RESUSCITATION PREFERENCES IN SURVIVORS OF PROLONGED MECHANICAL VENTILATION (PMV)/TRACHEOSTOMY

by

Kathleen Guentner

BSN, Indiana University of Pennsylvania, 1977

MSN, University of Pittsburgh, 1984

Submitted to the Graduate Faculty of

School of Nursing in partial fulfillment

of the requirements for the degree of
Doctor of Philosophy

University of Pittsburgh

2004

UNIVERSITY OF PITTSBURGH

FACULTY OF SCHOOL OF NURSING

This dissertation was presented

by

Kathleen Guentner

It was defended on

November 29, 2004

and approved by

Lakshmipathi Chelluri, MD, School of Medicine

Mary Beth Happ, RN, PhD

Yookyung Kim, PhD

Annette DeVito Dabbs, RN, PhD

Dissertation Director: Leslie Hoffman, RN, PhD

RESUSCITATION PREFERENCES IN SURVIVORS OF PROLONGED MECHANICAL VENTILATION (PMV)/TRACHEOSTOMY

Kathleen Guentner, RN, PhD

University of Pittsburgh, 2004

Background: Resuscitation preferences regarding prolonged mechanical ventilation (PMV) have rarely been explored. **Objectives:** To determine preferences of PMV survivors and influencing factors. **Methods:** Subjects were 29 (57% male) survivors of PMV (≥ 7 days) and tracheostomy interviewed ≥ 6 weeks after MV was initiated. Subjects were asked to: 1) indicate if they would choose MV again; 2) rate present health, pain/discomfort in ICU and from MV, perceived family financial burden and emotional/physical stress using a Likert scale (0=positive, 4=negative); 3) identify change changes that might alter this preference; and 4) complete questionnaires assessing quality of life (QoL) (SF-36), functional status (Health Assessment Questionnaire), depressive symptoms (Center for Epidemiological Studies Depression Scale) and communication (Patient Communication Survey). **Results:** Most (76%) would undergo PMV again. Median MV days were greater for those who would undergo MV again (98.5 vs. 70, p=NS), as were median tracheostomy days (102 vs. 64, p=NS). Those who would not undergo MV again were more likely to have depressive symptoms (p=0.051) and Medicare coverage (p=0.023). No other variables differed between groups, including age, ICU length-of-stay, QoL, functional status, or communication status. Individuals who preferred MV stated their preference would change if their health and/or the family's emotional/physical stress were worse. Those who did not prefer MV would change if family's financial burden and emotional/physical stress were reduced. **Conclusions**: Most patients would undergo PMV again despite substantial time on

MV. Preferences were most likely to change based on present health and family's financial burden and stress.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

PREFACE

I would like to acknowledge and sincerely thank the following people for their support during the seven years of the pursuit of this research and degree:

Leslie A. Hoffman, my advisor, mentor, and committee chair, for the many, many years of guidance, she has given me.

Mary Beth Happ, Yookyung Kim, Luke Chelluri, Aaron Mendelsohn, and Annette Dabbs for the generous sharing of their expertise, time, and assistance.

The participants of this research for their strength and hope were truly inspiring. I'm grateful for the opportunity to share their lived-experience.

The nurses, respiratory therapists and administrators of the facilities caring for these individuals and their willingness to allow the research.

My family and friends, especially my son, Jonathon and my Mom for their continued love, support, tolerance, and humor.

I will always be grateful to all of you.

1 THE PROBLEM

1.1 INTRODUCTION

Care in the intensive care unit (ICU) is associated with significant costs and critically ill patients who require prolonged mechanical ventilation (PMV) account for a substantial proportion of these costs (Heyland, Konopad, Noseworthy, Johnston, & Gafni, 1998). Although most individuals who require mechanical ventilation (MV) during an acute illness are quickly weaned from ventilatory support, a minority, estimated at 3 to 6% of all patients admitted to the ICU, require prolonged weaning (Rudy, Daly, Douglas, Montenegro, Song, & Dyer, 1995; Douglas, Daly, Brennan, Gordon & Uthis, 2001). The cost of caring for patients who are difficult to wean is related to the time and effort-intensive nature of the weaning process, extended stay in acute and long-term care facilities, and the morbidity associated with increased time on the ventilator (Clochesy, Burns, Shekleton, Hanneman, Knebel, & Ingersoll, 1997).

In addition to the high costs associated with treatment, a prolonged ICU stay is associated with a high mortality. In studies conducted within the past 10 years, mortality rates for patients who require PMV were 43%, 67%, and 61% at 2, 6, and 12 months after hospital discharge, respectively (Quality of life after mechanical ventilation in the aged study investigators [QOL-MV], 2002; Chelluri, Grenvik & Iverman, 1993; Seneff, Wagner, Thompson, Honeycutt & Silver, 2000). Higher mortality was associated with increased severity of illness, increased age, and poorer physical functioning before hospitalization (QOL-MV, 2002). Further, the need for PMV is an indication of increased severity of illness and prolonged recovery trajectory (Douglas, Daly, Gordon & Brennan, 2002).

Another outcome of prolonged critical illness is decline in physical functioning and subsequent need for an extended stay in long-term care facilities. Although one study reported that the majority of patients were independent in several daily activities, such as bathing, dressing, feeding, and walking from room to room, at six months following ICU discharge (Niskanen, Ruokonen, Takala, Rissanen, & Kari, 1999), most studies report a decline in physical functioning (Chelluri et al, 1995; QOL-MV, 2002; Wissam, Kreimer & Criner, 2001). In a prospective study that enrolled 817 patients who required MV for ³ 48 hours, Chelluri et al (2002) found that patients' physical functioning was worse at 2 months following ICU discharge compared to before hospital admission. Hoffman, et al (2002) reported that only 20% of patients were discharged to home 1-month following ICU discharge and 39% at 4-months after discharge in a prospective study that enrolled 80 patients who required MV for ³ 7 days.

Most studies examining outcomes following PMV have focused on physical functioning, quality of life (QoL), morbidity, mortality and the care giving experience. Patient preferences regarding PMV have rarely been explored (Mendelsohn, Belle, Fischhoff, Degenholtz & Chelluri, 2002). Other studies that examined preferences were anticipatory in nature. Patients were asked about future end-of-life decision-making, use of advanced directives, or treatment preferences for conditions likely to require MV such as end-stage chronic obstructive pulmonary disease (COPD), amyotrophic lateral sclerosis, and muscular dystrophy (Tilden, Tolle, Garland & Nelson, 1995; Hofmann, et al, 1997; and McKinley, Garrett, Evans & Danis, 1996). It is unclear whether patients, who have already experienced an episode of acute illness, including PMV, would have the same preferences as they verbalized before the event (Mendelsohn, et al 2002). In order to fully examine preferences in this setting, it is important to elicit preferences

from the perspective of those individuals who survived PMV and, therefore, have first hand knowledge of its impact.

In one of the few studies to investigate patient preferences after prolonged ICU admission, Teno and colleagues (2000) evaluated decision-making and outcomes for critically ill patients with an ICU length of stay of at least 14 days. Although 55% of these patients died within 6 months, and those surviving had a significant functional impairment, only 34% of patients or surrogates had discussed preferences with their physicians by the second week of hospitalization. In a second study of patient preferences, Mendelsohn et al. (2002) interviewed survivors of PMV (> 48 hours; median of 8 days) or their surrogates at one year after ICU discharge and found that most (86.5%) would again elect to have MV. A strength of this study was the prospective long-term follow-up. However, a substantial proportion of the original sample died (43% at 2 months) and 21% were lost to attrition (QOL-MV, 2002). In addition, PMV was defined as > 48 hours, whereas the more common definition is > 7 days (Wissam et al, 2001; Seneff et al, 2000; & Phelan, Cooper & Sangkachand, 2002). No studies were identified that examined patient preferences in regard to again undergoing MV when the initial period of time on MV was > 7 days.

There are a number of factors that might influence patient preferences regarding MV including its potential impact on ability to regain previous level of physical functioning, QoL, communication status, and depression. Survivors of PMV have been shown to have decreased QoL compared with the general population (Chatila, Kreimer, & Criner, 2001). Nasraway et al, 2000 described the outcomes of 97 survivors of prolonged critical illness, of whom 73.2% experienced PMV. One year later, only 11.5% of all patients had returned home and reported a fair or better quality of life, and good physical functioning.

Communication status may greatly impact patients' preferences regarding MV, but this aspect of functioning has received little examination. Initially, MV is provided with an endotracheal tube, which eliminates the ability to speak. Extended use of an endotracheal tube, especially for periods > 7 days, may result in hoarseness (41-71% of patients), vocal cord immobility (19%), and laryngeal stenosis (0-5%) resulting in impaired speech (Stauffer, 1999). To minimize risk and promote patient comfort, a tracheostomy is typically performed after 7-10 days of MV if the patient is unable to wean from MV or has problems managing airway secretions (Hefner, 1993). However, the need for a tracheostomy may also compromise patient ability to communicate, especially if a cuffed tube is required (Orringer, 1999). Although several augmentative communication methods can be used to assist communication, e.g., paper and pencil, tracheostomy tubes with speaking valves, and computer keyboards, such devices are infrequently and inconsistently used in the ICU setting (Happ, 2001).

Following chronic critical illness, limitations in physical functioning, QoL, and communication status, and depressive symptoms have often been observed. While we know that 13.7% of patients are depressed when admitted to the ICU (Rincon et al, 2001), recuperation from an extended hospital stay continues long after discharge and can result in a greater incidence of depression. In the QOL-MV study (2002) described above 35% of 232 patients who required PMV (> 48 hours) had symptoms of depression 2 months following hospital discharge.

Although, Mendelsohn et al (2002) found that patients, who survived 48hours of MV, continue to prefer MV, patients' preference after experiencing PMV (> 7 days) and tracheostomy are not known. Given the potential for compromise in physical functioning, QoL, communication ability, and depressive symptoms, it would seem likely that some patients would

prefer not to undergo MV if given the choice again. Further study is indicated to better define patient preferences for this significant and growing sub-population of the chronically critically ill and factors that may influence these preferences. This information would be beneficial to health care team members who discuss issues related to end of life decision making so as to better understand preference toward PMV from the patient perspective.

1.2 PURPOSE OF THE STUDY

The purpose of this preliminary study was: to elicit preferences regarding MV in patients who received PMV and tracheostomy and characteristics associated with these preferences and obtain pilot data for power analyses for a subsequent investigation. This study provided information about preferences of patients that clinicians can use to inform discussions of treatment options and decision-making with patients and families.

1.3 SPECIFIC AIMS

The specific aims of this study were:

1. to describe patient preferences regarding the use of MV in 2-month survivors of PMV and tracheostomy;
2. to examine relationships between MV preference and selected potential influencing factors including demographics, clinical characteristics, quality of life, functional status, depressive symptomatology, and communication status;
3. to obtain pilot data to facilitate estimating the sample size needed to insure adequate power for a subsequent study.

1.4 DEFINITION OF TERMS

Prolonged mechanical ventilation (PMV): individuals treated with positive pressure ventilation via endotracheal intubation for > 7 days.

Tracheostomy: the opening or stoma made in the trachea during a tracheotomy – the surgical incision into the trachea. A tracheotomy tube is a short artificial airway inserted into the trachea during a tracheostomy operation.

Cognitive functioning: absence of cognitive impairment, as measured by the Mini-mental State Exam (MMSE) (Folstein, Folstein & McHugh, 1975).

Quality of Life: In this study, quality of life (QoL) or specifically, health related quality of life (HRQoL) was defined as the way patients perceive and react to their health and to nonmedical aspects such as their residence situation and employment (Wehler, Geise, Hadzionerovic, et al, 2003). In this study, QoL was measured using the Short Form General Health Survey (SF-36v2) (Ware, Kosinski, 2002).

Physical functioning: the ability to perform the functions of daily living, such as bathing, eating, dressing, meal preparation, etc. In this study, physical functioning was measured using the Health Assessment Questionnaire (HAQ) (Fries, Spitz, Kraines & Holman, 1980).

Communication status: communication is the act of transmitting ideas through speech, writing, or other methods; communication status encompasses communication success, satisfaction and ease of communication. In this study, communication status was measured using the Patient Communication Survey (Happ, Roesch, & Kagan, unpublished data).

Depressive symptoms: the symptoms of an emotional state characterized by decreased appetite, sleep difficulties or increased fatigue, feelings of hopelessness and helplessness or fluctuations in mood, and indecisiveness and lower self-esteem with self-criticism. In this study,

depressive symptomalogy was measured with the Center for Epidemiological Studies Depression Scale (CES-D) (Radloff, 1977).

Preference: the choice of something judged to be better. Preference for mechanical ventilation was measured with the instrument described in Mendelsohn et al, 2002.

1.5 SIGNIFICANCE TO NURSING

Nurses are interested in identifying patient preferences toward life sustaining treatments to individualize their care. This is especially true in settings such as the ICU where some of the treatments, such as MV, can be viewed as artificial life support. Further, many patients admitted to the ICU have conditions associated with a high mortality, severe functional deficits, and an extended recovery. With patient and family input, the interdisciplinary treatment team may choose a plan of care that emphasizes comfort and pain relief to accommodate the patient's preferences.

Patients are routinely asked upon admission to a hospital about their preferences as they relate to advanced directives. "Advanced directives are instructions given by a patient while he or she has decisional capacity concerning medical treatment he or she would or would not like to receive in the event that decisional capacity is lost (Ahronheim, Moreno & Zuckerman, 2000, p. 23)." Sometimes those preferences or advance directives are written in the form of a living will or individuals may identify a durable power of attorney for health care. In a living will, a person requests that, if they become disabled beyond reasonable expectation of recovery, the decisions about care made a priori be followed. This is a powerful method to document preferences. However, individuals make advance directives based on sources other than experience. The use of MV is often considered an extraordinary measure, and as such, is often included in a living

will, along with treatments such as blood transfusions, tube feedings, and antibiotics. With very few exceptions, the individual writing a living will is likely to never have experienced MV, let alone PMV and tracheostomy.

Most studies that have examined recovery following PMV report that patients require a substantial period of time to regain their prior physical functioning, or never regain this ability (QOL-MV, 2002). In addition, the personal and economic cost of a critical illness and subsequent recuperation is significant and may have long-term implications for the family. Often this care is provided in a setting designed to provide a lower level of care, e.g., long-term acute care, acute rehabilitation, or skilled nursing facility. This recovery period may be followed by home care and outpatient services to help the person return to optimal health and functioning. Some patients spend the remainder of their life in a facility dependent for assistance with activities of daily living. When individuals become dependent on others for care at home or in an institution, there is a high cost to the family in lost wages, stress and anxiety.

It is important to learn about preferences following PMV and tracheostomy and examine how these preferences relate to perceptions of QoL, physical functioning, depressive symptoms and communication status. The information obtained from participants in this study may be useful in assisting other patients and families to make decisions about life support when facing a similar scenario. Additionally, ICU nurses often wonder about outcomes of patients they transfer to lower levels of care and how the patient feels about the outcome. Findings of this research may lead to nursing interventions that help patients and families make decisions about MV and tracheostomy and offer emotional support during a difficult time.

1.6 INNOVATION

This study was innovative in the following ways:

No prior studies were identified that evaluated patient preferences following PMV (>7 days) and tracheostomy.

The study described outcomes following PMV and tracheostomy in a comprehensive manner that include measures of QoL, physical function, depressive symptoms and communication status.

Study findings were designed to provide new insights into the preferences of a subset of patients who require extended support during their recovery from critical illness.

1.7 CONCEPTUAL FRAMEWORK

The conceptual framework for this study was based on an autonomy perspective in which medical treatment decisions are self-determined by patients and are directly related to the individual's experience or understanding of and preference for the treatment (Ahronheim, Moreno, & Zuckerman, 2000). "Autonomy is a concept anchored in humanistic and democratic ideals, with the recognition of a person's right to shape his life and destiny, influence decisions relating to his daily routine, and take an active part in his environment" (Barkay & Tabak, 2002) When able, individuals provide treatment decisions for MV by considering current health, pain and discomfort from MV, pain and discomfort experienced in the ICU, the burden family members experienced related to finance and emotional and physical stress (Mendelsohn et al, 2002).

Little is known about how individuals who experience PMV and tracheostomy perceive this experience, specifically whether they would undergo this treatment again or refuse this

therapy. In this framework, patient preference for MV treatment was viewed as being influenced by several factors including physical functioning, QoL, communication status and depressive symptoms. In this conceptualization, it was hypothesized that patients who experience a greater reduction in QOL and physical functioning, have more difficulty communicating and more depressive symptoms would be less likely to chose MV if offered this opportunity again.

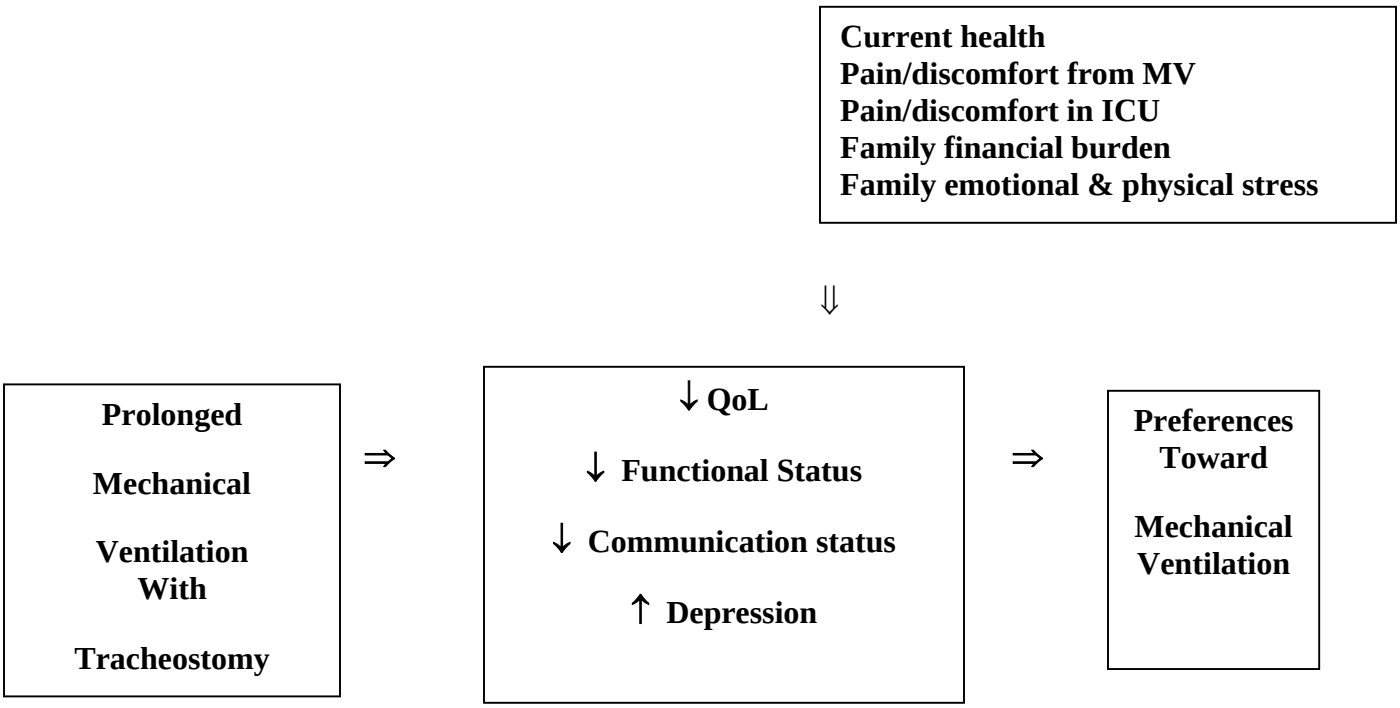

Figure 1 Conceptual Framework for Resuscitation Preferences

2 REVIEW OF LITERATURE

Today, people are living longer than at any other time in history. In no small part, the increased life expectancy is due to medical advances that can prevent cure and treat illness and disease, and ultimately prolong life. Unfortunately, medicine cannot accurately predict the long-term outcome of acute illness and the treatments provided (deVos, 2001). Therefore, it is important for consumers of health care to consider potential illnesses and the possible consequences.

The need for advanced directives was highlighted following the highly visible Quinlan case. Karen Ann Quinlan was the first case in the right-to-die debate. In 1975, the 21-year-old Quinlan collapsed after taking alcohol and tranquilizers at a party. She suffered brain damage and lapsed into a persistent vegetative state. Her family waged a much-publicized legal battle for the right to remove her life support machinery because the judge ruled that the physician's decision would prevail when it differed from the family's desire (Davis, Aroskar, Liaschenko & Drought, 1997).

A presidential commission was appointed in the early 80s to investigate ethical issues facing the country, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. This group issued a report, Deciding to Forego Life-Sustaining Treatments, that stated that nothing in the law prohibits ethical decision-making or requires patients to receive painful procedures if they wish to avoid life-sustaining treatments (Davis et al, 1977). This report set the stage for patient and surrogate decision-making regarding life sustaining treatments.

In 1991 the Patient Self Determination Act (PSDA) was enacted into law. The PDSA

"mandated that health care institutions and health maintenance organizations participating in Medicare and Medicaid programs provide patients with written information regarding their legal rights as outlined by state law; participate in medical decisions, including the right to accept or refuse treatment; and formalize treatment wishes by completing an advanced directive" (Maxfield et al, 2003, p38).

In 1998 it was estimated that "…despite diligent efforts by the American Association of Retired Persons (AARP), local senior citizen groups, community educators, lawyers, and medical personnel to teach the public about their legal rights, only about 15% of patients have advance directives in the form of a living will or health care proxy" (Haynor, 1998, p.26). AARP has been very active in educating seniors about advanced directives. Education, provided by AARP, appears on the American Medical Association web site and provides the rationale for having an advanced directive.

> "… If you cannot make or communicate decisions because of a temporary or permanent illness or injury, a Health Care Advance Directive helps you keep control over health care decisions that are important to you. In your Health Care Advance Directive, you state your wishes about any aspect of your health care, including decisions about life-sustaining treatment, and choose a person to make and communicate these decisions for you.
>
> Appointing an agent is particularly important. At the time a decision needs to be made, your agent can participate in discussions and weigh the pros and cons of treatment decisions based on your wishes. Your agent can decide for you wherever you cannot decide for yourself, even if your decision-making ability is only temporarily affected.

Unless you formally appoint someone to decide for you, many health care providers and institutions will make critical decisions for you that might not be based on your wishes. In some situations, a court may have to appoint a guardian unless you have an advance directive.

An advance directive also can relieve family stress. By expressing your wishes in advance, you help family or friends who might otherwise struggle to decide on their own what you would want done. (http://www.ama-assn.org/public/booklets/livgwill.htm, July 24, 2003)."

This statement succinctly explains the need for advanced directives to give individuals control over their care by stating their preferences a priori. The statement also explains the role of proxy decision-makers who can be authorized to make decisions that the individual would be likely to make, if able (substituted judgment). The challenge occurs when individuals fail to make advanced directive or discuss their preferences with a surrogate decision-maker. In such situations, family members may provide consent (make care decisions) regarding life-sustaining treatments. However, these decisions do not have guidance from the person receiving the care.

This literature review was completed by searching MEDLINE and CINAHL from 1966 to present to identify studies investigating end of life decision making; patient preferences following an ICU stay; QoL, physical function and depression following ICU, prolonged ICU, MV, prolonged MV; tracheostomy; and communication. The following terms were used: decision-making, patient decision-making, QoL, physical functioning, depression, ICU stay, MV, prolonged MV, tracheostomy, tracheotomy, and communication. Citations were limited to human studies and the English language. In addition, the reference lists of relevant articles were reviewed to identify additional papers.

2.1 FACTORS INFLUENCING END-OF-LIFE DECISION-MAKING

When patients' decisions about end of life situations, life-sustaining treatments, and intensive care have been examined, the most common approach has been to ask the individual to project what they might want in various situations. The following selected studies identify the varied factors that can influence preferences, including race, desire for physician input into decision-making, family input, and stability of decisions over time.

McKinley, Garrett, Evans, and Danis (1996) examined the differences in African-American and white individuals' preferences regarding end of life decision-making. The participants were 206 ambulatory cancer patients who were over 40 years old and under treatment by a medical oncologist. The study consisted of a 35-minute interview that included 90 closed-ended questions and several open-ended questions. The items asked about life sustaining treatments in general, and specifically about cardiopulmonary resuscitation, feeding tubes, ICU monitoring, and MV support. African-American patients were significantly more likely to prefer life-sustaining treatments (Odds ratio 2.8; 95% CI 1.4-5.3) and less likely to want to complete a living will (OR 0.36; 95% CI 0.17-0.75) than whites after controlling for socioeconomic variables. Nevertheless, the majority agreed that a living will would provide control over their terminal care.

Hofmann and colleagues (1977) examined preferences about communicating with physicians regarding end-of-life decisions, specifically cardiopulmonary resuscitation and PMV. However, they did not provide a definition of "prolonged". Entry criteria required that patients have one of 9 diagnostic categories: acute respiratory failure, COPD, congestive heart failure, cirrhosis, nontraumatic coma, metastatic colon disease, advanced non-small cell lung cancer, multiorgan system failure with sepsis or multiorgan system failure with a malignant condition. Patients were ineligible if they were comatose, intubated, could not communicate, were

cognitively impaired, or were discharged before the interview window. Of those approached, 1832 agreed to be interviewed and 330 were not interviewed. Most (90%) who were not interviewed refused participation. Compared with those interviewed, those who refused to participate were more likely to be white (94% vs. 84%, $p \leq 0.001$) and have a worse prognosis for survival at two months (71% vs. 76%, $p \leq 0.001$). The groups were similar with regard to age, gender and religious preference.

Of the 1223 patients who had not discussed their preference for cardiopulmonary resuscitation with their physician, 42% wanted to have that conversation and 70% wanted their physician to revive them. The 366 patients who had discussed preference for cardiopulmonary resuscitation with their physician were more likely to have advanced directives that stated no resuscitation. Most (88%) of those patients who responded to questions about PMV had not discussed preferences with their physician. Patients who had discussed preferences for MV with their physician were more likely to have advanced directives and to state that they did not want PMV ($p \leq 0.006$).

In addition, family decision-making has been examined when the patient was unable to make end-of-life decisions in regard to perceptions of physician and nurse behaviors during the process (Tilden, Tolle, Garland, & Nelson, 1995). The authors interviewed 32 family members of patients whose death resulted when care was withdrawn. Inclusion criteria required the patient be ≥ 21 years old, unable to make decisions at the time of death, hospitalized for ≥ 3 days before death, have no advanced directive, and have a family member who participated in the decision to withdraw life support. Behaviors of healthcare providers that families found supportive included encouraging advanced planning, timely communication, clarification of family roles, facilitating family consensus, and accommodating grief. Participants described

behaviors that lead to feelings of burden were related to attitude, communication, and timing of withdrawal, such as staffing rotations, withdrawal of care being discussed at the bedside and physicians who appear to view the patient's death as treatment failure.

Additional studies have considered whether patient decisions would be stable (not change) after an advance directive was made, e.g., would the patient have the same preferences months or years later. Everhart & Pearlman (1990) interviewed ICU patients to determine preferences for life-sustaining treatments, such as resuscitation, resuscitation with MV, and artificial hydration and nutrition, considering their current health and the possible scenarios of stroke and dementia. Thirty patients were interviewed immediately prior to or within 24 hours of ICU discharge and 20 of these individuals were interviewed again approximately 1 month following ICU discharge (20-40 days). Most patients preferred resuscitation in their current state of health (87%), but preference for resuscitation declined if the participant imagined stroke or dementia. Less than half (43%) of these participants favored resuscitation with MV if their current state of health involved stroke (27%) or dementia (24%). These preferences were found to be stable after 1 month (kappa=0.35 – 0.70).

In summary, factors that have been shown to influence patient decision making about end of life situations, include race, communication with physician, helpful behaviors of health care providers and the stability of the decision over time. It has been shown that African–American patients appear to prefer life-sustaining treatments, but would be less likely to have a living will. When patients prefer to decline treatment, they tend to inform their physician. Families are supported when they make end of life decisions by actions such as advanced care planning, timely communication, and facilitating family agreement. When patients make decisions about advance directives such as resuscitation and MV, the decisions appear to be stable to 1 month

based on a study of 20 patients. Clinicians can utilize this information when caring for patients and families.

2.2 PREFERENCES FOLLOWING ICU ADMISSION

In an early study, Danis, Patrick, Southerland, & Green (1988) interviewed 160 patients and family members who were in a medical or respiratory ICU for at least 24 hours regarding preferences for intensive care and the importance of the patient's life circumstances in determining those preferences. The patients were at least 55 years old and lived nearby the hospital (to facilitate interview). The patients were divided into 4 outcome groups: Group I (n=69), alive and competent, therefore patients were interviewed; Group II (n=8), alive but not competent to be interviewed; Group III (n=37), survived hospitalization to live at home for at least 30 days, but died before participation; and Group IV (n=46), patients who died during hospitalization or within 30 days of hospital discharge. Families were therefore interviewed for Groups II, III and IV regarding decisions they would make for the hospitalized person. Median ICU length of stay was 3-5 days and mean ($\pm$SD) APACHE II scores were: Group I = 13 $\pm$ 7, Group II = 12 $\pm$ 4, Group III = 16 $\pm$ 6 ($p<0.05$), and Group IV = 20 $\pm$ 8 which indicates low acuity.

Most patients (74%, n=51) stated they would be "completely willing" to undergo ICU for very brief periods of life prolongation. Only 4% (n=3) stated they would be "unwilling" to choose ICU for any period of life prolongation. Family preferences were similar. Within Groups II, III and IV combined (n=60), 67% of family members said they would choose ICU care regardless of the life prolongation outcome. Families of patients who died were significantly less likely to choose ICU ($p=0.02$). Patients (n=11) and families (n=17) would not

choose ICU if there was no hope of recovery, if the patient would be kept alive by machines (n=7, n=10, respectively) and if the patient were vegetative or neurologically impaired (n=7, n=10, respectively).

Elpern, Patterson, Gloskey, & Boone (1992) also reported findings from a study of patient preferences following a relatively brief ICU stay. The sample was comprised of adult patients discharged from the medical/coronary ICU following a stay of ≥ 48 hours, all of whom were alert and oriented. Patients were evaluated within 48 hours of discharge to determine eligibility and interviewed according to their availability and tolerance. Most participants (96%) stated they preferred life support to restore their usual state of health. If they were to remain mentally competent but be functionally dependent, this percentage decreased to 67%. If they were terminally ill, the percentage decreased further to 36% and to 30% if they were in a permanent vegetative state. As in the previous study, the average ICU length of stay was relatively short (4.5 days) and the mean APACHE II score (13.3) indicated low acuity. ICU stay and APACHE II scores were significantly higher (4.8 days and 17.9, respectively; $p < 0.003$) for patients who did not participate in the interviews.

More recently, researchers have examined decision-making and outcomes following substantially longer (≥ 14 day) ICU stays (Teno et al, 2000). The sample was recruited from 5 ICUs. Patients (n=1457) were at an advanced stage of the following conditions: non-traumatic coma, acute respiratory failure, multiple organ system failure with sepsis or malignancy, chronic obstructive pulmonary disease, congestive heart failure, cirrhosis, metastatic colon cancer, or inoperable non-small cell lung cancer. The patient or a family decision-maker was interviewed during the second week of hospitalization when the majority (91%) were still in the ICU. Slightly less than half of patients/families (45%) preferred a life extending approach, while 36%

expressed a preference for comfort even if it shortened life. The authors did not distinguish between the preferences provided by patients or family members. However, it is likely that because most of the patients were very ill family members would have been the primary decision-makers. Whether their decision was the same as that of the patient is not known.

In one of the few studies that focused on MV, Mendelsohn et al (2002) examined patients' preference for MV following a period of $\geq$ 48 hours of ventilator support. A total of 115 patients/family members were interviewed with the Patient Preference Tool one year following ICU admission. The patients were recruited from medical, neurological, trauma and general surgery ICUs. When the patients/family decision-maker was interviewed, 86.6% indicated they would choose MV again, with younger (< 65 years old) ($p = 0.0006$) (90% vs. 68%) and healthier (92.5% vs. 77.4%, $p = 0.01$) having higher odds of choosing MV compared to older and sicker patients. In addition, the authors examined the relationship between preference and QoL. Those patients who were more likely to choose MV had significantly better physical function as measured by the SF-36 physical component ($p = 0.004$), the activities of daily living (ADL) ($p = 0.02$) and instrumental activities of daily living (IADL) ($p = 0.004$).

In summary, most patients who experienced an ICU stay would be willing to experience a repeat ICU stay for even brief prolongation of life, but there were only 69 patients in this sample, who had experienced a median ICU stay of 3 days. Preference for life support increases if there would be a return to usual health, with a reduction in the number of people who prefer life support under the condition of functional or cognitive decline. Patients experiencing a longer ICU stay tend to have a reduced desire for continued life support or repeat treatment. Consequently, preference for ICU care and life support appears to be related to resultant QoL and physical functioning.

2.3 QUALITY OF LIFE, PHYSICAL FUNCTION, & DEPRESSION

Chelluri et al (1993) examined QoL, physical function, and symptoms of depression in 97 elderly (≥65 years) individuals following an ICU admission of approximately 7 days. Patients were excluded from the study if they were admitted to the ICU following uncomplicated elective surgery, transplantation, or had a poor prognosis secondary to cancer. Survivors were evaluated at 1, 6 and 12 months post hospital discharge. In this sample, mean APACHE score was 18 ± 0.9, mean ICU LOS was 5 ± 1.1, and duration of MV was 5 ± 0.9 days for patients 65-74 years of age (n=43). Among patients > 75 years old (n=54), mean APACHE score was 20 ± 0.8, mean ICU LOS was 7 ± 1.1 and mean duration of MV was 6 ± 0.9 for patients. QoL, measured by the perceived quality of life index (PQOL), tended to increase over the time post discharge for patients 65-74 years of age (n=12) and those > 75 years old (n=12), and there was no significant difference. Physical functioning data, measured by the ADL index, was available for 32 participants. Most of the patients were independent pre and post hospitalization and there were no significant differences. Depressive symptoms, measured using the CES-D, decreased over time when comparisons were made at the three follow-up time periods (10, 8.5, 6; $p = 0.009$). Although the sample was small, the PQOL and CES-D results are similar to previous reports of elderly cohorts living in the community, who did not experience an ICU admission.

Konopad, Noseworthy, Johnston, Shustack and Grace (1995) studied all adult (≥ 17 years old) patients admitted to a medical-surgical ICU with the exception of patients who died within 24 hours of admission. Although 504 patients were enrolled, only 293 completed the data collection at 12 months. Attrition was due to refusal (n=6), lost to follow-up (n=79), and death (n=126). If the patient was unable to complete the questionnaires, a proxy was asked. Table 1 shows the composition of those completing both sets of questionnaires.

Table 1 Number of patients and proxies completing questionnaires

Baseline & 12-month questionnaires	**N=293**
Patient completed both	226
Patient baseline, proxy at 12 months	11
Proxy baseline, patient 12 months	40
Proxy completed both	16

The perceived health for the total group was significantly higher at 12 months ($p< 0.05$); when patients completed the questionnaires for both time periods, perceived health was significantly higher ($p < 0.05$). Physical function, based on level of activity and ADL, decreased significantly ($p<0.001$) from baseline compared to one year later.

Eddleston, White & Guthrie (2000) evaluated the outcome of ICU patients alive at 3 months post ICU discharge. The outcomes of interest were survival, ICU related psychological morbidity, QoL, and employment status. Patients were contacted 8 weeks following ICU discharge to schedule a 12-week clinic interview, which consisted of questionnaire completion and interview. Follow-up at 6 and 12 months was done via telephone. During admission to the ICU, there were 370 eligible patients for the study; at 3 months, 227 were alive and 143 agreed to participate. Of interest, all deaths after 3 months occurred in those that declined participation. Approximately 80% were satisfied with the speed of their recovery at 3 months, although complaints of fatigue continued for 12 months (38.2% of women, 32% of men). Of note, everyone who had been employed prior to ICU admission had returned back to work by 12 months. Seven patients (2 men, and 5 women) had increased depression scores on the Hospital Anxiety and Depression Scale (HAD), but only 1 man had clinical depression that required treatment.

Rivera-Fernandez, Sanchez-Cruz, Abizanda-Campos & Vazquez-Mata (2001) conducted a prospective, observational study in Spain to examine QoL prior to an ICU admission. A patient or family member was interviewed using a researcher developed QoL instrument upon admission to the ICU. The admission QoL score was lower for patients who personally responded, then for those for whom a family member responded (3.62 ± 4.24 vs. 3.94 ± 4.66, respectively; $p < 0.005$). Although most patients had a good QoL prior to ICU admission, the < 10% who did not had a higher mortality ($p < 0.001$). In addition, lower QoL scores were associated with higher APACHE III score ($r = 0.217$, $p < 0.001$) and older age ($r = 0.289$, $p < 0.001$), supporting that older, sicker patients had a poorer QoL prior to admission.

Chelluri et al (2004) examined QoL, physical function and depressive symptoms following $\geq$ 48 hours of MV in 817 patients admitted to either a medical, neurologic, trauma, or surgical ICU. The survivors (n=359) were interviewed 12 months following the ICU stay. If patients were cognitively impaired or unable to participate because of medical condition, proxies were interviewed for all but the depression instrument (patient interview, n=155; proxy interview, n=76). Patients or proxies were asked to self-rate health status of the patient compared to one year ago. The majority (62%; n=106) rated their health as much better or somewhat better than one year ago. Mean scores for physical function using the ADL (ranges 0-6, with 6 indicating dependence) were 0.59 ± 1.28 for patients and 2.89 ± 2.52 by proxy. For IADL (ranges 0-8, with 8 indicating dependence), mean scores were 3.38 ± 2.86 for patients and 5.01 ± 2.96 for proxy responses. Scores on the SF-36 physical function component (ranges 0-100, with lower score indicating dependence) were 52.3 ± 33.09 for patients and 31.58 ± 38.17 by proxy. The depressive symptomalogy score as evaluated by the CES-D (scores > 16 indicate the presence of depressive symptoms) was 12.16 ± 11.02 for patients. Using a proportional odds

logistic model analysis, the factors (after adjusting for patient type, gender, and ICU acuity) associated with functional decline were age and baseline IADL scores.

In summary, the potential that patients who experience an ICU stay of less than seven days will return to pre-hospital status appears to be influenced by their age, pre-hospital physical functioning, and acuity. There are differences when surrogates are asked to assess QoL; patients self-rated QoL higher than proxy ratings. When adult patients, including the elderly, gave responses, ratings of perceived health were significantly higher than for proxies, but physical functioning was decreased. Patients who survived to 3 months following an ICU stay, complaints of fatigue continued for 12 months, but those employed prior to the ICU stay had all returned to work. In a study done in Spain, poor pre-ICU QoL was associated with higher acuity and older age.

2.4 QUALITY OF LIFE, PHYSICAL FUNCTION & DEPRESSION FOLLOWING PMV

In a sample of patients recruited from a broad variety of ICUs, researchers (QOL-MV, 2002) enrolled patients who had been on MV $\geq$ 48 hours, (median 8.6 days). Patients or proxies were interviewed during hospital stay and two months after ICU admission. The interviews were done either in person by telephone if the patient lived > 50 miles from the hospital. The 2-month mortality was 43%. The median (25^{th}, 75^{th} percentile) ADL score was 0 (0, 4) (n=261); IADL was 4 (0, 6) (n=213); SF-36 physical functioning was 25 (5, 70) (n=223). A higher score on all indicates greater dependence. Median ADL and IADL scores for patient results were 1 and 4, whereas proxy results were 5 and 7. Median SF-36 physical for patients was 30, but was 0 for proxies. The CES-D median was 14 and 13 (6 to 20) indicating that the patients were at risk for

depression. These results demonstrate decreased functioning from pre-hospital condition and a disagreement between scores provided by patients and proxies.

Researchers in Finland reported on the QoL and physical functioning of patients requiring a prolonged ICU stay of $\geq$ 4 days (mean 13.6 ± 11.8 days; n=718) and compared them to the general population (Niskanen et al, 1999). The Nottingham Health Profile, designed to measure QoL and a modified ADL index to measure physical function were mailed to the patients 6 months after ICU admission. Although some did not answer all questions, more than 85% reported functioning independently and the greater the independence, the greater the QOL. It appeared that physical functioning and QoL were related to increased length of time in the ICU.

In a study designed to compare outcomes of short (<24 hours) (mean 2.4 $\pm$ 1.3 days) and long term (>96 hours) (mean 16.3 $\pm$ 17.8 days) MV, Douglas, Daly, Gordon, & Brennan (2002) interviewed patients who had been admitted to an ICU by telephone within 2 weeks of hospital discharge and at 6 and 12 months to assess functional and psychosocial status. None of the clinical or demographic variables were significantly related to QoL as measured by the Sickness Impact Profile (SIP) at 12 months after adjusting for discharge QOL. Patients who required short term MV tended to have better QoL than long-term MV patients at all three time periods, but the difference was not statistically significant. Short-term patients did have a significantly better physical functioning at all three time periods (p=0.048). In addition, the short-term patients were more mobile (p=0.04) and better able to care for themselves (p=0.022).

Carson, Bach, Brzozowski & Leff (1999) reported outcomes of 133 patients who were transferred to a long-term acute care facility (LTAC) after spending > 14 days on mechanical ventilation. Mean age was 71 $\pm$12 years and the patients had 3.2 $\pm$ 1.6 comorbidities. Median

ICU stay prior to LTAC admission was 25 days (range 9-123 days) and all had a tracheostomy. The researchers contacted 1-year survivors or family by telephone to gather survival and physical functioning data. At 1 year, 66 (50%) patients had died in the LTAC, 51 (38%) were weaned from MV, 67 (50%) were discharged from the LTAC, and 30 (23%) survived 1 year. At LTAC admission, 19 (63%) of the survivors had been independent. At 1-year, 11 (8% of total sample & 42% of 1-year survivors) participants were oriented, ambulatory, and independent.

Nasraway et al (2000) examined the 1-year outcomes in 97 patients transferred to an extended care facility (ECF) after a $\geq$ 7 day ICU stay. Mean ICU stay was 39 days (range 7-276 days). The majority (96.9%, n=94) were on MV in the ICU, and 73.2% (n=71) were on MV at discharge from the ICU. At one year, 49 (50.5%) patients had died, 16 (16.5%) remained in an ECF, 3 (3.1%) remained in an acute care hospital 3 (3.1%), 4 (4.4%) where in a nursing home, and 24 (24.7%) were discharged to home. Thirty patients were interviewed and half rated their QOL as good or excellent and 9 (30%) as fair. Mean scores on the Barthel Activities of Daily Living Index were 11.5 $\pm$ 7.6, which indicates functional dependence.

In a study examining patients who had undergone an extended period of MV resulting in admission to a hospital-based ventilator rehabilitation unit, Chatila, Kreimer, & Criner (2001) reported on outcomes of patients who required MV for 45 $\pm$ 36 days. Patients or caregivers (n=46) were contacted by phone 1-2 years (23 $\pm$ 18 months) after their discharge from the unit. Those patients that agreed to participate (n=25) were contacted again three years (n=14) after the first phone call. The majority of patients had a physical score of 12 $\pm$ 12 on the Sickness Impact Profile (SIP), with the worse functioning in sleep and rest, ambulation, and physical dimension. During the 1-2 year follow-up evaluation, there were no significant differences in scores when

compared with the first evaluation. In this study, older patients (r=-0.40; p=0.045) had better QoL after recovery.

In addition, studies have examined the QoL of patients undergoing specific types of procedures that resulted in ICU admission, most commonly cardiac surgery. In a study by Engoren, Buderer & Zacharias (2000) patients who had cardiac surgery and required PMV (> 7 days) were contacted by phone, one to seven years post ICU discharge. During the study time frame, a minority (3%; n=123) of the 4,073 patients required PMV. Of these, 19 (15%) died in the hospital and 51 (41%) died after discharge. Of the 53 survivors, 40 participated in phone interviews. Some participants had limitations with ADLs (16%), more had limitations with moderate activity (60%), and most with vigorous activity (94%). Almost half (41%) had no limitations at home or work and most (59%) described their general health as good to excellent. Findings of this study support improved recovery in patients who undergo surgical procedures where the goal is resolution of the underlying condition. In patients who require ICU admission due to exacerbation of a chronic underlying health problem, e.g., COPD, outcomes may be less positive.

In summary, it has been shown that PMV is associated with high mortality, decreased QoL, functional limitations, and risk of depression. Decline in QoL and physical functioning appears to be related to length of time in the ICU and on MV. It seems that if this population survives for a year, about half of them will rate their QoL as good and be functioning independently, especially if a surgical procedure resulted in the ICU stay.

2.5 TRACHEOSTOMY

As the patient progresses to a chronic need for MV, physicians begin to consider the need for tracheostomy. It has generally been accepted that patients who require short term MV are well served with an endotracheal tube whereas those on long-term ventilation are better suited with a tracheotomy (Heffner, Miller, & Sahn, 1986 and Lewis, 1992). Two primary factors evaluated when considering the decision to perform a tracheostomy include anticipated time on MV and the discharge plan. The advantages of tracheotomy include decreased risk of airway complications when PMV is required and the ability to facilitate weaning from MV and nursing care, specifically airway suctioning and mouth care. In addition, having a tracheostomy promotes increased patient mobility because the tube is more secure which allows easier bed-to-chair transfer, allows transfer to a lower level of care, improves patient comfort, facilitates speech, allows oral nutrition, and psychological benefit (Lewis, 1992).

While there is agreement on the need for tracheostomy, there is no consensus on the ideal time for tracheostomy. In 1989, Bishop stated that the timing of tracheostomy should be driven by nursing issues – ease of nursing care, patient comfort, ability to communicate, and appearance to the family. He further stated that tracheotomy should be performed when the patient is medically stable, rather than because of the hypothetical benefit of sparing the larynx. Rodriguez and colleagues (1990) concluded that, in a homogenous group of critically ill patients, early tracheostomy was associated with a significant decrease in duration of MV, as well as shorter ICU and hospital stays, compared with endotracheal intubation. There were no deaths attributed to tracheostomy and overall morbidity of the procedure was 4%. They concluded that early tracheostomy has an overall risk equivalent to endotracheal intubation. Furthermore, they asserted that early tracheostomy shortens days on MV, in ICU, and in hospital and should be considered for patients in the ICU at risk for more than 7 days of intubation.

Heffner (1991) critically reviewed studies that have investigated timing of tracheostomy. He began with the premise that no available study definitively establishes an absolute ideal time for tracheostomy. His recommendations were that if extubation appears probable within 7 to 10 days from the onset of respiratory failure, tracheostomy should be avoided. Conversely, if it appears airway support will be required for > 21 days, an early tracheostomy should be performed to enhance patient care and comfort at the first opportunity after patient stabilization. When the anticipated duration of intubation appears unclear, he recommended daily re-evaluation. The author fails to provide guidance for patients on MV for 11 – 20 days.

Lesnik, Rappaport, Fulginiti, and Witzke (1992) retrospectively examined the medical records of 101 patients who had sustained a blunt, multiple organ injury and underwent tracheostomy. Group I (n=32) had the procedure performed within the first four days of injury (early tracheostomy) and Group II (n=69) more than 4 days after surgery (late tracheostomy). There was no significant difference between the two groups in terms of age, Injury Severity Score, Glasgow Coma Score, and associated injuries. Mean MV time for Group I was 6.0 ± 3.4 days and for Group II was 20.6 ± 12.2 days ($p < 0.001$). In addition, Group I had 6 (19%) nosocomial pneumonias versus 41 (59%) in Group II ($p < 0.001$).

Brook et al (2000) conducted a prospective cohort study of 90 consecutive patients in the medical ICU comparing patients who had an early tracheostomy with those having a late tracheostomy. Early tracheostomy (N=53) was defined as a procedure performed by day 10 of MV and late tracheostomy (N=37) after day 10. Tracheostomy was performed at 5.9 ± 7.2 days in the early group and at 16.7 ± 2.9 days in the late group ($p<0.001$). The early trach group had lower mean APACHE II scores on the first 24 hours of the ICU admission, a lower prevalence of ARDS, and fewer females compared to the late tracheostomy group. In addition, PaO_2/FiO_2

ratio was significantly greater in the early tracheostomy group than in the late tracheostomy group. Mean duration of MV was significantly shorter for the early tracheostomy group (28.3 $\pm$ 28.2 days) compared to the late tracheostomy group (34.4 $\pm$ 17.8 days) ($p<0.005$). In addition, the authors found that the ICU length of stay for the early trach group was 15.6 $\pm$ 9.3 days versus 29.3 $\pm$15.4 days ($p< 0.001$) for the late trach group. While these findings suggest that early tracheostomy may benefit patients by facilitating less time on the ventilator and reducing time in the ICU and hospital, there were substantial between group differences that suggested lower acuity of illness in the early tracheostomy group, e.g., lower APACHE scores, lower incidence of ARDS, higher PaO_2/FiO_2 ratio.

2.6 COMMUNICATION STATUS

There are frequent accounts of patients having difficulty communicating while in the ICU because of the critical nature of the illness, endotracheal intubation for MV, and medications that may be prescribed for analgesia and sedation (Happ, 2001; Connolly & Shekleton, 1991; Menzel, 1998). The inability to speak has been identified as the cause of feelings of anxiety, fear, and panic (Menzel, 1998; Bergbom-Engberg & Haljamae; 1989; Rotondi et al, 2002).

Pennock, Crawshaw, Maher, Price and Kaplan (1994) interviewed patients who were transferred out of the Surgical ICU (SICU) within 48 hours of coronary artery bypass surgery to determine which events occurring in the SICU were considered stressful. Patients (n=127) were asked to rate 23 potential stressors for degree of stress using a 4-item Likert scale (1- no stress to 4- extremely stressful), developed by the researchers. Participants were able to add to the list as well. A majority of patients (79% of 100 patients) rated endotracheal tubes and the inability to talk as extremely stressful or stressful. Improved communication techniques may help eliminate

this stressful experience, not only for acutely ill patients but also patient with PMV and tracheostomy.

The distress due to the inability to communicate is not unique to the United States, researcher in Sweden (Bergbom-Engberg & Haljamae, 1989) interviewed patients that experienced MV and found similar results. Patients were telephoned 2 months – 4 years after MV. If the patient could remember the experience of MV (n=158), they were interviewed for 1-2 hours about their ICU experience. Patients stated that fear and anxiety (47%) and the inability to talk (46%) was most distressful. The duration of MV was 6.4 $\pm$ 11.2 days (range 3 hours – 83 days). Patients on MV for > 7 days described their ICU stay as more threatening than patients on MV for 4-7 days. The authors did not mention if any of the patients had a tracheostomy.

Communication is compromised in the ICU because of critical illness, intubation, tracheostomy, neuromuscular disease, and paralytic medications. When the patient is unable to speak, communication in the ICU typically consists of non-vocal behaviors, for example mouthing words, hand gestures, and eye blinks (Happ, 2001). To prevent the fear, anxiety and stress associated with voiceless in the ICU, patients are assisted to write messages on paper or a 'magic slate', use alphabet boards, and computers (Lawless, 1975; Cronin & Carrizosa, 1984).

There are additional options to facilitate speech including an electrolarynx, a self-activated pneumatic voicing system, a speaking valve, and a speaking tracheostomy tube (Leder, 1990; Connolly et al, 1991; Happ, 2001). Evidence suggests that these techniques are infrequently and inconsistently applied. Although respiratory therapists occasionally initiate use of speaking valves, involvement of a speech therapist is dependent on a consultation with this discipline. "The significance of improved communication in ICU includes the ability to improve social interaction, the amelioration of suffering, patient participation in treatment decision-

making, and completion of relationships at the end of life (Happ, 2001, p.258)." Patients experienced an improved sense of well being when they could talk with a tracheostomy speaking-valve, and appeared happier and interacted better with family and nursing staff (Manzano, Lubillo, Henriquez, Martin, Perez & Wilson, 1993; Leder, 1990: Bell, 1996: Byrick, 1993).

Menzel (1998) examined the relationship between the intensity of intubated patients' feelings of anger and fear/worry at being unable to speak and severity of illness, communication status, the number of communication methods used, time on MV, MV history, and reason for MV. The intensity of emotional response was measured with the Emotion Scale, specifically the subscales for angry and worried/fearful, adapted by the researcher. The subscales were rated on a 5-point Likert-type scale, with responses ranging from "not at all" to "a great deal." Communication status was measured with a researcher-developed tool, consisting of 6 items rated on a 5 point Likert type scale. Mean scores on the emotion subscales indicated that the participants had moderate feelings of anger and worry/fear due to inability to speak. The patients used an average of 3.6 communication methods. Increased severity of illness ($p \leq 0.05$) and greater difficulty with communication ($p \leq 0.001$) were significantly associated with more intense feelings of anger at being unable to speak. Fewer MV days ($p \leq 0.05$) and greater difficulty with communication ($p \leq 0.001$) were significantly related with feelings of worry/fear at being unable to speak. Interestingly, patients' emotional responses and ease of communication scores changed 20% from intubated responses to post intubation responses, indicating instability of responses.

Researchers have also investigated types of communication aids that patients use when MV is required after hospital discharge. Bach (1993) reported outcomes from 89 patients

diagnosed with amyotrophic lateral sclerosis (ALS) who were supported by MV for 4.4 $\pm$ 3.9 years. Most (n=76) had a tracheostomy and the remainder was supported with non-invasive MV. Several types of communication methods were used including verbal (n=32), computer aided (n=21), non-verbal aids (n=32) and complete loss of communicative ability (n=4). Patients satisfied with the mode of communication established were more likely to remain at home and reported substantially improved QoL.

In summary, patients experience stress, anxiety, and worry because of the inability to communicate during acute critical illness resulting in MV. Long term it has been shown that patients who are satisfied with their ability to communicate have improved QoL, but no research has been done to examine the relationship between communication status and preference toward MV.

2.7 SUMMARY

Little research has focused on the preferences toward MV following PMV ($\geq$ 7 days) and tracheostomy, is the goal of this research. Two outcomes, QoL and physical functioning, have been the focus of most studies, examining long-term outcomes in patients experiencing PMV. Few studies have examined symptoms of depression and communication status. The goal of this study was to more broadly examine outcomes in patients who experienced PMV and tracheostomy including QoL, physical functioning, as well as symptoms of depression and communication status. Most prior studies used proxy decision makers to describe QoL and physical functioning when patients were unable to participate and findings indicate the responses often differ between patients and proxies. This research will collect preference data from patients to describe QoL, physical functioning, depressive symptomalogy and communication

status. Research has shown that long-term mortality for this population is high; therefore, data will be collected at 2 months to facilitate timely collection of this information and recruitment of a large sample. In addition, several sites, including hospital step down units, long-term acute facilities, and long-term care facilities will be used to access this population.

3 PRELIMINARY STUDY

A pilot study was done to describe decision-making about tracheostomy in medical ICU patients. The purpose was to describe the decision-making process undertaken by family members when asked to provide consent for tracheostomy in patients admitted to a medical intensive care unit (MICU). The research questions (RQ) answered by this pilot study were:

1. What factors influenced families in their decision to provide consent for tracheostomy tube placement?
2. What physician and nurse behaviors facilitated family decision-making regarding tracheostomy tube placement?
3. What behaviors hindered family decision-making regarding tracheostomy tube placement?

3.1 BACKGROUND

Patients who develop acute respiratory failure are typically managed with positive pressure mechanical ventilation and endotracheal intubation, a procedure that involves insertion of an airway into the nose or mouth (Whited, 1984). Endotracheal intubation can be quickly performed and quickly reversed in the event of improvement of the patient's condition (Austin, 1971). Therefore, it is the procedure of choice in emergent situations. Prolonged endotracheal intubation predisposes the patient to a number of risks. Laryngeal damage may result because the curvature of the endotracheal tube exerts pressure against the posterior laryngeal structures (Bishop, 1989). In addition, complications may result from excessive pressure of the

endotracheal tube cuff against the tracheal mucosa, which may produce mucosal ulceration and tracheomalacia (Lewis, 1992). Unplanned extubation, a major complication of endotracheal intubation, occurs in 3% to 16% of ventilator dependent patients and has the potential to worsen outcome by increasing mortality and prolonging ICU and hospital stay (Epstein, 2000). There are also important clinical considerations that result from the discomfort patients' experience from prolonged endotracheal intubation (Heffner, 1999).

For this reason, a tracheotomy is typically performed when prolonged intubation is required (Plummer & Gracey, 1989). There are several advantages to using a tracheostomy for airway management. A tracheostomy decreases airway resistance, which reduces the work of breathing, a factor that may promote weaning from mechanical ventilation (Diehl et al, 1999). Additional advantages include increased patient mobility (bed-to-chair transfers) by providing a more secure tube. There may be increased patient comfort because a tube holder is not required and decreased patient anxiety because it is easier to communicate with the health care team and family, with a consequent decrease in sedation needs. Tracheostomy may facilitate nursing care, specifically airway suctioning and mouth care (Heffner, 1999). Together, these factors may promote a more rapid recovery, resulting in shorter ICU and hospital length of stay (LOS).

However, families may view a request to provide consent for tracheostomy differently. The request may be viewed as an indication that the patient will not recover or that recovery may be extended for weeks or months. Families may view the request as the first step in preparing for transfer to another health care institution and wish to delay this outcome.

Family decision-making regarding the care of critically ill patients has primarily been studied in regard to withdrawing life-sustaining treatment. When making decisions about life-sustaining treatment, there are indications that families go through a series of steps that include

framing the question, reasoning about the decision, identifying a family spokesperson, and interacting with the healthcare team to obtain additional information (Tilden, Tolle, Garland, & Nelson, 1995). From interviews with families asked to make such decisions, Tilden and colleagues identified physician and nursing behaviors that were viewed as helpful to families including encouraging advanced planning, timely communication, clarification of families' roles, facilitation consensus among family members, and allowing expression of the family's grief. In several studies of decision-making about treatment for patients with cancer (Davison, Degner, & Morgan, 1995, Wallberg, Michelson, Nystedt, Bolund, Degner, & Wilking, 2000, and Pyke-Grimm, Degner, Small & Mueller, 1999), researchers reported that some patients preferred collaboration with their physician so that they were completely informed, but the majority preferred a passive role, allowing the physician to make decisions. Younger, educated patients tended to take a more active role in decision-making. Given long intervals spent in the ICU waiting room, it is likely that families also may also ask other families for their opinion.

Psychological aspects related to tracheostomy have been examined in several studies enrolling pediatric patients who received a tracheostomy. Baumgardner & Burtea (1998) assessed QoL in children who underwent tracheostomy in regard to family dynamics. Positive QoL aspects included growth as individual, intrinsic rewards for the child, and appreciation of others with a disability. Negative impacts on the family's QoL were mental and physical anguish, inhibitions of normal family functioning, and isolation. Cohen et al (1998) evaluated the QoL for children who had a tracheostomy for medically refractory obstructive sleep apnea versus surgery and reported that parents in the tracheostomy group ranked 95% of the items on their questionnaire as worse than parents in the surgery group. Bach & Campagnolo (1992) evaluated the psychosocial adjustment of 380 ventilator-dependent post-poliomyelitis patients

who used a tracheostomy versus noninvasive positive pressure ventilation (NIPPV) and found that 14.7% in the tracheostomy group expressed dissatisfaction with their lives in general, compared with 8.5% for the NIPPV group. Also, post polio individuals using NIPPV had higher ($p<0.02$) life satisfaction score than individuals with a tracheostomy.

Only one study was identified that assessed the perception of health care providers. Astrachan, et al., (1988) surveyed 60 critical care nurses to determine their perceptions of patient comfort and ease of care for patients with endotracheal intubation and tracheostomy. A large majority (77%) preferred tracheostomy for patients who required airway support. Almost all respondents (90%) felt that tracheostomy patients were more comfortable and, therefore, required less sedation and restraints. The majority (97%) also felt that patients with tracheostomies could communicate more effectively, and that airway care was simplified. In addition, 92% of nurses stated that they would prefer a tracheostomy for themselves or a loved one if more than 10 days of ventilatory support were required. A limitation of this study was that it focused on perceptions and did not assess whether conversion to tracheostomy changed patient management, e.g., mobility, sedation needs. Also, the study did not assess family perceptions.

When a tracheostomy is advised, the family is often asked to give consent for the procedure because the patient is unable to provide informed consent. A study of family decision making to withdraw life support in critically ill adults (Swigart, Lidz, Butterworth, and Arnold, 1995) described it as a deliberate process that involved gathering information from several sources, integrating it emotionally, and obtaining consensus with the other family members. Few studies have addressed how the family and patient (if able to provide consent) reason about the decision to provide consent for tracheostomy tube placement or attempted to identify physician

and nurse behaviors that facilitate family decision-making regarding this aspect of management or behaviors that hinder families and increase burden.

3.2 SIGNIFICANCE

Although most individuals on mechanical ventilation during an acute illness are readily weaned from ventilatory support once medically stable, a small percentage of patients require prolonged weaning (Rudy, Daly, Douglas, Montenegro, Song, and Dyer, 1995). Health care providers agree that prolonged ventilator weaning causes stress, anxiety, and financial hardships for the family members of the ventilator dependent individual as they wait nearby for recuperation. The process that families use to make proxy health care decisions during this time has not been thoroughly investigated. Understanding the process that families utilize to make a treatment decision, such as consent for tracheostomy, will be helpful in shaping professional behaviors that are supportive of that decision making process. Similarly, behaviors and communication styles that exclude family involvement or causes further burden can be identified and avoided.

3.3 RESEARCH DESIGN AND METHODS

Interviews were conducted with family members of patients who had given informed consent for tracheostomy tube placement in the MICU. A semi-structured interview guide was used. Family members were interviewed within 2 weeks of the procedure, as a result the experience would be fresh in their minds and they had an opportunity to recognize the benefits of their decision. The participants determined the duration of the interviews. The average has been about 30 minutes, and the longest has lasted an hour and twenty-five minutes. The

interviews were audiotaped to preserve originality of the data. The recordings were transcribed verbatim excluding personal identifiers. The interviewer made observational notes regarding the subject's tone of voice and non-verbal behavior during the interview. To ensure accuracy, the investigator read the transcripts while listening to the tapes. In addition, observations noted of the subject's body language (e.g., gestures, facial expressions) were inserted into the transcript. Once the audiotapes were transcribed, the tapes were destroyed. The investigator also collected basic information about the patient on the Pilot Study Demographic Tool.

3.3.1 Instruments

The semi-structured interview guide was used to direct the face-to-face interviews with subjects. Demographic characteristics and information about the patient was collected on the Pilot Study Demographic Tool. The information collected included the patient and family member's age, gender, and race; the subject's relationship to the patient, their years of education, and the primary decision-maker in the family prior to this illness from the family member's perspective. Patient data included gender, date of birth, age, race, diagnosis, reason for mechanical ventilation, Apache III score on admission and at the time of interview, any significant complications, e.g., sepsis, renal failure that occurred during this admission, number of days intubated prior to the tracheostomy, ICU and hospital length of stay on the interview date, and type of health care coverage.

3.4 DATA COLLECTION AND STATISTICAL CONSIDERATIONS

Family interviews were audio taped, transcribed and analyzed to extract meaning from the data. Analysis was concurrent with data collection. The constant comparative method was used to analyze the transcribed interviews. This process involved review of transcripts with the

goal of identifying main categories of data through micro-level coding and grouping codes into categories and coding these categories. Interrelated categories were collapsed to formulate concepts significant to the decision-making process about tracheostomy tube placement. Concepts that recurred frequently and appeared meaningful were used to identify themes that described the decision-making process, behaviors that facilitated family decision-making and behaviors that hindered families' decision making. Demographic data was analyzed with descriptive statistics and is used only to describe the sample.

3.5 SAMPLE GENERAL CHARACTERISTICS

The subjects for this pilot study were family members of 4 patients admitted to the MICU who require tracheostomy. The patient sample was selected purposively to include variability based on gender, age, and ethnicity characteristics. The racial, gender and ethnic characteristics of the proposed subject population reflects the demographics of Pittsburgh and the surrounding area and/or the patient population of the University of Pittsburgh Medical Center. There was no attempt to recruit subjects in respective proportion to these demographics. No exclusion criteria shall be based on race, ethnicity, gender, or HIV status.

3.6 INCLUSION/EXCLUSION CRITERIA

The family member was 1) at least 18 years old; 2) able to understand and speak English; 3) willing to be interviewed as part of the study; and 4) had given informed consent for elective tracheotomy tube placement for a family member in the MICU with a diagnosis of acute respiratory failure and no prior history of ventilator dependence or tracheostomy.

3.7 RECRUITMENT PROCEDURES

Prior to initiation of the pilot study, the principal investigator met with the MICU treatment team to explain the study. The medical director of the MICU informed the principal investigator daily of patients admitted who met the inclusion criteria. Medical and nursing personnel informed the family about the study and the opportunity to voluntarily participate. They explained that care would not be affected by a decision to participate. If a family member was willing to consider study entry, they were asked if their name and phone number could be given to the researcher, then the personnel notified the principal researcher. Once potential participants authorized release of their name and phone number, the principal investigator contacted them and explained the study.

The principal investigator met with the family member(s) in the location chosen by the family member, such as the patient room, quiet room or conference room. The study was explained, it's purpose, the subjects' and investigator's roles, the procedure for audio taping and interviewing. The principal investigator explained the potential risks and benefits of participation, privacy, confidentiality, and the right to decline enrollment or withdraw from the study without repercussions. An opportunity for the family member to ask questions and consider participation was provided. Once the investigator and family member agreed that the conditions of informed consent were met, the investigator and family member acknowledged agreement by signing the consent form. The interviews occurred at a time convenient for the family member. The goal was to recruit family members who had been asked to provide informed consent for a tracheostomy procedure because the patient was unable to give consent.

3.8 DATA ANALYSIS

Family interviews were audio taped, transcribed and analyzed to extract meaning from the data. Data collection and analysis in the grounded theory method was a cyclic and reiterative process. Analysis was done concurrent with data collection. The constant comparative method was used to analyze the transcribed interviews (Strauss, 1987). This process involved review of transcripts with the goal of identifying main categories of data through micro-level coding and grouping codes into categories and coding these categories. Open coding was performed line-by-line assigning axial codes to reflect the substance of the data. Interrelated categories were collapsed to formulate concepts significant to the decision-making process about tracheostomy tube placement. These axial codes were then assigned to build up a dense texture of relationships around the axis of the category (Strauss, 1987, p. 64). Concepts that recurred frequently and appeared meaningful were used to identify themes that describe the decision-making process, behaviors that facilitate family decision-making and behaviors that hinder families' decision making and classified as core categories (Strauss, p. 36). The relationship between core categories was proposed as a tentative conceptual framework for proxy decision making for tracheostomy. Demographic data was analyzed with descriptive statistics and used only to describe the sample.

3.9 RESULTS

3.9.1 Proxy Decision Maker Characteristics

Characteristics of the sample are displayed in Table II. They reflect diverse characteristics of proxy decision makers with regard to family relationship and sex.

Table 2 Demographics

Family Member	Age	Gender	Race	Relationship	Occupation of decision maker	Other family members present during interview
1	33	F	C	Wife	Secretary	None
2	64	F	C	Wife	Retired RN	Daughter
3	77	M	C	Son	Retired State Trooper	None
4	74	F	C	Wife	Housewife	3 daughters

3.9.2 Codes

There were 483 free nodes and 35 axial codes. The Axial codes are included in Table III. Some of the axial codes were specific to one participant, but most were shared by all of them.

Table 3 Axial Codes

Presentation	Consent	If asked sooner
Call for expert help	Risks	This experience
Failure by expert	Trach scheduled	Acceptance
Diagnosis	Recovery	Persuasion to seek treatment
Key happening	Restraints	Hospital course
Pre-impression of tracheostomy	Sedation	Planning
Why trach	Return of self	Trach explained
Trach first mentioned	Communication	Eased the trach idea
Initial reaction	Reaching equilibrium	Patient understanding
Nurse	Worries	Ventilator
Persuasion for trach	Post trach – physical	Trust
Learning about trach		Benefits

3.9.3 Core Categories

Five core categories emerged from the analysis of the transcribed interviews. These include groundwork, physician explanation, nurse support, risks and benefits, and self-work.

3.9.3.1 Groundwork

This category emerged as all of the proxies discussed their experience with giving permission. The participants told about receiving a warning or hint or clue that tracheostomy was going to be discussed. This gave them opportunity to begin self-work to learn more about tracheostomy. The axial codes that merged to form groundwork include learning about tracheostomy, trach first mentioned, pre-impression of tracheostomy. Proxies stated in the interviews statements that reflect this category:

"…we discussed with her (Lisa, a cousin, RN) earlier that this was going to be a possibility – that she told us that it would be a possibility down the road – and it came true. We were prepared…"(#3)

"…I've dealt with them… I guess I made it easy for myself." (#2)

"one of the nurses was the first one who told me. And she said, "Just so you know – if they can't get him – you know, he's not ready to go off the ventilator, they're going to have to do the tracheostomy." (#1)

"And we learned and learned and educated ourselves and spoke to everybody we possibly could." (#4)

3.9.3.2 Physician Explanation

All of the informants discussed at length the way the physician explained the family members condition and the rational for tracheostomy. Several points were stressed: he sat down;

he explained in terms that they could understand, and he answered all of their questions. The axial codes that were merged to form this concept include consent, explanation of tracheostomy, persuasion, and planning. Statements that demonstrate this category include:

"So, between the nurses and then Doctors D and K explained that to me…" (#1)

"At the time Dr. D sat down and explained to me exactly what it was and made sure that I understood …" (#2)

"It was easier with him just sitting down and explaining …" (#2)

"He brought us into a room, talked to us about what my mother had; what he was doing, what he and his staff thought about what needed to be done; and told us all the… he explained it really well." (#3)

"Well the way he sat down and explained to us – we felt very confident that was the way to go." (#3)

"Dr. K. couldn't have been more wonderful, more caring… and he explained it all to us." (#4)

3.9.3.3 Nurse support

This category explained as all of the participants discussed the helpful communication with the nurses. Some of the statements from the interviews that formed this category include:

"The first nurse, her name was C… she even said that if somebody in her family – like her husband or father and they said 'we need to do this' she'd say 'do it." (#1)

"With Jim's situation, she said it's definitely temporary. She said it's only to get him off the ventilator." (#1)

"And it was the nurse that explained it to her, not one of the doctors." (#2)

"… I made the nurse promise me that she would explain it to him when he woke up…" (#2)

3.9.3.4 Risks and benefits

This category emerged as all of the family members discussed the risks and benefits of tracheostomy. The axial codes that were merged were consent, persuasion, learning about trachs, benefits, restraints, sedation, worries, recovery, eased the trach, and patient understanding. Quotes from the interviews that highlight this concept includes:

"…because it's a good thing and it was better for him – and then when they said the risks of keeping the breathing tube in were to do permanent damage to your vocal cords, infection and things like that…" (#1)

"…since they did the trach, they could take the sedation down." (#1)

"… it had to be done." (#2 & 3)

"… as long as it was a temporary procedure that was fine." (#1 & 2 & 3)

"It leaves a small scar." (#3)

"We thought it would help." (#3)

"… she sure would be better without that tube down her – then she'd breathe easier with this trach on her." (#3)

"Dr. K did it… he got three inches from my father's face and told him everything." (#4)

"it would save his life" (#4)

3.9.3.5 Self-work

This category emerged as all of the participants discussed strategies that they used to learn more about tracheostomy. The axial codes that were merged include paramedic boyfriend, minister, family members, past experience, and the Internet. Direct quotes that represent this include:

"I knew it was a hole in the throat, and I've seen people with them." (#1)

"I talked to my parents about it and his father." (#1)

"…I mean I went home and looked up some stuff on the Internet…" (#1)

"And I had spoken with the minister and he …" (#2)

"I've seen enough done; been a part of enough that…" (#2)

"I've actually dealt with clients that have a medical condition as well." (#2)

"I've been around." (#2)

"So we've discussed it with her (Cousin, RN)." (#3)

"I've been taught to do a trach." (#3)

"My cousin's wife is a respiratory therapist." (#4)

"… so we learned about all this stuff." (#4)

3.9.4 Discussion

The proxies discussed a trajectory of acceptance and agreement with tracheostomy. This trajectory consists of groundwork being laid with the suggestion that tracheostomy was a possibility. When the physician sat down with the family, explained the treatment plan and rationale for tracheostomy, and answered the families' questions, the family was in a position to agree with tracheostomy and give permission. Nursing support, through an informal process substantiated the information given and provided emotional support. The proxies all conducted some type of self-work, that consisted of talking to known health care professionals, talking to other family and friends, and investigating sources of knowledge such as the Internet. It was beneficial when the information from all of these sources explained the risks and benefits of intubation and tracheostomy. In each situation, observing any improvement in the family member after the tracheostomy reinforced the decision as a good one.

The concept of decision making as a process that includes emotional and value-laden factors has been described in the disciplines of nursing, psychology, and economics Swigart et al, 1998). A rational-scientific model of decision making, similar to the "decision tree" that is often used for treatment protocols, is more familiar to health care providers (Swigart et al, 1998). This model of decision making that requires understanding of concepts and evaluation of the facts and possible outcomes is consistent with the process that the interviewed family members performed.

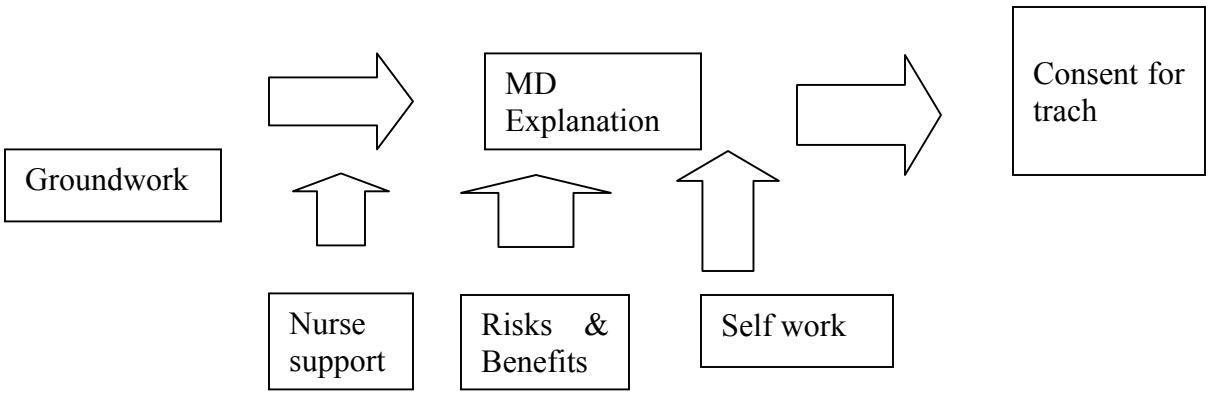

Figure 2 Conceptual Framework for Proxy Decision Making about Tracheostomy

The tentative conceptual framework of the process undertaken by family members when making proxy health cares decisions for tracheostomy is shown above.

3.10 LIMITATIONS

There were several limitations identified during this study. Most significant, is the lack of experience of the interviewer. A more experienced interviewer, skilled at probing would yield richer data. Second all of the participants were Caucasian and three of the decision-makers were the wives of the patient and one a son. Only four proxy decision-makers were interviewed. More participants would provide more information and husbands, daughters, and cousins might provide different viewpoints. It would be interesting to see if the experience is different for people of other nationalities, races, and religions.

Third, no decision-makers were interviewed who did not agree to consent for tracheostomy. Such individuals potentially could provide information on which heath care professional's behaviors hindered proxy decision-making about tracheostomy.

Fourth, only two physicians explained the patient's condition and the procedure to the family members and only four family members were interviewed. It would be interesting to examine the experience of proxy decision-makers that talked to other physicians in a larger sample. Finally, only one ICU and one hospital were used, which limited generalizability of the data gathered.

The results of this study can be used to guide the explanation and support provided to family members who are asked to make proxy health care decisions, such as permission for tracheostomy. Regardless of the timing of tracheostomy placement and the decision making regarding placement, for patients receiving MV, tracheostomy is a visible sign of the transition to prolonged mechanical ventilation or "chronic critical illness." Although these family members expressed satisfaction with the tracheostomy decision, little is known about the patient's perspective about prolonged MV and the resultant recuperation.

4 METHODS

4.1 SETTING AND SAMPLE

This study was conducted at the University of Pittsburgh Medical Center (UPMC) Health System and six of its long-term care referral sites. UPMC, a tertiary care facility, includes 9 high acuity ICUs that specialize in the care of medical (n=2), surgical (n=1), cardiac, cardiothoracic (n=3), neurosurgical, trauma (n=1), and transplant (n=2) patients. When a ventilator-dependent patient stabilized, they may be transferred to a long-term care referral site. When a patient, who met entry criteria, was discharged from the hospital and provided consent to participate, they were contacted at least 6 weeks following the entry point (surviving 7 days on MV and tracheostomy).

These facilities primarily served residents of Allegheny County which was comprised of Caucasians (83.8%), African Americans (12.4%), and Asians (1.7%) with nearly one-fifth (17.8%) of the population ≥ 65 years old (2000 U.S. Census data, retrieved March 15, 2003, from http://quickfacts.census.gov/qfd/states/42/42003.html). Greater Pittsburgh and Mountain View were located in Westmoreland County, which is adjacent to Allegheny County. Westmoreland County was comprised of Caucasians (96.6%), African Americans (2%), and Asians (0.5%) with a similar proportion of persons ≥ 65 years of age (18.3%) (2000 U.S Census data retrieved September 27, 2003, from http://quickfacts.census.gov/qfd/states/42/42129.html).

Study participants who met the following entry criteria were recruited: 1) able to speak English (needed for instrument completion); 2) ≥18 years of age; 3) on MV for at least 7 days; 4) received a tracheostomy during this episode on MV; alive 2 months post 7 days on MV; and 5)

cognitively intact as determined by the Mini-mental state examination (MMSE) (Folstein, Folstein & McHugh, 1975).

4.2 STUDY DESIGN

This exploratory study used a descriptive, cross-sectional design. Descriptive statistics were computed to characterize and summarize the data and bivariate parametric and nonparametric correlational analyses (based on the distribution) were conducted to examine the relationships between MV preference and other study variables. Each subject answered 5 questionnaires to assess: 1) preferences toward MV for actual and hypothetical situations (QOL-MV, 2002); 2) quality of life (Medical Outcomes Study [MOS] Short Form [SF]-36v2) (Ware, Kosinski & Gandek, 2002); 3) physical functioning (Health Assessment Questionnaire [HAQ] (Fries, Spitz & Young, 1980); 4) depressive symptoms (Center for Epidemiological Studies Depression Scale [CES-D] (Radloff, 1977); and 5) communication status (Patient Communication Survey [PCS] (Happ, Roesch, & Kagan, 2001-2003) The instruments were completed in the order listed during an interview session scheduled a minimum of 6 weeks (range 6 to 362.6 weeks) after the subject had been on MV for ≥ 7 days and received a tracheostomy. One investigator obtained all study data. The interview took place in the patients' room and lasted approximately 1.5 hours. All tools were administered verbally. A laminated card was presented to the patient to select answers. No proxy responses were used.

4.3 STUDY VARIABLES

4.4 DESCRIPTIVE DATA

4.4.1 Sociodemographic Characteristics

Demographic data were collected using the Demographic Information Questionnaire designed for this study (Appendix A.1). Variables of interest included: age, gender, ethnicity, education level, employment status prior to hospitalization, occupation, marital status, and insurance type.

4.4.2 Clinical Characteristics

Clinical data were obtained from the medical records using the Clinical Information Sheet designed for this study (Appendix A.2). Variables of interest included: primary diagnosis, comorbidities (Charlson Comorbidity Score [Charlson, Pompei, Ales, MacKenzie, 1987]), at the time of data collection, ICU and hospital length of stay, indication for MV, dates of intubation, tracheostomy, weaning from MV and decannulation.

4.4.3 Cognitive functioning

The instrument used to assess cognitive functioning is the Mini-mental state examination (Folstein, Folstein, & McHugh, 1975). This instrument is an 11-question general-purpose cognitive screening examination (Foreman, 1987) that exams the concepts of orientation, registration, attention and calculation, recall, and language. This instrument, which takes about 5 to 10 minutes to administer, quantifies the severity of cognitive impairment in persons with dementia or dementia-like conditions. A standardized score of < 24 indicates cognitive impairment. Patients with this score will be excluded from this study.

4.4.4 Dependent Variables

4.4.4.1 Preference regarding MV

The instrument used for assessing patient was designed for use in the Quality of Life After Mechanical Ventilation in the Aged Study (QOL-MV, 2002; Appendix A.3) to elicit preferences toward MV from critically ill patients who had recently received MV in an ICU. This instrument consisted of 18 questions for the purpose of eliciting preferences toward MV from critically ill patients who had recently received MV in an ICU and took about 15 minutes to administer. Initially patients were asked whether they would have chosen MV, given their ICU experience. Then the patients were asked to rate five domains related to their ICU and post-ICU experience: present health, pain/discomfort from MV, pain/discomfort in the ICU, family financial burden resulting from hospitalization, and family emotional and physical stress (caregiver burden) resulting from hospitalization. Each domain was measured on a 5-point Likert scale, ranging from 0 (positive side; i.e. excellent health, no pain/discomfort) to 4 (negative side; i.e. poor health, extreme pain/discomfort). To reduce order effects, patients were given the opportunity to change their responses after answering all five questions. If a response was changed, the new answer was recorded. Patients were given an opportunity to identify situations, which would alter their preference for MV. Then the levels of the five domains were manipulated individually until the patient changed his/her mind. This was the indifference point; i.e. the point at which the patient had no preference between the two alternatives.

This instrument can be administered in person or by telephone, but it was administered in person for this study. The principal investigator was trained and evaluated on her ability to satisfactorily administer and record the participants' responses for a series of practice interviews by the primary author of this instrument (Mendelsohn, 2002).

4.4.4.2 QOL

QoL was measured with the Short Form General Health Survey (SF-36v2) (Ware, Kosinski & Gandek, 2002). The SF36 was developed as a generic measure of physical functioning and well being (p.2: 3). It was comprised of eight subscales: physical functioning, role functioning, bodily pain, general health, vitality, social functioning, mental health, and reported health transition. Scores on four subscores (physical functioning, role functioning, bodily pain, and general health) were combined to yield a physical component score and scores on the remaining four subscales (vitality, social functioning, mental health, and reported health transition) combined to yield a mental component score. The total scores ranged from 0-100, where higher scores indicate greater QOL and general health. The reliability coefficients equal or exceed 0.80 (p. 7:4). Internal consistency and item discriminate validity equals or exceeds 0.40 (Ware, Kosinski & Dewey, 2000). The SF-36 has been used successfully with individuals with both acute and chronic illnesses, including individuals experiencing MV (Eddleston et al, 2000). In ongoing research involving patients on MV, the time to complete this instrument ranged from 15 to 20 minutes.

4.4.4.3 Physical Functioning

Physical Functioning was measured using the Health Assessment Questionnaire (Fries, Spitz & Young, 1980). The HAQ was first developed to evaluate physical functioning for patients with rheumatoid arthritis. The tool quantifies 8 general constructs (dressing, grooming, arising, eating, walking, hygiene, reach, grip, and outside activity with 18 items that are scored from 0 – 3 (without any difficulty, with some difficulty, with much difficulty, unable to do), an item about use of aids or devices, such as a cane or wheelchair or help from another person. The highest score on any question within the subdomain was the score for that subdomain. Adding

the scores and dividing by the total number of components answered calculated the index. This tool can be completed through self-administration, telephone or interview. Internal consistency estimates ranged from 0.71(Milligan, Hom, Ballou, Persse, Svilar & Coulton, 1993) to 0.94 (Pincus, Summey, Soraci, Wallston, & Hummon, 1983). Two-week test-retest reliability estimates ranged from 0.87 to 0.98 (Fries, Spitz & Young, 1982). In 32 patients with COPD, researchers obtained 2-week test-retest reliabilities, which ranged from 0.972 to 0.975 (unpublished data). Validity had been assessed by examining relationships with the Functional Status Index (r=0.75) and the Sickness Impact Profile (r=0.78) (Liang, Larson & Cullen, 1985). In ongoing research involving patients on MV, the time to complete this instrument ranged from 3 to 8 minutes.

4.4.4.4 Depressive symptomalogy

Depressive symptomalogy was measured using the Center for Epidemiological Studies Depression Scale (CES-D) (Radloff, 1977). This tool was a 20-item Likert scale, which included items of depressed mood, feelings of guilt and worthlessness, helplessness and hopelessness, loss of appetite and sleep disturbances. Scores ranged from 0-60, with established scores of $\geq$ 16 suggesting risk of clinical depression. Coefficient alpha ranged from 0.84-0.90. Correlations with nurses, and other scales ranged from 0.44-0.75. The time to complete this instrument ranged from 10 to 15 minutes.

4.4.4.5 Communication status

Communication status was evaluated using the Patient Communication Survey (Appendix A.7) (Happ, M, Roesch, T, Kagan, 2001-2003). This new tool in development was a 9-item Likert scale that elicited three dimensions of communication: communication satisfaction, ease of communication and success of communication. The lower the score the greater the

communication status. Scores ranged from 0-36. The time to complete this instrument ranged from 5 to 8 minutes. In addition, the survey collected information about the method(s) of communication used by the respondents.

4.5 JUSTIFICATION OF SAMPLE SIZE

This preliminary study was done to test the feasibility of a future study to establish effect size. The effect size will be used to establish the sample size needed to ensure adequate power for a future study to determine patient preference. Subjects were 30 patients who had experienced PMV (> 7 days) and tracheostomy and discharged from a high acuity ICU.

4.6 PROCEDURES FOR DATA COLLECTION

4.6.1 Recruitment Process

The study was explained to the staff of the participating units, including inclusion criteria. The researcher contacted staff to inquire about status of potential participants. Brochures were given to the staff to present to potential participants. If the patient expressed interest in study participation:

a. the patient was instructed to contact a member of the research team directly for additional information (See request for screening waiver below).

b. medical/nursing staff members who were not study investigators obtained IRB approved written authorization from the patient to: 1) share with the research team that he/she was interested in study participation; 2) share with the research team health information related to eligibility for study inclusion; and 3) allowed a member of the research team to contact the patient to further inform them about the study or

c. a medical/ nursing staff member who were study investigator reviewed the subject's health information to determine if the subject was eligible for study entry.

Screening Waiver: The PI requested IRB approval of a waiver of informed consent for screening to determine if potential participants entry criteria. This screening waiver applied to

any potential participants/family members who called the PI directly regarding their interest in the study. IRB criteria for granting this waiver was: 1) the respective research procedures presented no more than minimal risk of harm to the involved subjects; and 2) the information obtained during the screening phone call related to care normally required after admission to an intensive care unit, i.e., support with mechanical ventilation, tracheostomy, etc. A screening script was used for these phone calls. If the subject did not meet inclusion criteria, all information collected during the screening process was destroyed.

Investigator Waiver: The PI requested a waiver of informed consent/HIPAA authorization before a medical record review of the patient's chart for inclusion/exclusion criteria was conducted by medical/nursing staff members who were directly involved in the health care of the potential research subject and also research team members. Through this waiver, medical/nursing staff members were permitted to access protected health information to determine if the potential research subject qualified for study entry. Access to patient protected health information by these research team members involved no more than minimal risk to the privacy of the patient.

To ensure that the risk to privacy of the involved patient was minimal, any identifiable protected health information collected for the purpose of identifying potential subjects was stored in a secure manner (e.g., locked file and password protected database) accessible only to the PI and destroyed immediately after determining whether the patient qualified to participate in this research study. Any information recorded for the purpose of identifying patients for recruitment into this study was not used by or disclosed to any research study investigator who was not also directly involved in the care of that involved patient. Also, this information was not reused or

disclosed to any other person or entity, except as required by law or for authorized oversight of the research study.

4.6.2 Administration of study instruments

Questionnaires to assess Patient Preference for MV , QoL (SF-36v2), physical functioning (HAQ), depressive symptoms (CES-D), and communication status (PCS) were administered to participants in this order. All tools were administered verbally. A laminated card was presented to the patient to select answers. No proxy responses were used.

Table 4 Study instruments

	Instrument	Variables	Data Sources
1	Demographic Information Questionnaire	Age, gender, etc.	Chart
2	Clinical Information Sheet	Diagnosis, Apache, comorbidities, etc.	Chart
3	SF-36	QOL	Patient
4	HAQ	Physical functioning	Patient
5	Communication	Communication status	Patient
6	CES-D	Symptoms of depression	Patient
7	Preference	MV Preference	Patient

4.7 DATA ANALYSIS

A process for data management was implemented to ensure accuracy and completeness of data collection and recording on a case-by-case basis via proof reading and the generation of

descriptive statistics with graphical representation of the variables prior to data analysis. The descriptive statistics included mean, standard deviation, range and contingency checking. There was no missing data.

The underlying assumptions of the statistical procedures to be done were assessed. If there were violations of the assumptions, such as lack of independence of observations, non-normality, non-linearity, and homoscedasticity, data transformations were performed as appropriate and re-evaluated.

For all statistical tests (correlations, partial correlations, 2 group t tests, and Wilcoxon Rank Sum test), a p-value of less than 0.05 was selected apriori to indicate statistical significance.

Descriptive statistics were done to describe the sociodemographic, clinical characteristics, communication status, physical functioning, quality of life, depressive symptomatology, and preference characteristics of the sample. Frequency distributions and proportions were used for categorical data and measures of central tendency, including mean, median, range, and standard deviation, were analyzed for continuous variables. The non-parametric Wilcoxon Rank test for non-normally distributed variables and the two-group t test for normally distributed variables was conducted to compare the groups – preferred vs. not preferred.

4.8 LIMITATIONS

The limitations of this study included:

Only one health system and geographic area was used to recruit participants.

Data was only collected at one time period.

The participants recruited included those living at the time of the study.

Those cognitively impaired were not included.

Only one method of addressing preference was used. There may be a more effective method, such as a qualitative approach.

5 RESULTS AND DISCUSSION

(Presented in Manuscript format)

5.1 INTRODUCTION

Care in the intensive care unit (ICU) is associated with significant costs and critically ill patients who require prolonged mechanical ventilation (PMV) account for a substantial proportion of these costs (Heyland et al, 1998). Although most individuals who require mechanical ventilation (MV) during an acute illness are quickly weaned from ventilatory support, a minority, estimated at 3 to 6% of all patients admitted to the ICU, require prolonged weaning (Rudy et al, 1995; Douglas et al, 2001). The cost of caring for patients who are difficult to wean is related to the time and effort-intensive nature of the weaning process, extended stay in acute and long-term care facilities, and the morbidity associated with increased time on the ventilator (Clochesy et al, 1997).

In addition to the high costs associated with treatment, a prolonged ICU stay is associated with a high mortality. In studies conducted within the past 5 years, mortality rates for patients who require PMV ranged from 43% at 2 months after hospital discharge to 67 at 6 months after hospital discharge (QOL-MV, 2002; Seneff et al, 2000; & Douglas et al, 2002). Higher mortality was associated with increased severity of illness, increased age, and poorer physical functioning before hospitalization (QOL-MV, 2002). Further, the need for PMV is an indication of increased severity of illness and prolonged recovery trajectory (Douglas et al, 2001).

Another outcome of prolonged critical illness is decline in physical functioning and subsequent need for an extended stay in long-term care facilities. Although one study reported that the majority of patients were independent in several daily activities, such as bathing, dressing,

feeding, and walking from room to room, at six months following ICU discharge (Niskanen et al, 1999), most studies report a decline in physical functioning (QOL-MV, 2002; Chelluri et al, 1995; Wissam et al, 2001). In a prospective study that enrolled 817 patients who required MV for ≥ 48 hours, Chelluri et al. (2002) found that patients' physical functioning was worse at 2 months following ICU discharge compared to before hospital admission. Hoffman, et al (2003) reported that only 20% of patients were discharged to home 1-month following ICU discharge and 39% at 4-months after discharge in a prospective study that enrolled 80 patients who required MV for ≥ 7 days.

Most studies examining outcomes following PMV have focused on physical functioning, quality of life (QoL), morbidity, mortality and the care giving experience. Patient preferences regarding PMV have rarely been explored (Mendelsohn et al, 2002). Of studies that examined preferences, most were anticipatory in nature. Patients were asked about future end-of-life decision-making, use of advanced directives, or treatment preferences for conditions likely to require MV such as end-stage chronic obstructive pulmonary disease (COPD), amyotrophic lateral sclerosis, and muscular dystrophy (Tilden et al, 1995; Hoffman et al, 1997; & McKinley et al, 1996). It is unclear whether an individual who have experienced an episode of acute illness, including PMV, would have the same preferences as verbalized before the event (Mendelsohn et al, 2002). In order to fully examine preferences, it is important to elicit this information from individuals who undergone this experience and, therefore, have first hand knowledge of its impact.

In one of the few studies to examine preferences in ICU patients, Teno and colleagues (2000) interviewed 1494 patients who had been admitted to the ICU for ≥ 14 days (median 35 days) or their surrogate decision makers and physicians to determine how frequently prognosis,

preferences, and goals of medical care were discussed. Although 55% of these patients died within 6 months and those surviving had a significant functional impairment, only 34% of patients or surrogates had discussed preferences with their physicians by the second week of hospitalization. In a second study of patient preferences, Mendelsohn et al. (2002) interviewed 133 survivors of PMV ($\geq$ 48 hours; median 8 days) 12 months after ICU discharge and found that most (86.5%) would elect to undergo MV again. However, a substantial proportion of the original sample died (43% at 2 months) and 21% were lost to attrition (QOL-MV, 2002). In addition, PMV was defined as $\geq$ 48 hours, whereas the more common definition is $\geq$ 7 days (Seneff, 2000; Wissam et al, 2001; & Phelan, 2002).

There are a number of factors that might influence patient preferences regarding MV including its potential impact on ability to regain previous level of physical functioning, QoL, communication status, and depression. Survivors of PMV have been shown to have decreased QoL compared with the general population (Chatila et al, 2001). Nasraway et al (1999) described the outcomes of 97 survivors of prolonged critical illness (median ICU stay 39 days). One year later, only 11.5% of these patients were weaned from MV, had returned home and reported a fair or better quality of life, and good physical functioning. Communication status may also impact patients' preferences regarding MV, but this aspect of functioning has received little examination (Happ, 2001). Initially, MV is provided with an endotracheal tube, which eliminates the ability to speak. Extended use of an endotracheal tube, especially for periods > 7 days, may result in hoarseness (41-71% of patients), vocal cord immobility (19%), and laryngeal stenosis (0-5%), resulting in impaired speech (Stauffer, 1999). To minimize risk and promote patient comfort, a tracheostomy is typically performed after 7-10 days of MV if the patient is unable to wean from MV or has problems managing airway secretions (Heffner, 1993). However, the need for a

tracheostomy may also compromise patient ability to communicate, especially if a cuffed tube is required (Orringer, 1999). Although augmentative communication methods can be used, e.g., paper and pencil, tracheostomy tubes with speaking valves, and computer keyboards, such devices are infrequently and inconsistently used in the ICU setting (Happ, 2001). Recovery typically continues long after ICU discharge, an outcome which can increase risk for depression.

In the QOL-MV study (2002), 35% of 232 patients who required MV $\geq$ 48 hours had symptoms of depression 2 months following hospital discharge. Further study is indicated to better define patient preferences for the significant and growing population of chronically critically ill patients who require PMV.

The purpose of this study was to elicit preferences regarding MV in patients who received PMV and tracheostomy and characteristics associated with these preferences. The specific aims were to examine relationships between MV preference and selected potential influencing factors including demographics, clinical characteristics, QoL, functional status, depressive symptomatology, and communication status and identify factors influencing these preferences.

5.2 METHODS

5.2.1 Site and Sample

Subjects were recruited from a university-affiliated tertiary care institution located in southwestern PA (n=9) and six long-term care referral sites (n=21) during a 5-month interval (3/2004 – 7/2004). The referral sites included three long-term acute care (LTAC) hospitals and three skilled nursing facilities. Entry criteria were: 1) $\geq$18 years of age; 2) on MV for $\geq$ 7 days; 3) tracheostomy during this admission; and 4) able to understand English (required to answer

questionnaires); and 5) cognitively intact as determined by a standardized score of $\geq$ 24 on the Mini-Mental State Examination (MMSE) (Folstein et al, 1975). The study received Institutional Review Board approval and all subjects provided informed consent.

5.2.2 Design

Each subject answered 5 questionnaires to assess: 1) preferences toward MV for actual and hypothetical situations (Mendelsohn et al, 2002); 2) quality of life (Medical Outcomes Study [MOS] Short Form [SF]-36v2) (Ware et al, 2000); 3) physical functioning (Health Assessment Questionnaire [HAQ] (Fries et al, 1980); 4) depressive symptoms (Center for Epidemiological Studies Depression Scale [CES-D] (Radloff, 1977); and 5) communication status (Patient Communication Survey [PCS] (Happ, Roesch, Kagan, 2001-2003). The instruments were completed in the order listed during an interview session scheduled a minimum of 6 weeks (range 6 to 362.6 weeks) after the subject had been on MV for $\geq$ 7 days and received a tracheostomy. One investigator obtained all study data. The interview took place in the patients' room and lasted approximately 1.5 hours. All tools were administered verbally. A laminated card was presented to the patient to select answers. No proxy responses were used.

5.2.3 Instruments

Preferences Toward MV were assessed using an instrument designed to elicit preferences toward MV from critically ill patients who received MV in an ICU (Mendelsohn et al, 2002). When completing this portion of the study, subjects were first asked if they would choose MV again (yes/no) in view of their experience. They were then asked to rate five domains associated with their ICU and post-ICU experience: 1) present health state; 2) pain or discomfort from MV; 3) pain or discomfort in the ICU; 4) perceived family financial burden from hospitalization, and 5) perceived family emotional and physical stress (caregiver burden) from hospitalization using a

5-point Likert scale that ranged from 0 (positive, i.e., excellent health, no pain/discomfort) to 4 (negative, i.e., poor health, extreme pain/discomfort) (Appendix A 3). To reduce order effects, patients were given the opportunity to change their responses after answering all five questions. If a response was changed, the new answer was recorded. If the subject did not recall being in the ICU, MV or aspects of the experience (pain/discomfort), the response was coded as having "no pain/discomfort".

After these ratings were recorded, subjects were asked to identify changes in each of the domains that would alter their preference regarding MV. Each of the five domains was manipulated individually (holding the levels of the other four domains constant) until the subject changed his/her preference. As an example, a subject who indicated that he/she would have chosen MV again was asked if a more negative experience in regard to his/her present health state, pain/discomfort from MV, pain/discomfort in the ICU, etc. would alter this preference. Conversely, a subject who indicated he/she would not choose MV again was asked if a more positive experience in regard to each domain would alter this preference. Each subject was questioned regarding changes in his/her preference until he/she indicated a point between two consecutive points along the 5-point scale where this preference changed. This was termed the indifference point; i.e., the point at which there was no preference between the two alternatives (MV or no MV). Subjects whose preference did not change for any scale value were deemed to have no indifference point for that factor.

Demographic data included age, gender, ethnicity, education, employment prior to hospitalization, occupation, marital status, and insurance type. Clinical data, obtained from the medical record, included primary diagnosis, comorbidities (Charlson Comorbidity Score)

(Charlson, Pompei, Ales & MacKenzie, 1987), ICU and hospital length of stay, indication for MV, date of intubation and tracheostomy, weaning status and decannulation status.

QOL was measured with the SF-36v2 (Ware et al, 2000). The SF-36 was developed as a generic measure of physical functioning and well being. It was comprised of eight subscales: physical functioning, role functioning, bodily pain, general health, vitality, social functioning, mental health, and reported health transition. Scores on four subscores (physical functioning, role functioning, bodily pain, and general health) were combined to yield a physical component score and scores on the remaining four subscales (vitality, social functioning, mental health, and reported health transition) combined to yield a mental component score. The total score ranged from 0-100, with higher scores indicating greater QOL and general health. Reliability coefficients equal or exceed 0.80 (Ware et al, 2000). Internal consistency and item discriminate validity equals or exceeds 0.40 (Ware et al, 2000). The SF-36 has been used successfully with individuals with both acute and chronic illnesses, including individuals experiencing MV (Eddleston et all, 2000). Time to completion ranged from 15 to 20 minutes.

Physical Functioning was measured using the HAQ (Fries et al, 1980). The HAQ was developed to evaluate physical functioning for patients with rheumatoid arthritis. The tool quantified eight general constructs (dressing, grooming, arising, eating, walking, hygiene, reach, grip, and outside activity with 18 items that were scored using the scale 0=without any difficulty, 1=with some difficulty, 2=with much difficulty, 3=unable to do, and an item about use of aids or devices, such as a cane or wheelchair or help from another person. The highest score on any question within the subdomain was used as the score for that subdomain. A point is added when the individual needs to use a disability aid. The total score was determined by adding subdomain scores and dividing by the total number of subdomains completed. Scores ranged from 0 to 3,

with higher scores indicating greater functional impairment. Internal consistency estimates ranged from 0.71 (Milligan et al, 1993) to 0.94 (Pincus et al, 1983). Two-week test-retest reliability estimates ranged from 0.87 to 0.98 (Fries et al, 1982). In 32 patients with COPD, 2-week test-retest reliabilities ranged from 0.972 to 0.975 (unpublished data). Validity has been assessed by examining relationships with the Functional Status Index (r=0.75) and the Sickness Impact Profile (r=0.78) (Liang et al, 1985). Time to completion ranged from 3 to 8 minutes.

Depressive symptomalogy was measured using the CES-D (Radloff, 1977). The CES-D was a 20-item Likert scale, which assessed depressed mood, feelings of guilt and worthlessness, helplessness and hopelessness, loss of appetite, and sleep disturbances. The total score ranged from 0 to 60, with scores of $\geq$ 16 suggesting risk of clinical depression. Coefficient alpha ranged from 0.84-0.90 (Radloff, 1977). Time to completion ranged from 10 to 15 minutes.

Communication status was evaluated using the Patient Communication Survey (PCS). The PCS was a 9-item Likert scale that measured three dimensions of communication: communication satisfaction, ease of communication and success of communication (Happ et al, 2001-2003). The total score ranged from 0 to 36, with lower scores indicating greater ability to communicate. Time to completion ranged from 5 to 8 minutes. In addition, the survey collected information about the method(s) of communication used by the respondents.

Cognitive functioning was assessed with the Mini Mental State Exam (MMSE) (Folstein et al, 1975). The MMSE was an 11-question general-purpose cognitive screening examination that examined the concepts of orientation, registration, attention and calculation, recall, and language to quantify severity of cognitive impairment in persons with dementia or dementia-like conditions (Foreman, 1987). Time to completion ranged from 5 to 10 minutes. A score of < 24 indicates cognitive impairment and excluded study entry.

5.3 DATA MANAGEMENT AND ANALYSIS

A process was implemented to ensure accuracy and completeness of data collection and recording on a case-by-case basis via proof reading and the generation of descriptive statistics with graphical representation of the variables prior to data analysis. There were no missing data. However, one subject was unable to state a preference for MV despite prompting and time for contemplation. Responses from this individual were therefore not included in the analysis of preferences and influencing factors.

Statistical analysis of all variables included descriptive statistics. Categorical variables, such as gender, race, level of care, and marital status were analyzed using Pearson Chi-Square and Fisher's Exact Test, when the expected cell count was less than 5. Continuous variables, such as the SF-36, HAQ, CES-D, and PCS scores, were examined using two-group independent t test for normally distributed variables and non-parametric Wilcoxon Rank Sum test for non-normally distributed variables. Statistical analysis was performed using SPSS (version 11.5). A p-value of less than 0.05 was selected *a priori* to indicate statistical significance.

5.4 RESULTS

5.4.1 Demographic Characteristics

Thirty patients (17 male, 13 female) aged 62.7 $\pm$ 17.6 years (range 20-83 years) were enrolled in this study (Table V). With one exception, all were Caucasian (n=29, 96.7%). The group was included subjects who were married (n=13; 43.3%), single (n=7; 23.3%) and widowed or divorced (n=10; 33%). Most subjects had less than a high school education (n=19; 63.3%). However, the sample included 10 subjects with education beyond high school, including one nurse, one dentist and two attorneys. Most were not employed (n=18; 60%) at the time of

their hospitalization. The sample was evenly divided between those who were insured by Medicare (n=15; 50%) and other payors. The reason for admission included medical (n=15; 50%), surgical (n=12; 40%), and trauma (n=3; 10%) related diagnoses.

At the time of data collection, 17 subjects were on MV with a tracheostomy, including five subjects who remained in the ICU. Eight were in a long-term acute care facility and continued to participate in weaning trials. Four were in skilled nursing facility with no further weaning attempted because of a diagnosis of neuromuscular disease or chronic obstructive pulmonary disease (COPD). One subject was discharged home on nocturnal ventilation secondary to COPD and sleep apnea.

5.4.2 MV Preference

Of the 29 subjects, most (75.9%) stated they would elect to under go MV again (Table VI). Insurance status was significantly associated with MV preference ($p = .023$). Subjects not insured by Medicare were more likely to state that they would undergo MV again. Other demographic variables, including age, gender, residence in an acute care, long term acute care or skilled nursing facility, marital status, education, employment, diagnosis and current airway/ventilator support were not significantly associated with MV preference.

When trends were examined, subjects admitted to a LTAC indicated a strong preference for undergoing MV again (yes=9; 1=no), as did subjects admitted to a SNF (yes=8; no=2). Subjects hospitalized in an acute care institution, including those in an ICU, were more evenly divided regarding whether they would undergo MV again (yes=5; 4=no). All single respondents indicated that they would undergo MV again (yes=7), whereas those who were married (yes=9; no=3) or widowed/divorced (yes=6; no=4) were more varied in their choices. Subjects who had

more than a high school education were also more likely to state that they would undergo MV again (yes=9; no=1).

The number of days to tracheostomy ranged from 0 to 27 days (median 7) for the yes group and 6-20 days (median 9) for the no group (Table VII). Median ICU LOS compared closely for subjects who stated they would and would not undergo MV again (yes=31 days; no=27 days), but there was considerable variation in the range of days each group spent in the ICU (yes=7–186 days; no=14-83 days). The median hospital LOS was also similar for both groups (yes=31 days; no=29 days). Again, there was considerable difference in range of days in the hospital (yes=7-205 days; no=14-83 days). The number of MV days varied extensively because 6 of the SNF subjects had been on MV for several years.

Scores on the CES-D differed, albeit not significant (p=.051), with higher median scores for those who would have chosen MV versus those who would not have chosen MV (29 and 14 days, respectively). Many subjects enrolled in the study were being treated for depression, but most (56.67%) continued to display symptoms of depression as demonstrated by CES-D scores. Scores on instruments measuring QOL and functional ability did not differ in regard to those who would and would not undergo MV again. There were also no significant between group differences in scores measuring communication ability.

5.4.3 Hypothetical Scenarios

Of the 22 subjects who would choose MV again, a majority, consisting of 12 to 14 subjects, did not achieve an indifference point, i.e., their preference remained unchanged regardless of domain manipulation (Table 4). The remaining subjects changed their preference after manipulation of domain scales (n=6 to 7) or were unable identify an indifference point (n=1 to

3). Preference tended to be more likely to change if the domain involved the family's emotional and physical stress and the family's financial burden.

For the 7 subjects who indicated that they would not choose MV again, preference tended to be most stable in regard to pain/discomfort in the ICU. A variable number, ranging from 1 to 3 subjects, changed their preference after manipulation of the remaining domain scales. Preference was most likely to change in reference to present health status and the family's financial burden, the family's emotional and physical stress.

Table 5 presents characteristics of the 7 subjects who indicated they would not choose MV again and the subject who was undecided. With the exception of coverage by Medicare, there appeared to be no consistent characteristics that distinguished these individuals.

5.4.4 Effect Size

Because the sample size was small, effect size was calculated to provide an estimate of the adequacy of the sample. Effect size was highest for the CES-D (d=0.793), with lower values for the HAQ (d=.548), PCS (d=0.424), SF-36 physical (d=.166) and SF-mental (0.094). Thus, the study appeared adequately powered to detect the influence of depression and functional ability on preference for MV, but inadequately powered to detect differences in QOL or ease of communication.

Table 5 Demographics of Sample

Variable	**n(%) (n=30)**
Age, years (mean ± SD)	62.7 ± 17.6
Gender, % male	17 (56.7%)
Race	
Caucasian	29 (96.7%)
African-American	1 (3.3%)
Marital Status	
Married	13 (43.3%)
Widowed/Divorced	10 (33%)
Single	7 (23.3%)
Educational Level	
≤ High School	19 (63.3%)
> High School	11 (36.7%)
Employment	
Working	5 (16.7%)
Not working	18 (60.0%)
Other	7 (23.3%)
Insurance	
Medicare	15 (50%)
Other	15 (50%)
Preference for MV (Yes)	22 (73.3%)
Diagnosis	
Medical	15 (50.0%)
Surgical	12 (40.0%)
Trauma	3 (10.0%)
Airway/ventilator support *(at interview)*	
MV with tracheostomy	17 (56.7%)
Tracheostomy	8 (26.7%)
No MV or tracheostomy	5 (16.6%)

Table 6 Association of patient demographics and preference for MV

Variable	Preference for MV (Yes) (n=22)	Preference for MV (No) (n=7)	P value
Age, years	60.8 (19.2) 20-81	67 (11.7) 45-83	0.432
Gender, % male	13 (59.1%)	3 (42.9%)	0.452
Race Caucasian African-American	 21 (95.5%) 1 (4.5%)	 7 (100%) 0	0.566
Level of Care Acute Care LTAC SNF	 5 (22.7%) 9 (40.9%) 8 (36.4)	 4 (57.1%) 1 (14.3%) 2 (28.6%)	0.201
Marital Status Single Married Widowed/Divorced	 7 (31.8%) 9 (40.9%) 6 (27.2%)	 0 3 (42.9%) 4 (57.2%)	0.157
Education Level ≤ High School > High School	 13 (59.1%) 9 (40.9%)	 6 (85.7%) 1 (14.3%)	0.197
Employment Not Working Working Disabled	 11 (50.0%) 5 (22.7%) 6 (27.3%)	 6 (85.7%) 0 1 (14.3%)	0.210
Insurance Medicare Other	 8 (36.4%) 14 (63.6%)	 6 (85.7%) 1 (14.3%)	**0.023**
Diagnosis Medical Surgical Trauma	 10 (45.5%) 9 (40.9%) 3 (13.6%)	 4 (57.1%) 3 (42.9%) 0	0.574
Airway/ventilator support *(at study completion)* MV with tracheostomy Tracheostomy No MV or tracheostomy CTB	 8 (36.4%) 3 (36.4%) 9 (40.9%) 2 (9.1%)	 2 (28.6%) 0 5 (71.4%) 0	0.439

Table 7 Association of clinical patient data and preference for MV

Variable Median (Range)	Preference for MV (Yes) (n=22)	Preference for MV (No) (n=7)	P value
Days to tracheostomy	7 (0-27)	9 (6-20)	0.672
ICU LOS	31 (7-186)	27 (14-83)	0.539
Hospital LOS	31 (7-205)	29 (14-83)	0.554
MV Days	98.5 (8-2624)	70 (10-1668)	0.886
Tracheostomy Days	102 (21-2624)	64 (18-1662)	0.837
Charlson	4 (0-13)	5 (0-7)	0.522
Mini-mental[1] (< 24 excluded from study)	28 (24-30)	28 (26-30)	0.832
SF-36 Physical[1]	22.48 (13.3-36.9)	25.89 (20.2-43.7)	0.145
SF-36 Mental[1]	48.5 (19.1-65.6)	59.5 (36.2-71.2)	0.226
HAQ[2]	2.56 (0.04-3.00)	2.8 (1.7-3.0)	0.447
CES-D[2] ($\geq$ 16 indicates symptoms of depression)	14 (2-41)	29 (9-49)	0.051
Communication[2]	21.5 (6-32)	20.0 (8-24)	0.423

1 = higher scores = better cognition, & QOL
2 = lower scores = better functionality, depression, communication

Table 8 Factors Influencing a Change in Patient Preference for MV*

Domain	Change in Preference	Would choose MV (n=22)	Would not choose MV (n=7)
Present health status	**No change in preference**	14	3
	Unable to decide	1	1
	Change in Preference		
	Excellent → very good	0	2
	Very good → good	0	1
	Good → fair	1	0
	Fair → poor	6	0
Pain/discomfort from MV	**No change in preference**	14	6
	Unable to decide	1	0
	Change in preference		
	Excellent → very good	0	1
	Very good → good	0	0
	Good → fair	3	0
	Fair→ poor	4	0
Pain/discomfort from ICU	**No change in preferences**	14	3
	Unable to decide	2	2
	Change in preference		
	Excellent →very good	0	1
	Very good →good	0	1
	Good →fair	4	0
	Fair → poor	2	0
Family's financial burden	**No change in preference**	12	3
	Unable to decide	3	1
	Change in preference		
	Excellent → very good	0	3
	Very good → good	1	0
	Good → fair	3	0
	Fair → poor	3	0
Family's emotional and physical stress	No change in preference	13	3
	Unable to decide	2	1
	Change in preference		
	Excellent → very good	0	3
	Very good → good	0	0
	Good → fair	1	0
	Fair → poor	6	0

* Data presented for subjects with complete responses to all items in domain

Table 9 Characteristics of subjects who would not have chosen MV (n=7) or did not indicate a preference (n=1)

Age	Gender	LOC	Ventilation Status	Diagnosis	Insurance	MV days	Pain/ Discomfort in ICU or on MV	CES-D Score	SF36 Score (PC)	SF36 Score (MC	HAQ Score	Communication Method
SUBJECT UNDECIDED ABOUT CHOOSING MECHANICAL VENTILATION AGAIN												
74	M	SNF	Spontaneous	Guillian Barre	MC & Co-Pay	33	Undecided	19	36.17	50.53	3.00	Speaks Capped trach
SUBJECTS WHO STATED THEY WOULD NO CHOOSE MECHANICAL VENTILATION AGAIN												
65	M	SNF	MV with tracheostomy	COPD	MC/MA	1668	No (both)	18	23.40	59.51	1.96	Writes & mouths words
65	F	AC	MV with tracheostomy	End stage liver disease	MC & Co-Pay	149	No (both)	33	25.89	36.33	2.88	Writes & mouths words
72	F	AC	Spontaneous	Postoperative Complications	MC & Co-Pay	10	ICU undecided/ No	26	16.95	45.02	3.00	Mouths words
45	F	LTAC	Spontaneous	Acute respiratory failure	SSDI	12	Undecided	49	20.81	20.26	2.73	Speaks
74	M	SNF	Spontaneous	Acute respiratory failure	MC & Co-Pay	160	Yes (both)	9	19.25	58.64	1.69	Speaks
65	F	AC	MV with tracheostomy	Postoperative Complications	MC only	70	No (both)	43	25.97	28.47	2.81	Mouths words
83	M	AC	Spontaneous	Pancreatitis	MC & Co-Pay	23	Yes (both)	29	26.10	48.11	3.00	Fenestrated trach

Definition of abbreviations: M= male, F= female, SNF= skilled nursing facility, AC= acute care, LTAC= long term acute care, MC= Medicare; MA = medical assistance; PC = physical component SF-36; MC – mental component SF-36.

5.4.4.1.1.1

5.5 DISCUSSION

We evaluated preferences toward MV among patients who received PMV and tracheostomy. The major findings of this study were: 1) cognitively intact survivors of prolonged MV and tracheostomy choose MV even though 17 remained dependent on MV at the time of interview; 2) patients with non-Medicare insurance were significantly more likely to have chosen MV; and 3) survivors experiencing fewer symptoms of depression displayed a strong trend toward being more likely to have chosen MV.

Healthcare providers have an obligation to elicit patient preferences toward life sustaining treatments to order to individualize their care. This is especially true in settings such as the ICU where some treatments, such as MV, can be viewed as artificial life support. Many patients admitted to the ICU have conditions associated with a high mortality, severe functional deficits, and an extended recovery. With patient and family input, the healthcare team may choose a plan of care that emphasizes comfort and pain relief, rather than life-sustaining measures, to accommodate patient preferences.

Patients are routinely asked about their preferences as they relate to advanced directives when they are admitted to a hospital. Advanced directives are preferences for healthcare determined by an individual while he or she has decisional capacity about medical treatment he or she would or would not like to receive in the event that decisional capacity is lost (Ahronheim et al, 2000)." Sometimes those preferences or advance directives are written in the form of a living will or individuals may identify a durable power of attorney for health care. In a living will, a person requests that, if they become disabled beyond reasonable expectation of recovery, decisions about care that were made *a priori* be followed. This is a powerful method to document preferences. However, individuals commonly make advance directives based on sources other than experience. The use of MV is considered an extraordinary measure and, as

such, is often included in a living will, along with treatments such as blood transfusions, tube feedings, and antibiotics. With very few exceptions, the individual writing a living will is likely to never have experienced MV, let alone PMV and tracheostomy.

Most studies that have examined recovery following PMV report that patients require a long period of time to regain their prior physical functioning, or never regain this ability (Mendelsohn et al, 2002, Teno et al, 2000, Danis et al, 1988, & Elpern et al, 1992). Consequently, the personal and economic cost of a critical illness and extended recovery trajectory is substantial. Often care is provided in a setting designed to provide a lower level of care, e.g., long-term acute care, acute rehabilitation, or skilled nursing facility. This recovery period may be followed by home care and outpatient services to help the person return to optimal health and functioning. Some patients spend the remainder of their life in a facility dependent for assistance with activities of daily living. When individuals become dependent on others for care at home or in an institution, there is a high cost to the family in lost wages, stress and anxiety.

Regardless of these issues, findings of this study suggest that the majority of cognitively intact patients would elect to undergo MV, if given the opportunity to make this choice. In the present study, 76% of patients indicated a preference for MV. Those indicating a preference for MV spent an extended period of time on in the ICU (median 31 days) and on MV (median 99; range 8-2624 days), as did those who did not indicate a preference for undergoing MV. In fact, the duration of time in the ICU (median 27 days) was very similar and time on MV slightly less for those who would not elect MV (median 70 days; range 10-1668 days). Therefore, neither the duration of time on MV or time in the ICU appeared to influence patient preferences. A significant difference between groups was found for insurance status, with those preferring MV less likely to have Medicare as their insurance provider. The explanation for this finding is not

clear, as age did not differ significantly between preference groups. It is possible that individuals who were insured by Medicare had less extensive benefits, but we did not examine this potential.

Patients who had fewer symptoms of depression tended to be more likely to indicate a preference to undergo MV again, but this finding did not reach statistical significance. Unexpectedly, there were no significant differences in scores on instruments measuring functional ability, QoL, or communication status. Likely, this was due to the limited sample size and consequently limited statistical power for instruments measuring QoL, functional ability, and communication status, as indicated by effect size.

Findings of the present study support those of Mendelsohn et al. (2002) who used the same instrument to assess preferences at 12 months post ICU discharge in patients who had been on MV for $\geq$ 48 hours (median 8.6 days). Of 133 patients interviewed, 87% would have chosen MV, with younger (< 65 years old) patients (90% vs. 68%; $p = 0.0006$) and healthier (92.5% vs. 77.4%, $p = 0.01$) patients more likely to have chosen MV compared to older and sicker patients. It is interesting to note that, although the time at which interviews were conducted varied between the two studies, the proportion of patients electing to choose MV again was similar.

When change in preferences was examined in regard to the hypothetical scenarios, Mendelsohn et al (2002) reported that 25% of those who would have initially chosen indicated they would refuse this therapy if their families' financial burden were beyond certain thresholds. A similar proportion would have refused MV if it were associated greater pain or discomfort. This study showed that for individuals who would initially chose MV would refuse if their present health were poor and if the family's stress was worse. Patients who would not chose MV would change their mind if their family's financial burden and stress were reduced.

Several additional studies have examined patient preferences for ICU care and life sustaining treatments. In 1988, Danis et al. (1988) interviewed 160 patients and family members who were in a medical or respiratory ICU for at least 24 hours to determine preferences for ICU care and the importance of the life circumstances in determining those preferences. Families were interviewed regarding decisions they would make for the hospitalized person if the patient was unable to participate. Median ICU length of stay was 3-5 days and mean ($\pm$SD) APACHE II scores were: Group I = 13 $\pm$ 7, Group II = 12 $\pm$ 4, Group III = 16 $\pm$ 6 ($p<0.05$), and Group IV = 20 $\pm$ 8 which indicates low acuity. Most patients (74%, n=51) stated they would be "completely willing" to undergo ICU for very brief periods of life prolongation. Family preferences were similar. Patients (n=11) and families (n=17) would not choose ICU if there was no hope of recovery, if the patient would be kept alive by machines (n=7, n=10, respectively) and if the patient were vegetative or neurologically impaired (n=7, n=10, respectively). These findings are similar to comments made by patients in the present study regarding preference being influenced by survival, cognitive ability and the need for tube feedings.

In 1992, Elpern, et al. (1992) reported findings from a study of patient preferences following an ICU stay of ≥ 48 hours. Patients were evaluated within 48 hours of ICU discharge to determine eligibility (entry criteria required they be alert and oriented) and interviewed according to their availability and tolerance. Most participants (96%) stated they preferred life support to restore their usual state of health. As scenarios of declining functional and cognitive ability were presented, preference decreased. In this study, the average ICU length of stay was relatively short (4.5 days), the mean APACHE II score (13.3) indicated low acuity, and all patients were breathing spontaneously. However, preferences were similar to the present study.

In 2000, Teno et al. (2000) examined decision-making and outcomes following an ICU stay of ≥ 14 days in 1494 patients recruited from five ICUs who were enrolled in the SUPPORT (Study To Understand Prognoses and Preferences for Risks and Outcomes of Treatment) study. The patient or a family decision-maker was interviewed during the second week of hospitalization while most (91%) patients were still in the ICU. Slightly less than half of patients/families (45%) preferred a life extending approach, while 36% expressed a preference for comfort, even if it shortened life. The authors did not distinguish between the preferences provided by patients or family members. However, it is likely that, because most of the patients were hospitalized in the ICU, family members would have been the primary information providers. Accordingly, it is not clear if their preferences were those of the patients. In the present study, patients, rather than proxies, provided all study data and those who were interviewed in the ICU consistently stated they would undergo MV again.

No studies were found that examined the effect of communication status on preference for MV, ICU or life support. All participants were cognitively intact and able to communicate. However, most expressed frustration with their ability to communicate as desired; one even said, somewhat jokingly, that his inability almost caused a divorce.

5.6 LIMITATIONS

This study was subject to several limitations. First, the sample size was relatively small which limits the strength and generalizability of the findings. In particular, we had limited statistical power to find difference between the preference groups. However, study findings were consistent with those of larger studies employing different and similar methods. Second, entry criteria required that patients be on MV for ≥ 2 months and have tracheostomy. However,

there was no restriction on the length of time on MV, which varied considerably for those enrolled in this study. It is possible that length of time on MV influenced patient preferences. However, median days on MV were longer for those who stated they would elect to receive MV. Finally, the sample only included cognitively intact survivors of PMV. It is possible that survivors who were unable to function at this level might have very different preferences. However, a goal of the study was to elicit preferences from the patients themselves, rather than proxies, which required they be able to understand questionnaire item and share their responses.

5.7 CONCLUSION

In summary, most cognitively intact patients who experienced PMV and tracheostomy would be willing to experience a repeat episode MV. As one individual, so eloquently stated, "Of course, I would go on the breathing machine again – I'm alive." Preference for MV increases if there would be a return to usual health, with a reduction in the number of people who prefer MV if it resulted in increase family stress and financial burden. Those individuals who were insured by Medicare were less likely to choose MV and those with more depressive symptoms tended to also not indicate a preference for MV. Although the effects of depression on preference for life support are understandable, the effect of Medicare was unclear because it was not a surrogate for age or disability.

As critical care nurses, we often speculate on the wisdom, appropriateness, and effectiveness of life saving strategies. We wonder about patient preferences. The results of this study support the provision of resuscitation, including MV and tracheostomy for the chronically critically ill. Further research is needed to explore preferences for PMV in situations where the outcome of survivors results in cognitive impairment and / or a vegetative state.

APPENDIX A.1 Demographic Information Sheet

Study ID _____

Gender: Male Female

Date of birth: _____ Age _____

Race: _____ White _____ African American
_____ Latino (Mexican/Latin American/Caribbean) _____ American Indian
_____ Asian _____ Other

Insurance:

_____ Medicare only _____ Medicare w/co-insurance
_____ Blue Cross _____ HMO
_____ Medicaid _____ None
_____ Other: _____

Highest level of education completed:

_____ Grade School (1-8) _____ High School (9-12)
_____ High school graduate _____ Earned GED
_____ Vocational/Technical School _____ 2-year college (AD)
_____ 4-year college (Bachelors) _____ Graduate School (Masters)
_____ Professional School (MD, JD) _____ Graduate School (PhD)

Employment prior to hospitalization:

_____ Working full time _____ Working part time
_____ Retired, not working _____ Retired, working
_____ Disabled/unable to work _____ Full time homemaker

Occupation: _____

Marital Status:

_____ Single (never married) _____ Married
_____ Widowed _____ Divorced

Next of kin (for decision making):

Name _____

Relationship _____

APPENDIX A.2Clinical Information

Date Hospital Admission	Date ICU Admission	Was there ICU readmission?	Date ICU discharge
Diagnosis			
Comorbidities			
Prime reason for vent (including precipitation factors)			
Brief history of ICU stay			
Any significant complications			
Date of intubation	Episode of reintubation	#Days intubated before trach	Date of trach decannulation
ICU LOS	Hospital LOS	ICU discharge location & date	LOS
Date weaned from vent	Final f/u location		

Appendix A3 Patient Preference Study

1. **I would like to ask you about the decision to have a breathing tube. Still thinking about that hospitalization, if you knew then what you know now about the whole experience, would you have chosen to have the breathing tube?**

___[1] Yes ___[0] No ___[-3] Unknown ___[-4] Refused

2. **I would like to probe further into your ICU experience.** (If necessary): **I would like to conduct this part of the interview without anyone else present, if possible. Please answer the questions to the best of your knowledge.**

2.1 **How would you rate your overall health before your hospitalization?**
(Read choices and circle response.)

0 **Excellent**	1 **Very Good**	2 **Good**	3 **Fair**	4 **Poor**	-3 Unk.	-4 Ref.

2.2 **In general, would you say your health is:**
(Read choices and circle response.)

0 **Excellent**	1 **Very Good**	2 **Good**	3 **Fair**	4 **Poor**	-3 Unk.	-4 Ref.

2.3 **How do you think your health will be a year from now?**
(Read choices and circle response.)

0 **Excellent**	1 **Very Good**	2 **Good**	3 **Fair**	4 **Poor**	-3 Unk.	-4 Ref.

3. Record response to 2.2 on Scoring Sheet, and proceed to Baseline questions 3.2 - 3.5

4. On this board, I've recorded how you evaluated your ICU experience in terms of these factors. (Repeat patient's answers)
Would you like to change any of your responses? (Record any changes both on the device, and on the scoring sheet in the CHANGES column.)

5. PATIENT PREFERENCE:
I am asking this question again to see if you have changed your mind after thinking about these factors (gesture to device):

If you knew then what you know now about the whole experience, would you have chosen to have the breathing tube?

___[1] Yes ___[0] No ___[-3] Unknown ___[-4] Refused

6. UNIVARIATE EXERCISE: Do separately for each of 5 factors on scoring sheet, recording both scale position and Would or Would Not on scoring sheet in UNIVARIATE column. When reading the following, select the proper wording based upon the preference recorded in #5 above.

You said that you would/would not have chosen to have the breathing tube.
Imagine now that everything was the same (gesture to device), **except that**

… your health now was (adjust scale per study instructions).
Would you still/then agree to have a breathing tube?

… the pain and discomfort that you experienced from the breathing tube was (adjust scale).
Would you still/then agree to have a breathing tube?

… the pain and discomfort that you experienced from being in the ICU was (adjust scale).
Would you still/then agree to have a breathing tube?

… your family's financial burden was (adjust scale).
Would you still/then agree to have a breathing tube?

… your family's emotional and physical stress was (adjust scale).
Would you still/then agree to have a breathing tube?

7. MULTIVARIATE EXERCISE: If the univariate responses are all would not and 0 or all would and 4 then ask:

"Is there any combination of these factors that would make you change your mind and refuse/agree to have the breathing tube again?"

If yes,

Hand device to patient and ask them to indicate their answers, assisting if necessary. Record final positions on the scoring sheet in the MULTIVARIATE column.

8. **Are there any other factors that could be changed that would make you change your mind and <u>refuse/agree</u> to have the breathing tube again?**
(Code 0 if answer is don't know)

____[1] Yes ___[0] No ___[-4] Refused

If Yes,

Factor #6:
Factor #7:
Factor #8:
Factor #9:
(30 characters)

9. **Here are the five factors that I was asking you about** (show device), **and the** (x number of factors from question #8) **that you mentioned. Can you rank them for me, in terms of how important they are to you in making the decision of whether to have the breathing tube again?**
(Rank factors, using 1 for most important factor. Code -3 if patient can't rank a factor. Use -2 in unneeded blanks.)

9.1	Present health status	_____
9.2	Pain/discomfort from the breathing tube	_____
9.3	Pain/discomfort in the ICU	_____
9.4	Financial burden	_____
9.5	Family's emotional/physical stress	_____
9.6	Factor #6	_____
9.7	Factor #7	_____
9.8	Factor #8	_____
9.9	Factor #9	_____

10. **How TRUE or FALSE is the following statement for you?** (Read statement and answer choices, and circle response.)

"I would have survived without the breathing tube."

1 **Definitely true**	2 **Mostly true**	3 **Neither false nor true**	4 **Mostly false**	5 **Definitely false**	-3 Unk.	-4 Ref.

11. INTERVIEWER'S PERCEPTION (not to be read to the patient):

Did the patient seem to understand the exercise? ____[0] No ____[1] Yes

12. Comments: ____[0] No ____[1] Yes

If yes,

PATIENT PREFERENCE SCORING SHEET

(Begin with question 3.2 for BASELINE responses)	**BASELINE**	**CHANGES**	**UNIVARIATE**			**MULTIVARIATE** ___ 0 No __-2 N/A ___ 1Yes ___-3 Unk. ___-4 Ref. If yes,
3.1 In general, would you say your health is:	(Copy from 2.2) 0 1 2 3 4 -3 Unk. -4 Ref	0 1 2 3 4 -2 No change -3 Unk. -4 Ref.	0	-3Unk.-4 Ref. Would 1 Would Not 2 3	4	0 1 2 3 4
3.2 How much pain or discomfort do you remember experiencing because of the breathing tube?	0 1 2 3 4 -3 Unk. -4 Ref.	0 1 2 3 4 -2 No change -3 Unk. -4 Ref.	0	-3Unk.-4 Ref. Would 1 Would Not 2 3	4	0 1 2 3 4
3.3 How much pain or discomfort do you remember experiencing from being in the ICU?	0 1 2 3 4 -3 Unk. -4 Ref.	0 1 2 3 4 -2 No change -3 Unk. -4 Ref	0	-3 Unk.-4 Ref. Would 1 Would Not 2 3	4	0 1 2 3 4
3.4 How much of a financial burden do you think you or your family experienced since the event that resulted in your hospitalization?	0 1 2 3 4 -3 Unk. -4 Ref.	0 1 2 3 4 -2 No change -3 Unk. -4 Ref.	0	-3 Unk. -4Ref. Would 1 Would Not 2 3	4	0 1 2 3 4
3.5 How emotionally and physically stressful do you think it has been for your family since the event that resulted in your hospitalization?	0 1 2 3 4 -3 Unk. -4 Ref.	0 1 2 3 4 -2 No change -3 Unk. -4 Ref.	0	-3 Unk.4 Ref. Would 1 Would Not 2 3	4	0 1 2 3 4
	Record responses on device, then prompt for CHANGES (q.4)	Ask (q.5) and proceed with UNIVARIATE exercise (q.6)	Proceed with MULTIVARIATE exercise (q.7), if **all Would not/0** or **all Would/4**			Continue with question 8

Present Health Status

|_____|_____|_____|_____|

Excellent Very Good Good Fair Poor

Pain/Discomfort from the Breathing Tube

|_____|_____|_____|_____|

No Pain Some Pain Moderate Pain Serious Pain Extreme Pain

Pain/Discomfort in the ICU

|_____|_____|_____|_____|

No Pain Some Pain Moderate Pain Serious Pain Extreme Pain

Financial Burden

|_____|_____|_____|_____|

No Burden Some Burden Moderate Burden Serious Burden Extreme Burden

Family's Emotional and Physical Stress

|_____|_____|_____|_____|

No Stress Some Stress Moderate Stress Serious Stress Extreme Stress

APPENDIX A7 Patient Communication Survey

Please check the box beside the answer that best describes your opinion.

1. I can make most people understand me without speaking.

- ❑ Strongly disagree
- ❑ Disagree
- ❑ Not sure
- ❑ Agree
- ❑ Strongly agree

2. My family can understand me even through I am unable to speak.

- ❑ Strongly disagree
- ❑ Disagree
- ❑ Not sure
- ❑ Agree
- ❑ Strongly agree

3. The nurses can understand me even through I am unable to speak.

- ❑ Strongly disagree
- ❑ Disagree
- ❑ Not sure
- ❑ Agree
- ❑ Strongly agree

4. The doctors can understand me even through I am unable to speak.

- ❑ Strongly disagree
- ❑ Disagree
- ❑ Not sure
- ❑ Agree
- ❑ Strongly agree

5. My way of communicating meets my current needs.

- ❑ Strongly disagree
- ❑ Disagree
- ❑ Not sure
- ❑ Agree
- ❑ Strongly agree

6. I can say everything that I need to say right now.

- ❑ Strongly disagree
- ❑ Disagree
- ❑ Not sure
- ❑ Agree
- ❑ Strongly agree

7. I am satisfied with the way I communicate in the hospital.

- ❑ Strongly disagree
- ❑ Disagree
- ❑ Not sure
- ❑ Agree
- ❑ Strongly agree

8. I have difficulty getting my point across since the (surgery) being on the vent.

- ❑ Strongly disagree
- ❑ Disagree
- ❑ Not sure
- ❑ Agree
- ❑ Strongly agree

9. Not being able to speak makes me feel:

- ❑ Angry
- ❑ Frustrated
- ❑ Sad
- ❑ Lonely
- ❑ Don't Care
- ❑ Quiet

10. Method of communication _____

BIBLIOGRAPHY

2000 U.S. Census Data. 2003. http://quickfacts.census.gov/qfd/states/42/42003.html & http://quickfacts.census.gov/qfd/states/42/42129.html

Ahronheim, J.C., Moreno, J.D. & Zuckerman, C. Ethics in clinical practice. Gaithersburg, MD: Aspen Publishers, Inc. 2000.

Bach, J.R. 1993. Amyotrophic lateral sclerosis: Communication status and survival with ventilatory support. American Journal of Physical Medicine and Rehabilitation, 72, 6, 343-349.

Bell, S.D. 1996. Use of Passy-Muir tracheostomy speaking valve in mechanically ventilated neurological patients. Critical Care Nursing, 16, 1, 63-68.

Bergbom-Engberg, I. & Haljamae, H. 1989. Assessment of patients' experience of discomforts during respirator therapy. Critical Care Medicine, 17. 10, 1068-1072.

Bishop, M.J. (1989). Mechanisms of laryngotracheal injury following prolonged tracheal intubation. Chest, 96, 1, 185-190.

Bone, R.C. & Elpern, E.H. 1991. Honoring patient preferences and rationing intensive care: Are these compatible goals? Archives of Internal Medicine: 151, 1061-1063.

Brook, A.D., Sherman, G., Malen, J., & Kollef, M.H. 2000. Early versus late tracheostomy in patients who require prolonged mechanical ventilation. American Journal of Critical Care, 9: 352-359.

Byrick, R.J. 1993. Improved communication with the Passy-Muir valve: The aim of technology and the result of training. Critical Care Medicine, 21, 4, 483-484.

Carson, S.S., Bach, P.B., Brzozowski, L. & Leff, A. 1999. Outcomes after long-term acute care: An analysis of 133 mechanically ventilated patients. American Journal of Respiratory and Critical Care Medicine, 159, 1568-1573.

Charlson, M, Pompei, P, Ales, K, MacKenzie, C. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. Journal of Chronic Disease, 1987; 40 (5): 373-83.

Chatila, W, Kreimer, D.T. & Criner, G.J. 2001. Quality of life in survivors of prolonged mechanical ventilatory support. Critical Care Medicine: 29, 4: 737-742.

Chelluri, L., Grenvik, A. & lverman, M. 1995. Intensive Care for Critically Ill Elderly: Mortality, Costs, and Quality of Life: Review of the Literature. Archives of Internal Medicine: 155, 10: 1013-1022.

Chelluri, L., Pinsky, M.R., Donahoe, M.P, & Grenvik, A. 1993. Long-term outcome of critically ill elderly patients requiring intensive care. The Journal of the American Medical Association: 269, 24:3119-3123.

Chelluri, L., Im, K.A., Belle, S.H., Schulz, R., Rotondi, A.J., Donahoe, M.P., Sirio, C.A., Mendelsohn, A.B., & Pinsky, M.R. 2004. Long-term mortality and quality of life after prolonged mechanical ventilation. Critical Care Medicine, 32, 1, 61-69.

Clochesy, J. M., Burns, S. M., Shekleton, M. E., Hanneman, S. K., Knebel, A. R., & Ingersoll, G. L. (1997). A volunteers in participatory sampling survey of weaning practices. Critical Care Nurse, 17, 2: 72-78.

Connolly, M.A. & Shekleton, M.E. 1991. Communicating with ventilator dependent patients. Dimensions of Critical Care, 10, 2, 115-121.

Cronin, L.R. & Carrizosa, A.A. 1984. The computer as a communication device for ventilator and tracheostomy patients in the intensive care unit. Critical Care Nurse, January/February, 72-76.

Danis, M, Patrick, D.L., Southerland, L.I. & Green, M.L. 1988. Patients' and families' preferences for medical intensive care. Journal of American Medical Association, 260, 6, 797-802.

Davis, A.J., Aroskar, M.A., Liaschenko, J. & Drought, T.S. Ethical Dilemmas & Nursing Practice. Stamford, Connecticut: Appleton & Lange, 1997.

DeVos, R. 2001. To be resuscitated or not: The concepts in decision making. The Journal of Cardiovascular Nursing, 16, 1: 21-27.

Douglas, S.L., Daly, B.J., Brennan, P.F., Gordon, N.H. & Uthis, P. 2001. Hospital readmission among long-term ventilator patients. Chest: 120, 4: 1278-1286.

Douglas, S.L., Daly, B.J., Gordon, N., & Brennan, P.F. 2002. Survival and quality of life: short-term versus long-term ventilator patients. Critical Care Medicine, 30, 12, 2655-2662.

Eddleston, J.M, White, P.W. & Guthrie, E. 2000. Survival, morbidity, and quality of life after discharge from intensive care. Critical Care Medicine, 28, 7, 2293-2299.

Elpern, E.H., Patterson, P.A., Gloskey, D. & Boone, R.C. 1992. Patients' preferences for intensive care. Critical Care Medicine, 20, 1, 43-47.

Ely E.W., Evans, G.W., & Haponik, E.F. 1999. Mechanical ventilation in a cohort of elderly patients admitted to an intensive care unit. Annals of Internal Medicine, 131, 2:96-104.

Engoren, M., Buderer, N.F. & Zacharias, A. 2000. Long-term survival and health status after prolonged mechanical ventilation after cardiac surgery. Critical Care Medicine, 28, 8, 2742-2749.

Everhart, M.A. & Pearlman, R.A. 1990. Stability of patient preferences regarding life-sustaining treatments. Chest, 97, 159-164.

Folstein, M.F., Folstein, S. E., & McHugh, P.R. 1975. "Mini-mental state" A practical method for grading cognitive state of patients for the clinician. Journal of Psychiatric Research, 12, 189-197.

Foreman, M.D. 1987. Reliability and validity of mental status questionnaires in elderly hospitalized patients. Nursing Research, 36, 4, 216-219.

Fries, J.F., Spitz, P., Kraines, R.G., & Holman, H.R. 1980. Measurement of patient outcomes in arthritis. Arthritis and Rheumatism, 23, 2: 137-145.

Fries, J.F., Spitz, P.W., & Young, D.Y. 1982. The dimensions of health outcomes: The health assessment questionnaire, disability and pain scales. The Journal of Rheumatology, 9, 5: 789-793.

Happ, M.B. 2001. Communicating with mechanically ventilated patients: State of the science. AACN Clinical Issues: Advanced Practice in Acute and Critical Care, 12, 2: 247-258.

Happ, M, Roesch, T, Kagan, S. 2001-2003. Feasibility Study of an Augmentative Communication Device with Voiceless Head and Neck Cancer Patients following Reconstructive Surgery. Oncology Nursing Society Foundation/Orthobiotech. Unpublished data.

Haynor, P.M. 1998. Meeting the challenge of advanced directives. American Journal of Nursing, 98, 3, 26-32.

Heffner, J.E. (1991). Timing of tracheotomy in ventilator-dependent patients. Clinics in Chest Medicine, 12, 3, 611-625.

Heffner, J.E. 1993. Timing of tracheotomy in mechanically ventilated patients. American Review of Respiratory Disease, 147: 768-771.

Heffner, J.E., Miller, K.S., and Sahn, S.A. (1986). Tracheotomy in the intensive care unit, Part 1: Indications, Technique, Management. Chest, 90, 2, 269-274.

Heyland, D.K., Konopad, E., Noseworthy, T.W., Johnston, R. & Gafni, A. 1998. Is it 'worthwhile' to continue treating patients with a prolonged stay (>14 days) in the ICU: An economic evaluation. Chest, 114, 1:192-198.

Hoffman, L.A., Tasota, F.J., Scharfenberg, C.J., Zullo, T.G., & Donahoe, M.P. 2002. Pending publication. Recovery trajectory after prolonged mechanical ventilation: 4-month followup. American Journal of Respiratory and Critical Care Medicine, 167, A458.

Hofmann, J.C., Wenger, N.S., Davis, R.B., Teno, J., Connors, A.F., Desbiens, N., Lynn, J., & Phillips, R.S. 1997. Patient preferences for communication with physicians about end of life decisions. Annals of Internal Medicine, 127, 1: 1-12.

Hoit, J.D., Shea, S.A. & Banzett, R.B. 1994. Speech production during mechanical ventilation in tracheostomized individuals. Journal of Speech and Hearing Research, 37, 53-63.

Kim, Y., Hoffman, L.A., Tasota, F.J., Scharfenberg, C.J., Donahoe, M.P. 2003. Use of structural equation modeling in quality of life measurement with mechanically ventilate patients. American Journal of Respiratory and Critical care Medicine, 167, 7, A460.

Knaus, W.A., Wagner, D.P., Draper, E.A., Zimmerman, J.E., Bergner, M., Bastos, P.G., Sirio, C.A., Murphy, D.J., Lotring, T., Damiano, A., & Harrell, F.E. 1991. The apache III prognostic system: Risk prediction of hospital mortality for critically ill hospitalized adults. Chest, 100, 6: 1619-1636.

Lawless, C.A. 1975. Helping patients with endotracheal and tracheostomy tubes communicate. American Journal of Nursing, 75, 12, 2151-2153.

Lawton, M.P. & Brody, E.M. 1969. Assessment of older people: self-maintaining and instrumental activities of daily living. Gerontologist, 9, 3: 179-186.

Leder, S.B. 1990. Verbal communication for the ventilator-dependent patient: Voice intensity with the Portex "Talk"® Tracheostomy Tube. Laryngoscope, 100, 1116-1121.

Lesnik, I., Rappaport, W., Fulginiti, J. and Witzke, D. (1992). The American Surgeon, 58, 346-349.

Lewis, R.J. (1992). Tracheostomies, indications, timing, and complications. Clinics in Chest Medicine, 33, 1, 137-147.

Liang, M., Larson, M., Cullen, K., & Schwartz, J. 1985. Comparative measurement efficiency and sensitivity of five health status instruments for arthritis research. Arthritis and Rheumatism, 28, 5, 542-547.

Manzano, J.L., Lubillo, S., Henriquez, D., Martin, J.C., Perez, M.C. & Wilson, D.J. 1993. Verbal communication of ventilator-dependent patients. Critical Care Medicine, 21, 512-517.

Maxfield, C.L., Pohl, J & Colling, K. 2003. Advanced directives: A guide for patient discussions. The Nurse Practitioner, 28, 5, 38, 41, 43-47.

McKinley, E.D., Garrett, J.M., Evans, A.T., & Danis, M. 1996. Differences in end-of-life decision making among black and white ambulatory cancer patients. Journal of General Internal Medicine, 11, 11: 651-656.

Mendelsohn, A.B., Belle, S.H., Fischhoff, B., Wisniewski, S.R., Degenholtz, H., & Chelluri, L. 2002. How patients feel about prolonged mechanical ventilation 1 yr later. Critical Care Medicine, 30, 7: 1439-1445.

Menzel, L. 1994. Need for communication-related research in mechanically ventilated patients. American Journal of Critical Care, 3, 3, 165-167.

Menzel, L.K. 1997. A comparison of patient's communication-related responses during intubation and after extubation. Heart & Lung, 26, 5, 363-371.

Menzel, L.K. 1998. Factors related to the emotional responses of intubated patients to being unable to speak. Heart & Lung, 27, 4, 245-252.

Milligan, S.E., Hom, D.L., Ballou, S.P., Persse, L.J., Svilar, G.M., & Coulton, C.J. 1993. An assessment of the health assessment questionnaire functional ability index among women with system lupus erythematosus. The Journal of Rheumatology, 20, 972-976.

Nasraway, S., Button, G., Rand, W., Hudson-Jinks, T., & Gustafson, M. 2000. Survivors of catastrophic illness: Outcome after direct transfer from intensive care to extended care facilities. Critical Care Medicine, 28, 1: 19-25.

Niskanen, M, Ruokonen, E., Takala, J., Rissanen, P., & Kari, A. 1999. Quality of life after prolonged intensive care. Critical Care Medicine, 27, 6:1132-1139.

Orringer, M.K. (1999). The effects of tracheostomy tube placement on communication and swallowing. Respiratory Care, 44, 7, 845-855.

Passy, V., Baydur, A., Prentice, W. & Darnell-Neal, R. 1993. Passy-Muir® Tracheostomy Speaking Valve on ventilator-dependent patients. Laryngoscope, 103, 653-658.

Pennock, B.E., Crawshaw, L., Maher, T., Price, T. & Kaplan, P.D. 1994. Distressing events in the ICU as perceived by patients recovering from coronary artery bypass surgery. Heart & Lung, 23, 4. 323-327.

Phelan, B.A., Cooper, D.A., & Sangkachand, P. 2002. Prolonged mechanical ventilation and tracheostomy in the elderly. Advanced practice in acute and critical care, 13, 1: 84-93.

Pincus, T., Spitz, P., Soraci, S., Wallston, K., & Hummon, N. 1983. Assessment of patient satisfaction in activities of daily living using a modified Stanford Health Assessment Questionnaire. The Journal of Rheumatology, 20, 972-976.

Plummer, A. L. & Gracey, D. R. 1989. Consensus conference on artificial airways in patients receiving mechanical ventilation. Chest, 96: 178-180.

Quality of Life After Mechanical Ventilation in the Aged Study Investigators. 2002. 2-month mortality and functional status of critically ill adult patients receiving prolonged mechanical ventilation. Chest, 121, 549-558.

Radloff, L.S. 1977. The CES-D scale: a self-report depression scale for research in the general population. Applied Psychological Measurement, 1, 385-401.

Rincon, H.G., Granados, M., Unutzer, J. Gomez, M., Duran, R., Badiel, M., Salas, C., Martinez, J., Mejia, J., Ordonez, C., Florez, N., Rosso, F., & Echeverri, P. 2001. Prevalence, detection and treatment of anxiety, depression, and delirium in the adult critical care unit. Psychosomatics, 42, 3: 391-396.

Rivera-Fernandez, R., Sanchez-Cruz, J.J. Abizanda-Campos, R. & Vazquez-Mata, G. 2001. Quality of life before intensive care unit admission and its influence on resource utilization and mortality rate. Critical Care Medicine, 29, 9, 1701-1709.

Rodriguez, J. L., Steinberg, S. M., Luchetti, F. A., Gibbons, K. J., Taheri, P. A., & Flint, L. M. (1990). Early tracheostomy for primary airway management in the surgical critical care setting. Surgery, 108, 4, 655-659.

Rotondi, A.J., Chelluri, L., Sirio, C., Mendelsohn, A., Schultz, R., Belle, S., Im, K., Donahoe, M. & Pinsky, M.R. 2002. Patients' recollection of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit. Critical Care Medicine, 30, 4, 746-752.

Rudy, E.B., Daly, B.J., Douglas, S., Montenegro, H.D., Song, R., & Dyer, M.A. 1995. Patient outcomes for the chronically critically ill: Special care unit versus intensive care unit. Nursing Research, 44, 6: 324-331.

Seneff, M.G., Wagner, D., Thompson, D., Honeycutt, C., & Silver, M.R. 2000. The impact of long-term acute-care facilities on the outcome and costs of care for patients undergoing prolonged mechanical ventilation. Critical Care Medicine, 28, 2: 342-350.

Shape your health care future with health care advance directives. 2003. Retrieved July 24, 2003 from http://www.ama-assn.org/public/booklets/livgwill.htm.

Sherman, R.A. 1992. Doing our part to match patient preferences with rationed intensive care. Archives in Internal Medicine, 152, 1332-1333.

Stauffer, J.L. (1999). Complications of endotracheal intubation and tracheostomy. Respiratory Care, 44, 7, 828-843.

Stewart, A.L., Hays, R.D. & Ware, J.E. 1988. The MOS Short-form general health survey: Reliability and validity in a patient population. Medical Care, 26, 7: 724-735.

Stiggelbout, A.M. & de Haes, J.C.J.M. 2001. Patient preference for cancer therapy: An overview of measurement approaches. Journal of Clinical Oncology, 19, 1: 220-230.

Sugarman, H.J., Wolfe, L., Pasquale, M.D., Rogers, F.B, O'Malley, K.F., Knudson, M., DiNardo, L., Gordon, M., & Schaffer, S. 1997. Multicenter, randomized, prospective trial of early tracheostomy. The Journal of Trauma: Injury, Infection, and Critical Care, 43, 5, 741-747.

Teno, J.M., Fisher, E., Hamel, M.B., Wu, A.W., Murphy, D.J., Wenger, N.S., Lynn, J. & Harrell, F.E. 2000. Decision making and outcomes of prolonged ICU stays in seriously ill patients. Journal of American Geriatric Society, 48: S70-S74.

Tilden, V.P., Tolle, S.W., Garland, M.J., & Nelson, C.A. 1995. Decisions about life-sustaining treatment: Impact of physicians' behaviors on the family. Archives of Internal Medicine, 155, 6: 633-638.

Ware. J.E, Jr., Kosinski, M. & Dewey, J.E. How to Score Version 2 of the SF-36® Health Survey. Lincoln, RI: Quality Metric Incorporated, 2000.

Ware, J.E., Jr., Kosinski, M., & Gandek, B. 2002. SF-36 ® Health Survey: Manual & Interpretation Guide. Lincoln, RI: Quality Metric Incorporated, 1993, 2000.

WHOQOL Group. 1955. The World Health Organization Quality of Life Assessment (WHOQOL): position paper from the World Health Organization. Social Science Medicine, 41: 1403-1409.

Wissam, C., Kreimer, D.T., & Criner, G.J. 2001. Quality of life in survivors of prolonged mechanical ventilatory support. Critical Care Medicine, 29, 4: 737-742.