitations in this study that potentially limit transferability to all critically ill patients. Methodologic limitations include the broad focus on ventilator weaning during the parent study. Participants described anxiety and agitation in formal and informal interviews relating to events beyond ventilator weaning. However, the focus of the parent study was on ventilator weaning. Anxiety experienced during weaning may be different from anxiety

experienced in other situations. While we did observe patients during and outside of ventilator weaning events, anxiety may be different for patients who have not yet begun weaning trials. Finally, the study was conducted in a single ICU setting and, although findings were consistent with others ICUs in this institution, they may not represent other geographical or institutional settings.

This study contributes to critical care practice in several ways. First, the model illustrates the wide range of both patient responses and clinician interpretations associated with everyday critical care experiences. Careful reflection by clinicians may reveal how knowing the patient and their own attributions about anxiety and agitation influence their assessment and management of critically ill patients. This may enable consideration of a wider range of possible explanations for patient responses. Using this model, clinicians may also deliberately and consciously target interventions to stimulus, appraisal or response.

Findings provide direction for further research of anxiety and agitation experienced during critical illness. Further work is needed to define determinants of anxiety and agitation which may improve assessment. Studies to describe the effects of non-pharmacologic interventions such as presence, music and verbal support strategies are needed. Further studies of the process clinicians use to assess the need for sedation might include observation and debriefing of clinicians and patients. This study provides a foundation for identification and testing of interventions to manage anxiety and agitation.

Empirical studies are needed to explore anxiety specifically experienced during ventilator weaning. Specifically, these findings point to the need for further research to: 1) refine definitions of anxiety associated with ventilator weaning and discriminate anxiety from other responses such as fatigue or fear; 2) determine the effect of social support strategies used during

ventilator weaning; 3) investigate sedation practices during ventilator weaning trials; and 4) describe consequence of withholding information and/or presence during weaning trials from critically ill patients.

**4.0 MANUSCRIPT 2 ANXIETY AND AGITATION IN MECHANICALLY
VENTILATED PATIENTS**

4.1 LETTER TO EDITOR

Janice M. Morse, RN, PhD
Editor, Qualitative Health Research
University of Utah, School of Nursing
10 South 2000 East
Salt Lake City, UT 84112-5880

Dear Dr. Morse;

Please find the enclosed manuscript entitled “Anxiety and agitation in mechanically ventilated patients” for your consideration for publication in Qualitative Health Research. Patients experience physical and psychological distress during critical illness. Anxiety and agitation are frequently occurring discomforts associated with critical illness. We present a secondary analysis of data from an existing ethnography conducted in an ICU. Our paper is different from other papers about patient experience in the ICU because we utilize observations of care; interviews of patients proximal or during their ICU stay, and present multiple perspectives. This paper should be useful to many of your readers including experienced researchers and students and addresses a timely clinical challenge.

The authors have made contributions to preparing this manuscript and no others have made significant contributions. All authors read and reviewed this manuscript. We appreciate your effort and the effort of our peer reviewers. This paper has not been published before and is not being considered for publication elsewhere. Please feel free to contact me with any questions. I look forward to your comments.

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Conflict of interest and disclosures:

There are not conflicts of interest or disclosures associated with this manuscript.

4.2 MANUSCRIPT

Anxiety and agitation in mechanically ventilated patients

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4.3 ABSTRACT

During an ethnography conducted in an ICU, that anxiety and agitation occurred frequently and were important considerations in patient care, communication and management of 30 patients who were weaning from prolonged mechanical ventilation. We conducted a qualitative secondary analysis to 1) describe characteristics of anxiety and agitation experienced by critically ill patients; 2) explore how caregivers recognize and interpret manifestations of anxiety and agitation and 3) describe strategies and interventions used to manage anxiety and agitation in the critical care setting. Patients exhibited or expressed anxiety or agitated behaviors on at least one occasion. The Anxiety-Agitation in Critical Illness Model illustrates the multi-dimensional features of symptom recognition and management. Patients' ability to interact with the environment provided the basis for clinician identification and management of anxiety or agitation. Clinicians' attributions about anxiety or agitation and "knowing the patient" contributed to their assessment of patient responses. Clinicians chose strategies to overcome either the stimulus or patient's appraisal of risk of the stimulus. This paper contributes to the body of knowledge about symptom recognition and management in the ICU by providing a comprehensive model with potential for guiding future research and practice improvements.

Keywords: health care, acute/critical; relationships patient provider; symptom management; research, qualitative; comfort; communication; event analysis

4.4 INTRODUCTION

Over 6 million adults per year experience critical illness (Angus, et al., 2004) and face consequent physical discomfort and psychological distress (Adamson, et al., 2004; Bergbom-Engberg & Haljamae, 1989; Granberg, Bergbom Engberg, & Lundberg, 1998; Green, 1996; Gries & Fernsler, 1988; Jablonski, 1994; Logan & Jenny, 1997; Nelson, et al., 2001; Novaes, et al., 1999; Pang & Suen, 2008; Rotondi, et al., 2002; Stein-Parbury & McKinley, 2000). Patients report unpleasant physical symptoms such as pain, dyspnea and thirst and psychological symptoms such as anxiety and agitation (Nelson, et al., 2001; Rotondi, et al., 2002). Psychological symptoms are attributed to a variety of factors such as inability to communicate, family absence, and weaning from the ventilator (Rotondi, et al., 2002).

Anxiety and agitation are particularly challenging for several reasons. They have behavioral manifestations and symptom profiles similar to other conditions such as pain and delirium. Most critically ill patients are unable to express their feelings verbally or confirm clinicians' interpretations of the meaning of their behavioral responses. Symptom assessment that is inaccurate, incomplete, or ineffective may negatively impact clinical outcomes (Campbell & Happ, 2010; Nelson, et al., 2004; Nelson, et al., 2001).

Although studies of critical illness document anxiety and agitation as distressing, limited attention has been paid to assessment and management. Studies report variability in administration of sedation (Curley et al., 1992; Dasta et al., 1994; Egerod, 2002; Samuelson, Larsson, Lundberg, & Fridlund, 2003; Weinert & Calvin, 2007; Weinert, et al., 2001), yet few

studies address the process critical care clinicians employ to assess and manage anxiety and agitation.

During an ethnographic study of weaning from prolonged mechanical ventilation in a critical care unit [R01-NR7973, PI Happ], we observed patients frequently exhibiting anxiety and agitation. These symptoms undermined patient comfort and stability and interfered with therapeutic goals, including successful ventilator weaning (Tate, et al., 2005). Although weaning from prolonged mechanical ventilation was the context, these symptoms were pervasive and seemed inextricably linked with the experience of being critically ill. The prominence and prevalence of anxiety and agitation in this setting highlighted the importance of gaining a more in-depth understanding of the manifestations, interpretation and management of anxiety and agitation. This led us to explore anxiety and agitation events both within and outside of ventilator weaning trials as a distinct and logical extension of the parent study.

4.5 BACKGROUND

4.5.1 Anxiety

Anxiety, defined as a feeling of dread, fear and/or lack of control in response to a perceived threat to homeostasis (Bay & Algase, 1999) is experienced universally across cultures, has existed in humans throughout history and can be observed in many species of animals (DeGrazia & Rowan, 1991). Anxiety is a complex phenomenon that can profoundly affect psychological wellbeing and physiologic stability. This is especially troublesome for critically ill patients who are susceptible to even minor changes in equilibrium.

Patients' descriptions about the experience of being critically ill have been relatively consistent over the last 20 years. Patients associate anxiety with the inability to communicate, difficulty sleeping, and distorted perceptions (Bergbom-Engberg & Haljamae, 1989; Claesson, et al., 2005; Gries & Fernsler, 1988; Nelson, et al., 2001; Novaes, et al., 1999; Rotondi, et al., 2002). Anxiety is commonly reported (Adamson, et al., 2004; Bergbom-Engberg & Haljamae, 1989; Claesson, et al., 2005; Green, 1996; Gries & Fernsler, 1988; Hupcey & Zimmerman, 2000; Jablonski, 1994; Johnson & Sexton, 1990; Johnson, et al., 2006; Logan & Jenny, 1997; Lusardi & Schwartz-Barcott, 1996; Novaes, et al., 1999; Papathanassoglou, 2003; Pochard, et al., 1995; Rundshagen, et al., 2002; Russell, 1999; Wunderlich, et al., 1999) with an incidence that ranges from 30.8% (Kress et al., 2003) to 80% (Chlan, 2003). Notably, literature on patient reports of anxiety during critical illness is limited to survivors of critical illness who are cognitively intact and able to communicate about and reflect on their ICU experience. Consequently, the literature may not fully describe the experience.

While critical care nurses acknowledge that anxiety assessment is an important component of their practice (Frazier et al., 2002), assessment of anxiety is not routinely or systematically performed (O'Brien et al., 2001). When assessment *is* performed, critical care nurses rely on behavioral signs such as agitation or restlessness or physiologic indicators of anxiety (Frazier, et al., 2002). ICU physicians, nurses and members of the health care team use inconsistent and variable terms to describe anxiety and other psychological symptoms (Broyles, L. M., Colbert, A. M., Tate, J. A., Swigart, V. A., & Happ, M. B., 2008; Egerod, 2002). They exhibit variable expertise in diagnosing anxiety and often misinterpret patient's behaviors and communication attempts as anxiety or agitation and act upon those interpretations inconsistently (Bair et al., 2000; Egerod, 2002).

4.5.2 Agitation

Agitation is defined as “tumultuous behavior” and “extreme emotional disturbance”, (<http://dictionary.reference.com/browse/agitation>) and involves increased intensity in behavioral and psychological dimensions (Chevrolet & Jolliet, 2007). Agitation is a visible cue that can occur in isolation, or accompany extreme anxiety (Frazier, et al., 2003), delirium (Chevrolet & Jolliet, 2007) or brain dysfunction (Crippen & Ermakov, 1992). Agitation is common in critical care as patients awaken from sedation or their level of consciousness waxes and wanes. Agitated patients exhibit behaviors such as restlessness or thrashing, that interfere with care and place themselves and others at potential risk for harm. The reported incidence of agitation in critically ill patients is highly variable, ranging from 16-71% (Fraser & Riker, 2001; Jaber, et al., 2005; Woods, et al., 2004). The substantial variability likely results from the varying definitions of agitation used in these studies as stricter definitions are associated with a lower reported incidence.

Potential negative outcomes of anxiety and agitation include medical device disruption and increased oxygen consumption (Woods, et al., 2004), yet interventions are not benign. Iatrogenic complications associated with interventions such as sedation or restrains include immobility, changes in level of consciousness and loss of protective reflexes (Sessler, et al., 2001). Excessive or prolonged sedation may prolong mechanical ventilation and hospitalization, predisposing the patient to ventilator associated pneumonia (Heyland, et al., 1999), lung injury, malnutrition, polyneuropathy and long term negative psychiatric outcomes, such as depression and post-traumatic stress disorder (Jones, et al., 2001; Nelson, et al., 2000).

No studies were identified that examined the combination of anxiety and agitation symptoms and few studies have explored anxiety and agitation from multiple perspectives.

The aims of this study were to (1) describe characteristics of anxiety and agitation experienced by critically ill patients; (2) explore how caregivers recognize and interpret manifestations of anxiety and agitation; and (3) describe strategies and interventions used to manage anxiety and agitation in the critical care setting.

4.6 METHODS

4.6.1 Design

This study used existing data from an ethnographic study of 30 critically ill patients who were weaning from prolonged mechanical ventilation. The dataset for the parent study included observational, interview, and medical record data. The periods of observation ranged from 3-65 days per patient with a total of 655 days in the dataset for the cohort (Happ, Swigart, Tate, Hoffman, & Arnold, 2007; Happ et al., 2007). Qualitative secondary analysis was chosen for this study because (1) the phenomena of anxiety and agitation were frequently occurring in the existing dataset; (2) the dataset was extensive; and (3) use of the dataset maximized participation of this vulnerable population (Heaton, 2004). The principal investigator (JT) utilized analytic expansion and extension of questions that arose during the analysis of the original dataset to achieve study aims. The principal investigator (JT) and two research team members (MBH; LAH) were part of the original study team; three members with prior qualitative experience were

involved in analysis (MBH, JT, ADD). Fieldwork was conducted from November 2001 to July 2003. The study was approved by the Institutional Review Board.

4.6.2 Sample and Setting

The sample for the parent study consisted of 30 purposively selected patients who were admitted to a 28-bed medical step-down intensive care unit (ICU), required mechanical ventilation for at least 4 days and failed at least two weaning attempts, their family members and the clinicians who cared for them. The sample selection resulted in variability in severity of illness (APACHE III), neurologic status (Glasgow Coma Scale), medical diagnosis, age, sex, and race (Table 1). All patients experienced or reported anxiety or agitation on at least one occasion.

Table 9 Patient characteristics

	Mean + SD	Median	Range
N = 30			
Age (years)	59.5 + 17.64	59.5	25 – 87
APACHE III *	58.5 + 19.58	54.0	19–106
Glasgow Coma Score	11.93 +/-3.07	13.0	5-15
Hospital LOS (days)	76.5 + 163.0	32.0	7 – 876
ICU LOS (days)	47.5 + 63.0	30.0	7 – 350
Duration of MV (days)	67.8 + 164.6	28.0	5 – 875

Glasgow Coma Score Mode = 14
(on admission to SD-ICU)

N =30 N (%)
Female Gender: 16 (53)

Ethnicity:
African-American 4 (13)
Caucasian 26 (87)

Primary Medical Diagnosis:
Cardio-pulmonary 17 (57)
Surgical complication 5 (17)
Cancer 3 (10)
Neuromuscular 5 (17)

Hospital Discharge Disposition
Home 8 (27)
Long Term Care 12 (40)
Long Term Acute Care 2 (7)
Other 3 (10)
Died prior to discharge 5 (17)

Reprinted from Heart & Lung: The Journal of Acute and Critical Care, 36(1), Happ, Swigart, Tate, Arnold, Sereika, & Hoffman; *Family presence and surveillance during weaning from prolonged mechanical ventilation*. (2007). with permission from Elsevier

During the parent study, patients, clinicians caring for these patients and family members were observed during clinical care and medical rounds. De-briefing interviews were conducted after observations of care and recorded in field notes. Formal interviews were conducted with clinicians to obtain additional information about specific cases and the effects of anxiety and agitation on practice in critical care. The clinicians represented several disciplines and included 11 physicians, 10 nurses, 7 respiratory therapists (RT), and 3 others. Follow-up interviews were conducted with 5 clinician participants to provide additional data about management of anxiety and agitation. Patients and family members also participated in formal interviews to describe their perceptions of mechanical ventilation and barriers and facilitators of weaning. Family members included 15 spouses, 8 adult children, 5 parents, and 3 siblings. Patients were interviewed after they were extubated or when a tracheostomy speaking valve was applied. Others communicated by mouthing words or pointing to a letter board.

4.6.3 Data Collection

4.6.3.1 Documents

To prepare data for analysis, an uncoded version of the original dataset was transferred into a new Atlas.TI database (version 5.6.3, Scientific Software Development GmbH) for management of qualitative data and coding. Data were abstracted using keywords (Table 3) derived from the literature and clinical experts as indicators of anxiety or agitation events (Fraser, et al., 2000; Fraser & Riker, 2001; Jaber, et al., 2005; Woods, et al., 2004). Narrative clinical documentation recorded by direct caregivers provided “real time” descriptions of anxiety-agitation events from

the clinician perspective. Additional data available from the medical record included vital signs, lab data, ventilator settings and duration of daily weaning trials as well as demographic (admission diagnosis, hospital and ICU length of stay, etc), medication administration, and other therapeutic records. In addition, documentation of pharmacological treatments such as sedatives, anxiolytics or analgesics identified episodes and treatments of anxiety and agitation and conditions for treatment selection. Analgesics were included in the review because of their anxiolytic effect, but limited to instances in which there was a corresponding behavior indicating anxiety or agitation. Each instance of anxiety or agitation described in the clinical record or observational field notes was identified.

4.6.4 Data Analysis

Event analysis was used to describe and explain human interaction related to the recognition and management of anxiety and agitation (Happ, et al., 2004). Each event was analyzed using dimensional analysis techniques to identify properties and dimensions of causal conditions, patient responses, clinician actions and strategies, intervening conditions, consequences and context (Kools, et al., 1996). Corresponding numerical and textual data for each event were merged with textual data that corresponded by date and time in a tabular form (matrix) to examine patterns of anxiety and agitation events within and across cases (Miles & Huberman, 1994). Matrices were analyzed to describe the contextual factors and clinician actions, including pharmacologic and non-pharmacologic interventions, used to manage anxiety and agitation.

Qualitative coding of text and matrices was conducted within and between cases. The unit of analysis was phrases and sentences that described dimensions of anxiety or agitation. Once descriptions and coding for several cases were conducted, cross-case analysis compared

events of anxiety and agitation. Each event generated questions such as “What is going on here?” “With whom?” “What are the circumstances?”(Kools, et al., 1996). Patterns within and between cases were examined using constant comparative analysis (Strauss & Corbin 1990). This led to collapsing of codes into themes or categories.

Patterns were confirmed by examining graphic displays of data (Figure 1). For instance, sedation and analgesia administration was re-displayed in a graphic with an overlay of anxiety descriptions. The analytic process also included diagramming relationships between concepts.

During analysis, opposing views about attribution of anxiety and agitation became apparent. Because two conflicting stances often existed in the same context, the data coded as attribution were re-analyzed using dialectic inquiry, a qualitative analytic technique that explores competing models of thought about the same phenomenon (Berniker & McNabb, 2006). Dialectic inquiry was used to confirm, define, and explain these coexisting opposing viewpoints. Methodologic rigor and trustworthiness were maintained in four ways (Lincoln & Guba, 1985; Morse & Field 1995; Sandelowski, 1986). An audit trail of methodologic notes and analytic memos was recorded systematically to detail thoughts and establish dependability (Morse & Field 1995; Sandelowski, 1986). Multiple data sources were cross-checked or triangulated to support confirmability. *Credibility* was established through member checks with 5 clinician participants and consultation with critical care colleagues to determine if the analysis accurately reflected critical care practice. Prolonged engagement within the ICU enhanced the potential to achieve a thorough understanding of the phenomenon. Weekly analysis meetings established credibility and fittingness as findings were validated (Morse & Field 1995); this included review and critique of analytic lines as analysis progressed. The purposive sample as well as thick descriptive data and rich description of context established transferability.

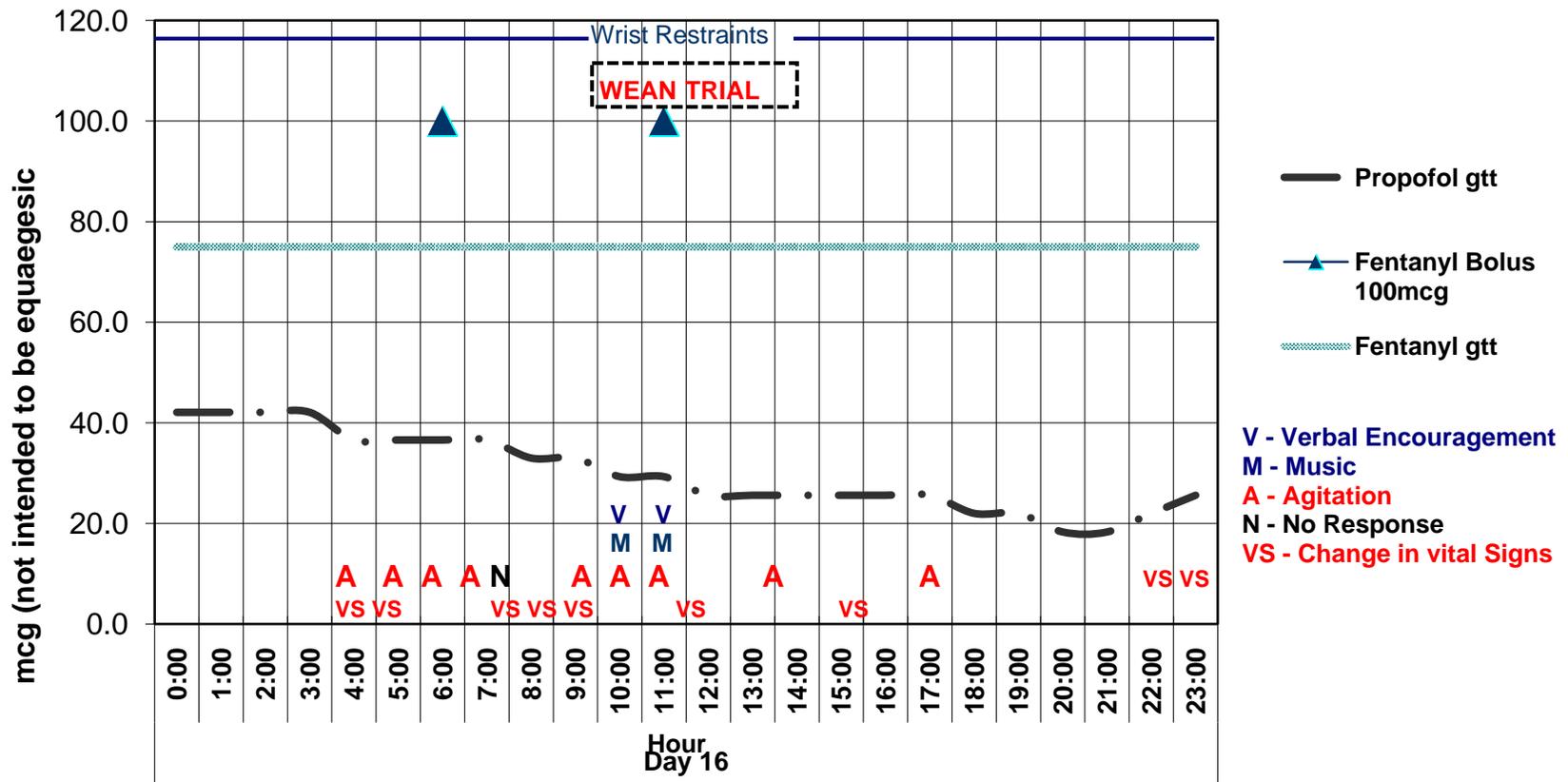


Figure 1 Data graph

4.7 RESULTS

4.7.1 Prevalence of anxiety & agitation events

All patients exhibited agitation or described feeling anxious at least once during the study period. The incidence of anxiety or agitation events ranged from 1 to greater than 200 events per patient case. Of the 30 patients, 22 expressed feelings of fear and/or anxiety during direct observation, recorded clinician notes, or interviews. The 8 remaining patients who were less interactive with the environment, demonstrated agitation in the form of hyperactive psychomotor movement at least once during the study period. Of the 18 patients able to participate in interviews, 12 indicated instances of feeling afraid or anxious. Patients did not use the term, “anxiety,” to describe their experience; rather, they used words linked conceptually to anxiety (Fraser & Riker, 2001) to describe their feelings, such as fear, panic, and frustration. Fear was included because of conceptual overlap with anxiety (Bay & Algase, 1999; Whitley, 1994) and linkages between fear, anxiety and agitation in the literature (Bergbom-Engberg & Haljamae, 1989; Claesson, et al., 2005; McKinley, Nagy, Stein-Parbury, Bramwell, & Hudson, 2002; Pochard, et al., 1995; Roberts, et al, 2007; Rotondi, et al., 2002).

4.7.2 Interaction as the Core Process

The patient’s level of interaction with the environment was identified as the *core process* in recognizing and managing anxiety and agitation in the ICU. This concept was chosen as a core process because: 1) the patient’s ability to interact was repeatedly used to describe patients’

behaviors, 2) the patient's level of interaction influenced other actions and consequences and 3) interaction integrated all other processes associated with events of anxiety or agitation. To demonstrate the importance of interaction as a core process, we clustered patients along a diagonal continuum from low to high according to their usual state of interaction with the environment during the observation period (Figure 2). Based on these clusters, we were able to parsimoniously relate level of interaction to clinicians' attributions, assessments and interventions.

Cluster 1 patients were the least interactive i.e., two brain injured patients who had little to no interaction with the environment. They were observed "biting on the endotracheal tube" which is considered a behavior indicative of agitation.(Fraser, et al., 2000)

Cluster 2 patients were minimally interactive. They reacted to stimuli but did not seem to understand or respond appropriately. They did not respond consistently to verbal or tactile stimuli nor did they follow verbal commands. Clinicians interpreted their behaviors as "resisting care" and "agitated with care" during turning and bathing, suggesting ability to interpret the touch of the nurse in a meaningful and non-threatening way was impaired. As an example, one elderly woman lay motionless the majority of time. She opened her eyes to command, followed a few simple commands and responded to yes/no questions by nodding her head. However, she became agitated during care activities. The nursing note read, "Becomes agitated with certain aspects of care (turning, mouth care, eye drops)." Patients' responses to care activities in this cluster were immediate and often accompanied by physiologic reactions such as tachycardia, tachypnea, and hypertension. Patients exhibited large muscle or head movements such as "thrashing" with no apparent purpose and often appeared restless. Attempts to calm patients in Cluster 2 using verbal reassurance were largely ineffective.

Cluster 3 patients exhibited greater levels of interaction, had increased periods of wakefulness, and less immediate and strong physiologic responses to care procedures than their counterparts in Cluster 2. They appeared to be able to respond to stimuli such as verbal comments or touch. Their behaviors were more purposeful, but their ability to accurately assess the meaning of stimuli was often impaired. For example, these patients were more likely to try to remove the source of discomfort (e.g., “pull at lines and tubes”) or attempt to flee the situation (“legs over siderails”).

Cluster 4 patients were the most interactive; they were able to communicate wants and needs effectively and appropriately, most often by non-vocal methods. They reacted more calmly to tactile or verbal stimuli and were more cooperative with care. In fact, several patients in this group were able to express preferences for daily care activities. At times, they admitted to inaccurate perceptions of the environment and to experiencing delusions or altered thought processes. Over time certain stimuli induced anxiety as patients anticipated discomfort based on memories of prior encounters. For example, one patient described disturbing aspects of respiratory distress that persisted even after he was extubated. “I actually still have that fear of choking. And not being able to get enough air. That was always in the back of my mind.” Verbal strategies to reassure or calm were more successful when applied to patients in Cluster 4.

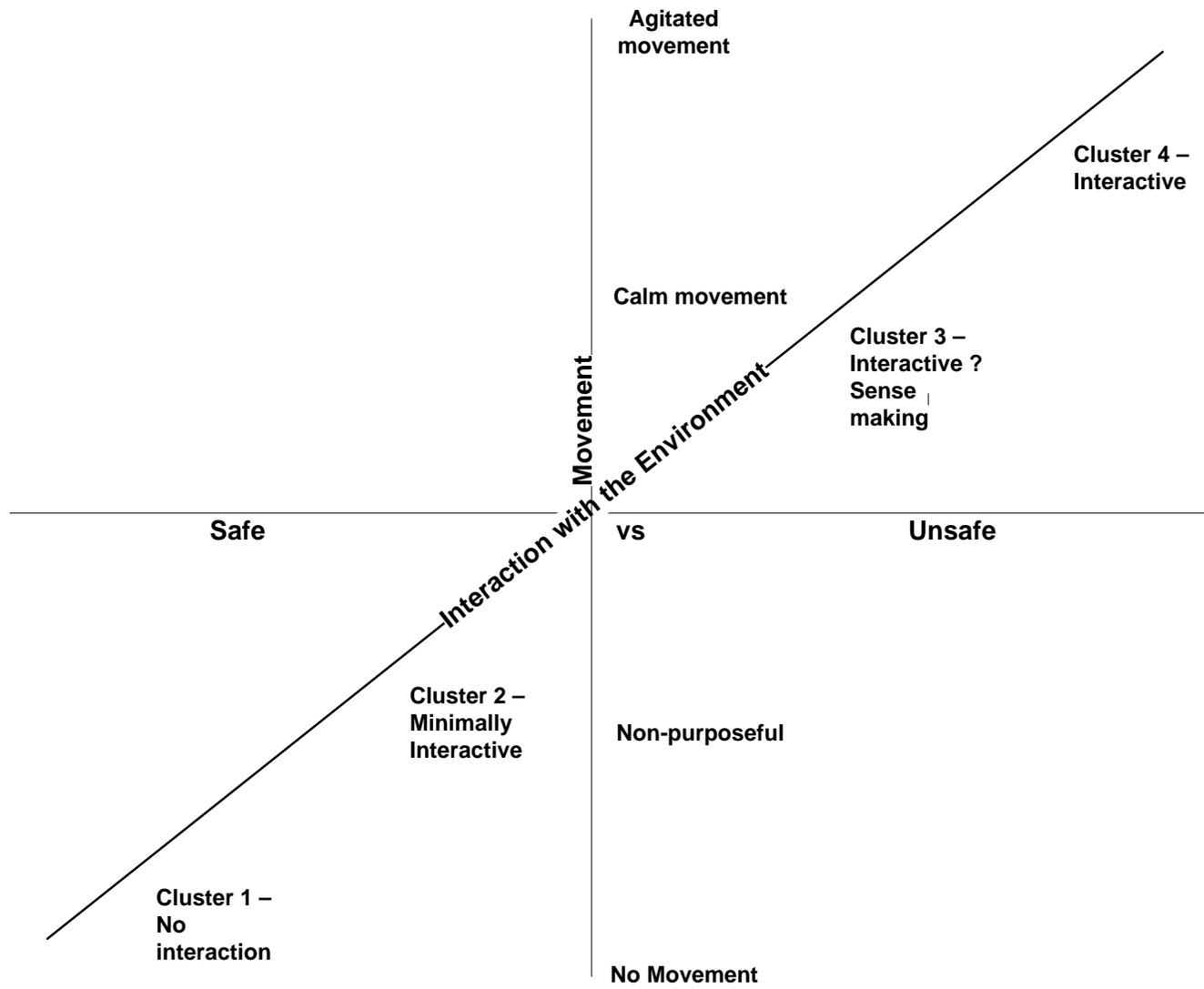


Figure 2 Interaction with environment

4.7.3 Model Development

The **Anxiety – Agitation in Critical Illness Model** (Figure 3) illustrates the process of anxiety - agitation symptom recognition and management in critical illness developed from findings of this study. Interaction was identified as the core process. In this model, a *stimulus* or stimulation is the causal condition for anxiety and agitation events. Cognitive or emotional *appraisal* of the stimulus determines the individual patient's response. The patient's response occurred in three dimensions – physiological, psychological, and behavioral. Physiologic responses included vital sign changes. Psychologic responses involved emotions or cognition and included (but were not limited to) anxiety, fear, and anger. Behavioral responses involved movement and included restlessness and agitation. Anxiety and agitation overlapped when agitation occurred as an extreme behavioral manifestation of anxiety. Restlessness occurred as a less severe sign of anxiety.

Clinician management strategies to prevent, relieve, or control anxiety and agitation were instituted based on their assessment of the responses exhibited by the patient, attributions about anxiety and agitation, and “knowing the patient” contributed to assessment which guided choices for interventions. Interventions removed or modified the stimulus for anxiety or agitation or modified patients' appraisal of the stimulus.

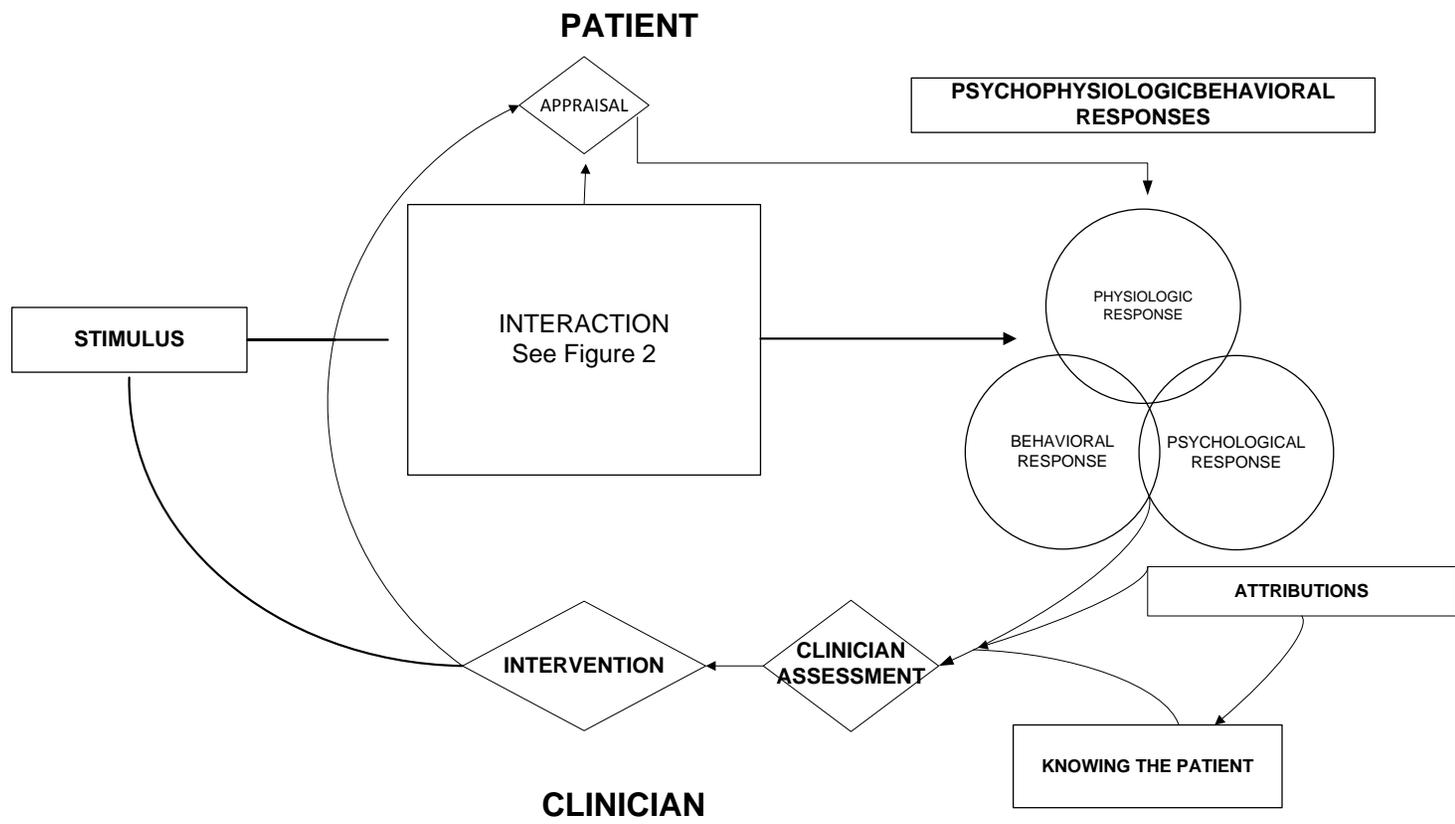


Figure 3 Anxiety - Agitation in critical illness model

4.7.4 Stimulus

Any occurrences reported verbally or documented as preceding episodes of anxiety or agitation were defined as *stimuli*. Agitation and anxiety occurred in response to an irritating or uncomfortable stimulus and/or an attempt to remove/relieve this stimulus. “They’re agitated because they’re breathing rapidly and shallowly because they have horrible lungs and they are in distress.” (MD)

Many common care interventions, such as position changes, dressing changes, and suctioning were identified as stimuli. The nurses’ notes often described care activities as the stimulus for agitation: “agitated with care”, “agitated with assessment”, or “resists care”. Other stimuli commonly associated with agitation included physical restraints, endotracheal tubes, nasogastric tubes, intravenous lines, urinary catheters, or rectal tubes. One physician said, “... so they start waking up, but all they’re aware of at first is that they’re very uncomfortable and that they’re tied down in bed. So, that would seem to make anyone agitated.” A nurse described agitation in the clinical record, ““With light tactile stimuli, patient arouses and becomes very agitated with constant grimacing and pulling at restraints; acute tachycardia and hypertension observed.” Another nurse described the patient’s response to a position change, “When I put the head of bed up [position change] and it wasn’t even to the full 45-degree angle, she was crying, became too anxious.”

Patients described mechanical ventilation and the experience of having an artificial airway as stimulus of anxiety. Patients attributed anxiety to worries about breathlessness, choking, being left alone, or encountering caregivers who were considered “mean” or impatient.

Patient: I basically felt totally helpless. What is going to happen if I can't get my next breath and so that's what's going through my head? I guess I just pass out and start to breathe out of my mouth. That was my greatest concern about if they were out in the hall or whatever; you know maybe not paying attention to me.

Another patient described the effect that bathing (stimulus) had on his efforts to maintain an effective breathing pattern. "Once I got it [effective breathing pattern] anything that would interfere would make me go back to panic. Like washing".

Ventilator dysynchrony and cough also stimulated fear and panic, as described in the following patient's account and his father's confirmation that repeated episodes of ventilator dysynchrony led to the emotional response fear and panic. The patient said, "It was the choking back up. I was scared to death of that. That backing up, I couldn't control the choking." His father recalled, "He wanted to breathe faster than the ventilator would allow him. That was causing him anxiety too".

Family members' thoughts about stimuli for anxiety paralleled patients' perceptions, specifically the situation of being left alone, or the experience of tube or ventilator discomfort/dysynchrony. A spouse described her husband's response when the family left the room, "When we left he was in a panic situation. He didn't know where he was."

Clinicians attributed visits by family members as stimuli that produced or reduced anxiety. Visits were viewed as producing anxiety when families over-reacted to changes in the patient's condition or over-stimulated the patient. For other patients, the presence of families was considered therapeutic, calming and reassuring. Families who were able to be "part of the process" were viewed as valuable components to managing anxiety or "a partial care provider". Families who approached the bedside with "unreasonable" expectations, were overly vigilant or

were “unable to handle the stress of the room” were viewed as contributing to the patient’s overall stress and anxiety. Two nurses described their thoughts about how some families contribute to the patient’s anxiety, ““She [patient] always has a bad day when her husband’s here,” and “They might be the type of family member that gets their patient all worked up.”

4.7.5 Patient Appraisal

Interaction was the basis for patients’ ability to process and appraise the nature of the stimulus. Patients’ ability to mount an effective risk appraisal was often impaired by cognitive and perceptual dysfunction that accompanies critical illness. When patients could not engage in appraisal, their response to the stimulus was limited to physiologic arousal, e.g., vital sign changes, movement.

4.7.6 Patient Responses

4.7.6.1 Physiologic responses

Vital signs were the most significant evidence for clinicians in determining whether the patient was anxious. Physiologic cues included a change in vital signs such as tachycardia and tachypnea, or coughing and were often accompanied by movement. “You sort of have to go by his heart rate and other factors to figure out whether he’s anxious or if he’s in pain”. A nurse’s note described a variety of physiologic and behavioral cues used to determine anxiety, “Patient attempting to sit upright in bed and pulling off EKG leads. Systolic blood pressure 178/81 with heart rate 120. Ativan 4 mg IV given and effective for anxiety control.”

Nurses labeled vital sign changes as indicative of anxiety, when patients had decreased ability to demonstrate behavioral cues (movement). “He seemed pretty calm but about 2 hours into the wean (ventilator weaning trial) his heart rate and respiratory rate went up so I gave it [anxiolytic] cause I thought he was anxious.” (RN) They often gave priority to particular vital signs such as hear rate or used vital signs as the sole indicator to intervene with anxiolytics or analgesics. Nurse’s note:”Patient tachycardic, heart rate 160's-180's. Doppler blood pressure 140's -160's. prn Ativan and prn Fentanyl given without significant change.”

4.7.6.2 Behavioral responses

Patient movement was classified on three dimensions: 1) Purposeful – non-purposeful; 2) Safe – unsafe; and 3) Intensity. The patient’s behavior and movements provided cues to distinguish between anxiety and agitation. The behavioral signs of agitation-anxiety included certain body movements such as tensing facial muscles, grimacing, wincing, withdrawing, resisting care, restlessness, and thrashing.

Nurse: How would I diagnose the restless, the anxiousness? Pretty much if their blood pressure’s okay and their sats (oxygen saturation) okay and for some reason they just can’t sit still or they’re just constantly like up and down and can’t get comfortable and maybe those are reasons why it’s making their heart rate and respiratory rate a little bit better, a little bit faster or whatever. You might just think, well, maybe they’re anxious.

Patients demonstrated behaviors on a continuum from little or no movement, to large muscle movement (agitation). Some anxious patients become withdrawn, with little movement, decreased responses, and detached. This response had a negative effect on ventilator weaning.

A nurse's note described this decrease in patient response, "Patient appears more drowsy and a little withdrawn than earlier in the week, as well as more anxious about weaning off the vent/breathing. Patient states that he 'doesn't want to die'."

Intensity of movement was a distinguishing criterion for agitation. Movement associated with agitation was viewed as the most dangerous because it often involved large muscle groups. Examples included attempts to sit up in bed, kicking legs or banging on the siderail. Movement involving smaller muscle groups was viewed as less dangerous. Examples included picking at sheets, grimacing or rhythmic head movement. These movements were often isolated descriptions in the clinical record or were associated with descriptions of "restlessness." Restlessness was a less intense, less dangerous form of agitation.

4.7.6.3 Psychological responses

Psychological responses associated with anxiety included fear, frustration, anger and withdrawal. Patients' emotional responses to stimuli such as crying and changes in facial expression were interpretations of anxiety and were described in nursing notes as "Patient anxious and crying" and "Patient became very emotional. Crying and very anxious." A nurse described her ideas of why the patient was anxious, "He's frustrated with communication and depressed. He's been here a long time."

Occasionally patients became angry to the point of agitation. In the following example, the patient became angry with his wife's inability to carry out his wishes. "Well, right now he is very mad at me 'cause I can't take him home. He wants to go home. So he is mad at me right now. But that is ok. It is just a response." The patient in the following example was angry and upset during a complex dressing change. Her stay had been lengthy and difficult. "Yesterday, we turned her to do her dressing change and she got wild. She was pulling at her trach. She was

angry. She actually started to bleed from her trach. I gave her some sedation but it didn't really hold her." (Nurse)

4.7.7 Clinician Assessment

Clinicians observed and interpreted patient responses (physiologic, behavioral, psychological) to formulate their assessments and select interventions. When patients were unable to communicate, clinicians looked for other cues or signs to make judgments about their responses and guide clinical management. "I react based on how the patient responds. You know you can read different things. Are they agitated? Are they hyperactive? Are they calm? Are they too calm? Are they lethargic? You know you just watch the patient, watch the vital signs." (Nurse)

They also used knowledge and interpretation of the patient's responses to inform their decisions about recognizing and managing anxiety and agitation. Clinicians' attributions about anxiety and agitation contributed to their assessment. The following sections describe how "knowing the patient" and clinicians' attributions for anxiety and agitation contributed to their assessment and choice of interventions.

4.7.7.1 Knowing the Patient

"Knowing the patient" refers to familiarity with the patient's typical response and preferences. This unique knowledge of the patient enables clinicians to interpret the response and choose individualized interventions (Curley, 1998; Tanner, Benner, Chesla, & Gordon, 1993). Usually, clinicians relied on their knowledge of the patient's unique history and responses to guide actions. Clinicians also relied on what they learned about the patient from past assignments (continuity), remembering which strategies were successful and which to avoid. Many times,

clinicians took steps to avoid situations believed to induce the causal condition or stimulus in a particular patient.

Information about patient's anxiety and agitation was shared between clinicians formally during clinical hand-offs, through written progress notes and care plans and informally through conversations with family members. This information was used to plan individualized interventions. "They both (nurses and RT's) need to be in tune as to where the process is because if they're not then it ain't going to work, i.e. if there is mild sedation that may be required obviously it has to be coordinated with the nursing personnel." (RT) "Patient appears to be slightly calmer. Report forwarded to dayshift nurse." (Nurses Note).

4.7.7.2 Attributions

Clinicians offered two competing explanations or attributions for anxiety and agitation. These attributions were explored using dialectic inquiry, an analytic technique used to examine conflicting stances. The two opposing attributions that contributed to clinician assessment were *discrimination vs. generalization* and *expected response vs. character flaw*. Dialectics exemplify the difficulty of determining what influenced behaviors in the context of critical illness where patients are unable to communicate their feelings and emotions. These attributions contributed to differences and inconsistencies in assessment and choices for intervention.

Discrimination vs. Generalization

Clinicians cited "anxiety" as the cause of many patient responses outside the norm of calm and cooperative without regard for other explanations. The term, "delirium," was not considered nor used by bedside clinicians (nurses and respiratory therapists) and rarely used by physicians to describe behaviors. In these instances, "anxiety" may have been used as a catch-all, general

term. Conversely, clinicians also demonstrated efforts to discriminate anxiety from other symptoms, such as pain, dyspnea or fatigue. In these instances, clinicians explored symptoms of anxiety and agitation by considering a broader range of potential explanations. In one instance, a patient was “anxious” and demanding for days. The RT noted a pneumothorax on a chest x-ray report which explained and validated the patient’s anxiety. This RT sought other explanations for the patient’s behavior and did not accept labeling the patient as “anxious”.

Signs of anxiety mimic other psychological symptoms frequently experienced in the ICU such as delirium, pain or frustration with communication and can make accurate interpretation difficult. Clinicians acknowledged this difficulty in sorting out the meaning of overlapping signs. “Even in a patient who can speak to you, trying to sort out pain and anxiety acutely, not having a long-term relationship with the patient is very difficult.” (MD)

Interviewer: Can you discern an agitated delirium from anxiety?

Nurse: (slight laugh) I don’t know if you can.

In summary, these opposing views occurred within and across cases and within individual clinicians. While some clinicians were more prone to generalize, clinician efforts to discriminate were evident throughout the data and within and across clinicians.

Expected response vs. character flaw

The view of anxiety-agitation as an “appropriate” response was strongly endorsed by some clinicians. This view was evident in the previous exemplars regarding the physiologic stimuli for anxiety-agitation. “They’re agitated because they’re breathing rapidly and shallowly because they have horrible lungs.” (MD). Clinicians generally acknowledged that endotracheal tube discomfort and physical restraint “would seem to make anyone agitated.” (MD) Others viewed anxiety-agitation as a personal deficit or a perception that could be willed or controlled.

“Anxiety in the brain is a powerful thing because I’ve also seen it cause hypoxia, tachycardia and just whirlwind downhill.” (RT). “You want them awake to wean but then sometimes when they’re awake they can be more anxious. I really think that’s the patient personality. You know, their perception of what’s going on is the biggest barrier for them.” (Nurse)

The belief that anxiety was within patients’ control seemed to arise from interactions with patients who were having difficulty weaning. Some clinicians believed if patients really “wanted” to wean, they could exert the self-control necessary to overcome feelings of dread and anxiety. Lack of control was viewed as a character flaw or weakness, described using terms such as “wimpy” and “lazy”.

“When they’re having an anxiety attack because they get that little twinge of not being able to breathe and they don’t try and bring themselves back down. It’s really not any kind of oxygen hunger. It’s really not carbon dioxide related. It’s just them.” (Nurse)

“I think if he has a way of controlling his anxiety, he can wean. I really think he [emphasis added] just needs to get the anxiety under control.” (RT) ““Physically he could [wean] it’s just mental with him...he’s crazy.” (RT) “An experienced physician thought this perspective was misguided and expressed concern. “ The context of anxiety is that it’s some sort of pathologic state of the patient that they should be able to control if they were a stronger mental human being. That’s why I don’t like the term.”

4.7.8 Managing anxiety and agitation

Symptom management included both pharmacologic and non-pharmacologic interventions. Interventions to manage anxiety involved removing or modifying stimuli. Distraction was a common strategy to disengage negative thoughts (cognitive appraisal) that contributed to fear

and anxiety. The cognitive effort necessary to attend, listen, and respond distracted the patient from the negative appraisal of stimuli. Sometimes this was accomplished by simple conversation with the patient about topics outside the patient's environment. Distracting talk was initiated by families and clinicians regardless of the patient's ability to fully engage in these conversations.

Observer: The patient seemed restless.

Sister: You just want to get off this [ventilator], don't you?

[The patient turned back and looked at her sister. The patient raised her hand.]

Sister: Your nails need a good soaking. They look pretty though (They had been polished a rose color and looked almost professionally done). Is today the first day of spring? I don't know. [sister looked at TV which was on the noon news] You'll get rid of all that and feel much better. Remember CJ was here? Friday or Saturday. [sister stroking patient's upper arm]

RT: [to patient] The television, do you watch soap operas? Do you want a movie? Yes. Oh, this is a good show. It'll make you laugh. Just give it a shot. Do you want me to decrease the lights? How's that? It's a little intense. You don't need sunburn. (Referring to TV program Animal planet. A dog) I used to have a dog that looked like that.

Music was used in more than half of the cases by clinicians and family members to reduce anxiety. Patient's families brought selections that matched the individual's taste and they were more likely than clinicians to use music as a source of relaxation and distraction. Clinicians acknowledged music selections and used it as a non-clinical conversation topic but did not suggest that families bring music nor did they turn on music to manage anxiety. Patients

admitted that certain types of music helped create a calm, relaxed state. In one case, the family put headphones on the patient so he could listen to music and said they thought it would help him to relax. Another patient chose music specifically to calm himself.

Field Note: There was classical music playing on his radio.

Interviewer: You changed selections (of music).

(Patient pointed to head)

Interviewer: Head music?

(Patient nodded, “yes” and motioned with his hands both pushing down)

Interviewer: It calms you?

(Patient nodded, “yes”)

If the patient was able to interact, clinicians initiated interventions that included verbal reassurance, redirection, reminders and warnings. If the patient was minimally interactive, interventions involved less verbal communication. Less interactive patients were more often physically restrained when exhibiting behaviors viewed as unsafe.

Verbal strategies focused on patient progress and were classified as reassurance, encouragement, or coaching. We defined reassurance as non-specific conversation about progress and future well-being. Reassurance was a form of verbal encouragement and support designed to assist the patient (1) to become more confident, (2) to feel safe, and (3) to dispel patient’s fears. “The nurses basically were telling them (the patient) right along that it’s (ventilator) just a temporary thing and as soon as she gets stronger or he gets stronger whoever, you know, they’ll all be taken off. It [the ventilator] probably is a little scary at first.” (Family)

The following is an example of communication from a nurse reassuring a patient that she would stay in the immediate area until the patient was less anxious. The patient was frantic after

being suctioned, fearful that he wasn't getting enough oxygen. The goal for this interaction was to increase feelings of patient security. The nurse looked at the patient directly and said, "We're out here in the hall and we won't leave until you're totally okay."

A respiratory therapist offered reassurance to a patient, upset after a social worker told her of plans for a transfer to a weaning facility,

"You're looking good. Your x-ray looks good. You have a lot of potential, [patient name]. Right now you need to get people to work with you, with your whole body. Think about it. One thing you have going for you is your age."

A patient who had been told that she would never wean from mechanical ventilation described the contribution encouragement from respiratory therapists made to her overall recovery. "They explain things really well. They've been real straight with me. [RT name], he's been all happy, very encouraging. Here I was told I would never get off the vent but he's good with that."

Coaching was defined as a deliberate set of verbal cues designed to instruct the patient on the "right way" to perform a function such as breathing. It included efforts to redirect the patient. "Deep breath [patient's name], one more. Good! All done." (RT) Families engaged in coaching to assist their family members with breathing difficulties most often.

"But I just grabbed hold of both of his hands with all my strength and I kept trying to get him to breathe evenly, you know. I said, "Breathe with me. We did this before a long time ago when I was having you. Let's breathe together." And he eventually did slow down somewhat." (Mother)

4.7.8.1 Pharmacologic Interventions

Of the 30 patients, 29 received at least one dose of sedation or analgesia. Sedation offered the ability to modify a physiologic response by decreasing blood pressure and pulse, and mediating a stress (anxiety) response. In this case the referent stimulus is ventilator weaning.

There will be certain patients whose stress of spontaneous breathing is going to be so high that you need to regulate it. You need to regulate the (tachypneic) sensation that they're getting which is exceptionally real, not an inappropriate reaction to weaning.
(MD)

This ICU had not adopted sedation protocols at the time the study was conducted. Clinicians based sedation management on trial and error; their sedation practices appeared to be random or focused on convenience. It's very patient dependent. You have to know what's going on with the patient. There's no science. You just try it and see what happens as long as everything is okay." (RT) Some tried verbal strategies as the initial intervention, whereas others chose sedation. "You might just think well maybe they're anxious. Maybe if we try a little something [sedation], see if that calms them down and then if it doesn't then say well maybe it is the wean." (Nurse) In the following quote, a physician described trying to decrease a patient's anxiety and increase cooperation indicated the first choice was to talk with the patient.

"Well usually I do it [talk] unless it's 3 in the morning, then I just push drugs. Usually when that fails then I'll do a Fentanyl challenge. I'll usually ask the nurse to give a fairly nice dose of Fentanyl and see if that evens out their breathing."

The availability of medications and the immediacy of response was an attractive solution when vital signs exceeded a safe range or comfortable threshold for nurses. Administering sedation was characterized as a timesaver; non-pharmacologic interventions took more time. "I

say that after a while dealing with someone who's anxious you want to medicate them rather than take the long way out." (Nurse)

Sometimes clinicians did not administer PRN ("as needed", discretionary) sedation in a deliberative fashion. In the following exemplar, the interviewer debriefed the nurse and RT after a difficult weaning trial. The RT discontinued the weaning trial because the patient became agitated and had changes in his respiratory rate and effort.

Interviewer: Did he get anything for agitation?

RT: (blank look – nervously looks at nurse)

Nurse: (looks at Kardex) No, he didn't get anything but he can have Ativan. Let me know before your next wean and I'll give him something.

Clinicians held widely varying and conflicting views on the best strategies to achieve comfort and calm while maintaining the patient in a wakeful, interactive state. The following is a discussion with two nurses who disagreed with modifications to sedation orders given by the nurse practitioner.

Nurse1: The anxiety is out of control. The NP won't let us give her anything. (RN1 makes a face.) She (NP) doesn't want her snowed.

Interviewer: Then what did you do for it?

Nurse2: Oh, 4 mgs of morphine and just one (mg) of Ativan. Plus, she had her Oxycodone but that's not enough Ativan.

(Both nurses are shaking their heads at the Ativan dosage.)

The following exemplifies a very heated interaction between a nurse and two resident physicians. The patient was thrashing in bed, was hypertensive and had bloody secretions.

Field Note: The nurse was saying that the patient needed sedation. The resident must have smiled or laughed.

Nurse: You laugh, sedation is important! She's been thrashing. She's on a 100% FiO2 and she's hypertensive.

Resident MD: Give her five of Haldol.

Nurse: Five (mg) of Haldol, don't waste my time!

Anticipatory sedation was administered prior to care activities to prevent anxiety or agitation. "The nurse said yesterday that she pre-medicates him [with an anxiolytic] before care. So if you can anticipate things, then his heart rate won't go up" (MD)

Patients described the positive effects that anxiolytic medications had on anxiety. "I got everything I need, nice medicine to calm me down, the pillows where I need so I'm not in aching pain. So those things come from God the things that bring comfort." "The fellow seen that [panic during ventilator weaning]. He started giving me the Serax."

4.8 DISCUSSION

This study utilized novel methodology and produced unique findings. Unlike other studies, sources of data included the experience of patients with varying neurocognitive states and patients who did not survive their critical illness. The study employed multiple data sources including observations and de-briefing proximal to the anxiety or agitation event. Most interviews with patient participants took place while the patient remained in the ICU, an important consideration as patients' memories can be distorted or lost over time and the amnesic effects of sedatives (Adamson, et al., 2004; Granberg, et al., 1998; Green, 1996; Hafsteindottir, 1996; Jones, et al., 2001; Rotondi, et al., 2002; Rundshagen, et al., 2002). This study gave a

voice to non-speaking patients who described instances of fear and panic during mechanical ventilation and critical illness. Patients were included despite the severity of their illness or impaired verbal communication in an attempt to provide more comprehensive understanding of the experience of anxiety and agitation.

The *Anxiety and Agitation in Critical Illness* model (Figure 3) developed from this analysis is unique in depicting the complex, multi-dimensional features of anxiety and agitation recognition and management and incorporates patient and clinician perspectives. Our model is compatible with the “Transactional Model of Stress and Coping” (Lazarus & Folkman, 1984) but is specific to the ICU context and unique in incorporating assessment and management by clinicians. The human interaction between the clinician, patient and others is integral for understanding and explaining identification and management of anxiety and agitation in critical illness. Attributions from clinicians about whether patient responses were purely physiologic or emotional agitation guided choices of management strategies. In addition, the model incorporates considerations related to cognitive and perceptual ability that fluctuate during the course of critical illness.

Dialectic inquiry of clinician attributions about anxiety exposed contradictory views that co-exist in practice and within individuals and have not been described in the literature. The view that anxiety was an expected response from common ICU stimuli led clinicians to a more active management stance. In contrast, the view of anxiety as a character flaw restricted clinician management options as pre-existing patient characteristics cannot be reversed during critical illness. The second dialectic, discrimination vs. generalization, describes opposing clinician symptom assessment where some clinicians approached patient responses with a singular causal view while other clinicians viewed patient responses as having multiple possible

explanations. Interestingly, none of the patients used the word “anxiety” to describe their experiences while clinicians used “anxiety” to describe a wide range of patient responses. This generalized use of the term “anxiety” may have provided a basis for intervention and common understanding among clinicians who were able to manage anxiety more easily than “fear”.

This study is the first to provide a comprehensive picture of non-pharmacologic strategies used by clinicians and families to manage anxiety in the ICU. Our analysis confirms a link between isolation and anxiety and agitation and suggests that further work is needed to identify and test social support or presence interventions to decrease anxiety in the context of ICU and the experience of critical illness. Patients reported difficulty being left alone and associated the absence of family or clinician presence with fear. The contribution of family or clinician presence to patients’ feelings of safety and security has been reported previously (Hupcey, 2000; Logan & Jenny, 1997; Russell, 1999) however, a full explication of activities that constitute such support in this setting is lacking.

Music, present in 15 (50%) patient rooms, was mostly provided by families and used to distract or to relax the patient. Although calming effects of music were noted by clinicians in progress notes and during informal interviews, we did not observe its intentional use by clinicians despite evidence from studies by Chlan describing the positive effects of music on critically ill patients (Chlan, 1998; Chlan, 1995, 2000; Chlan, Engeland, Anthony, & Guttormson, 2007). This is the first study to document a pattern of family initiated music as an intervention to relieve anxiety in the ICU. This is an example of the way that families may provide personalization that contributes to clinicians’ ability to “know the patient”.

Our findings regarding sedation practices documented tension and conflict within and between clinicians about sedation administration as clinicians were faced with the often

competing clinical objectives of maintaining the patient awake and calm. Risks of sedation were acknowledged yet anxiety and agitation were seen as unsafe responses that necessitated interventions by clinicians. This is consistent with previous findings that sedation goals often differ between nurses and physicians (Weinert, et al., 2001). Decision-making regarding sedation was largely left to the assessment of bedside nurses. Even in the presence of sedation protocols, studies report that discretionary nursing judgment remains a significant component of application of clinical protocols and guidelines (Fry et al., 2009; Weir & O'Neill, 2008). Pinpointing the exact patient state that necessitates administration of sedation is difficult due to conceptual overlap between several different patient conditions (i.e., anxiety, pain, delirium, fear). Some of the difficulties in adopting sedation protocols (Bair, et al., 2000; Payen, Chanques, Mantz, Hercule, Auriant, Leguillou, Binhas, Genty, Rolland, & Bosson, 2007) or in making decisions to sedate patients (Egerod, 2002; Weinert & Calvin, 2007) reported in other studies may be due to this conceptual overlap or to clinician tendencies to generalize rather than discriminate causal attributions for patient responses. Efforts to discriminate can be enhanced by adoption of formal delirium assessment, assisted communication or interpret ventilator waveforms.

Consistent with previous studies, patients, clinicians and families indicated that anxiety and agitation were important, distressing and difficult to assess and manage. The core process identified in this study, interaction, provided a means of distinguishing between anxiety and agitation and was frequently used by clinicians to determine the most appropriate intervention. Similarly interaction has been reported as an important consideration for nurses when deciding when to sedate or restrain critically ill patients (Aitken, et al., 2009; Happ, 2000)). Li ((Li, Miaskowski, Burkhardt, & Puntillo, 2009) detected changes in vital signs and cortical arousal in

deeply sedated patients when they underwent noxious stimuli (endotracheal suctioning or position changes). Similarly care activities such as bathing, position changes and suctioning were identified as stimuli preceding anxiety and agitation across all patient clusters in the present study, including those who were least responsive (Cluster1).

As in other studies (Frazier, et al., 2002; Li, et al., 2009), clinicians used physiologic signs to determine the presence of anxiety. This approach is not without pitfall as conditions other than anxiety (i.e., activity or changes in intravascular fluid status) can contribute to changes in vital signs (Olson, et al., 2007). Changes in vital signs are non-specific and not recommended as the sole determinant of anxiety or agitation (Jacobi, et al., 2002). Our clinician participants confirmed ambiguity in this approach to symptom identification.

Multiple interventions were used to modify the anxiety-agitation stimulus. Verbal reassurance, coaching or verbal distraction were used frequently as a first line approach even when patients' ability to process and respond was limited. Verbal strategies are acknowledged in the literature as helpful according to patients (Granberg, et al., 1998; Logan & Jenny, 1997) and are utilized by nurses as part of a range of strategies to assist patients with anxiety (Frazier, et al., 2003; Hedlund, Ronne-Engstrom, Ekselius, & Carlsson, 2008; Moser, Chung, McKinley, Riegel, & An, 2003; Wilkin & Slevin, 2004) and prevent device disruption (Happ, 2000). Practice recommendations for anxiety – agitation management are based in part on evidence non-ICU patients. Communication difficulties and neurocognitive dysfunction in critically ill patients may make application of evidence of beneficial effects of positive verbal support from other patient populations difficult. Further work to test approaches is necessary.

4.8.1 Limitations

Several factors may limit transferability of study findings to all critically ill patients. While observations of patients were conducted during and outside of ventilator weaning events, anxiety and its manifestations may be different for patients who have not yet begun weaning trials. Although interviews from clinicians from another unit confirm our findings, this study was conducted in a single institution. The ICU in which observation took place did not have a protocol for routinely assessing level of sedation or presence of delirium or for providing daily wake up session, as currently done in many ICUs. The actions of clinicians and response of patients may differ in settings where such protocols are used routinely. This limitation is mitigated somewhat by our observations of current practice in diverse ICU settings.

4.8.2 IMPLICATIONS FOR PRACTICE

This study contributes to critical care practice in several ways. First, the model illustrates the wide range of both patient responses and clinician interpretations associated with everyday critical care experiences. Careful reflection by clinicians may reveal how knowing the patient and their own attributions about anxiety and agitation influence their assessment and management of critically ill patients. This may enable consideration of a wider range of possible explanations for patient responses. Using this model, clinicians may also deliberately and consciously target interventions to stimulus, appraisal or response. The results may improve critical care practice and address the American Association of Critical Care Nurses' research priority area of symptom management by pinpointing issues crucial to reliable interpretation and management of anxiety and agitation.

4.8.3 IMPLICATIONS FOR FURTHER RESEARCH

These findings provide foundation for further research of anxiety and agitation experienced during critical illness. The model developed from this study can be used to prompt further research regarding anxiety and agitation in critically ill patients. Additionally, this study may serve as a basis for development and testing of interventions to improve patient care in the ICU.

Suggestions for further work include refining definitions to achieve better specificity regarding the presence of anxiety and agitation and testing assessment – discrimination skill development through the use of simulation scenarios and de-briefing about critical observations indicative of anxiety and agitation. Studies are needed to explain the effects of nurse and family presence and clarify the affect of specific verbal support strategies for critically ill patients. Descriptive studies of sedation practices have been reported frequently yet acceptance of sedation protocols continues to vary across settings. Further work is necessary to explore the process clinicians use to assess the need for sedation through observation and de-briefing of clinicians and patients.

**5.0 MANUSCRIPT 3: RECOGNITION AND MANAGEMENT OF ANXIETY IN
PATIENTS WEANING FROM PROLONGED MECHANICAL VENTILATION**

5.1 LETTER TO EDITOR

Joseph E. Parrillo, MD, FCCM
Professor of Medicine, Robert Wood Johnson Medical School,
University of Medicine and Dentistry of New Jersey
Chief, Department of Medicine,
Edward D. Viner MD Chair, Department of Medicine
Director, Cooper Heart Institute, Cooper University Hospital,
Camden, NJ

Dear Dr. Parillo;

Please find the enclosed manuscript entitled “Anxiety and agitation: Identification and management in patients weaning from prolonged mechanical ventilation” for your consideration for publication in the American Journal of Critical Care. This paper describes events of anxiety and agitation during weaning from the perspectives of critically ill patients, their families and clinicians who cared for them. Unlike other studies that utilize surveys or interviews of a single participant type to measure attitudes and preferences, this paper is different from others in that it uses both interview and observational data from perspectives. We describe a wide range of strategies to manage anxiety responses to ventilator weaning, again offering a description of challenges that have not been addressed – how do we manage anxiety associated with prolonged mechanical ventilation?

The authors have made contributions to preparing this manuscript and no others have made significant contributions. All authors read and reviewed this manuscript. We appreciate your effort and the effort of our peer reviewers. This paper has not been published before and is not being considered for publication elsewhere. Please feel free to contact me with any questions. I look forward to your comments.

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5.2 MANUSCRIPT

Recognition and management of anxiety in patients weaning from prolonged mechanical ventilation

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5.3 ABSTRACT

Background: Patients describe physiologic and psychologic distress that accompanies critical illness. Anxiety associated with ventilator weaning can result in negative outcomes and produce management challenges for clinicians.

Objectives: The aims of this secondary qualitative analysis are to 1) describe events of anxiety during ventilator weaning trials; 2) describe clinicians', families' and patients' perceptions and descriptions of anxiety associated with weaning trials 3) identify and describe strategies used to decrease anxiety specific to ventilator weaning events.

Methods: Qualitative secondary analysis of an existing ethnographic study of weaning from prolonged mechanical ventilation was undertaken with a focus on anxiety and agitation associated with ventilator weaning experienced by 30 patients, their families and clinicians who cared for them.

Results: Participants described anxiety as a response to ventilator weaning and a significant barrier to weaning success. Identification of anxiety can be difficult because of symptom profiles overlap with other common patient problems such as delirium and pain. Various pharmacologic and non-pharmacologic strategies are presented from the perspective of patients, families and clinicians. Verbal supportive strategies and information sharing were observed. Sedation management was inconsistent and variable. Withholding information was utilized to overcome anxiety associated with prolonged mechanical ventilation

Conclusions: Ventilator weaning can stimulate anxiety. Further studies are necessary to 1) refine definitions of anxiety seen during ventilator weaning; 2) measure the effect of supportive verbal

support within the special context of ventilator weaning; 3) explore more fully sedation practices during ventilator weaning trials; and 4) describe effects of withholding information during weaning trials from critically ill patients from patients' perspectives.

5.4 INTRODUCTION

Although weaning from mechanical ventilation is multi-factorial, most studies isolate physiological predictors from psychological factors (Carlucci et al., 2009; Crocker, 2009; Knebel, 1989; Martensson & Fridlund, 2002; Modawal et al., 2002). While commonly viewed as a cause of weaning failure, few studies have explored the association between anxiety and ventilator weaning. Consequently, few empirically tested strategies exist to help patients overcome anxiety during weaning (Burns et al., 1995). The aims of this paper are to describe clinicians', families' and patients' perceptions and descriptions of anxiety associated with weaning trials and describe strategies used to prevent or decrease the anxiety associated ventilator weaning.

5.5 MATERIALS AND METHODS

This was a qualitative secondary analysis from a study that examined care processes and communication during weaning from mechanical ventilation. A detailed description of the methods used in the parent study was published previously (Happ, Swigart, Tate, Hoffman, et al., 2007; Happ, Swigart, Tate, Arnold, et al., 2007). The study received Institutional Review Board approval and participants or surrogates provided informed consent. Participants were assigned pseudonyms.

5.5.1 Sample and Setting

The sample included patient cases (n=30) admitted to a 28-bed medical intensive care unit (MICU) who received mechanical ventilation for at least 4 days and failed at least 2 weaning attempts, their families (n=31) and clinicians who cared for them (n=28). Patients represented variability in age, gender, ethnicity, diagnosis, and severity of illness (Table 8). Clinicians from a surgical unit in the same institution were interviewed to assess representativeness of information obtained from the MICU (Table 10).

Table 10 Demographics of clinician and family member participants

Clinicians	n	Sex		Race			
		male	female	W	AA	L	Asian
Physicians (MD)	11	10	1	5	1	1	4
Respiratory Therapists (RT)	7	4	3	7	0	0	0
Nurses (RN)	10	0	10	10	0	0	0
Subtotal	28	14	14	22	1	1	4
Family Members (n=31)	n	Sex		Race			
		male	female	W	AA		
Spouse	15	8	7	15	0		
Adult Child	8	1	7	8	1		
Parent	5	2	3	5	0		
Sibling	3	1	2	1	2		
Subtotal	31	12	19	28	3		

MDs include attending physicians, critical care medicine & pulmonary medicine fellows.

Nurses include acute care nurse practitioner and nurse case manager.

W= white/Caucasian; AA= African American; L= Latino/Hispanic; Asian = Asian-

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5.5.2 Data Collection and Analysis

Data for the parent study were collected by field observation, interview and record review over 16 months representing 439 days that patients underwent weaning trials. Observations of clinical care, interactions and communication between clinicians, patients and families were recorded in field notes. Formal interviews were conducted with 18 patients, 31 family members and 28 clinicians. Clinicians provided information about specific cases and discussed the effects of anxiety and agitation on ventilator weaning. All medical records (e.g., nurse's notes, physician progress notes, therapy notes, medication records, etc), and numeric data (e.g., vital signs, lab data, ventilator settings and duration of daily weaning trials) were reviewed for the period of weaning (range 3-65 days) for each patient.

All data were transferred into Atlas.TI (version 5.6.3, Scientific Software Development GmbH) and searched to identify all anxiety-related events during weaning, using keywords derived from the literature and clinical experts. Each administration of medication such as sedatives, anxiolytics or analgesics was documented. Analgesics were included because of their anxiolytic effect but only when associated with behavior indicating anxiety.

Employing qualitative event analysis, (Happ, et al., 2004) each anxiety event was reviewed to identify causal conditions, patient responses, clinician actions and strategies, intervening conditions, consequences and context (Kools, et al, 1996). Numeric data and textual data were merged by date and time in a tabular form (matrix) to examine patterns of anxiety events (Miles, 1994). Data were coded to identify salient dimensions of anxiety and to explore the social and environmental conditions in which it occurred. Each data type (interview, observation, analytic memo, clinical record text and numerical data) was compared to identify

conceptual similarities and differences within and between cases using constant comparative analysis (Strauss, 1990).

5.6 RESULTS

5.6.1 Ventilator weaning as a stimulus for anxiety

Clinicians described ventilator weaning as an anxiety producing stimulus and barrier to successful weaning. Feelings of breathlessness were viewed as a normal response that contributed to anxiety. “I mean, when you can’t breathe, that’s very anxiety-producing. (MD) “

If you get tachypneic and uncomfortable during a weaning trial that may not be anxiety necessarily in the usual sense that you have an inappropriate stress reaction. That may be (laughter) normal.” (MD)

5.6.2 Anxiety as a Conditioned Response

For some patients with multiple unsuccessful weaning attempts, anxiety became a conditioned response and all weaning attempts were appraised by patients as a threatening event. Patients displayed varying levels of interaction, an essential condition for appraising the threat that ventilator weaning posed. Conditioning required memory, thought and appraisal of risk a situation presents as evidenced by patient descriptions of a cognitive component associated with ventilator weaning and managing anxiety with thoughts and self-talk. They described “thinking”, “trusting” and “wanting” to wean and being engaged in a cognitive process of “thinking of every breath”. Raymond was awake and aware and using a tracheostomy speaking

valve. In Raymond's case, anxiety was related to his fear (appraisal) that weaning (stimulus) could result in death. Another patient confirmed the cognitive effort as she felt compelled to think about breathing independently.

Raymond: You know the fear factor is the worse. It's matter fact. The last one I had was maybe a week and a half ago where they want to wean you like they're doing now. They [the clinicians] want to take away the air [wean]. So, in taking away the air, the fear found its power. Through not being able to breathe...now here I am saying "oh lord take me out", but when it's time to go I kick and scream like everybody else for the last breath. So, what happened was I started going through the anxiety when they said to take him off the air [wean]. I don't want to take off the air [wean].

Patient: I'd sit there and I'd breathe and make sure I'm breathing. Then all of a sudden, I couldn't move air, just for a moment but it was enough to make me think that I'd lost track of breathing. And it would make me panic.

Fear led to anticipatory anxiety. One patient, Gena, exemplified this process to the extreme. Recently transferred to the step-down medical intensive care unit for a more intense, consistent ventilator weaning program, she was extremely anxious, as acknowledged by the staff and her family.

MD2: People who have failed multiple times often...have a lot of despair, very high levels of anxiety and fear because each process, each failure to wean, leads to a set of circumstances that causes tremendous suffering and discomfort to the patient.

MD2: She is very terrified with the sensation of shortness of breath. That's why when she's asleep you can turn her (vent) down to five (of pressure support) but when she wakes up you've got turn her back up to fifteen. She's terrified of it. After two years of repeatedly having that happen to her, she's psychologically not in the right state of mind to be weaned.

5.6.3 Assessment

Clinicians frequently used vital signs to recognize anxiety, particularly when patients were less communicative. In addition to heart rate, respiratory rate and blood pressure, respiratory therapists (RT) analyzed waveforms and graphic displays to distinguish anxiety from other possible explanations.

RT1: I'll probably start her on pressure support of 10 and not work her too hard. ... I think she's better off with a little something to help with anxiety. I'd really like the ACNP to give her something. See her (respiratory) rate increase and her tidal volume down. The (respiratory) rate increase means anxiety. The tidal volume down means she's weak.

RT1: (pointing to a graphics curve on the ventilator screen) That's truncating. It should be angling straight down. This tells me she may need some sedation.

5.6.4 Knowing the patient

Clinicians used previous experience with the patient to assess patient responses and used this knowledge to predict an anxiety response, a practice referred to as “knowing the patient” (Curley, 1998; Tanner, et al., 1993). This personal knowledge came in three dimensions; (1) continuity; (2) transfer of care information, and (3) history (See Table 11). Clinicians used previous experience with the patient to plan for the next weaning trial. This included delaying a weaning trial or sedating the patient to avoid an anxiety response. If the weaning trial was accompanied by anxiety, this information was conveyed to the next caregiver who used this information to plan strategies.

Clinicians also used the patient’s history to assess likelihood of anxiety and confirm their assessment. For example, if the patient had a history of anxiety prior to their critical illness, anxiety was viewed as more likely during weaning and, if present, attributed to the prior diagnosis. Similarly after several episodes, anxiety became the patient’s “new” history.

Table 11 Exemplar data for dimensions of "Knowing the Patient"

Dimension	Quote
Continuity	<p>RT5: If they've weaned a couple days and then you get to know the patients. And you know that they get rattled, if they think they're not on full support, They need that security (of full support).</p> <p>RT1: Her nurse asked me before the wean if she should give Ativan. I said "no," I thought that she didn't need it that we've been doing it (wean) without (sedation) but I will ask her for a touch of it now.</p> <p>RT2: After yesterday with him. He was out of control. He needs something for anxiety. I had to go in about 5 times, bag and suction him. He would de-sat just from anxiety.</p>
Transfer of Care Information	<p>RN: We'll know what works for them or they'll [the previous shift] say, "The patient failed yesterday because she was anxious."</p>
Patient History	<p>RN: They (MD's) want me to wean the Fentanyl off. I don't feel comfortable with that. She has a baseline anxiety disorder.</p>

5.6.5 Strategies to prevent or treat anxiety

5.6.5.1 Informing patients of the plan to wean

Generally, the clinician (RT or physician) approached the bedside and informed the patient that ventilatory support would be decreased. Instructions were given to breathe “slow and deep” and reassurance that clinicians would monitor progress and remain nearby.

MD: I’m going to make some changes to the ventilator. I’m going to be with you the whole time. It’s a little different feeling, don’t get anxious. The oxygen’s 100%. Slow deep breathing, you’re doing good...Our goal is to get you off this breathing machine so you can talk to your family. I’ll be right here. Work with the machine. .

5.6.5.2 Coaching and Reassurance

Clinicians’ efforts to coach and reassure patients were targeted to the patients’ cognitive appraisal of the event. Verbal feedback was used to disrupt the patient’s cognitive appraisal of weaning as a threat.

RT: (to patient) Whatsa matter? You’re ok. You are doing very well. You can do it. (RT walked around bed, looking at monitors). OK I’m gonna clean out your tube. That gurgly sound. That’s scary. (RT suctioned patient) This is gonna make you cough. (Suctioned again.) Listen, no more of that sound. No really, you are doing good. Listen. You are clear. Mucus? Well that's normal. Your lungs are always making mucus. That’s what keeps them clean. It’s always there. Come on. You can do it. You gotta believe that you can do it. You gotta make yourself do it. Come on. That feel better? Your tube is clear. Look I'm here I'll help you.

5.6.5.3 Out of sight, out of mind

Clinicians noted that some patients became calm if they were left alone and viewed their presence as a stimulus for anxiety. They removed themselves from patients' line of sight to avoid the stimulus for anxiety while maintaining the ability to observe and monitor the patient safely.

RN: You know someone like her that's so anxious, I find that if I stay out of her line of vision she will do really well [on her wean]. So, I try to consolidate my work so I am not in the room as often. As soon as she sees me, she needs a [mouth] swab, turned, pain meds whatever. Then she de-sats [oxygen saturation decreases]. Her respiratory rate, heart rate and blood pressure go up.

Families also expressed fear that their presence would cause a negative response. Some family members avoided close contact with the patient as they associated their presence with stimulating a physiologic response that jeopardized a successful weaning trial.

Sister: I don't want to get near him. When I got near him his rate (respiratory) went up. He's on pressure support of 5 [ventilator weaning setting]. Isn't that good?

Husband: I wonder if it's maybe better [weaning trial] if we weren't there. We held her hand and we tried to give her support. But the next day we weren't there when they put her on her wean, she went for two hours. The next day she went for four hours. So we thought that maybe that our presence maybe made her a little more anxious.

5.6.5.4 “Sneaking” the Wean

At times when patients exhibited anxiety, clinicians would decrease ventilatory support without informing the patient. This approach was reported by nurses, RTs, and physicians as a collaborative effort to avoid stimulating anticipatory anxiety. This practice occurred in two separate ICUs of the hospital.

RN: Well, she had this problem. She got anxious this morning and RT3 took her off the wean but he snuck her on (a weaning trial) when we got her in the chair at 12:10.

RT5: Some patients you don't tell. The characteristics of those patients you don't tell include anxiety, agitation, people in whom you have told in the past and they become anxious; people who do well when they are asleep and unaware.

In one case, the RT proceeded to “sneak her down” [reduce ventilator settings] while reassuring the patient. Once the patient was somewhat calm, he provided distraction by offering a choice of TV stations and providing commentary while changing channels. Clinicians termed this strategy “sneaking the wean”. Family members occasionally supported or suggested this strategy as having therapeutic value.

Husband: In fact, when they don't tell her that she's going to be weaned, it's probably better. The RT would say hello, then he checked the machine, fixed the dials and then all of a sudden she was doing the wean. Maybe she didn't know that she was on the wean initially. That probably worked in her favor that nobody told her until the middle of the process, you know, that she was actually doing it on her own.

The practice of “sneaking the wean” did not appear to enhance overall weaning success. There were patients who admitted they preferred not knowing when clinicians were initiating weaning trials and were annoyed by coaching. Some patients were able to breathe with less support for hours during the night without being informed of a weaning trial. While patients could tolerate an individual weaning trial initiated by “sneaking”, this practice was not sustained by clinicians for individual patients. It appeared to be part of an arsenal of strategies that were used by clinicians to manage anxiety resulting from prolonged mechanical ventilation.

Unfortunately, “sneaking the wean” also resulted in negative consequences. With one patient, multiple weaning trials failed and clinicians resorted to “sneaking” weaning trials and weaning her at night while she slept. This eventually created mistrust.

RN3: I think that [sneaking the wean] contributed to this patient’s anxiety. She has real trust issues related to us not telling her when we were weaning her.

A second patient described her experience as a consequence of a “surprise,” silent wean at night. She had difficulty weaning and was told by a physician that she wasn’t ready to wean. However, she awakened one night to a progressive feeling of difficulty breathing. She called the RT who admitted to trying “to sneak one in on you.” This led to a broken trust with her nurses and RT.

Patient: I told the doctors please don’t do that (weaning) again...And they did it [placed her on a wean] at night. And I laid there for a while and it just kept getting harder to breathe and harder to breathe. Something was wrong, you know. And then I thought “are they surprising me about this?” They swore they wouldn’t, but who knows?

So I called for the technician and told her. And she said “yep, they tried to sneak one in on you.”

5.6.5.5 Sedation

Clinicians inconsistently used sedation to manage anxiety during weaning. Sedation was administered before a weaning trial when an anxiety response was anticipated and less often during a weaning trial to manage anxiety. Clinicians disagreed about benefits of sedation. Some clinicians thought sedation mediated the psychological response in a positive way.

RN: (the previous shift) They’ll say, “The patient failed yesterday because she was anxious.” And just simply try like a small dose of, like a milligram of Ativan or a few milligrams of Haldol and see if that helps them with their wean. Sometimes you give it twenty minutes before we put them on the wean and then they don’t get anxious.

Others thought that the patient needed to be awake to wean and sedation adversely affected ability to breathe independent of the ventilator.

MD8: When they’re sedated or when they have a very flat affect, they just don’t put the effort into breathing. And you can see that pretty dramatically when you have someone sedated and you put them on little bit of pressure support and they develop rapid shallow breathing right away, and you come back 6 hours later and they’re wide awake and alert, and fly [wean easily] without any difficulties.

On occasion, when sedation reduction led to negative behavioral consequences, clinicians faced a conundrum – “should I wake the patient to wean or sedate them to manage their behavior?”

RN8: I’ll tell why she’s not weaning. Whenever we decrease the sedation, she thrashes around. It’s not so much that she can’t wean. It’s that the sedation and her behavior

really prohibit us from being effective. Her pulse and her blood pressure both go up. Her respiratory rate goes up and we really have to re-sedate her and terminate the wean.

5.6.5.6 Aborting the wean

Clinicians reported or were observed delaying or curtailing a weaning trial for anxiety or agitation. Of the 439 days of weaning trials observed, clinicians documented the decision to abort a weaning trial due to anxiety or agitation on 27 days (6.2%) or with 12 patients.

Field note: RT2 commented that the patient didn't last long on her wean this morning that the RN requested that the wean stop.

RT2: She had the same numbers, was pulling good tidal volume. It's all anxiety but they wanted her to be taken off (the weaning trial).

5.7 DISCUSSION

This study was unique in several ways. Anxiety during weaning was explored from multiple perspectives using multiple sources (and triangulated to provide a comprehensive description of the experience, assessment and management of patient anxiety associated with ventilator weaning. Patients were interviewed despite their inability to communicate verbally. Clinicians provided details about critical care practice that have not been addressed in other studies.

Findings from this study illustrate anxiety responses to ventilator weaning trials that have not been previously described. Anxiety was clearly a consideration for management of ventilator weaning and thought to be a barrier to successful weaning. Ventilator weaning stimulated

anxiety and multiple weaning failures led to a conditioned anxiety response. The challenge for patients and clinicians is to individualize strategies to prevent or reduce anxiety during weaning.

Multiple strategies including pharmacologic and non-pharmacologic, were employed to reduce the impact of anxiety and increase the likelihood of weaning success. Clinicians approached non-pharmacologic interventions in two ways. The first approach includes the patient an active role. Information sharing was a standard preparatory approach while supportive verbal strategies were initial strategies used to overcome an episode of anxiety. These verbal strategies actively engaged the patient in the weaning trial and established a partnership between the patient and clinician to accomplish the goal of maintaining the patient in a calm state.

The second group of approaches was used when clinicians thought that involving the patient would undermine weaning success. Eliminating visual stimulation or withdrawing presence (“out of sight, out of mind”) was used when patients had experienced recurring anxiety and when clinicians associated anxiety as a response to weaning trials with “stimulation” of clinician presence. Although clinicians maintained their ability to monitor the patient safely, the practice of leaving the patient alone or avoiding visual contact runs counter to beliefs and patient reports regarding benefit from a supportive clinician’s presence. Thus, prior studies recommend clinician presence during weaning (Schou & Egerod, 2008). This study illustrates the tension that exists between the views of isolation and presence as stimuli to the development of anxiety.

The term “sneaking the wean” is a direct quote from clinicians who participated in the study. Although negative in connotation, their intention was the opposite. Numerous studies describe the benefits of keeping the patient informed regarding their plan of care (Lof, Berggren, & Ahlstrom, 2008; Logan & Jenny, 1997; Moser et al., 2003; Novaes, Aronovich, Ferraz, & Knobel, 1997; Wunderlich, 1999). The decision to withhold information is counter to the high

value placed on patient autonomy and informed consent. Patient-provider communication in the critical care setting has been studied most extensively related to end of life decision making rather than during routine care practices. In the present study, clinicians' use of a value laden term, ("sneaking,") likely reflected the tension they felt about withholding information despite the belief that this action would facilitate success. In a phenomenological study of strategies to facilitate weaning conducted in a European ICU, Eckerblad et al (Eckerblad, Eriksson, Karner, & Edell-Gustafsson, 2009) describe withholding information as a "distraction" strategy, a value neutral term. The authors reported that clinicians used their clinical judgment to determine if sharing information would facilitate or undermine success. In the present study, clinicians also individualized the amount of information they shared but chose a value laden term to describe their actions.

The practice of withholding information can serve a protective function. In an auto-ethnography, Rier (Rier, 2000) describes experiencing anticipatory anxiety when a nurse told him of an impending extubation. Although he contracted with the nurse to keep him informed, Rier admits that he was quite distressed at the prospect of losing ventilatory support. His analysis questions the value of using full disclosure in all situations. A few patient participants in the current study supported the judicious use of information about weaning.

Findings from the present study, however, also indicate that for some patients withholding information can be a double-edged sword resulting in mistrust of staff. This reaction was a central concern in Logan and Jenny's study of patients' work during mechanical ventilation and weaning (Logan & Jenny, 1997). Lowery and Anderson (Lowry & Anderson, 1993) found that fear and anxiety decreased as days on ventilation increased and hypothesized that mechanical ventilation became less of a stressor and more of a comfort. Perhaps the

simplest way to determine which approach is most acceptable is to ask the patient whether they would prefer to know when a weaning trial is being initiated (D. White, personal communication).

Sedation was administered to manage anxiety in anticipation of or management during ventilator weaning and was used inconsistently. Occasionally, weaning trials were aborted when patients became anxious. It is difficult to determine how successful or appropriate these interventions were to manage anxiety associated with weaning.

Firsthand or shared information was extremely valuable in planning care activities and interventions. Our findings confirmed the value of “knowing the patient”. This concept has been previously described as an essential element for successful weaning, (Logan & Jenny, 1997) discerning subtle changes and selecting appropriate interventions to overcome anxiety (Blackwood, 2000; Crocker & Scholes, 2009).

This study was subject to several limitations. Anxiety events were not the focus of the parent study and therefore may not have been fully explicated. However, data collection involved the assessment of anxiety from multiple perspectives, e.g., patient, family, clinician. The study was conducted in a single unit at a single institution and may not be representative of all setting. To overcome this limitation, we validated that observations were not unique to one ICU by confirming findings with clinicians from other ICU’s within the institution and outside the geographical area.

5.8 CONCLUSION

This study provides new insights regarding clinical practice in the assessment and management anxiety associated with weaning. Our findings raise concerns about potential detrimental effects

of withholding information and the importance of continuity of care, knowing the patient, and cultivating continuous and trusting relationships with patients who experience anxiety during PMV weaning.

Our findings point to the need for further research of anxiety during ventilator weaning including empirical studies to: 1) refine definitions of anxiety associated with ventilator weaning; 2) measure the effect of supportive verbal support within the special context of ventilator weaning; 3) explore more fully sedation practices during ventilator weaning trials; and 4) describe effects of withholding information during weaning trials from critically ill patients from patients' perspectives.

APPENDIX A

IRB APPROVAL LETTER



University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)

MEMORANDUM

TO: Mary Beth Happ, PhD, RN

FROM: Christopher Ryan, PhD, Vice Chair *Chris*

DATE: March 15, 2010

SUBJECT: IRB #0307094: Study of Patient-Nurse Effectiveness with Assisted
Communication Strategies (SPEACS) in the ICU

Your renewal of the above-referenced proposal has received expedited review and approval by the Institutional Review Board under 45 CFR 46.110 (9). **This approval is for analysis of data only.**

Approval Date: March 10, 2010

Renewal Date: April 01, 2011

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CR:kh

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