

**PATIENT-CENTERED OUTCOMES AND USE OF PALLIATIVE CARE AMONG
SERIOUSLY-ILL AND NON-SURVIVING MECHANICALLY VENTILATED ICU
PATIENTS**

by

Jennifer Burgher Seaman

BSN, University of Rochester, 1988

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This dissertation was presented

by

Jennifer Burgher Seaman

It was defended on

December 10, 2014

and approved by

Mary Beth Happ, PhD, RN, Distinguished Professor, College of Nursing, The Ohio State
University

Susan M. Sereika, PhD, Professor, School of Nursing

Amber Barnato, MD, Associate Professor, School of Medicine

Jennifer H. Lingler, PhD, RN, Assistant Professor, School of Nursing

Dissertation Chair: Judith A. Erlen, PhD, Professor, School of Nursing

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Jennifer Burgher Seaman, BSN

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A considerable proportion of mechanically ventilated (MV) patients in the ICU are at high risk of dying or die during hospitalization. Patients face threats to comfort, social connectedness, and dignity as a result of experiencing pain, ICU-acquired pressure ulcers, heavy sedation, and physical restraint, all inconsistent with standards for high quality end-of-life (EOL) care. Receipt of palliative care consultation (PCC) services has been associated with improved outcomes for seriously-ill and dying individuals. Objectives were to: 1) Describe patient-centered outcomes (unrelieved pain, ICU-acquired pressure ulcers, heavy sedation and days in restraint) among sampled patients who were seriously-ill or non-surviving; 2) Identify patient-level predictors of targeted outcomes; and 3) Explore the relationship between presence, timing and duration of PCC services and patient outcomes among sampled patients who were seriously-ill or non-surviving.

A retrospective cohort design was used to conduct an expanded secondary analysis of data from the parent study (SPEACS-2; RWJF INQRI #66633). Additional data on receipt of PCC services were abstracted from the electronic medical records of parent study subjects. Of the 1440 sampled patients, 773 were at high risk of dying or did not survive hospitalization. This cohort had a mortality rate of 29.8%; and of evaluated ICU days, they spent on average 50% with unrelieved pain, 40% with some heavy sedation, and 40.8% with physical restraint. 12.3% experienced at least one ICU-acquired pressure ulcer. Being at EOL was independently associated with greater odds of experiencing heavy sedation (OR=2.64) and ICU-acquired pressure ulcer (OR=1.60);

greater percentage of the ICU stay in heavy sedation ($b=0.088$; $p<.001$); and lower percentage of ICU days with unrelieved pain ($b=-0.063$; $p=.002$), after adjusting demographic and clinical covariates. Among those at EOL, 73 (9.4%) received PCC services, occurring on average, after 62% of the stay had elapsed. Compared to pre-consultation, subjects post consultation experienced a lower proportion of days in restraint (-0.17 , $p<.001$), a higher proportion of days in heavy sedation (0.13 , $p=.015$), and similar proportions of days with pain. These findings suggest that seriously-ill and non-surviving MV adults in the ICU experience a high prevalence of poor outcomes on measures of patient-centered care.

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PREFACE

This study was supported by funding from the National Institutes of Health (NINR F31 NR014078). Support for preliminary work in the development of my proposal was provided by the John A. Hartford Foundation, and support for data collection on palliative care was supported by the Mayday Fund and the University of Pittsburgh, School of Nursing, which provided a student research assistant through the Undergraduate Research Mentorship Program. I would like to acknowledge the funding of the *Study of Patient-Nurse Effectiveness with Assisted Communication Strategies; Improving Patient Communication and Quality Outcomes in the ICU* (SPEACS-2), (Robert Wood Johnson Foundation, Interdisciplinary Nursing Quality Research Initiative grant; #66633—M. Happ & A. Barnato; 2009-2011). I wish to thank my dissertation chair and committee members for their mentorship and their contributions to this project. I would also like to thank Elise Gamertsfelder for her work on data collection. I offer heartfelt thanks to my family and friends for their support and encouragement. And finally, I want to thank my children, who travelled this journey with me—their good humor and generosity of spirit have been a great gift.

1.0 INTRODUCTION

One in five US citizens will die having received intensive care unit (ICU) services at end-of-life (EOL), a large proportion of whom will have received mechanical ventilation (MV) (Angus et al., 2004). Many of these individuals will experience considerable discomfort (Puntillo et al., 2010), isolation (Downey, Curtis, Lafferty, Herting, & Engelberg, 2010), indignity (Cook & Rocker, 2014), and a death that is not consistent with their values and preferences (Olden, Holloway, Ladwig, Quill, & van Wijngaarden, 2011; Steinhauser et al., 2000). These patient-related concerns were first brought to the attention of the broader medical community with the findings of the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT) (SUPPORT Investigators et al., 1995); and they continue to be the target of ongoing research efforts. However, much of EOL research in the ICU has focused on provider-family communication, decision-making regarding life-sustaining treatment, cost-containment, and family satisfaction (Casarett et al., 2008; Curtis et al., 2011; Curtis, Engelberg, Bensink, & Ramsey, 2012; Heyland et al., 2009; Levin, Moreno, Silvester, & Kissane, 2010; O'Mahony et al., 2010; Teno, Gruneir, Schwartz, Nanda, & Wetle, 2007; Wright et al., 2008) without substantive improvement in patients' quality of dying (Curtis et al., 2011; Goodman et al., 2010). To more directly affect patients' quality of dying, EOL research in the ICU must expand from focusing on clinicians and family members to addressing the perspective of the ICU patient.

Many clinicians assume that seriously-ill and MV ICU patients have a limited or no level of conscious awareness; yet there is growing evidence that ICU patients are often or frequently aware of their environment and sufficiently conscious to communicate and interact with family and caregivers (Happ et al., 2014). Given the context of current sedation practices and the direction of best-practice standards toward less sedation, an increasing proportion of ICU patients are likely to experience periods of sustained wakefulness and responsiveness prior to death (Luetz, Goldmann, Weber-Carstens, & Spies, 2012; Mehta, McCullagh, & Burry, 2011). Patients who have sustained wakefulness while receiving mechanical ventilation (MV) report a high prevalence of pain (Hweidi, 2007; Nelson et al., 2001; Puntillo et al., 2010; Puntillo et al., 2004; Rotondi et al., 2002; Samuelson, 2011), distress related to physical restraint (Strout, 2010; Strumpf & Evans, 1988), and social disconnectedness (Cutler, Hayter, & Ryan). In addition, these patients report multiple disturbing effects such as nightmares and hallucinations related to the use of sedating medications (Rundshagen, Schnabel, Wegner, & Schulte am Esch, 2002). This high prevalence of pain and distress translates directly to poor quality of dying for those patients who do not survive hospitalization, as well as for their families who observe them in distress.

Inadequate pain relief, heavy sedation, and physical restraint use contribute to suffering, isolation, and indignity among these patients, increasing their vulnerability, and directly conflicting with established goals of quality EOL care. Yet, there is scant extant literature regarding patient-centered outcomes at EOL. Adequate pain and symptom relief, promotion of patient dignity, and preserving a patient's ability to interact and experience the presence of family and significant others are considered to be markers of good quality of dying (Emanuel & Emanuel, 1998; Rosenfeld & Wenger, 2000; Ruland & Moore, 1998; Steinhauser et al., 2000).

Patient-centered outcomes such as unrelieved pain, ICU-acquired pressure ulcers, heavy sedation and physical restraint offer a more direct reflection of the patient experience than previously used EOL care quality measures. The use of these patient-centered outcomes can provide needed insight into the quality of dying for this vulnerable population and address the call of the National Institute of Nursing Research (NINR) to advance EOL and palliative care science.

This study is significant and innovative, making a clear shift from clinician and family-focused EOL research toward a patient-centered perspective that more directly captures the patient's quality of dying. This work is foundational to the investigator's research trajectory in EOL care in the ICU. Findings have the potential to illuminate areas for improving the care of critically adults at high risk of dying in ICU and will form the basis for developing patient-centered assessment tools and focused interventions to enhance quality of dying for this vulnerable population.

1.1 PURPOSE AND SPECIFIC AIMS

The purpose of this study, guided by a framework adapted from Emanuel and Emanuel (Emanuel & Emanuel, 1998), is to provide insight into the quality of dying in the ICU among patients at EOL (non-survivors and those at high risk of dying) who experience sustained periods of wakefulness prior to death. This expanded secondary analysis will use data from the **Study of Patient-Nurse Effectiveness with Assisted Communication Strategies; Improving Patient Communication and Quality Outcomes in the ICU (SPEACS-2)**, Robert Wood Johnson Foundation Interdisciplinary Nursing Quality Research Initiative grant (#66633—M. Happ & A. Barnato; 2009-2011). The parent study dataset offers clinically-detailed data drawn from the

electronic medical records (EMR) of 1440 patients from 6 ICUs in 2 hospitals who received MV for at least 2 days and experienced at least one 12 hour shift of sustained wakefulness between August 2009 and July 2011. (Further details about the parent study are provided in section 3.2.) In addition, the investigator will expand the secondary analysis by collecting information on palliative care consultation services for the parent study subjects from the EMR.

The specific aims are to: 1) describe patient-centered outcomes (unrelieved pain, ICU-acquired pressure ulcers, heavy sedation and days in restraint) among sampled patients who were at EOL (non-survivors and those at high risk of dying); 2) identify patient-level predictors (category of age, admission diagnosis, severity of illness on admission, and functional status) of these patient outcomes; and 3) explore the relationship between presence, timing and duration of palliative care consultation services and these patient outcomes among sampled patients at EOL (non-survivors and those at high risk of dying).

2.0 BACKGROUND AND SIGNIFICANCE

Critically ill adults receiving MV are at risk for EOL care outcomes and therefore poor quality of dying. Since the publication of the SUPPORT study, increased attention has focused on the quality of dying experienced by seriously ill, hospitalized patients (SUPPORT Investigators et al., 1995). Considerable efforts have been made over the past 18 years to raise awareness of deficits in EOL care and promote programmatic research to improve quality of dying. These include the Institute of Medicine report, *Approaching Death: Improving Care at the End of Life* (Institute of Medicine, 1997); the Hastings Center Report, *Improving Care at End of Life; Why Has It Been So Difficult?* (Jennings et al. 2005); and the establishment of the National Institute of Nursing Research's Office of Research on End-of-Life Science and Palliative Care, Investigator Training, and Education (OEPC) in 2007. Yet measurable improvement in EOL care, especially for ICU patients, remains elusive (Curtis et al., 2011). In the meantime, quality of dying has become a mainstream concern, with broad public interest in the improvement of patient outcomes. In 2010, *The Economist* commissioned a 34 page report on quality of dying worldwide, which included the development of a 24-item Quality of Death Index (Murray, 2010). The findings revealed that resource-rich countries, including the U.S., often failed to achieve high rankings despite well-developed health care infrastructures; the U.S. ranked only 9th in overall quality of dying.

Little of the research conducted has explored ICU EOL care outcomes *from the perspective of the patient*, and the lack of patient-oriented research may offer insight into why progress has been so slow. Early work that established criteria for EOL care evaluation was based on care processes as opposed to outcomes (Clarke et al., 2003; Curtis & Engelberg, 2006; Nelson, Mulkerin, Adams, & Pronovost, 2006). Subsequently, the preponderance of published research

has used processes of care such as family-provider communication and EOL decision making, or indirect outcome measures such as family satisfaction (Curtis et al., 2011; Glavan, Engelberg, Downey, & Curtis, 2008; Penrod et al., 2012). As a result, there is little EOL research focused on patient-centered outcomes (Kahn, 2012), which may better capture actual quality of dying.

The risk of dying in ICU is high, especially for those requiring MV. Overall, one in five U.S. citizens will die having received ICU services (Angus et al., 2004), and ICU patients who receive ≥ 48 hours of MV have an estimated 36% in-hospital mortality rate (Cox et al., 2007). The likelihood of death increases with age, and even for those who survive the ICU stay, the average one-year mortality rate for adults with ≥ 48 hours of MV ranges from 56-59% (Chelluri et al., 2004; Cox et al., 2007). Yet, the current reality is that many adults who are faced with life-threatening illness will opt for a trial of care in ICU (Curtis & Vincent, 2010). According to some projections, the incidence of prolonged acute MV (≥ 96 hours) will increase by 5.5% annually for U. S. adults; and by 2020 an estimated 605,898 adult patients will face prolonged MV in the ICU each year (Zilberberg, de Wit, Pirone, & Shorr, 2008).

Most seriously-ill adults surveyed rank factors related to comfort, dignity and social connectedness as most important at EOL (Steinhauser et al., 2000); yet, critically ill patients receiving MV in ICU are at risk for experiencing pain, ICU-acquired pressure ulcers, heavy sedation, and physical restraint. A high risk of dying together with a high likelihood of pain, pressure ulcers, heavy sedation, and physical restraints puts MV ICU patients at a particularly high risk for poor quality of dying. Research indicates that palliative care consultation services may improve quality of dying (Casarett et al., 2008; O'Mahony et al., 2010); however, there is little research that links palliative care consultation services with patient outcomes for this population.

2.1 UNRELIEVED PAIN

The problem of unrelieved pain continues to be a major concern in the campaign to improve care at end-of-life (EOL), now spanning nearly two decades (Institute of Medicine, 1997; SUPPORT Investigators et al., 1995) Implementation of MV requires endotracheal or tracheal intubation. The combination of intubation and artificial respiration has been identified as a major source of pain and discomfort for patients (Bergbom-Engberg & Haljamae, 1989; Hweidi, 2007; Nelson et al., 2004; Rotondi et al., 2002) Patients receiving MV in ICU report experiencing anxiety, dyspnea, sleep disturbance, hunger, and thirst (Li & Puntillo, 2006; Nelson et al., 2001; Puntillo et al., 2010; Rotondi et al., 2002; Samuelson, 2011). Ironically, the sedating medications that are administered to relieve pain and discomfort of MV can also significantly impair the patient's ability to communicate pain information, resulting in a high risk for underassessment of pain by nurses (Gélinas, Puntillo, Joffe, & Barr, 2013).

Added discomfort associated with procedures such as suctioning, turning, dressing changes, and line insertions is also described (Bergbom-Engberg & Haljamae, 1989; Jablonski, 1994; Puntillo et al., 2004; Wang, Zhang, Li, & Wang, 2009). Patient characteristics that predict unrelieved pain at EOL are not known.

2.2 PRESSURE ULCERS

The ICU has the highest incidence of pressure ulcer development in the acute care setting (Keller, Wille, van Ramshorst, & van der Werken, 2002; Shahin, Dassen, & Halfens, 2008). Estimates vary by geographical location and ICU type but incidence ranges between 3.8 and 12.4% while

prevalence is estimated to be between 4 and 71% (Keller et al., 2002; Shahin et al., 2008). The incidence of ICU acquired pressure ulcers can be as high as 32% in those over age 70 years (Gorecki, Closs, Nixon, & Briggs, 2011; Slowikowski & Funk, 2010). Advanced age, use of sedating medication, restriction imposed by MV and severity of illness are factors associated with an increased risk for pressure ulcer development (Shahin et al., 2008). Patients with pressure ulcers report pain, burning, and other uncomfortable symptoms at rest and with turning, repositioning, and dressing changes. For patients already experiencing the discomfort of MV, the added pain posed by pressure ulcer can only serve to compound their distress. The incidence of ICU-acquired pressure ulcers as a potential source of suffering for MV patients at end-of-life has not been explored.

2.3 HEAVY SEDATION

In response to the distress and discomfort of MV, patients are often heavily sedated (Hofsø & Coyer, 2007). The combination of oral intubation and heavy sedation can significantly impair a patient's ability to communicate about pain, uncomfortable symptoms, and treatment preferences (Happ, 2000a). Heavy sedation has been associated with increased incidence of delirium, prolonged MV (Arroliga et al., 2005; Frontera, 2011; Pandharipande et al., 2006; Pisani et al., 2009) and nightmares, which persist beyond the ICU stay (Granja et al., 2005; Rundshagen, Schnabel, Wegner, & am Esch, 2002). In addition, heavy sedation prevents patients from experiencing the presence of loved ones, which patients have described as comforting during intubation (Samuelson, 2011) and highly important at EOL (Gruenewald & White, 2006).

Some states of heavy sedation are secondary to intrinsic neurological conditions (e.g. stroke, anoxic encephalopathy, etc.) and therefore not subject to the clinician's control. In rare instances, pharmacologically induced heavy sedation may be necessary to control intractable pain and agitation in the final few days of life (Cowan & Walsh, 2001; Hahn, 2012; Olsen, Swetz, & Mueller, 2010). However, analysis of the **Study of Patient-Nurse Effectiveness with Assisted Communication Strategies: Improving Patient Communication and Quality Outcomes in the ICU (SPEACS-2)** data shows that nearly half of MV patients experience at least 12 hours during which they exhibit sustained wakefulness (Happ et al., 2014). Research shows sedation practices are variable, and heavy sedation of patients occurs often (Mehta et al., 2011). Since heavy sedation reduces or precludes opportunities for patient-family interaction, is associated with increased incidence of delirium and nightmares, can prolong MV, and is not consistent with current practice guidelines (Frontera, 2011; Morandi, Brummel, & Ely, 2011), the prevalence of heavy sedation among MV patients at EOL bears investigation.

2.4 RESTRAINT USE

Although the use of physical restraints has been reduced or eliminated in many clinical settings, the practice remains prevalent in the ICU environment with 58% of patients on average being restrained (Minnick, Mion, Johnson, Catrambone, & Leipzig, 2007; Mion, 2008). Restraints are implemented during MV in response to potential or observed efforts by the patient to touch or dislodge the endotracheal tube, termed patient-initiated device disruption (PDD) or treatment interference (Happ, 1998; Happ, 2000b, 2002). Despite evidence that restraints are not effective against PDD and have been associated with higher rates of agitation, delirium, and death (Miles &

Irvine, 1992), their use in the ICU persists (Mion, Minnick, Leipzig, Catrambone, & Johnson, 2007). Physical restraint has been identified as a major source of discomfort during MV (Hofsø & Coyer, 2007; Hweidi, 2007) and a source of frustration and anxiety to patients (Hofsø & Coyer, 2007). Furthermore, the use of restraints among MV patients has been associated with a decrease in patient communication with clinicians (Happ, Tuite, Dobbin, DiVirgilio-Thomas, & Kitutu, 2004). The effects of being physically restrained are profound; individuals who are physically restrained report feeling anger, fear, and humiliation (Strout, 2010; Strumpf & Evans, 1988). Yet, the extent to which dying patients experience physical restraint use and the conditions and characteristics that predict restraint use at EOL are unknown.

2.5 PALLIATIVE CARE SERVICE

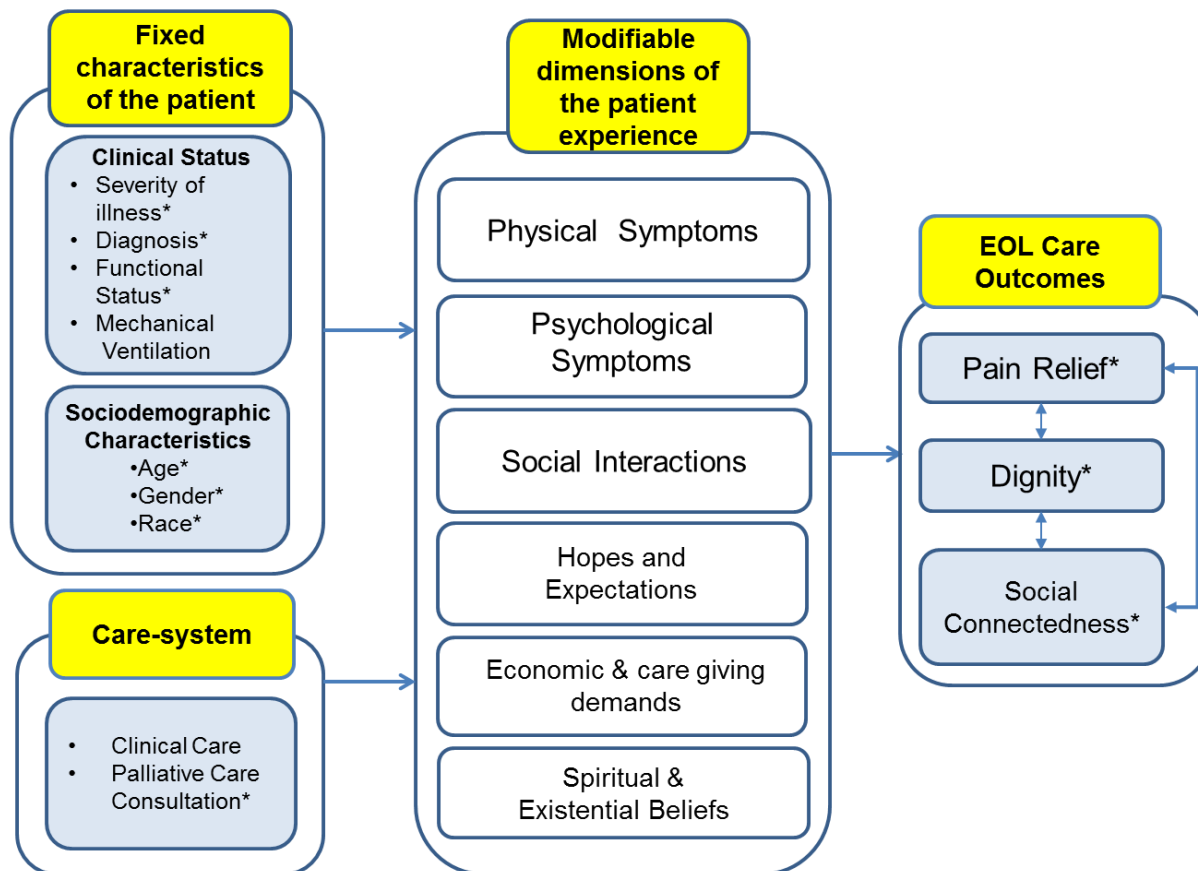
With the growth of palliative care programs in acute care hospitals there has been a steady expansion of palliative care services into the ICU setting (Casarett et al., 2008; Clark, 2002; Norton et al., 2011; O'Mahony et al., 2010). Studies evaluating care outcomes at EOL for ICU patients receiving palliative care services have shown improved outcomes for those with palliative care consults, especially when consultation occurs early in the ICU stay (Casarett et al., 2008; O'Mahony et al., 2010). However, these studies of palliative care consultation services and EOL care have overwhelmingly used proxy measures such as medication ordering practices, provider-family communication and quality of death as assessed by family members for outcome assessments (Casarett et al., 2008; O'Mahony et al., 2010). The proposed study will instead use a patient-centered approach to exploring the relationship between palliative care consultation and patient outcomes among decedents and those at high risk of dying. Specifically, the outcome

measures selected will directly reflect conditions experienced by the patient that relate conceptually to models for good quality EOL care.

2.6 THEORETICAL FRAMEWORK

There is wide concordance on the core elements of good EOL care and patient outcomes. Published models universally include pain and symptom management, respect for treatment preferences, contact with family and close friends, spiritual support, and practical support (Emanuel & Emanuel, 1998; Rosenfeld & Wenger, 2000; Ruland & Moore, 1998; Steinhauser et al., 2000). This study is based on a theoretical framework adapted from Emanuel and Emanuel (Emanuel & Emanuel, 1998) that considers the impact of patient characteristics and care system factors on modifiable dimensions of the patient experience (e.g., physical and psychological symptoms, social interactions) to produce EOL care outcomes (Figure 1). The Emanuel and Emanuel model is particularly appropriate for exploring EOL care in the ICU because it considers the role of the care system, thus addressing the unique barriers and considerations inherent in the context of the ICU environment. Blue shading and an asterisk in the model denote those constructs to be measured in the proposed study.

Framework for EOL Care in the ICU



adapted from: Emanuel, E. J. & Emanuel, L. J. (1998) The promise of a good death. *Lancet*, 351, S1121-S1129.

Figure 1: Conceptual Framework for End-of –Life Care

As described above, the EOL care outcomes of interest to this study include pain relief, social connectedness, and dignity. The extent to which these outcomes are achieved is a reflection of quality of dying. Pain relief can be examined by evaluating the frequency and intensity of pain as it is captured in the ongoing pain assessments documented in the EMR. Additionally, the occurrence of ICU acquired pressure ulcers, a source of ongoing pain and discomfort, can be evaluated to capture the extent to which pain relief is not obtained. Social connectedness is dependent on a patient’s capacity to engage in social interactions, and derive comfort from the presence of others. Exploring the time patients spend under heavy sedation, a factor limiting social

connectedness, reflects the degree to which social connectedness is not achieved. Dignity has been defined as having self-esteem, respect, well-being, and pride (Chochinov, 2002; Gruenewald & White, 2006; Hall et al., 2009). It is a self-defined concept and is dependent upon how one believes he or she is perceived (and treated) by others. Any care modality which decreases an individual's sense of self-esteem and pride and conveys that he or she is not respected, serves to erode dignity. The psychological effects of being restrained are overwhelmingly negative, and the practice of restraint use has a profound effect on patients' dignity (Evans & Strumpf, 1990; Strumpf & Evans, 1988; Sullivan-Marx, 1995). Evaluating the time spent in physical restraint and the number of restraints applied reveals the extent to which dignity is threatened.

In this study, the selected patient care outcomes serve as proxy measures for the constructs of interest as identified in the adapted model. Furthermore, the EOL care outcomes are linked to patient and care system characteristics. The goal of the study is to use the model not only to describe patient outcomes, but also to explore patient and care system predictors, thus permitting insight into an otherwise difficult area to study.

2.7 SUMMARY

Considerable research has been undertaken to improve EOL care in the ICU and quality of dying, yet progress has been minimal. It has been well demonstrated that ICU patients at high risk of dying experience pain, heavy sedation, ICU-acquired pressure ulcers and physical restraint. These outcomes are considered suboptimal for all ICU patients, but they have potentially greater significance for those at EOL. While pain, restraint and the disturbing dreams associated with heavy sedation are negative for any patient, they are of perhaps greatest concern for patients at

EOL, since it is unlikely they will have the occasion to later reflect on the ICU experience and construct a meaning for it. Heavy sedation impairs social connectedness and can preclude opportunities for interaction with family members. For the dying individual, these may represent the only opportunities to communicate with loved ones, experience their presence, receive emotional or spiritual support, and achieve closure.

Considering the high mortality in ICU and the risk for poor outcomes, especially for those receiving MV, innovative research is needed to identify the unique needs of patients at EOL and to facilitate the development of targeted interventions. Quality of dying conceptually demands a patient-centered approach. Exploring the experience at the point of the patient, along with the perspectives of clinicians and family members, will provide a more comprehensive understanding of dying in the ICU and move the science of patient-centered EOL care forward.

2.8 INSTRUMENT DEVELOPMENT

Development of the data collection instrument for the parent study is described in a manuscript which has been submitted for publication (Appendix A). The manuscript outlines the process of developing an instrument for collecting patient outcome data via medical record abstraction from the EMR. The manuscript includes methods used to test and refine the tool, as well as the procedures for inter-rater reliability testing of abstracted data and training of abstractors. Results on reliability testing of the parent study data are also reported.

The resulting dataset constitutes a rich resource for studying patient-centered care outcomes, with over 15,000 days of patient data. Given the historical difficulty with EOL research, a health services approach using secondary analysis is a novel and ethical means to answer research

questions with a vulnerable population. Development of a data collection tool and reliability testing for the collected data were important steps towards creation of a dataset with which to conduct patient-centered EOL research.

3.0 RESEARCH DESIGN AND METHODS

The proposed research study is an expanded secondary analysis. The study capitalizes on the availability of a large, information-dense dataset from the SPEACS-2 study (*SPEACS-2: Improving Patient Communication and Quality Outcomes in the ICU*) (Happ & Barnato, 2009-2011). The parent study dataset contains a constellation of patient-centered outcome variables considered important at EOL.

3.1 STUDY DESIGN

This proposed study is an expanded secondary analysis of clinical data collected for the SPEACS-2 study using a retrospective observational cohort design, accounting for design effects from the parent study as appropriate. EOL is conceptualized using two distinct analytic constructs: “prospective” identification of patients who, by clinical criteria, would have been considered by clinicians at high probability of dying at the time of ICU admission (per Acute Physiology and Chronic Health Evaluation III [APACHE III] score (Knaus et al., 1991) and “retrospective” identification of patients who did, indeed, die during hospitalization (non-survivors). Using this dual approach addresses the concern that a retrospective case series of decedents may produce a biased estimate of treatment patterns of “dying” patients (Bach, Schrag, & Begg, 2004). First, not all decedents are expected to die (and hence they likely to receive treatment different from those whose anticipated risk of dying is high). Secondly, the course of treatment may be varied in response to patient preferences and values. Finally, the set range of days during which data was

collected may fail to capture EOL outcomes for subjects who are outliers in terms of their anticipated and actual survival times.

3.2 PARENT STUDY

The parent study, SPEACS-2, is a randomized, controlled, stepped-wedge designed trial evaluating the effect of a unit-level communication intervention on nursing care quality outcomes among mechanically ventilated adults led by Drs. Happ and Barnato and funded by the Robert Wood Johnson Foundation Interdisciplinary Nursing Quality Research Initiative (INQRI). The quality of care outcomes measured in the SPEACS-2 study include: pain, ICU-acquired pressure ulcers, heavy sedation, and restraint use.

3.2.1 Setting

The parent study was conducted in six ICUs within two academic medical center affiliated hospitals. One, a quaternary care facility, has 795 beds, ten ICU units and is a designated Level I Regional Resource Trauma Center, and the second is a 535-bed tertiary care center. Subjects were drawn from the transplant, neurological, trauma, neurotrauma, general medical, and cardiovascular ICUs. The hospitals' critical care services share medical leadership but have separate nursing administrations. The nurse-to-patient ratio in each ICU ranges from 1:1 to 1:2, depending upon patient acuity. Both institutions share the electronic medical record (EMR) and utilize a common database. The study was approved by the Institutional Review Board of the University of Pittsburgh with a waiver of informed consent granted.

3.2.2 Intervention

The multi-component intervention in the parent study consisted of a 1-hour on-line communication training course for nurses, low-technology communication supplies, educational posters, and weekly bedside communication rounds conducted by a speech-language pathologist (Happ et al., 2010). The intervention, built on previous research (Happ et al., 2011; Radtke, Tate, & Happ, 2012), was implemented on each unit in consecutive 3-month blocks using a randomized, staggered implementation order.

3.2.3 Sample

The total sample consisted of 1,440 adult patients admitted to one of 6 ICUs who were mechanically ventilated for at least two consecutive days and awake for at least one 12-hour nursing shift while mechanically ventilated. Patients were considered awake if they were able to follow commands (sub-score of 6 on the Glasgow Coma Scale (GCS) (Teasdale & Jennett, 1974) (or nursing documentation indicated the ability to follow commands), were described in the nursing documentation as continuously awake or alert, or were given a Ramsey Sedation Score <4. Subjects were not considered awake if criteria were met only during sedation interruption. The subjects were randomly selected from a list of all MV patients admitted to study ICUs on a schedule of 30 subjects per unit, per quarter, over 8 quarters from August 2009 thru July 2011. Data collection for the parent study has been completed; the sample is 52.4% male, with an average (\pm SD) age of 61.2 ± 16.9 years and a mean (\pm SD) APACHE III score of 66.0 ± 27.5 on admission. The racial composition is 86.4% white, 9.1% Black or African American, and 4.1% other or unknown.

3.2.4 Data Collection Procedures

A data collection tool was developed for abstraction of data from the EMR. Abstractors were trained using specially developed standardized operating procedure (SOP) documents; abstractor reliability was established using standardized test patients prior to actual study data collection. Inter-rater reliability (IRR) of the data was evaluated by calculating the Cohen's κ statistics for 108 cases selected randomly from 1440 cases abstracted by 8 raters (10% for quarters 1-4; 5% for quarters 5-8), which were co-abstracted by a single rater. Testing for the 108 randomly selected cases revealed substantial to excellent IRR (Landis & Koch, 1977) with mean Cohen's κ values of 0.61 to 0.99 for all target indicators. The manuscript detailing instrument development and testing, as well as data collection procedures and reliability testing has been included (Appendix A).

3.3 MEASUREMENT

The primary outcome variables were percent days with pain, mean highest pain score, number of ICU-acquired pressure ulcers, percent days with any heavy sedation, proportion of evaluated ICU stay in heavy sedation, percent days with restraint, and mean number of restraints per day for days with restraint. Percent days were calculated based on the total evaluated ICU days, up to 28. EMR review has been used successfully in prior research to measure the presence of nursing pain assessment, pressure ulcer occurrence and sedation and restraint use (Edwards et al., 2006; Gélinas, Fortier, Viens, Fillion, & Puntillo, 2004; Gunningberg, Dahm, & Ehrenberg, 2008; Tate, Happ, & Sereika, 2005).

For Aim 2, predictor variables included basic demographic information (age, race/ethnicity, gender, and survival status), diagnosis, severity of illness (APACHE III) on admission to ICU, functional status prior to admission and palliative care consultation. Exposure to the parent study intervention (see 3.2) and ventilation status were covariates, and were explored in the analysis. Main concepts from the theoretical framework, variables, and operationalized measures are summarized in Table 1. Further details about the measures are included in section 3.3.1.

Table 1. Variables, Measures and EMR Data Collection Time Points

Concept from the Theoretical Framework	Variable	Measure	Time Point
Clinical Status	Severity of Illness	APACHE-III score (Knaus et al., 1991)	Admission
	Admission diagnosis	Primary diagnosis on admission to ICU (category)	Admission
	Functional status prior to admission	ADL/IADL** status	Admission
	Mechanical ventilation	Presence/Absence positive pressure ventilation	Daily
	Palliative care services	Palliative care service member consultation notes Number of ICU days of palliative care service in ICU Time to consultation	Daily
	Intervention exposure	Admission to the ICU before/during/after intervention	Daily
Fixed Patient Characteristics	Age	Chronological age in years	Admission
	Gender	Gender (M/F)	Admission
	Race/Ethnicity	Race/Ethnicity (White, African-American, Other)	Admission
	Survival	Disposition upon discharge (died/alive)	Discharge
Pain Relief	% Days with pain	Presence of pain by nursing assessment (patient report or nurses' behavioral assessment)	Daily
	Pain intensity	Mean highest daily pain score (1-10 numeric scale)	Daily
	ICU acquired pressure ulcer	Number of pressure ulcers \geq stage II incurred during the ICU stay (enterostomal nurse consultation note)	Discharge
Social Connectedness	% Days with heavy sedation	Being in a heavily sedated state for some portion of 24 hours	Daily
	% Days with heavy sedation, AND some sustained wakefulness	State of heavy sedation, AND awake at least 8 out of 12 hours, AM or PM	Every 12 hours
	% Days with heavy sedation and no sustained wakefulness	State of heavy sedation, and NOT awake at least 8 out of 12 hours, AM or PM	Every 12 hours
Dignity	Restraint Use*	Restraint use for any portion of the day	Daily
		Number of restraints per day (mean)	Daily

* The application of a mechanical device for the purpose of restricting one's movement (Retsas, 1998).

** Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL).

3.3.1 Instrumentation

The variables that constitute *Clinical Status* were measured as follows:

Severity of Illness: The Acute Physiology and Chronic Health Evaluation (APACHE III) was used in the parent study as a measure of severity of illness. APACHE III is a well-validated, accurate tool measuring acuity of illness and mortality risk. The range for APACHE III scores is 0-299, with a higher score reflecting greater severity of illness and greater mortality risk. Psychometric testing of APACHE III scores indicate high predictive accuracy of mortality; for 95% of subjects, scores generated after 24 hours of ICU admission provided a risk estimate for hospital mortality that was within 3% of actual mortality, $r^2 = 0.41$; area under the receiver operating characteristic (ROC) curve = 0.90 (Knaus et al., 1991). In the parent study, APACHE III score was calculated by the abstractors, based on clinical data in the EMR from the first 24 hours of the ICU stay.

Admission diagnosis: The data collection tool contained a categorized list of primary and secondary diagnoses (see Appendix A). Admission diagnoses reflected conditions that were present upon admission to the ICU, and were collected by abstractors from the EMR.

Functional Status: Functional status data were abstracted from the nursing admission assessment, containing items indicating activities of daily living (ADL) and instrumental activities of daily living (IADL) status prior to hospital admission (Albert & Freedman, 2010; Katz & Akpom, 1976). For the proposed study, a functional status index scores based on ADL and IADL information were generated using the method described by Barnato (Barnato, Albert, Angus, Lave,

& Degenholtz, 2011). Functional status scores ranged from 0 to 100, with a score of zero indicating no functional disability and 100 indicating complete functional disability with ADLs or IADLs.

Mechanical Ventilation: Mechanical ventilation was defined as the continuous delivery of positive-pressure ventilation via endotracheal or tracheostomy tube. Ventilation status was evaluated daily, and subjects were considered MV for the day if they received positive-pressure ventilation for any portion of the day.

Intervention Exposure: Intervention exposure was determined by patient location in conjunction with the intervention deployment schedule.

Palliative Care Service consultation: Palliative Care Service consultation was defined as Palliative Care Services consultation and evaluation by a consult service team member during the ICU stay as evidenced by a written consultation note in the EMR. Also measured were the number of days of Palliative Care service delivered, as a proportion of total ICU days (up to 28) and time to consultation. Time to consultation was measured in days beginning with the first MV day in ICU to the date of the first palliative care service note.

The key outcome variables were operationalized as follows:

Pain: Pain represented a lack of *pain relief*. Pain was measured in two ways: days with pain as a percentage of total evaluated ICU days and mean highest daily pain score (patient-reported).

Heavy Sedation: Heavy sedation represented an inability to maintain *social connectedness*. *Heavy Sedation* was measured as: a documented unresponsiveness to verbal/tactile stimulation, Modified Ramsey Sedation Score ≥ 4 , Riker Sedation-Agitation Scale score of 1-2, or GCS motor response score < 6 at any point in the 24 hour interval (12:00am-11:59pm). Sustained wakefulness was documentation of a GCS motor response score of 6 or nursing documentation of the any of

following descriptors: neurologically within normal limits, oriented, alert, attempting to communicate, following commands, or responding to questions/commands for 8 of 12 hours. Sustained wakefulness was measured for both AM and PM intervals daily, based on assessments of neurological status, which were performed at least every 4 hours. For the proposed study, heavy sedation was measured as days with heavy sedation, days with heavy sedation but some period of sustained wakefulness, and days with heavy sedation and no sustained wakefulness, all as a percentage of total measured ICU days. This level of granularity was indicated, given the fluctuations in patient condition in the ICU.

ICU-acquired pressure ulcer: ICU-acquired pressure ulcer was defined as the number of pressure ulcers, Stage II or greater, that were acquired during the ICU stay as documented by the enterostomal therapy team nurse.

Restraint: Restraint use was defined as any device applied for the purpose of restricting a patient's movement. *Restraint use* represented an erosion of patient *dignity*, and was measured as days in restraint as a percentage of total measured ICU days and mean number of restraints per day.

3.4 ANALYSIS

SPSS (version 21, IBM, Inc., Armonk, NY) was used. The level of significance when testing hypotheses was set at $p < .05$. Prior to executing the analyses to address the research aims, data quality was assessed by exploring univariate and bivariate distributions, screening for outliers, and evaluation of the amount and pattern of missing data with appropriate data imputation if needed.

3.4.1 Preliminary Analysis Procedures

Preliminary analysis of the parent study data revealed very little missingness of basic demographic data, but considerable missing data on functional status. (There was <.01% missingness for race/ethnicity, but about 30% missing data for items measuring functional status.) In addition, about 37% of patients had days where nursing documentation indicated pain was present, but a score was not provided. To retain this valuable information about how completely pain was assessed, a derived variable representing scored vs. un-scored pain was generated to capture the prevalence of this condition. Data were analyzed using techniques appropriate to retrospective cohort studies. Systematic biases were addressed and caution was exercised in interpreting the results, which provided information about prediction and association but not causation.

3.4.2 Analysis for Aim 1

Specific Aim 1 described patient outcomes (unrelieved pain, ICU-acquired pressure ulcers, heavy sedation and days in restraint) among sampled patients who were at EOL (decedents and/or those at high risk of dying). As it is difficult to predict who is at EOL, and retrospective analysis of decedents may be a biased measure of treatment provided to “dying” patients, descriptive statistical analysis of the primary outcomes were performed among decedents and among patients who were at high risk of dying upon admission (as defined by 50th percentile for APACHE III score). (See section 3.5.1 for additional details on this procedure.) Appropriate parametric or non-parametric descriptive statistics (with confidence intervals) were used based on the level of measurement and the observed distribution for the derived outcome measures for patient care outcomes related to pain, ICU acquired pressure ulcers, heavy sedation and restraint use.

Continuous-type variables, such as days with heavy sedation, were described using measures of central tendency (mean, median) and dispersion (standard deviation, inter-quartile range). ICU-acquired pressure ulcer was described using frequency counts and percentages. In addition group comparative methods, such as t-tests or Wilcoxon rank-sum tests, were employed for comparisons of groups based on predicted risk (50th percentile on APACHE III score) and vital status (died, survived). Pressure ulcer development, a dichotomous outcome, was analyzed and compared based on survival status using contingency table analyses and binary logistic regression with chi-square type test statistics. In instances of low cell count, the Fisher Exact test was used. The rate of pressure ulcer occurrence, as a count of events per day (i.e., rate of occurrence), was analyzed and compared based on risk/survival status using Poisson regression.

3.4.3 Analysis for Aim 2

Specific Aim 2 identified patient-level predictors (age, admission diagnosis, severity of illness on admission, and functional status) of the targeted patient-centered outcomes. Hierarchical multivariable regression models were constructed for each of the primary outcomes of interest, adjusting for clustering of patients within units and for intervention effects. Potential predictors of interest included: age, diagnosis, functional status prior to admission, and severity of illness. Interaction effects were tested as part of the model building process to determine whether there was any effect modification of predictors on outcomes by risk of death/survival status. It was hypothesized that more advanced age, admitting diagnosis, poorer functional status and greater severity of illness upon admission would be associated with more unrelieved pain, ICU-acquired pressure ulcers, heavy sedation, and restraint use.

3.4.4 Analysis for Aim 3

Specific Aim 3 explored the relationship between presence, timing and duration of palliative care service consultations and patient-centered outcomes (pain, ICU-acquired pressure ulcer, heavy sedation and restraint use) among sample patients at EOL (decedents and/or those at high risk of dying). Propensity matching was employed for the identification of control subjects (from among those without palliative care service consultation) because there was a likelihood of indication bias. Specifically, patients in more pain and those at highest risk for dying were more likely to have palliative care consultation. To assess the incremental effect of palliative care consultation on the primary outcomes, propensity score matched case (palliative care service consultation recipients) and control subjects were compared. The relationship between timing and duration of palliative care consultation (proportion of ICU stay with palliative care consultation) and primary outcomes was also explored among patients at EOL who received palliative care consultation. It was hypothesized that patients at EOL with palliative care service consultation would have improved outcomes, after accounting for indication bias (e.g. bias towards more acutely ill and symptomatic patients receiving palliative care service consultation).

3.4.5 Limitations

Although this work has the potential to offer new insight into the quality of dying of older adults in ICU, several limitations must be acknowledged. First, retrospective chart review has the potential to introduce error, and some missing data are unavoidable. Second, the study was conducted in two large, academic-affiliated tertiary/quaternary-care institutions, and findings may

not be generalizable to all acute care settings. Finally, use of decedents to study EOL has the potential to introduce bias, which can be minimized, but not completely eliminated.

3.5 ADDITIONS AND CHANGES TO THE PROPOSED STUDY

Expanded descriptions of procedures used in the study as well as changes to the proposed study are detailed below.

3.5.1 Identification of the EOL Cohort

To identify the cohort of those at high risk of dying, APACHE III severity of illness scores, collected in the parent study, were used. Prior studies of this patient population have used APACHE II scoring. For example, Puntillo and colleagues (2010) selected an APACHE II score of ≥ 20 , which corresponds to $> 40\%$ risk of dying, as the threshold for patient inclusion in a study of symptoms among ICU patients at high risk of dying. White (2011) used the APACHE II cut-point of ≥ 25 , which corresponds to a $> 55\%$ risk of dying, as the threshold for inclusion in a pilot study of a decision support intervention for ICU patients at high risk of death or functional impairment. For those studies, the criteria yielded samples with in-hospital mortality rates of 22% and 37.5%, respectively.

Unfortunately there is no existing method to convert APACHE III scores to predicted risk of in-hospital mortality, as with APACHE II, nor is there a direct method to convert APACHE II scores into comparable APACHE III values. However, work by Barie and colleagues suggests that the values are fairly highly correlated ($r = 0.7$) among surgical ICU patients (Barie, Hydo, &

Fischer, 1995). Therefore, we explored several possible APACHE III cut-points (32nd, 50th, 60th, 70th and 80th percentiles) and assessed the observed in-hospital mortality of the resulting subsamples. We arbitrarily began with the 50th percentile (APACHE III score ≥ 63), or the top half of illness severity in the sample. This threshold yielded a subsample of 773 patients with a predicted mortality rate of 24.7% and an actual mortality rate (including those decedents not predicted to die) of 29.7%. This rate is comparable to that of other studies examining those at high risk of dying. Using an APACHE III score of ≥ 63 corresponds with a true positive rate (sensitivity) of 77% and a false positive rate (1-specificity) of 43%. As would be expected, lower cut-points increased sensitivity and decreased specificity; higher cut-points decreased sensitivity and increased specificity. We chose to err on the side of improved sensitivity by selecting an APACHE III score of ≥ 63 , corresponding to the 50th percentile in our sample.

Furthermore, it is likely that the patients in this subsample are at high risk of death in the ensuing year. It is estimated that 56% of all adults receiving MV for ≥ 48 hours (Chelluri et al., 2004) and over 70% of older adults receiving MV ≥ 96 hours will die within 1 year (Cox et al., 2007). Of the 773 in our subsample, 440 (56.9%) were older adults with a mean duration of 9.42 days of MV. While some of these patients may survive hospitalization, they are at high risk of dying in the year following ICU discharge, further supporting their inclusion in the EOL cohort.

3.5.2 Derivation of summary scores for functional status

For the parent study, data on functional status prior to admission were abstracted from EMR admission assessment documentation, which was collected from the patient/family by the nurse within 48 hours of hospital admission. The data collected consisted of functional disability ratings

(independent/needs assist/dependent) for each of 7 activity of daily living (ADL) and 8 instrumental activity of daily living (IADL) items. The ADL items included eating, bathing, dressing, toileting, grooming transfers, and home ambulation; IADL items included cooking, cleaning, laundry, grocery shopping, money management, community ambulation, driving and medication management.

Using a validated weighting approach developed by Finch et al. (1995) we applied weighted values to key ADL and IADL items reflective of the relative disability associated with loss of function for a given item. (For example, requiring assistance with eating would be given a higher weight than requiring assistance with ambulation.) Since the ADL and IADL items available in the parent dataset differed from those in the Finch scoring rubric, we mapped items in our dataset as closely as possible to those listed by Finch, an approach described by Barnato and colleagues in a study of disability among elderly survivors of MV (2011). This resulted in 6 ADL items and 5 IADL items being selected.

In addition, the Finch weighting rubric accounted for more granularity in the level of assistance required for ADL items, compared to the parent study data. (For example, for the item “bathing”, there are scores for “needs a little assistance” and “needs a lot of assistance”.) In order to select the most accurate weight to apply, we derived summary scores using both high and low assistance weights. These scores were then graphed against the total count of items for which there was any functional disability, and the relationship was assessed for linearity. The scores using the high assist weights resulted in the most linear relationship ($R^2 = 0.977$), and therefore the high assist values were used.

For both ADLs and IADLs, the weighted scores were added to create a summary score, and the summary score was scaled to 100 to create a continuous measure with a score of zero

indicating no functional disability and a score of 100 reflecting total functional disability. For each subject we derived an ADL and IADL functional disability score. It should be noted that there was considerable missing data on functional status in the parent study dataset, reflective of incomplete data collection/documentation at the time of hospital admission. Analysis of missing data for this clinical variable is described further in sections 3.5.4 and 3.5.5

3.5.3 Data collection on Palliative Care Consultation services

To address the questions in Aim 3, we abstracted data on the presence, timing and duration of palliative care consultation services for the 1440 sampled patients. In addition, we collected data on reason for consult, consulting physician (specialty and role), and palliative care service provider role. Prior to initiating data collection, a data collection form and standard operating procedure (SOP) were developed (see Appendix C for data collection tool). The SOP and forms were pilot-tested for usability and necessary adjustments were made. Data on palliative care consultation (PCC) services were collected by the principal investigator (J.B.S.) and a trained student abstractor. Any questions that arose during the process of collection were discussed with the dissertation chair and other committee members, as needed.

The two hospitals used in the parent study had differing models of palliative care service delivery—Hospital A had a well-developed service and used a team model. The team consisted of palliative care physicians, fellows, and nurse practitioners (NPs), as well as dedicated palliative care social workers and psychologists. Pastoral care was provided by staff from the hospital’s pastoral care department, who coordinated with the service and participated in interdisciplinary palliative care team meetings. On the other hand, Hospital B had a nurse-led service, with consultation provided by nurses with specialty training in palliative care, some of whom had

advanced degrees. Nurses on the palliative care service coordinated with social workers and members of the pastoral care staff as needed, but the service did not have any dedicated staff beyond the nurses. When collecting data on the number and palliative care service provider role, we made the decision to include social work and pastoral care visits as palliative care visits if the provider documented coordination with the palliative care nurse, participation in family meetings convened by the palliative care service RN, or discussion with the patient/family about EOL concerns or issues.

Upon completion of abstraction, we scanned the data collection forms into the electronic database, and data-cleaning procedures were performed. To ensure the reliability of collected data, a random selection of 10% of cases were abstracted by both the student and principal investigator to assess the reliability of palliative care consultation identification. All cases with an identified palliative care service consult were abstracted by the student research assistant and checked by the principal investigator. We performed analysis of inter-rater reliability (IRR) for the 10% of dually-coded cases, and testing showed 98.6% agreement on identification of palliative care consultations.

3.5.4 Changes to statistical analysis plan for aim 2

Preliminary analysis of the data on the main outcomes revealed non-normal distribution on daily measures of pain, heavy sedation, and restraint use. The frequency distribution was bi-modal, with a large number of zero values and a fairly normal distribution of the remaining values. We used a two-step approach to model each of these outcomes, first using logistic regression to model the odds of experiencing the outcome, then linear regression to model the outcome among those who did experience it. We provide additional details about this approach and the rationale for its selection in Section 4.0, in the methods section of the manuscript (Chapter 4). In the course of

data exploration and modeling for aim 2, we fitted parsimonious logistic models predicting patient outcomes. Results are reported in Section 6.0.

As discussed in section 3.5.2, there was considerable missing data on functional status prior to admission. Analysis of missingness showed approximately 30% of subjects had missing data. Imputation strategies were considered; however, exploration of patterns of missingness revealed that the missingness was not random. Furthermore, the accuracy of the data was questionable, since the data were not necessarily collected directly from the patient or caregiver. For these reasons, imputation was not pursued. Instead, we performed the regression testing with and without controlling for functional status. We give specific details about missing functional status data in Section 4.0, in the results section of the manuscript (Chapter 4).

3.5.5 Changes to statistical analysis plan for aim 3

We conducted testing of the incremental effect of receiving palliative care consultation services on the primary outcomes as specified, comparing palliative care service consultation recipients with propensity-matched control subjects. We generated propensity scores for those in the EOL cohort (N=773), adjusting for age, gender, race, severity of illness, ventilator days, ICU days and clustering by ICU unit. We then used nearest-neighbor matching to select a control subject (who had not received palliative care consultation services) for each of those in the cohort receiving PCC (n=73), for a total of 176 subjects in the total sample. We compared case and control subjects on the primary outcomes—proportion of days with pain, heavy sedation, and restraint and presence of ICU-acquired pressure ulcer over the course of the ICU stay.

Because palliative care consultation services were initiated late in the ICU stay for many of the patients who received them, we performed an additional analyses to determine if there were

significant differences in the outcomes, pre- and post-consultation, among palliative care consultation recipients. We also conducted testing to determine if there were differences, pre- and post-consultation, between survivors and non-survivors who received palliative care consultation services. The results of these analyses are reported in Chapter 5.

3.6 HUMAN SUBJECTS INVOLVEMENT

De-identified data from the Study of Patient-Nurse Effectiveness with Communication Strategies: Improving Patient Communication and Quality Outcomes in the ICU (SPEACS-2) (RWJF INQRI; Happ & Barnato, 2009-2011, IRB Approval # PRO09060348, 02/18/14) were provided. Data from all 1440 subjects were used in the proposed study. We abstracted additional data on palliative care consultation services from the EMR on study subjects in order to complete Aim 3.

3.6.1 Source of Materials

Demographic and patient outcome data were collected previously and obtained from the parent study database (SPEACS-2: Improving Patient Communication and Quality Outcomes in the ICU; Happ 2009-2011, IRB Approval # PRO09060348, 02/18/14). A waiver of informed consent was granted for collection of the parent study data. Data on presence and duration of palliative care consultation were collected via retrospective EMR review. To answer the aims of the proposed study, a modification to the existing IRB protocol was obtained through the University of Pittsburgh IRB. The modification approved both the use of existing data for secondary analysis and the collection of the additional data on palliative care consultation (MOD09060348-

07/PRO09060348, 07/02/2013). A second modification was obtained in order to abstract additional information on referring providers and palliative care consultation team providers (MOD09060348-09/ PRO09060348, 06/23/2014). As with the parent study, a waiver of informed consent was obtained. (See Appendix B for IRB approvals.) Both the parent study and the current study met the following criteria for a waiver of informed consent: the study procedures involved no more than minimal risk to study subjects, and it would not have been feasible to conduct the research without such a waiver.

3.6.2 Potential Risks, Benefits and Protections from Risks

This was a minimal risk study. The primary risk of the study was a potential breach of privacy or confidentiality. To minimize this risk, the following practices were exercised: (1) Parent study data were de-identified and could only be linked to the subject by the unique study identification code; (2) All data abstracted from the EMR (beyond that extracted in the parent study) were collected by the investigator or a trained student research assistant; (3) Abstractors completed all research privacy training modules as required by IRB regulations; (4) The principles of privacy and confidentiality of the medical record were reinforced with student research assistants; (5) All patient data were abstracted without identifying information; (6) All paper study documents were stored in a locked file cabinet in the investigator's office; (7) and the file linking the patient's medical record number and study identification number was stored in a separate password protected folder on the restricted Critical Care Medicine Department data drive, located on the secure UPMC network server.

Potential Benefits: There were no direct benefits to study subjects. However, findings from this study have the potential to provide needed insight into patient outcomes at EOL for

seriously-ill patients in the ICU and inform the development of interventions and clinical practice guidelines to improve EOL care.

Data & Safety Monitoring Plan: Data and safety monitoring for studies using retrospective medical record review centers primarily on maintaining the privacy and confidentiality of the subjects. Data and safety monitoring was conducted at weekly meetings with the dissertation chair and selected committee members, during which data acquisition and management activities were reviewed. No adverse events related to the study were identified. A data safety monitoring report was provided to the IRB at the time of annual renewal (01/29/2014) and will be provided to the IRB at the time of the next annual renewal (02/18/2015).

**4.0 DATA-BASED MANUSCRIPT (AIMS 1 & 2): PATIENT-CENTERED CARE
QUALITY OUTCOMES AMONG SERIOUSLY-ILL AND NON-SURVIVING
MECHANICALLY VENTILATED ADULTS**

**PATIENT-CENTERED CARE QUALITY OUTCOMES AMONG SERIOUSLY-ILL
AND NON-SURVIVING MECHANICALLY VENTILATED ADULTS**

Jennifer B. Seaman, BSN, Susan M. Sereika, PhD, Amber E. Barnato, MD, MPH, MS,
Judith A. Erlen, PhD, Howard Degenholtz, PhD, Mary Beth Happ, PhD

University of Pittsburgh, Pittsburgh, Pennsylvania (Ms. Seaman, Drs. Sereika, Barnato,
Degenholtz and Erlen); The Ohio State University (Dr. Happ).

Word Count:

Address for correspondence:

Jennifer B. Seaman, BSN, RN

415 Victoria Building

School of Nursing

3500 Victoria Street

Pittsburgh, PA 15261

412-352-6545

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Ms. Seaman had full access to all the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis.

ABSTRACT

Objectives. Many seriously-ill and non-surviving patients who receive mechanical ventilation (MV) experience sustained wakefulness in ICU, yet most measures of quality of dying in the ICU are not focused on the direct experiences of patients. We sought to identify and describe patient-centered outcomes in the ICU among critically-ill patients who also experienced sustained periods of wakefulness during the admission, and to determine, in a subsample those at end-of-life (EOL), if being at EOL independently predicted poorer outcomes on measures of restraint, heavy sedation, pain, and ICU-acquired pressure ulcer.

Design. Secondary data analysis using a retrospective cohort design.

Setting and Subjects. Patients from 6 ICUs within 2 tertiary care centers in a Mid-Atlantic health system who received MV for ≥ 2 days and experienced at least some sustained wakefulness during the ICU stay (2-28 days).

Measurement and Main Results. We evaluated patient outcomes on measures of restraint, heavy sedation, pain and ICU-acquired pressure ulcer for the sample and defined a subsample of those at EOL, which consisted of subjects at high risk of dying and those who did not survive hospitalization. Patients at EOL spent a large percentage of ICU days in restraint (40.8%), states of heavy sedation (40.0%) and unrelieved pain (50.0%), and experienced a high incidence of ICU-acquired pressure ulcer (12.3%). Being at EOL was independently associated with greater odds of experiencing heavy sedation during the ICU stay (OR=2.64); greater percentage of the ICU stay in heavy sedation ($b=0.088$; $p<.001$); and lower percentage of ICU days with unrelieved pain ($b=-0.063$;

$p=.002$), after adjusting for age, gender, race, functional status, ICU days, functional status and ICU unit. Being at EOL was also independently associated with greater odds of ICU-acquired pressure ulcer ($OR=1.60$; $p=.041$), after adjusting for age, gender, race, ICU days, and ICU unit.

Conclusion. Critically-ill MV ICU patients who were at high risk of dying and those who did not survive hospitalization experienced markedly poor outcomes on these patient-centered measures of care quality. These patients also experienced periods of sustained wakefulness, and the extent to which these poor care quality outcomes were endured by these patients is a reflection of their quality of dying. Approaches that seek to measure EOL care quality outcomes directly experienced by patients are needed to adequately evaluate quality of dying in the ICU.

Keywords: end-of-life care, critical care, patient-centered outcomes, quality of dying

INTRODUCTION

Many clinicians assume that critically ill intensive care unit (ICU) patients have minimal conscious awareness. However, with current sedation recommendations and practices, a greater percentage of these patients are experiencing sustained wakefulness and responsiveness, including those who die. A recent study by Happ et al. revealed that among critically-ill, mechanically ventilated patients, 53.8% of those screened experienced at least 12 hours of sustained wakefulness during the ICU stay, 16% of whom did not survive the hospitalization [1]. Given the extent to which critically ill patients will be aware of their surroundings, their direct experiences are an important focus for research on end-of-life (EOL) care quality.

High quality EOL care preserves patient dignity and promotes autonomy, social connectedness, and comfort [2-4]. Yet, critically ill patients, especially those receiving mechanical ventilation (MV), experience physical restraint – impairing dignity[5, 6], heavy sedation – impairing social connectedness [7], and unrelieved pain [8, 9] and ICU-acquired pressure ulcers – impairing comfort [10]. Evaluating these patient-centered outcomes offers a more direct assessment of EOL quality than those predominantly focused on surrogate reports of their loved one’s quality of dying [11].

The purpose of this study was to identify and describe patient-centered outcomes in the ICU among critically ill patients who also experienced sustained periods of wakefulness during the admission. We defined the subgroup of critically ill patients at “EOL” as those at highest risk for dying, based on illness severity upon admission, and/or those who actually died during the hospitalization. Specifically, we evaluated

physical restraint, heavy sedation, unrelieved pain and ICU-acquired pressure ulcers and assessed whether being at EOL was independently associated with poorer patient outcomes on these measures.

MATERIALS AND METHODS

Study design, participants and sample size

We performed a secondary analysis using a retrospective cohort design to evaluate the extent to which critically ill, MV adults experienced poor outcomes on patient-centered measures of care quality and to determine whether being at the EOL was independently associated with worse outcomes. In the parent trial, investigators employed a randomized, stepped-wedge design to test a multi-component intervention to improve communication between nurses and MV patients. To evaluate the effect of the communication intervention, the study collected clinically detailed clinical data from the electronic medical records (EMRs) of 1440 randomly selected patients from 6 ICUs, in 2 hospitals between August 2009 and July 2011. Patients met inclusion criteria if they received MV for at least 2 days and experienced at least one 12 hour shift of sustained wakefulness while receiving MV.

Measures

The parent study collected EMR data on the following patient-centered care outcomes: physical restraint, heavy sedation, unrelieved pain and ICU-acquired pressure ulcer. Data on physical restraint, heavy sedation and unrelieved pain were collected daily, beginning on the first day of MV and continuing until departure from the

ICU or a maximum of 28 days. Data on ICU-acquired pressure ulcer were collected for the duration of evaluated days in ICU ranging from 2 to 28 days. A detailed description of the criteria for each measure and methodology for data collection have been reported by Seaman et al. (2014, under review).

Physical Restraint

We defined physical restraint as use of any device intended to restrict movement [12] including soft extremity restraints, vests, waist belts, full side-rails, mitts, or enclosure beds. Physical restraint was measured daily, and a patient was considered restrained if any of the above devices was applied within the 24-hour interval. We evaluated physical restraint in two ways: any physical restraint during the ICU stay (yes, no) and percentage of evaluated ICU days with restraint.

Heavy Sedation

We conceptualized heavy sedation as a state, as opposed to the receipt of sedating medications. In the parent study, data on heavy sedation were collected in two ways: heavy sedation at any point in the 24-hour interval and sustained wakefulness (being free from heavy sedation) for 8 out of 12 hours during each half (AM/PM) of the 24-hour interval. We measured heavy sedation in three ways: any heavy sedation during the evaluated ICU stay (yes, no); percentage of evaluated ICU days with any heavy sedation; and proportion of evaluated ICU stay spent in a state of heavy sedation. Proportion of the ICU stay in heavy sedation was calculated by adding the number of 12 hour intervals

during which the patient was not in a state of wakefulness for at least 8 hours and dividing by the total number of 12-hour intervals in the evaluated ICU stay.

Unrelieved Pain

On a day by day basis, we measured unrelieved pain as the documented presence of unrelieved pain at any point during the 24 hour interval and the highest patient-provided pain score (on a 1-10 scale) documented during the 24 interval (if available). We assessed unrelieved pain in several ways: any unrelieved pain during the evaluated ICU stay (yes, no); proportion of evaluated ICU days where the patient had unrelieved pain; mean highest daily pain score (0-10) for those evaluated ICU days where unrelieved pain was present; and proportion of days with unrelieved pain where a pain score was documented.

ICU-acquired Pressure Ulcer

We defined ICU-acquired pressure ulcer as any pressure ulcer, Stage II or greater, not documented as present on admission to the ICU, but present at the time of transfer out of ICU or by day 28 of the ICU stay. We evaluated ICU-acquired pressure ulcer in two ways: any pressure ulcer acquired during the evaluated ICU stay (yes, no) and rate of pressure ulcer occurrence over time.

Identification of the EOL Cohort

Predicting who is at EOL is challenging, and performing a retrospective analysis of only non-survivors may produce a biased evaluation of the treatment provided to dying patients [13]. Therefore, we selected a cohort composed of non-survivors and patients who were at high risk of dying, based on admitting APACHE III [14] severity of illness scores. Using severity of illness cut-points established in prior studies of patients at high risk of dying [8, 15] we identified a threshold that yielded a cohort with a mortality rate comparable to studies with a similar target population and met our criteria of favoring sensitivity to risk of dying (over specificity). Combining those patients with an APACHE III cut-point of ≥ 63 (50th percentile) and non-survivors below this threshold produced a cohort of 773 patients with a predicted mortality of 24.7%, actual mortality rate of 29.7%, and sensitivity (true positive rate) of 77%.

Demographic and Clinical Covariates

We utilized additional basic demographic and clinical information collected in the parent study: age, gender, race, ICU unit, admission diagnosis, functional status prior to admission, discharge disposition, and APACHE III score for the first 24 hours of the ICU stay. Data on functional status prior to admission from the parent study consisted of functional disability ratings (independent/needs assistance/dependent) for each of seven basic activities of daily living (ADL) and eight instrumental ADL (IADL) items. Using a validated weighting approach developed by Finch et al. (1995) we applied weighted values to key ADL and IADL items reflective of the relative disability

associated with loss of function for a given item. (For example, requiring assistance with eating would be given a higher weight than requiring assistance with ambulation.) We then added the scores for each item to create a summary score and scaled the summary score to 100, thereby creating a continuous measure where a score of zero indicates no functional disability and a score of 100 reflects total functional disability. For each subject we derived ADL and IADL functional disability scores. However, a considerable amount of data on functional status was missing, with roughly 25% of subjects missing information for each of the ADL and IADL items. Exploration of patterns of missingness revealed significantly more missing data from the two units belonging to one of the clinical sites. Since those units both had higher proportions of subjects in the EOL cohort, there is more missing data for the EOL cohort. Within the EOL cohort 64.2% of subjects had complete ADL data and 62.5% had complete IADL data. For the non-EOL cohort, 73.8% had complete ADL data and 71.4% had complete IADL data.

Statistical analysis

Characteristics of the Sample and Prevalence of Primary Outcomes

We conducted exploratory data analysis for demographic and clinical characteristics and outcome variables to compute descriptive statistics; determine univariate and bivariate distributions; and detect any data anomalies such as outliers or missing data. Using bivariate analyses we compared the clinical characteristics and outcomes for those in the EOL cohort and those not in the EOL cohort using the appropriate parametric or non-parametric procedure.

Multivariate Modeling of Outcomes

We used a two-step approach to test the independent association of EOL status and the primary outcomes since the preliminary analysis of the frequency distributions of all four primary outcomes showed a mode of zero, and a reasonably normal distribution of the observations greater than 0. A two-step approach is appropriate as it considers that the patients with a zero score (e.g. no time in restraint) are likely different from those with a non-zero score (those who experienced some restraint). In addition, this approach satisfies the ordinary least squares (OLS) regression assumption of normality, since the remaining non-zero data points then exhibit an approximately normal distribution [16].

In modeling the risk for each of the four outcomes of interest, we first modeled the probability of being free from restraint, heavy sedation, unrelieved pain, or ICU-acquired pressure ulcer during the evaluated ICU stay among all subjects (n=1440) using multivariate logistic regression, yielding odds ratios (ORs) and 95% confidence intervals (CIs). Then, using multiple linear regression we modeled the degree to which EOL status was an independent predictor of patient outcomes, controlling for demographic and clinical characteristics and clustering by unit, among those who had experienced the target outcomes. The specific outcomes predicted were: percent days restrained, proportion of the ICU stay in heavy sedation, and percent of evaluated days with unrelieved pain. Outcomes were adjusted for age, gender, race, functional status prior to admission, duration of ICU stay and clustering by specialty unit. Because of the large amount of missing data on functional status, and the percent missingness being

significantly greater among those at EOL, regression analyses were conducted for each outcome with and without controlling for functional status prior to admission. We conducted analyses using SPSS, version 21 software (IBM Corporation, Armonk, NY), and set the level of significance at $p < .05$.

RESULTS

Participant Characteristics

The overall sample had a mean age of 61.2 years, with 52% of participants being male and 10.3% non-white. The demographic and clinical characteristics of the sample are displayed in Table 1. Comparing the EOL and non-EOL cohorts, the EOL cohort was significantly older, with a significantly longer average ICU stay and number of days with MV. Although there was a slightly higher percentage of females in the EOL cohort, the difference was not significant ($p=0.080$), and the groups did not differ by racial composition. The distribution of primary admitting diagnoses was significantly different between the cohorts, and a distinctive clustering pattern by specialty unit was observed. Roughly two-thirds of sampled patients from the liver transplant, cardiovascular, and medical units fell into the EOL cohort, and roughly one-third of patient in the neuro-trauma, neurological and general trauma units fell into the EOL cohort.

Subjects in the EOL and non-EOL cohorts also differed in their functional status prior to admission, with the EOL group on average having more functional disability before the ICU admission, particularly with IADL functions. However, as previously noted, a considerable number of subjects had missing functional status data.

Patient-Centered Outcomes for the EOL Cohort

The prevalence of poor outcomes on the selected patient-centered measures of care quality was remarkably high. A summary of findings on each of the outcomes of interest is shown in Table 2.

Physical Restraint. Only 18.8% of patients in the EOL cohort experienced a restraint free ICU stay; and on average, those who experienced restraint spent about half (50.2%) of ICU days with physical restraint.

Heavy Sedation. Of patients in the EOL cohort, nearly all (90%) experienced some heavy sedation during their ICU stay and on average, spent about one-third of that time in a state of heavy sedation.

Unrelieved Pain. Few patients in the EOL group were free from unrelieved pain during the duration of the measured ICU days (5.6%), and on average, they spent about half of ICU days with unrelieved pain. Among those in the EOL cohort, pain was unscored on 63.4% of days where pain was documented. In terms of pain intensity, when pain was present *and* scored, the mean pain score was 6.81 (0-10), reflecting moderate, bordering on severe pain.

ICU-acquired Pressure Ulcer. The prevalence of ICU-acquired pressure ulcer was 12.3% in the EOL cohort, and the rate of pressure ulcer occurrence over the course of the evaluated ICU stay (2-28 days) was .016 per day.

Association of EOL Status with Care Quality Outcomes

While patients in both groups experienced poor outcomes, subjects in the EOL cohort experienced significantly poorer care quality than those in the non-EOL cohort on a number of measures. For the EOL cohort, the odds of experiencing restraint during the ICU stay was greater (OR=1.33), when compared to their non-EOL counterparts. Those in the EOL cohort were more likely to experience heavy sedation (OR=3.07) during the ICU stay, and to experience significantly more time in heavy sedation, on average, than their non-EOL counterparts (Table 2). No differences were observed between the groups on the likelihood of experiencing unrelieved pain during the ICU stay; the proportion of ICU days with evaluated pain, or highest daily pain score on day with unrelieved pain. However, those in the EOL group were significantly *less* likely to have their pain scored on days with unrelieved pain. Patients in the EOL cohort were significantly more likely to develop an ICU-acquired pressure ulcer (OR=2.33) than their non-EOL counterparts.

Being at EOL was independently associated with poorer outcomes on measures of heavy sedation and ICU-acquired pressure ulcer and trended toward significance on the probability of experiencing restraint (see Table 3). Status in the EOL cohort was associated with a significantly greater likelihood of heavy sedation during the ICU stay (OR=2.64; $p<.001$) and a greater proportion of the ICU stay spent heavily sedated ($b= 0.190$; $p<.001$) after adjusting for age, gender, race, ICU days, functional status, and ICU unit. Being at EOL was also associated with a significantly greater likelihood of ICU-acquired pressure ulcer (OR=1.62; $p=.041$) after adjusting for age, gender, race, ICU days and ICU unit. On the other hand, being at EOL was independently associated with a lower percent of ICU

days with pain ($b=-0.063$; $p=.002$), after controlling for age, gender, race, ICU days, and ICU unit.

DISCUSSION

In this large sample of critically ill MV patients with periods of sustained wakefulness, we demonstrate high rates of pain, restraint, heavy sedation, and pressure ulcer. Among the subsample at the EOL, we observed higher rates of heavy sedation, but lower rates of pain, which may be related. However, with less than 40% of pain days scored among EOL patients, inferring a relationship between pain and heavy sedation is difficult.

Comparing our findings with those in the literature is somewhat challenging as other research conducted on similar populations used different measures. Although those in our EOL cohort experienced somewhat fewer days with pain when compared with those in the non-EOL group, they still experienced a pain prevalence of 50.0%. These findings are not unlike those reported by Puntillo and colleagues, who in their study of symptoms experienced by ICU patients at high risk of dying [8] found the prevalence of pain to be 40.4% for evaluated days using a modified Edmonton Symptom Assessment Scale. Likewise, Nelson and colleagues found that among a sample of chronically, critically ill ICU patients, the prevalence of patient-reported pain (using the Memorial Symptom Assessment Scale) was approximately 60%, with 44% of patients reporting their pain to be at a high level of intensity [9]. While our sample involved patients from a variety of ICU settings, a much larger sample and more repeated assessments, these

studies used niche populations and involved smaller samples that were assessed at fewer time points.

The prevalence of physical restraint in our sample (41% of days) was similar to that identified by Minnick et al. [17], who reported 58% of days restrained among the ICUs of 40 randomly selected hospitals in 6 metropolitan areas in the US. Again, although the prevalence of restraint was not greater among those in the EOL cohort, it suggests restraints are a pervasive feature of ICU care at end of life.

Comparisons with prior findings on heavy sedation (as with those on pain) are difficult, due to the differing settings or measures used. Payen et al. studied 1,381 ICU patients across 144 French ICUs where the Ramsay Sedation Scale, Riker Sedation-Agitation Scale or Richmond Agitation-Sedation Scale were used to assess heavy sedation and threshold scores on the Ramsey and Riker scales were identical to those used in our study [18]. That study, which assessed heavy sedation at 48 hours, day 4 and day 6, found the prevalence of heavy sedation among patients to be 57%, 48% and 41% respectively. Shehabi and colleagues evaluated sedation depth in 251 MV ICU patients in Australia and New Zealand using every 4 hour Richmond Agitation-Sedation Scale (RASS) scores and found heavy sedation in 35% of all RASS assessments in the 28 evaluated days of patients' ICU stays [19]. They repeated the study in a sample of 259 patients in 11 Malaysian ICUs and found very similar results [20]. Although the settings and instruments differed, the results are not dissimilar, and point to a high prevalence of heavy sedation among critically ill, MV ICU patients across a variety of geographic settings.

A literature review by Shahin and colleagues of articles reporting ICU pressure ulcer prevalence and incidence in US and European ICUs [21] found incidence rates among ICUs ranged from 3.8% to 12.4%, the upper level of which is concordant with our finding of 12.3% for our EOL cohort. Considering the demonstrated association between discomfort and pressure ulcers, reduction in the incidence of pressure ulcers among critically ill patients represents an opportunity for mitigating discomfort.

We acknowledge several limitations to the study. The study is a secondary analysis using data abstracted from the EMR, and although the data were reliably abstracted, the accuracy of the original records cannot be determined. In addition, there was a large amount of missing data on functional status prior to admission. Finally, although we included both patients at high risk of dying and non-survivors in our sample, we may not have eliminated completely the bias inherent in retrospectively evaluating the care of non-survivors.

Overall, the findings of this study mirror the outcomes described in other cohorts of ICU patients and suggest multiple opportunities for improvement in critical care, and EOL care in particular. Because patients in this study experienced sustained periods of wakefulness, these outcomes potentially resulted in increased suffering, indignity and social disconnectedness. The extent to which these poor care quality outcomes were experienced by these patients is a reflection of their quality of dying.

Providing high quality of care to seriously ill and dying patients in the ICU environment is an area of ongoing research [22, 23] and quality monitoring [24]. Yet, much EOL research in the ICU remains focused on processes of care and outcomes not

immediately reflective of patients' experiences (clinician-family communication; decision making, family satisfaction, and resource use). Approaches that seek to measure EOL care outcomes directly experienced by patients are few; consequently, current research may not provide a patient-centered assessment of quality of dying. Future studies that utilize patient-centered outcomes to evaluate care are needed in order to guide the development of effective interventions to improve care outcomes and quality of dying in this population.

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Table 1—Sample Demographic and Clinical Characteristics

	Patients at End-of-Life n=773	Patients not at End-of-Life n=667	Test Statistic	p
Characteristic	Mean±SD(min-max)			
Age	65.5±16.0(18-98)	56.2±16.6(18-94)	U=17,2331.500	<.001
APACHE III score	84.8±22.9(15-191)	44.2±12.2(8-62)		n/a
Mortality Rate%	29.8	0		n/a
Evaluated Days in ICU	11.8±7.3(2-28)	9.5±7.1(2-28)	U=201015.000	<.001
Percent Days Ventilated	77±0.22(18-100)	68±0.21(13-100)	U=319,172.000	<.001
Composite Functional Dependency Score (0-100)				
ADL	18.79±35.7(100)	8.96±24.9(100)	U=142.902	<.001
IADL	25.5±35.7(99.4)	11.39±27.3(99.4)	U=142.436	<.001
	n(%)			
Older Adult	212(31.8)	440(56.9)	t=91.310	<.001
Gender				
Male	391(50.6)	363(54.4)	X ² =2.117	.080
Race				
White	689(89.1)	602(90.3)	X ² =0.532	.767
Black/African American	74(9.6)	58(8.7)		
Other/Unknown	10(1.3)	7(1.0)		
Specialty Unit				
Liver Transplant	168(21.7)	72(10.8)	X ² =115.275	.001
Neuro Trauma	99(12.8)	141(21.1)		
Neurological	90(11.6)	150(22.5)		
General Trauma	97(12.5)	143(21.4)		
Cardiovascular	154(19.9)	96(12.9)		
Medical	165(21.3)	75(11.2)		
Primary Admitting Diagnosis				
Respiratory	221(28.6)	109(16.3)	X ² =138.779	.001
Post-surgical**	90(11.6)	148(22.2)		
Neurological	114(14.7)	121(18.1)		
Cardiovascular*	111(14.4)	123(18.4)		
Trauma	21(2.7)	121(18.1)		
Gastrointestinal	69(8.9)	14(2.1)		
Sepsis	48(6.2)	14(2.1)		
Transplant	22(2.8)	6(0.9)		
Liver/Renal	21(2.7)	4(0.6)		
Other†	11(1.5)	7(0.7)		

*Including cardiac, cardiothoracic and cardiovascular surgery

**Not including cardiovascular, cardiothoracic, or transplantation surgery

†Including hematology/oncology

Table 2—Primary Outcomes

	Patients at End-of-Life n=773	Patients not at End-of-Life n=667	Test Statistic	p
Restraint Use	M±SD or n(%)	M±SD or n(%)		
Restraint free stay	145(18.8)	157(23.5)	$\chi^2=4.936$.026
Percent days in restraint				
<i>all subjects</i>	40.8	41.2	W=556,069	.911
<i>among those restrained</i>	50.2	53.9	W=344,445	.017
Odds of experiencing restraint	1.33			
Heavy Sedation				
Sedation free stay*	78(10.0)	171(25.6)	$\chi^2=60.510$.001
Percent days with any heavy sedation*	40.0	27.6	t= -8.870	.001
Proportion of ICU stay in heavy sedation	.35	.24	W=629,314.50	.001
Odd of experiencing heavy sedation	3.07			
Unrelieved Pain				
Pain free stay (n=1439)	43(5.6)	47(7.0)	$\chi^2=1.331$.249
Percent of evaluated days with unrelieved pain	50.0	58.5	t=5.348	.001
Percent of patients where all pain days are scored (n=1349)	83(11.4)	131(21.1)	$\chi^2=23.832$.001
Percent days where pain is present but un-scored (n=1349)	63.4	49.2	F=3.155	.001
Highest daily pain score when pain is scored (n=969)	6.81(±2.14)	6.98(±2.12)	F=0.099	.243
ICU-acquired Pressure Ulcer				
Prevalence of ICU-acquired pressure ulcer	12.3	5.7	$\chi^2= 18.690$.001
Incidence rate/day (mean)	.0158	.0080		
Odds of ICU-acquired pressure ulcer	2.33			

*Not including episodic procedural or operative sedation.

Table 3—EOL Status as an Independent Predictor of Care Quality Outcomes

	Including Functional Status (N=950)		Without Functional Status (N=1440)	
	Estimate	p-value	Estimate	p-value
Restraint Use				
Experiencing restraint during the ICU stay ^a	OR=1.42(95%CI=.958, 2.105)	.081	OR=1.34(95%CI=.994, 1.806)	.055
	(n=761)		(n=1138)	
Percent days in restraint among those restrained ^b	b = 0.021(95%CI=-.017, .059)	.288	b <.001(95%CI=-.030, .031)	.976
Heavy Sedation				
Experiencing Heavy Sedation during the ICU stay ^c	OR=2.64(95%CI=1.687,4.119)	.001	OR=2.26(95%CI=1.607, 3.181)	<.001 [†]
	(n=793)		(n=1191)	
Proportion of ICU stay in heavy sedation among those experiencing heavy sedation ^c	b = 0.088(95%CI=.793, 1.260)	.001	b = 0.074(95%CI=.841, 1.189)	<.001
Unrelieved Pain				
Experiencing unrelieved pain during the ICU stay ^d	OR=1.04(95%CI=.582, 1.858)	.895 [‡]	OR=1.08(95%CI=.667, 1.738)	.763
	(n=883)		(n=1349)	
Percent of evaluated days with unrelieved pain among those who experienced pain ^e	b = -0.063(95%CI=.792, 1.263)	.002	b = -0.067(95%CI=.831, 1.204)	<.001
Pressure Ulcer				
Pressure Ulcer during the ICU stay ^f	OR=1.44(95%CI=.844, 2.454)	.182	OR=1.60(95%CI=1.018, 2.498)	.041

*Duration of evaluated days 2-28

†Controlling for age, gender, race, functional status, ICU days, and ICU Unit.

‡Test is significant, although model fit is somewhat diminished, as indicated by significant Hosmer-Lemsehow goodness of fit test.

^aAge and outcome effect varied by ICU days, with age having a protective effect; EOL status and outcome effect also varied by ICU days.

^bAge and outcome effect varied by ICU unit.

^cICU days, ICU unit and the outcome effect varied by race.

^dRace and the outcome effect varied by ICU days.

^eEOL status and outcome effect varied by ICU days and ICU unit; ICU days and the outcome effect varied by ICU unit.

^fAge and outcome effect varies by race; ICU days and outcome effect varies by ICU unit.

**5.0 DATA-BASED MANUSCRIPT (AIM 3): PATTERNS OF PALLIATIVE CARE
SERVICE CONSULTATION AND CARE QUALITY OUTCOMES IN A SAMPLE OF
SERIOUSLY ILL AND NON-SURVIVING ADULT ICU PATIENTS**

Patterns of Palliative Care Service Consultation and End-of-Life Care Quality Outcomes
in a Sample of Seriously-Ill and Non-Surviving Adult ICU Patients

Jennifer B. Seaman, BSN, RN, Amber E. Barnato, MD, MPH, MS, Susan M. Sereika,
PhD, Mary Beth Happ, PhD, RN, FSGA, FAAN, and Judith A. Erlen, PhD, RN, FAAN

Abstract

Background: Critically-ill ICU patients receiving mechanical ventilation (MV) face threats to comfort, social connectedness and dignity in the form of pain, heavy sedation and physical restraint. This has special significance for quality of dying among those who may be at the end of life. Palliative care (PC) consultation services may mitigate poor outcomes.

Objective: To explore the patterns of PC service referral among a sample of seriously-ill and non-surviving ICU patients and compare outcomes on measures of patient-centered care quality between PC recipients and non-recipients.

Design: Retrospective cohort analysis with a descriptive, comparative design using propensity matching to compare palliative care recipients and non-recipients.

Setting/Subjects: Patients (1440) with ≥ 2 days of MV and ≥ 12 hours of sustained wakefulness admitted to 6 specialty ICUs within 2 tertiary-care sites.

Measurements: Daily measures of pain, heavy sedation, physical restraint and PC consultation services over the ICU stay and ICU-acquired pressure ulcer over the total stay, drawn from the electronic medical record.

Results: Just over half (773/1400 [54%]) of the cohort was at high risk of dying and/or did not survive the admission, 73(9.4%) of whom received PC consultation. On average, referral occurred after 62% of the ICU stay had elapsed, and for most (52/73 [72.2%]) the reason for consult was clarification of goals of care. No differences were observed between the PC recipients and the propensity-matched control group regarding the proportion of ICU days with pain (.49 vs. .54, $p=.863$), heavy sedation (.38 vs. .42, $p=.427$)

or physical restraint (.40 vs. .40, $p=.912$) or prevalence of pressure ulcers (.38 vs. .42, $p=.427$).

Conclusions: Among seriously-ill and non-surviving MV ICU patients, PC service consultation occurs infrequently and late in the ICU stay. Poor outcomes on measures of patient-centered care quality are prevalent; therefore, early PC is clinically-indicated.

Introduction

Critically-ill patients in the intensive care unit (ICU), especially those receiving mechanical ventilation (MV), face multiple threats to their comfort [1-6], dignity [7, 8], and social connectedness [9, 10]. Given that approximately 20% of US patients die having received ICU services, and the ICU remains the most common hospital setting wherein death occurs [11], the extent to which patient comfort, dignity and social connectedness are impacted reflects those patients' quality of dying [12, 13].

Palliative care is a specialty and a multidisciplinary approach to care that is focused on pain and symptom management; psychological and spiritual support; elicitation of patient values and preferences; communication about prognosis and treatment options; and alignment of treatment with goals of care for seriously ill patients and their families [14]. The use of palliative care consultation services has been shown to improve patient outcomes related to quality of dying [15,16]; however, few studies have explored the impact of palliative care consultation services on outcomes directly reflective of the ICU patient experience. In addition, there is considerable variability in types of services available [17] as well as the timing, duration and mode of palliative care service delivery among ICU patients and across ICU units.

With the increasing likelihood of receiving ICU care in the last month of life [18] and a heightened interest in improving end-of-life (EOL) care [19], exploration of patterns of palliative care referral in the ICU and the impact of receiving consultative services are of critical interest. In this study we sought to explore the patterns of palliative care consultation service referral among a sample of seriously-ill and non-surviving patients in

the ICU and to compare outcomes on measures of patient-centered care quality between those who received palliative care consultation services and those who did not.

Methods

Overview

This study, an expanded secondary analysis, is a retrospective cohort study of patients with ≥ 2 days of MV and ≥ 12 hours of sustained wakefulness admitted to 6 specialty ICUs within 2 tertiary-care sites from August, 2009 through July, 2011. The original cohort and most outcome measures were drawn from a parent study testing the efficacy of a unit-level multi-component communication intervention (see Parent Study, below). For the current study, we abstracted additional information regarding palliative care consultation from electronic medical records (EMRs). The University of Pittsburgh IRB reviewed and approved the study.

Parent Study and Setting

The parent study collected outcome data on multiple measures of patient-centered care quality for a sample of 1440 randomly selected patients from 6 ICUs (transplant, neuro-trauma, neurological, general trauma, cardiovascular and general medical) in 2 tertiary care hospitals belonging to a single health system located in the Mid-Atlantic region. Patients selected for the study experienced at least 2 days of mechanical ventilation (MV) and 12 hours of sustained wakefulness while receiving MV during the ICU stay. The rationale for these criteria was the selection of patients who could

potentially benefit from the intervention. Details of the study design and methods have been reported by Happ and colleagues (in review).

For the parent study, we abstracted data from the electronic medical record (EMR): demographic and clinical characteristics and daily measures of pain, heavy sedation, and restraint use for the ICU stay, up to 28 days. A full description of the development and testing of the data collection tool and procedures was reported by Seaman and colleagues (in review).

Palliative Care Consultation Data Collection

Both hospital sites had a palliative care service available for consultation; however, the composition and the model of service delivery differed. Hospital A had a well-established team consisting of palliative care physicians, nurse practitioners (NPs), social workers, and a psychologist. Spiritual care was provided via the hospital pastoral care staff, who coordinated with the palliative care service team. Consultation was obtained via a formal medical order entered into the EMR. On the other hand, the palliative care service at Hospital B, during the study interval, was primarily nurse-led and consisted of nurses with specialized training in delivery of palliative care consultation services, some of whom had advanced degrees. The palliative care nurses coordinated with hospital social workers and pastoral care staff, but did not have dedicated social workers or psychologists on the team. Referrals to the palliative care service were made by physicians as well as other staff, and a formal order was often entered into the EMR after the first consultation visit was made.

We abstracted data on palliative care consultation from among the 1440 subjects via EMR review. We determined if the patient had received a palliative care consultation

and collected information regarding the referring physician; timing and duration of the consultation services within the ICU stay; and the palliative care team members who provided services (physician, nurse, social worker, and pastoral care). In terms of evaluating social work and pastoral care visits among palliative care service recipients at Hospital B (where there were not dedicated palliative care team social workers or pastoral care providers), we counted visits by a social worker or pastoral care provider as palliative care service-related if the provider's note included discussion with palliative care service nurse, attendance at family meetings convened by the palliative care service nurse, or discussion with the patient/family about EOL concerns or issues.

A trained student research assistant, along with the principal investigator (JBS) abstracted the data from the EMR. To evaluate the reliability of data collected, 10% of cases were co-abstracted for reliability of palliative care consultation identification, and all cases with an identified palliative care service consultation were dually abstracted by the research assistant and the investigator. Analysis of inter-rater reliability (IRR) showed 98.6% agreement on palliative care consultation identification.

Sample

We identified a cohort of seriously-ill and non-surviving patients from among the larger sample using severity of illness score (APACHE III) [20] and survival data from the parent study. Using benchmarks established in prior studies of patients considered at high risk of dying [2, 21], we established a cut-point in the APACHE III score. We used an admission APACHE III score of 63 and above as the range within which patients could be considered at high-risk of dying and/or non-survival of the hospitalization to generate our sample. The resulting sample consisted of 773 patients, 230 (29.8%) of whom died

during the hospitalization. Of those who died, 178 (77.4%) had admitting APACHE III scores ≥ 63 , suggesting high risk of dying, while 52 scores fell below this threshold, indicating a low expectation of in-hospital mortality. We refer to this group of 773 patients as our end-of-life (EOL) cohort.

Outcome Measures

We selected patient-centered care quality outcome measures from the parent study that were reflective of the patient experience and conceptually relevant to EOL care and quality of dying.

Unrelieved Pain is a persistent problem among critically-ill ICU patients and is perhaps the single most important concern of seriously-ill and dying patients [22]. Pain was measured in the parent study as the documentation by nurses of unrelieved pain and was abstracted daily across the ICU stay (2-28 days). Days with unrelieved pain is a sum of the number of days during which unrelieved pain was present within the 24 hour interval; percent days with pain was calculated by dividing days with unrelieved pain by the number of evaluated days (2-28) of the ICU stay.

ICU-acquired Pressure Ulcers are a source of considerable pain for critically-ill patients [5] and frequently necessitate the implementation of burdensome treatment [23]. Of all acute care settings, ICUs have the highest rate of iatrogenic pressure ulcer development [24]. In the parent study ICU-acquired pressure ulcer was defined as any pressure ulcer Stage II or greater, not present on admission, but documented by the enterostomal therapy nurses during the course of the ICU stay. ICU-acquired pressure ulcer (presence and number) was measured for the overall duration of the ICU stay.

Heavy Sedation is a state which precludes patients from interacting with others and experiencing the presence of loved-ones, activities which critically-ill and dying individuals have identified as highly important [9, 10, 13, 25]. In addition, the medications given to achieve sedation have been linked to nightmares and hallucinations which are reported to be frightening and distressing, and often persist beyond the administration of the drugs [26, 27]. In the parent study, heavy sedation was defined as a Modified Ramsey Score ≥ 4 , Riker Sedation-Agitation Scale score of 1-2, Glasgow Coma Scale Score (GCS) motor score < 6 or nursing documentation of unresponsiveness to verbal or tactile stimulation, or being comatose or anesthetized. Heavy sedation was assessed daily for the duration of the ICU stay, and days with heavy sedation were those during which the patient experienced a state of heavy sedation at any point during the 24 hour interval (not including operative or episodic procedural sedation). Percent days with heavy sedation was calculated by dividing days with heavy sedation by the by the number of evaluated days (2-28) of the ICU stay. Proportion of the ICU stay in heavy sedation was calculated by adding the number of 12 hour intervals during which the patient was not in a state of wakefulness for at least 8 hours and dividing by the total number of 12-hour intervals in the evaluated ICU stay.

Restraint Use has been largely eliminated in most residential, outpatient, and acute care settings, but persists in the ICU environment at an average prevalence rate of 58% in US hospitals [28, 29]. The experience of physical restraint has been described by patients as frustrating, humiliating and negatively impacting dignity [7, 8, 30]. In the parent study restraint was defined as the application of any mechanical device for the purpose of restricting one's movement [31]. Restraint was assessed daily for the duration of the ICU

stay, and days in restraint were those during which a physical restraint was applied at any point during the 24 hour interval. Percent days in restraint was calculated by dividing days with restraint by the by the number of evaluated days (2-28) of the ICU stay.

Analysis

We conducted data analysis using SPSS (version 22.0, IBM, Inc., Armonk, NY), and set the level of significance at $p<.05$. We used descriptive statistics to evaluate demographic and clinical characteristics of the sample as well as characteristics of the palliative care consultation (reason(s) for consult, referring physician specialty/role, timing and duration of consultation, and palliative care provider roles). We used and group comparative analyses to compare those with and without palliative care consultations.

To address indication bias (e.g., patients with higher acuity of illness and those with prolonged ICU stays being more likely to receive palliative care consultation services), we compared outcomes between palliative care consultation recipients (n=73) and a propensity matched cohort of patients without palliative care consultation (n=73). Specifically, we used a logistic regression model to predict the probability of palliative care consult as a function of demographic, clinical, and unit characteristics. In the model we adjusted for age, gender, race, severity of illness (APACHE III), ICU days (2-28) and ventilator days. We then matched palliative care recipients to non-recipients on the predicted probabilities of palliative care consultation estimated via logistic regression, using one-to-one nearest neighbor matching. This resulted in a subsample of 146 subjects. We then compared the two groups on the primary outcomes: proportion of days with pain, heavy sedation and physical restraint; percent pain days scored, highest daily

pain score, and prevalence of ICU-acquired pressure ulcer across the stay. Due to variability in the time to palliative care consultation and the duration of palliative care service delivery, we also conducted post-hoc analyses of the mean difference in outcomes pre- and post-consultation among those who received palliative care consultation services (n=73) as well as the mean difference in outcomes between survivors and non-survivors.

Results

Prevalence and Patterns of Palliative Care Consultation

Among the total sample of 1440 patients, 91(6.3%) received PCC during the evaluated ICU stay, 73 (9.4%) of whom were in the EOL cohort. Those in the EOL cohort who received palliative care consultation services were older and had a greater number of ICU days compared to those who did not receive palliative care consultation services ($t=-4.95$, $p<.001$ and $t=-2.48$, $p=.013$, respectively). Not surprisingly, the proportion of non-survivors receiving palliative care consultation was greater than that of survivors of the hospital stay (14.2% vs. 7.2%, $p=.001$). Patients in the medical and neurological (neurological and neuro-trauma) ICUs had higher percentages of palliative care consultation than the other specialty ICUs. No differences in gender, race or admitting severity of illness score were observed between palliative care consultation recipients and non-recipients. Demographic and clinical characteristics of palliative care consultation recipients in the EOL cohort are summarized in Table 1.

The most frequent reason listed for palliative care consultation was clarification of goals of care (71%), followed by hospice evaluation/discharge planning (27.9%) and pain/symptom management (17.9%). Those initiating the consult were most frequently

critical care medicine (CCM) physicians (41.4%) or neurologists (12%), and in the majority of cases the referring physician was listed as the attending (57.5%). A complete listing of reasons for consultation and referring physician specialty and role is provided in Table 2.

In terms of timing and duration of consultation among the EOL cohort, patients were in the ICU for an average of nearly 9 days (or 62% of the total ICU stay) before receiving palliative care services; and the mean duration of palliative care consultation services was 4.64 days. Of the 73 patients receiving palliative care consultation services, 13(18%) had services initiated the day prior to death or discharge/transfer from ICU and 16(21.9%) began receiving services on the day of death or discharge/transfer from the ICU. Complete statistics on timing and duration of palliative care consultation services are shown in Table 3.

Patients who received palliative care consultation services received an average of 3.6 visits during the duration of consultation, most of which were from the physician (Hospital A) or palliative care service nurse (Hospital B). Nearly 40% of patients received social work services and approximately 30% received services from a pastoral care provider; among palliative care service recipients, none had documentation of services from the palliative care team psychologist. Details of the number and multidisciplinary composition of palliative care provider visits are shown in Table 4.

Care Quality Outcomes

The baseline characteristics of the propensity matched sample are shown in Table 5. No differences were observed between case and control subjects on demographic and clinical characteristics. No differences were observed when comparing the palliative

care recipients and non-recipients on days with unrelieved pain, heavy sedation and physical restraint, or ICU-acquired pressure ulcer prevalence (see Table 6). Post-hoc analysis of outcomes pre- and post-consultation within the subsample of palliative care recipients showed a significant decrease in the mean proportion of ICU days with restraint ($p=.015$) and a significant increase in the mean proportion of ICU days with heavy sedation ($p<.001$). No significant difference was found pre- and post-consultation on mean proportion of ICU days with unrelieved pain (see Table 7). When the sample was stratified by survival status, survivors experienced a significant decrease in mean proportion of days with restraint ($p=.002$). Non-survivors experienced a significant decrease in the mean proportion of days in restraint ($p=.003$); an increase in the mean proportion of days with heavy sedation was observed, but was not significant ($p=.061$). Survivors experienced a significant decrease in the mean proportion of days in restraint ($p=.002$); no differences were found pre- and post-consultation in the proportion of days with pain or heavy sedation.

Discussion

Numerous studies have evaluated the impact of palliative care consultation services on patient outcomes related to utilization and cost [19, 32, 33], but few have looked at patient-centric outcomes specifically in the ICU. Of those that have used more patient-centered outcomes, all have employed exclusively proxy measures such as family satisfaction and prescription of opioids [16]. This study provides unique insight into quality of dying and patterns of palliative care consultation service referral and delivery in a large sample of patients, from diverse specialty ICU units, for whom over 15,000 patient days of outcome data were collected and who all experienced some sustained wakefulness.

While receipt of palliative care services is the established standard for all seriously-ill ICU patients [14], our findings suggest that pain, heavy sedation, and restraint are highly prevalent. And while this study did not attempt to capture information about primary palliative care efforts, we observed a very low rate of referral to specialty palliative care services, with consultation typically occurring late in the course of the ICU stay.

The patient-centered outcomes we observed are inconsistent with established standards for high-quality EOL care; and while they are important to all critically-ill patients in ICU, they may be of particular importance to patients at EOL. Unlike ICU survivors, non-survivors are not likely to have the opportunity to reflect on their experiences of pain, disturbing dreams, or restraint and attribute meaning to them. Furthermore, heavy sedation may preempt the only opportunities that patients have for closure and communication with loved ones. Although approximately 70% of patients in the cohort did survive hospitalization, looking at their mean duration of MV (11.53 ± 6.8 days), the one year mortality rate is likely to be 56-59% [34, 35], suggesting they are appropriately categorized as being at EOL.

While much progress has been made in peripheral aspects of EOL care (clinician-family communication, surrogate decision-making, etc.) there has been less emphasis on outcomes experienced directly by the patient. Efforts are ongoing to move patient-centered EOL care in ICU forward, yet much of the work focuses on interventions implemented *only after* the goals of care have shifted away from life-sustaining treatment or the patient is actively dying [12]. This is reflective of what Bishop and colleagues describe as a “bifurcated” model, where patients travel on one of two mutually exclusive tracks, either the “care” track or the “cure” track [36]. Yet, results of this study indicate

that high risk of dying (as assessed by severity of illness scoring) was known within 24 hours of ICU admission. (Only 52 of the 230 non-survivors in our sample fell below the APACHE-III threshold for high risk of dying.) These findings suggest it is possible to identify *a priori* those whose face a high risk of experiencing poor quality of dying, providing an opportunity for intervention.

Dignity-conserving care, which stresses the importance of meaning, social connectedness and closure, has been set forth as a model for EOL care in ICU [12]. Yet, if we only turn our attention on these key elements after a change in goals of care or when the individual is actively dying, we will miss what may be the only opportunities to mitigate suffering and facilitate social connectedness and closure. By failing to integrate compassionate and curative treatment, we limit our ability to provide high quality EOL care when prognosis and survival are uncertain or while decisions around goals of care being deliberated.

Early palliative care consultation for all patients at high risk of dying is one means of reaching this goal; however, there are multiple obstacles to implementing this, the greatest being the sheer number of palliative care providers that would be required to achieve it. Hua and colleagues estimate that future needs for specialty palliative care providers will far outstrip the supply [37]. Strategies which seek to improve EOL care through the integration of palliative care principles and practices into the culture of care within the ICU have been recommended [14]. Such an approach may be the most feasible and effective means to advance the quality of dying for this population.

We must acknowledge several limitations to this study. Data on patient outcomes were abstracted from clinical documentation, the validity and reliability of which cannot

be absolutely determined. The models of palliative care consultation service delivery differed between the two clinical sites, and over the course of data collection each site experienced programmatic changes in the palliative care program. In addition, both clinical sites were part of the same health system, which may limit the generalizability of the findings. And finally, the pre-post differences seen in the palliative care recipients may have also occurred in the control sample over the trajectory of the ICU stay. However, the level of measurement of the parent study data limited the extent to which we could use statistical modeling to assess these temporal changes. But despite these limitations, the findings reflect an ongoing need to improve EOL care for critically-ill patients.

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Tables

Table 1—Demographic and Clinical Characteristics of Palliative Care Consultation Recipients

Characteristic	Palliative Care Consult (n=73)	No Palliative Care Consult (n=700)	Test Statistic	p
Mean±SD(min-max)			t	
Age	72.72±12.88(34-98)	64.70±16.06(18-97)	-4.95	<.001
APACHE III Score	85.85±25.78(15-172)	84.65±22.65(23-191)	-0.43	.670
ICU Days* M(SD)	13.77±7.26(4-28)	11.56±7.23(2-28)	-2.48	.013
n(%)			X ²	
Female	40(10.5)	342(89.5)	0.93	.334
Race				
White (n=689)	64(9.3)	625(90.7)	1.70	.472
Black/AA (n=74)	9(12.2)	65(87.8)		
Other/Unknown (n=10)	0	10(100)		
Non-survivors (n=230)	34(14.8)	196(85.2)	10.91	.001
Unit n(%)				
Transplant (n=168)	10(6.0)	158(94.0)	10.92	.053
Neuro-trauma (n=99)	6(6.1)	93(93.9)		
Neuro ICU (n=90)	11(12.2)	79(87.8)		
Trauma (n=97)	11(11.3)	86(88.7)		
Cardiovascular (n=154)	11(7.1)	143(92.9)		
Medical (n=165)	24(14.5)	141(85.5)		

Table 2—Reasons for Consult and Referring Physician Specialty and Role

Reason for Consult n(%)*	(n=73)
Pain and Symptom Management	12(16.5)
Clarification of Goals of Care	52(71.2)
Family Support	6(8.2)
Hospice Evaluation/Discharge Planning	13(27.9)
Unknown	5(6.8)
Other n(%)	
Per Family Request	4(5.5)
Per ICU Request	2(2.7)
Per Care Management/Social Work Request	3(4.1)
Continuity of Care after ICU D/C	2(2.7)
Specialty or Service of Referring Physician n(%)	
Critical Care Medicine (CCM)	30(41.1)
Transplant	1(1.4)
General Surgery/Trauma	2(2.7)
General Surgery	4(5.5)
Neurology	9(12.3)
Neurosurgery	2(2.7)
General Medicine	3(4.1)
Nephrology	1(1.4)
Otorhinolaryngology	1(1.4)
Unknown	20(27.4)
Role of Referring Physician n(%)	
Attending	42(57.5)
Surgeon, non-attending	1(1.4)
Physician, non-attending	9(12.3)
Resident	3(4.2)
Unknown	21(28.8)

*Total is greater than 100% as multiple reasons could be chosen.

Table 3—Timing and Duration of Palliative Care Consultation (PCC)

Interval (n=73)	M±SD(min-max)
Days elapsed to PCC	8.89±6.02(0-26)
Proportion of ICU Stay* to PCC	.62±.27(0-.96)
Duration of PCC Services (days)	4.64±4.11(1-20)
Proportion of ICU Stay* with PCC	.36±.26(.04-1.0)

*2-28 days

Table 4—Number and Multidisciplinary Composition of PCC* Services

Provider Visits (n=73)	Mean±SD(min-max)
Total PCC* service visits	3.6±2.5(1-14)
Mean visits per day during consultation	1.1±.76(.14-5.0)
Diversity of PCC* Services	
Physician Visits	1.26±1.56(0-6)
NP** Visits	.03±0.16(0-1)
Social Worker Visits	.60±0.92(0-4)
Pastoral Care Visits	.48±0.88(0-5)
Palliative Care Nurse Visits***	1.2±1.93(0-9)
Patients receiving services in addition to those of MD/NP/RN	n(%)
Social Work	29(39.7)
Pastoral Care	23(31.5)
Psychology	0

*Palliative Care Consultation

**Nurse Practitioner Visits (Hospital A)

***Palliative Care Nurse Visits (Hospital B)

Table 5—Baseline Characteristics of Palliative Care and Control Group

	Palliative Care Consult (n=73)	No Palliative Care Consult (n=73)	Test Statistic	p
Characteristic				
Mean±SD(min-max)			t	
Age	72.74±12.87(34-98)	72.79±11.32(48-96)	0.027	.978
APACHE-III Score	85.85±25.78(15-172)	86.26±20.92(40-133)	0.106	.916
ICU Days* Mean(SD)	13.77±6.71(4-28)	13.62±6.71(3-28)	-0.130	.897
Ventilator Days	11.58±7.05(2-28)	11.48±6.59(2-27)	-0.085	.932
n(%)			χ²	
Female	40(48.2)	43(51.8)		.738**
Race				
White (n=689)	64(87.7)	69(94.5)		.244**
Black/African American (n=74)	9(12.3)	4(5.5)		
Non-survivors (n=230)	34(46.6)	33(43.9)		1.000**
Unit n(%)				
Transplant (n=168)	10(13.7)	7(9.6)	2.352	.799
Neuro-trauma (n=99)	6(8.2)	9(12.3)		
Neuro ICU (n=90)	11(15.1)	7(9.6)		
Trauma (n=97)	11(15.1)	13(17.8)		
Cardiovascular (n=154)	11(15.1)	13(17.8)		
Medical (n=165)	24(50.0)	24(50.0)		

*2-28 Evaluated Days

**Fisher's Exact Test

Table 6—Comparison of Outcomes for Palliative Care and Propensity Matched Control Group

	Patients with PCC n=73	Patients without PCC n=73	Test Statistic	p
Restraint Use				
Restraint free stay	14(51.7%)	14(48.3%)	X ² =0.043	p=.836
Percent days in restraint				
<i>all subjects (n=146)</i>	39.61	40.18	t=-0.111	p=.912
<i>those restrained (n=117)</i>	49.85	49.72	t=0.027	p=.978
Pain				
Pain free stay	1(1.4)	6(6.9)		p=.058*
Percent of evaluated days with unrelieved pain				
	48.77	49.59	t=-1.173	p=.863
Percent of patients where all pain days are scored				
	1(1.4)	2(1.4)		p=.611
Percent days pain is present but un-scored (n=139)				
	77.98	76.64	t=0.287	p=.774
Highest daily pain score when pain is scored (n=78)				
	6.51	7.17	t=-1.220	p=.226
Heavy Sedation				
Sedation free stay**	3(2.1)	3(2.1)		p=1.00*
Percent days with any heavy sedation**				
	43.52	46.44	t=-0.632	p=.529
Proportion of ICU stay in heavy sedation				
	.38	.42	t=-0.797	p=.427
Pressure Ulcer (n=145)				
Prevalence of ICU-acquired pressure ulcer				
	20.5	16.7		p=.670*
Incidence rate/day (mean)				
	.0209	.0221		

*Fisher's Exact Test

**Not including episodic procedural or operative sedation

Table 7—Comparison of outcomes pre- and post-palliative care consultation (n=73)

Outcome (n=66)*	Change with PCC**		Mean difference	p
	Pre-PCC	Post-PCC		
Pain				
Proportion of days with unrelieved pain Mean(95%CI)	.4795(.4057-.5533)	.4441(.3565-.5318)	-.0354	.355
Heavy Sedation				
Proportion of days with Heavy sedation Mean(95%CI)	.4507(.3751-.5263)	.5815(.4738-.6892)	.1218	<.001
Restraint Use				
Proportion of days with physical restraint Mean(95%CI)	.4432(.3556-.5309)	.2709(.1769-.3650)	-.1723	.015

*Subjects who had palliative care during the entire stay were dropped as they had no pre-PCC interval.

**palliative care consultation

Table 8—Comparison of outcomes pre and post palliative care for survivors and non-survivors

Outcome (n=66)*	Survivors		Mean Difference	P	Non-Survivors		Mean Difference	P
	Pre-PCC**	Post-PCC**			Pre-PCC**	Post-PCC**		
Pain								
Proportion of days with unrelieved pain (M)	.4542	.4251	-.0291	.428	.5132	.4615	-.0517	.405
Heavy Sedation								
Proportion of days with Heavy sedation (M)	.3557	.4511	.0954	.209	.5291	.6689	.1398	.061
Restraint Use								
Proportion of days with physical restraint (M)	.4641	.2895	-.1746	.002	.4115	.2227	-.1888	.003

*Subjects who had palliative care during the entire stay were dropped as they had no pre-PCC interval.

**palliative care consultation

6.0 STUDY SUMMARY

The purpose of this dissertation research was to 1) describe patient outcomes (unrelieved pain, ICU-acquired pressure ulcers, heavy sedation and days in restraint) among sample patients who were at EOL (decedents and/or those at high risk of dying); 2) identify patient-level predictors (category of age, admission diagnosis, severity of illness on admission, and functional status) of these patient outcomes; and 3) explore the relationship between presence, timing and duration of palliative care consultation services and these patient outcomes among sample patients at EOL (decedents and/or those at high risk of dying). The results of specific aims 1 and 2 are presented in Chapter 4.0 and the results of specific aim 3 are presented in the Chapter 5.0. Additional analyses performed for Aim 2 are described in 6.1.

6.1 ADDITIONAL FINDINGS

Besides the findings reported in Chapters 4.0 and 5.0, additional analyses were conducted and the results are reported below.

6.1.1 Modeling Outcomes

In addition to determining if EOL status was independently associated with poorer outcomes on measures of pain, heavy sedation and restraint use, parsimonious logistic models predicting each outcome were fitted.

6.1.1.1 Unrelieved Pain

Logistic regression analysis was conducted to identify candidate predictors that were associated with the experience of unrelieved pain during the ICU stay (n=1439). The model fit was adequate using the Hosmer-Lemeshow goodness of fit test ($\chi^2_{(df=8)} = 7.691, p = .464$), but classification was poor. Classification of having pain during the stay was 100% correct; however, classification of being pain free was 0%. After adjusting for age and clustering by ICU unit, ICU days (b=0.165, OR=1.18, CI=1.115, 1.248, p<.001) and being admitted to the ICU postoperatively (based on admission diagnosis) (b=0.984, OR=2.68, CI=1.183, 6.051, p=.018) were the only predictors independently and positively associated with experiencing pain during the ICU stay.

6.1.1.2 ICU-acquired Pressure Ulcer

Logistic regression analysis was conducted to identify candidate predictors associated with the development of at least one pressure ulcer during the ICU stay. Model fit was adequate using the Hosmer-Lemeshow goodness of fit test ($\chi^2_{(df=8)} = 8.103, p = .423$). Classification of not developing a pressure ulcer was 99.2% correct; but classification of developing a pressure ulcer was only 12.0% correct. After adjusting for clustering by ICU unit, age (b=0.020, OR=1.02, CI=1.007, 1.033, p<.001), ICU days (b=0.119, OR=1.13, CI=1.127, 1.154, p<.001) and APACHE III score (b=0.081, OR=1.08, CI=1.009, 1.165, p=.027) were all positively and independently associated with development of a pressure ulcer. However, being female was independently associated with a decrease in the likelihood of developing a pressure ulcer (b=-0.621, OR=0.54, CI=0.355, 0.813, p=.003). Of note, an interaction effect was found between ICU days and ICU unit such that the risk associated with ICU days was attenuated for patients in ICUs other than the transplant ICU.

6.1.1.3 Heavy Sedation

Logistic regression analysis was conducted to identify predictors associated with experiencing heavy sedation during the ICU stay. Model fit was adequate using the Hosmer-Lemeshow goodness of fit test ($\chi^2_{(df=8)} = 12.986, p = .112$). Correct classification of being heavily sedated during the stay was 29.3%, while correct classification of having some heavy sedation during the stay was 96.6%. Only ICU days ($b=0.220, OR=1.125, CI=1.203, 1.120, p<.001$) and being at EOL ($b=0.801, OR=2.23, CI=1.626, 3.052, p<.001$) were independently and significantly associated with experiencing heavy sedation during the ICU stay.

6.1.1.4 Physical Restraint

Logistic regression analysis was conducted to identify, among the candidate predictors, which were associated with experiencing physical restraint during the ICU stay. Model fit was adequate using the Hosmer-Lemeshow goodness of fit test ($\chi^2_{(df=8)} = 4.837, p = .775$). Correct classification of being restraint free was 21.8%, while correct classification of experiencing restraint during the ICU stay was 97.7%. After adjusting for functional status with regards to ADLs, and clustering by ICU unit, only APACHE III score ($b=0.122, OR= 1.13, CI=1.051, 1.214, p=.001$) and ICU days ($b=0.114, OR=1.12, CI=1.085, 1.158, p<.001$) were independently and significantly associated with experiencing physical restraint during the ICU stay. Functional status and the outcome association varied by unit; and functional status and the outcome association varied by APACHE III score.

6.2 DISCUSSION OF RESULTS

This study contributes to knowledge on EOL care in the ICU setting in several ways. First the study demonstrates how quality of care and patient outcome data abstracted from the EMR can be used for research purposes in the population of seriously-ill patients in ICU. This is important for ethical as well as practical reasons. Use of EMR data can shift the burden of data collection away from nurses and research staff, prevent intrusive observation of seriously-ill ICU patients and families by research staff, and decrease research costs by leveraging this valuable resource.

Second, these findings demonstrate in a large sample, the extent to which seriously-ill and non-surviving MV ICU patients with sustained wakefulness experienced outcomes which are inconsistent with standards set for high quality EOL care. It is also one of the few studies that has evaluated patient-centered outcomes beyond pain. The findings on restraint and heavy sedation are concerning; however those on pain and pain measurement are most disappointing, since pain has been the focus of so much of the research conducted in the past two decades on EOL care in the ICU.

Finally, this work provides insight into patterns of palliative care consultation among a wide variety of ICU units and attempts to demonstrate the impact of palliative care consultation services on the patient-centered outcomes of interest. The findings demonstrate that palliative care consultations occur infrequently, late in the ICU stay, and often right before death or transfer from the ICU. Only 14.8% of non-survivors in our sample received palliative consultation services. Furthermore, only 16.5% of consultations were made for the indication of pain and symptom management, while 72% were for that of clarification of goal of care. These findings support the assertion of Bishop and colleagues (Bishop, Perry, & Hine, 2014) that care in U.S. ICU's remains almost exclusively "curative" or "palliative" in focus and integration remains a challenge.

6.3 STRENGTHS AND LIMITATIONS

There are several notable strengths to this study. First, we utilized a large, longitudinal dataset that captured over 15,000 days of patient data on the target outcomes. Additionally, the data from the parent study were highly reliable, with *kappa* values for all of the variables of interest falling within the range of “substantial agreement”. The setting included two hospital sites and six specialty ICUs, which enhances the generalizability of the findings. The study also brings a novel perspective to the study of care of seriously-ill and non-surviving MV ICU patients by utilizing outcome measures that very directly reflect the patient experience. These are quite different from other measures used in this field, which are largely indirect (like family satisfaction) or not at all patient-centered (such as cost or ICU length of stay).

There are also several limitations to the study. As with any secondary analysis, there are limitations to the information available in the data. Although data in the parent study were very reliably abstracted from the EMR, it is retrospective chart data, and the accuracy of such data cannot be confirmed. Missing data were also of concern; specifically, we encountered a considerable amount of missing data for functional status, and ultimately this limited the use of that variable in our analysis.

In the parent study, heavy sedation was defined as a state, not the receipt of medications to induce sedation. Therefore it is not possible to differentiate between states of heavy sedation that were pharmacologically induced and those related to endogenous states such as neurological insult or metabolic derangements. Another limitation is the different palliative care service delivery models used by the two sites. Consequently, findings on the number of visits made by the various palliative care providers may be biased. Finally, there were factors related to level of measurement in the parent study that limited analytic options; because data on pain, heavy sedation, and physical

restraint were collected for each day, and not as a continuous hourly measurement, more complex multivariate regression modeling to evaluate the impact of palliative care consultation was not possible.

6.4 IMPLICATIONS AND DIRECTIONS FOR FUTURE STUDY

Improving the care of seriously-ill and non-surviving ICU patients is a growing concern. With the aging of the population, the number of ICU patients requiring MV is expected to rise, and many of them will be seriously-ill and not survive. The most recent IOM report (2014) highlights the need to improve EOL care across all settings, make palliative care more widely available, and make EOL care more patient-centered. The results of the current study underscore EOL care needs consistent with those cited in the IOM report and point to potential applications of our findings within the domain of nursing.

Nurses are uniquely positioned to contribute, as members of the multidisciplinary ICU team to improving outcomes for all seriously-ill patients, and especially those at EOL. Additional descriptive studies that evaluate similar outcomes in other settings and geographic locations are needed. The development and testing of interventions that translate these findings into clinical practice are indicated. Further research is needed to test and implement tools that permit nurses to accurately assess and treat pain in patients who often have varying levels of consciousness and communication ability. Additional research is also needed to develop accurate predictors of poor EOL outcomes so that nurses and other members of the multidisciplinary team can utilize palliative care resources earlier in the trajectory of the ICU stay.

APPENDIX A

[METHODOLOGY MANUSCRIPT]

TITLE

Electronic Medical Record as a Data Source for ICU Nursing Care Quality Measurement:
Instrument Development and Testing

AUTHORS

Jennifer B. Seaman, BSN, RN
Pre-doctoral Scholar, Department of Health and Community Systems
University of Pittsburgh, School of Nursing, Pittsburgh, PA, USA

Anna E. Evans, MD
Department of Internal Medicine
Yale University, School of Medicine, New Haven, CT, USA

Andrea M. Sciulli, BA
Research Assistant
University of Pittsburgh, School of Nursing, USA, Pittsburgh, PA, USA

Amber E. Barnato, MD, MPH, MS
Associate Professor, Department of Medicine
University of Pittsburgh, School of Medicine, Pittsburgh, PA, USA

Susan M. Sereika, PhD
Professor, Center for Research and Evaluation
University of Pittsburg, School of Nursing, Pittsburgh, PA, USA

Mary Beth Happ, PhD, RN
Professor, Center of Excellence in Critical and Complex Care
The Ohio State University, College of Nursing, Columbus, OH, USA

CORRESPONDING AUTHOR

Jennifer B. Seaman, BSN, RN
University of Pittsburgh, School of Nursing
451 Victoria Building, 3500 Victoria St., Pittsburgh, PA 15261
Ph. (412) 624-2469 Fax. (412) 383-7293
jbs31@pitt.edu

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ABSTRACT

Background: Although the patient electronic medical record (EMR) is a potentially rich source of research data on nursing care quality in the intensive care unit (ICU), there has been little methodological work toward standardizing this approach for use in research measuring nursing care quality. The purpose of this study was to develop and test a data abstraction tool for collection of ICU nursing care quality indicators from the EMR.

Methods: We conducted an iterative, multi-step process to develop and test a tool for abstraction of care quality data from the EMR. Initially we mapped quality indicators to data elements within the EMR and drafted a preliminary tool. We then undertook an iterative process of testing for consistency between raters, tool refinement, and dataset application to achieve the target IRR. We created training materials and established 4 fully-vetted, adjudicated cases as “gold-standard” training cases. We trained 9 total abstractors to 90% agreement on the gold-standard cases. From among the 1440 abstracted cases, 108 were randomly selected for co-abstraction by a single rater (10% for quarters 1-4; 5% for quarters 5-8). We then calculated κ between the two independent ratings for the 108 reliability test cases.

Results: For the initial IRR testing (using the 4 gold-standard cases with 4 independent raters, $n=16$), the mean Cohen’s κ exceeded the 0.6 threshold for all indicators except heavy sedation. In subsequent IRR testing of study data ($n=108$ cases, 8 independent raters) after tool refinement, the mean Cohen’s κ values were 0.80 to 0.99 for all indicators except ICU-acquired pressure ulcer. We then undertook further criteria refinement and training for pressure ulcer data abstraction and achieved our target reliability of Cohen’s $\kappa \geq 0.61$.

Conclusions: Nursing care quality data can be accurately and reliably abstracted from the EMR of ICU patients using a well-developed data collection tool and detailed procedure manual. This methodology presents an alternative to direct patient observation for the purposes of assessing nursing care quality outcomes in the critical care setting and for research evaluating the effectiveness of interventions to improve care quality outcomes.

INTRODUCTION

With an increased focus on strategies for measurement of patient care quality and safety outcomes and the need to rapidly, efficiently and economically assess the effectiveness of competing patient care protocols, novel paradigms for care quality outcome measurement are needed. Although direct observation has long been the standard for measurement of nursing care quality, this approach is labor intensive, expensive, limited to single time point, and results in missing data when patients are off the unit for tests or procedures. Direct observation is particularly problematic in the ICU, where patients are characteristically unstable and the type and intensity of treatment delivered can change rapidly. In this setting, the use of direct observation to measure care quality, in addition to being labor-intensive and expensive, is unlikely to capture the full range of care processes and patient outcomes which can occur over a twenty four hour interval.

Medical record abstraction (Hellings, 2004; Hulley, 2007), and, more recently, electronic medical record (EMR) abstraction (Behier, Reynier, Bertoye, & Vray, 2010), offers the ability to collect process and outcome data where direct observation would simply not be feasible due to geographic, temporal and financial obstacles (Flaatten, 2012; Kahn, Gunn, Lorenz, Alvarez, & Angus, 2014). Furthermore, the EMR may be superior to observation as a source for ICU care quality data, as the ICU medical record contains round-the-clock, structured documentation of patient assessments and care provided. Medical record abstraction has demonstrated utility as a means to measure quality (Glavan, Engelberg, Downey, & Curtis, 2008), and systematic approaches to medical record abstraction have generated reliable data (Liddy, Wiens, & Hogg, 2011). This approach is increasingly an option as over 30% of acute care institutions now use an EMR for documentation of nursing care (HIMSS Analytics, 2014). The use of EMR yields

immediate access to a patient's medical and surgical reports as well as nurse-sensitive process and outcomes data, and it allows for easier sharing of data (Behier et al., 2010). This approach is particularly valuable when the quality indicators selected are standardized and relate to recognized best-practice standards, thereby allowing for meaningful comparisons across studies (Flaatten, 2012). Measurement of nurse-sensitive quality of care indicators via EMR abstraction has the potential to provide dense, patient-level data over time, thereby offering powerful insight into care processes, patient safety, and patient outcomes and serve as a valuable methodology in quality of care research.

Yet, to date, there are no published tools available for collecting ICU nursing care quality data from the EMR, despite there being multiple, well-established indicators. This paper describes the development and testing of the data collection tool and standard operating procedure (SOP) for collection of data, from the EMR, on selected nursing care quality indicators used in a multi-site ICU quality improvement research study and demonstrates the utility of this methodological approach.

METHODS

Overview

We tested the utility of a tool for care quality data abstraction from the EMR as part of the conduct of a single-blind, randomized, crossover cluster (stepped-wedge) quality improvement trial of the SPEACS-2 communication skills training intervention (**Study of Patient-Nurse Effectiveness with Assisted Communication Strategies-2**) in 6 specialty ICUs across two academic health system hospitals. Details of the trial are reported by Happ et al. (in review). Given the large sample size (n=1440) and multi-site design of the study, the most feasible choice for collection of care quality data was retrospective abstraction from the EMR. This approach was further supported by the presence of a shared EMR system among the study ICUs. Specifically we iteratively developed, refined, and evaluated an EMR data abstraction tool for retrospective assessment of the effectiveness of SPEACS-2 on patient-level care quality measures.

Measure selection-rationale/definitions

Our choice of care quality measures was based on the hypothesized conceptual relationship(s) to successful and effective nurse-patient communication (Bergbom-Engberg & Haljamae, 1989; Hweidi, 2007; Nelson et al., 2004; Patak et al., 2006; Rotondi et al., 2002; Samuelson, 2011), endorsement by quality and safety standards bodies (American Nurses Association, 2014), and evidence they could be reliably assessed and abstracted from the EMR (Edwards et al., 2006; Gélinas, Fortier, Viens, Fillion, & Puntillo, 2004; Gunningberg, Dahm, & Ehrenberg, 2008; Tate, Happ, & Sereika, 2005). We operationalized the following quality

outcome measures: heavy sedation, physical restraint, pain presence, highest daily pain score, unplanned extubation and ICU-acquired pressure ulcers. For each measure, the operational definition and criteria are described in Table 1.

Preliminary tool development: mapping indicators onto data fields in the EMR

At the outset of the project, the research team drafted a pilot data collection tool which contained the target data elements related to the variables selected. The pilot instrument consisted of sections for both single time point data (e.g., demographics) and repeated daily measurement of quality indicators, see Tables 1 and 2. We first located data elements within the EMR, and revised the preliminary tool so that nomenclature was consistent with the EMR.

In situations where data could be stored in multiple locations within the EMR, we evaluated all locations for data accuracy and ease of abstraction and accuracy (Utter et al., 2011). For example, to determine if any ICU-acquired pressure ulcer had occurred, one could review the bedside nursing documentation over the course of the ICU stay. Another option, however, was to review the documentation by the Enterostomal Therapy (ET) nurses, who are automatically (electronically) consulted with any skin breakdown that is Stage II or greater. The process in such cases was as follows: we (tool developers J.S. and A.E.) evaluated the options for accuracy of the data and efficiency of abstraction, with input from expert clinicians (most often clinical nurse specialists) if needed; we presented the options to the study team for evaluation; and the team made a consensus decision. In the case of pressure ulcer data, the ET nurse documentation was more accurate in terms of differentiation of wound type (pressure ulcer vs. other forms of skin breakdown) and wound staging. In addition, ET nurse documentation was easily isolated in a single view, allowing for more efficient abstraction.

Once the optimal location of each data element was determined, we developed a corresponding standardized operating procedure (SOP) containing detailed instructions and EMR screenshots to guide the data collection process (see Appendix 1).

Initial Testing and Refinement

To test the data collection tool and SOP, two patient cases were selected and we (J.S. and A.E.) worked separately to complete data collection for the first case, noting any questions or ambiguities. After independently abstracting the chart, we compared results. Any discrepancies we were unable to resolve, we brought to the study team to adjudicate. We made necessary clarifications and corrections to the SOP and repeated the process with the second record.

Examples of refinements made during this iterative testing phase included: adding categories to the list of admission diagnoses; expanding the process for determining presence of heavy sedation; and specifying situations where one type of documentation should be weighted more heavily/supersede another. (For example, we determined that free-text neurological descriptions should supersede vague “forced choice” assessment descriptors from the neurological assessment drop-down menu in the EMR.)

In the next step, we (J.S. & A.E.) completed four more cases independently and then followed the same process of comparison of results, discussion and adjudication of discrepancies, and revision of the SOP and/or data collection tool accordingly. Upon achieving consensus on all data elements for these four cases, we used these 4 abstracted cases as the “gold standard” against which to compare future abstractors during training.

Analyses

To evaluate reliability of patient-level care quality data collected, we computed Cohen's κ statistics across co-abstracted cases for the following variables: heavy sedation, restraint use, pain presence, highest daily pain score, unplanned extubation, and ICU-acquired pressure ulcer. See Table 1 for a detailed descriptions and operational definitions for each of the care quality measures. The data were analyzed using SAS 9.3.

Inter-rater Reliability Testing

Phase I—Development and Testing

For the first phase of inter-rater reliability (IRR) testing, we trained four student abstractors without prior experience with the EMR to use the tool. After initial training, these four abstractors independently abstracted the four “gold standard” charts. We calculated percent agreement and Cohen's kappa (κ) for each abstractor against the “gold standard” and summarized the mean κ for each quality indicator across the four abstractors. For items with mean $\kappa < 0.6$, we discussed discrepancies and modified the tool and SOP to address sources of ambiguity or inaccuracy

With the data abstraction tool finalized, we trained additional abstractors and began the abstraction of patient-level care quality data for the SPEACS-2 study. Of the two study team members involved in the tool's development, one (J.S.) consistently served as the second rater for IRR testing and was responsible for tool refinement, SOP development, and training. The other (A.E.) abstracted study data.

Phase II—Quality Assurance

In the second phase of IRR testing we randomly selected 10% (n=18) of Quarter I cases (n=180) for independent abstraction by a second data collector. We used a stratification sampling plan for case selection to ensure equal sampling of ICU units and abstractors. We computed Cohen's κ statistics for the co-abstracted cases, and the team discussed the results. Feedback was provided to the abstractors to remediate any deficiencies in reliability of collected data.

We continued to conduct IRR testing as described above on 10% of randomly selected cases through Quarter 4, evaluating the results after each quarter's reliability statistics had been calculated. To maintain reliability of abstracted data, we employed consistent data collectors for the last 5 quarters of the study, and the team reviewed and discussed significant discrepancies. The majority of the EMR data collection (1126/1440) was conducted by a single reviewer (AS). For Quarter 5 through Quarter 8, reliability testing was conducted for 5% of randomly selected cases, as stability in IRR had been achieved. This yielded a total sample of 108 cases for IRR testing.

RESULTS

Phase I—Development and Testing

The results of the initial IRR testing by 4 raters across 4 cases are displayed in Table 3. Results showed excellent inter-rater reliability for restraint use, heavy sedation (AM) and unplanned extubation ($\kappa = 1.00, .84, \text{ and } 1.00$ respectively); substantial inter-rater reliability for pain, pain score, and heavy sedation (PM) ($\kappa = .63, .73, \text{ and } .70$ respectively) and moderate reliability for heavy sedation (any in 24 hour period) ($\kappa = .56$). Reliability for ICU-acquired

pressure ulcer was also excellent ($\kappa = 1.00$), however there were no negative cases in the set to robustly assess abstraction of this measure. An additional finding of early IRR testing was the selection, by nurses, of the response option, “Unable to Communicate” when documenting (presence of) pain and pain score for mechanically ventilated patients. Since the purpose of the study is to improve communication with mechanically ventilated patients, we added this descriptor as a variable indicating an incomplete pain assessment and collected these data to determine if the use of ‘Unable to Communicate’ decreased after the intervention. Reliability testing for the ‘unable to communicate’ pain variable showed excellent agreement across raters ($\kappa = .88$).

Phase II—Quality Assurance

Analysis of IRR for study data from Q1-Q8 showed substantial to excellent inter-rater reliability over multiple quarters of data collection for all indicators except ICU-acquired pressure ulcer. Early results for ICU-acquired pressure ulcer, were problematic, with poor agreement ($\kappa = .050$). We provided additional training to the data abstractors and the data collection SOP was updated to provide more detailed direction.

Detailed IRR testing indicated some continued variability between individual raters in comparison with the standard for the heavy sedation item, especially early in the ICU stay. However, overall, inter-rater reliability was maintained or improved for all outcome variables except pressure ulcer, Table 4. Ultimately we re-abstracted pressure ulcer data for Q1-4, which resulted in an improved agreement ($\kappa = .791$) for data from Q1-3 and acceptable cumulative agreement for Q 1-8 ($\kappa = .610$).

DISCUSSION

This work on tool refinement and reliability testing contributes to the science of critical care quality improvement in several ways. First, it demonstrates the feasibility of collecting data on quality of care and patient outcomes in the ICU using abstraction of nationally-recognized quality indicators from the EMR. By using quality indicators endorsed by regulatory/advisory bodies, benchmarks can be established and meaningful comparisons *across* institutions can be made (Flaatten, 2012). Secondly, this tool shows how EMR abstraction can provide rich and detailed longitudinal data for the systematic study of quality issues. With such detailed data it is possible to explore patterns and trends in care quality and patient outcomes and determine correlations with different patient-level or unit-level conditions such as diagnosis, time of day, provider mix, etc. In addition, it becomes possible to rapidly and efficiently assess the effectiveness of interventions to improve quality processes and outcomes. In effect, EMR data represents a source of big data for the purposes of quality monitoring and improvement as well as clinical practice research.

Perhaps most importantly, this work links to the next stage in quality improvement science—automated quality monitoring via the EMR. Increasingly EMRs are being used in health care quality research (Swan, 2014). As EMRs become the dominant repository for healthcare information, including records of hospital-based care, clinicians are leveraging this resource to develop and test novel models for continuous quality monitoring and improvement (Kahn et al., 2014). While the process described in this paper was labor-intensive and produced a tool with limited generalizability, these limitations can be overcome through healthcare informatics and big data analytics. As EMR systems become the norm in ICUs and standardized quality indicators are integrated into system documentation, the prevalence of automated quality

improvement monitoring will greatly increase, and it will be possible to rapidly assess the effectiveness of interventions designed to improve care.

Nevertheless, it is important to recognize the limitations of using abstracted EMR data for quality improvement and especially for patient outcomes research (Terry et al., 2010). Validity of the data obtained from the EMR depends heavily on the accuracy of the nurse's assessment and documentation. Data selected and available from the medical record may be inadequate or represent invalid proxy measures for the phenomenon of interest (e.g., awake, alert as indicators of "no heavy sedation").

We discovered that nurses commonly used "Unable to Communicate" - an option from the EMR drop down menu for pain assessment. Although sedation and waning consciousness are clearly factors impeding pain communication and accurate assessment, for some, "Unable to Communicate" may be a habitual default used instead of arousing the patient and applying assistive communication techniques to ascertain pain presence, location and intensity. Similarly, Swan (2014) identified that ICU clinicians routinely recorded "Unable to Assess" neurological status in lieu of a thorough examination of arousability. A program to improve screening neurological status as part of the use of the CAM-ICU showed improvements in nurse attentiveness to patient arousal before administering the CAM-ICU (Swan, 2014). The circumstances (heavy sedation, intubation type, etc) and use of "Unable to Communicate" deserve further study. We collected data on the use of the term, "Unable to Communicate," as an additional measure of communication improvement during mechanical ventilation in ICU

Thorough knowledge of the EMR system and confirmation of the validity of selected indicators/variables is required. Because most health record documentation is not entered into required fields, the problem of missing data becomes a significant one (Landis & Koch, 1977;

Terry et al., 2010). In addition, data that are manually abstracted require a robust process for tool validation and assessment of data reliability.

To advance the use of EMR data for quality improvement, further testing and refinement of quality indicators is needed. Finally, broad organizational support, including the input of clinical practice experts from multiple disciplines and adequate information technology (IT) resources, including data analytics, will be needed to fully integrate quality improvement into the ICU EMR (Damberg et al., 2009).

CONCLUSIONS

We have demonstrated that data on patient-level care quality indicators can be accurately and reliably abstracted from the EMR of ICU patients using a well-developed data collection tool and detailed SOP document. An iterative development process ensured a robust instrument, adequate to collect the desired data across a variety of practice settings and types of illness while maintaining goal inter-rater reliability of a Cohen's κ at or above 0.6 - 0.7, a level generally accepted as substantial agreement (Landis & Koch, 1977). Thorough training on the use of the abstraction tool and SOP using a "training to competency" approach resulted in a high level of reliability across 12 individual abstractors. Given the transition to EMR systems nationally, this method represents an efficient and cost effective means to assess quality of care in rapidly changing care environments such as the ICU.

TABLES

Table 1—Quality Indicators*

Quality Indicator	Definition
Heavy Sedation	<p>Evidence of heavy sedation <i>at any point</i> during the 24 hour interval as measured by:</p> <ul style="list-style-type: none"> • Modified Ramsay score 4-6 <i>or</i> • Riker score of 1-2 <i>or</i> • Nursing note description of unresponsiveness to verbal or tactile stimulation, or being comatose or anesthetized <p>Awake for 8 out of 12 hours for AM (12:00am-11:59am) or PM (12:00pm-11:59pm) as defined by:</p> <ul style="list-style-type: none"> • Modified Ramsay score 1-3 • GCS motor score of 6 • Nursing note documentation of being alert, awake, arousable, responsive, or communicative
Restraint Use	<p>All restraint devices used within the 24 hour interval being evaluated including: soft extremity restraints (specify number of limbs restrained), vests, waist belts, full side-rails, mitts, and enclosure beds.</p>
Pain	<p>Presence of any pain during the 24 hour period being evaluated (Y/N)</p> <p>Highest pain score on a scale of 1-10 (including half scores) for the 24 hour interval</p> <p>Any use of the descriptor “unable to communicate” in the pain assessment documentation during the 24 hour interval (Y/N)</p>
Unplanned Extubation	<p>Documentation of self-extubation or any dislodging of the endotracheal or tracheostomy tube that is not part of a routine, intentional extubation by the clinical staff.</p>
ICU Acquired Pressure Ulcers	<p>Any pressure ulcer, Stage II or greater, occurring during the index ICU stay that was not documented on admission [cumulative for ICU stay]</p>

*All items are daily observations and calculated as a proportion of days observed, except ICU-Acquired Pressure Ulcers which is calculated a cumulative total for the ICU stay.

Table 2—Demographic and Clinical Characteristics

Demographic Characteristics	Definition
Age	Age of the patient on the day of hospital admission
Gender	Male/Female
Admission Date	Date of admission to the study ICU during which the subject was mechanically ventilated for ≥ 2 days and awake for one nursing shift. (Referred to as the Index ICU stay)
ICU Location	Name of the ICU to which the patient was admitted on the admission date
Admitting Diagnosis	Indication for admission to the ICU
Pre-hospital Functional Status	Functional ability related to ADLs & IADLs collected in the nursing admission assessment upon admission to the ICU
Admission Braden Score	Braden score assigned within 72 hours of admission to the hospital
Community-Acquired Pressure Ulcers	Documentation of any pressure ulcers (Stage II or greater) present on admission to the hospital

Table 3—IRR Results on Training Cases (n=16)

Indicator	mean Cohen's Kappa*
Restraint Use	1.00
Heavy Sedation (any in 24°)	.555
Awake (AM)	.843
Awake (PM)	.698
Pain Presence	.630
Pain Score	.729
Pain-Unable to Communicate	.883
Unplanned Extubation	1.00
ICU-acquired pressure ulcer	1.00

*Kappa Agreement: < 0 Less than chance agreement; 0.01–0.20 Slight agreement; 0.21– 0.40 Fair agreement; 0.41–0.60 Moderate agreement; 0.61–0.80 Substantial agreement; 0.81–0.99 Almost perfect agreement (Landis & Koch, 1977).

Table 4—IRR Results on QA cases, Q1 (n=18) and Q1- Q8 (n=108)

Indicator	mean Cohen's Kappa	
	Q1	Q1-8
Restraint Use	.930	.981
Heavy Sedation (any in 24°)	.885	.803
Awake (AM)	.931	.863
Awake (PM)	.793	.825
Pain Presence	.905	.861
Pain Score	.992	.991
Pain-Unable to Communicate	.884	.887
Unplanned Extubation	1.00	.989
ICU-acquired pressure ulcer	1.00*	.610

*Presence of ICU-acquired pressure ulcer after re-abstraction.

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COMPETING INTERESTS

The authors have no competing interests to declare.

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Instrument Number:

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Study ID:

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15452



DEMOGRAPHICS SPEACS-2

Case Number:

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Hospital Admission Date:

		/			/				
(month)			(day)			(year)			

Abstraction Date:

		/			/				
(month)			(day)			(year)			

Collector ID Number:

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1. Gender: 1 Male
 2 Female

2. Age:

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For optimum accuracy, it is recommended that characters be written block style without touching the sides of the blocks, such as in the following example. Place only one letter or one number in each box as shown . . .

0	1	2	3	4	5	6	7	8	9
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3. Race:

a.

b.

c.

Do you consider yourself to be Hispanic or Latino, that is, of Mexican, Puerto Rican, Cuban, or of Latin American descent?

- 1 Yes
 2 No
 3 Unknown

Please choose the ONE category that best applies to you:

- ⁽¹⁾
 1 White
 2 Black or African American
 3 American Indian;
Please specify: _____
 4 Alaska Native
 5 Native Hawaiian or other Pacific Islander
 6 Asian
 7 Other;
Please specify: _____
 8 Unknown

Are you of more than one racial/ethnic background?

- | | | |
|-----------------------|-----------------------|-----------------------|
| Yes | No | Unknown |
| 1 | 2 | 3 |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Please specify all categories that apply to you . . .

- ⁽¹⁾
 1 White
 2 Black or African American
 3 American Indian
 4 Alaska Native
 5 Native Hawaiian or other Pacific Islander
 6 Asian
 7 Other
 8 Unknown

Case Number: _____
(for internal use only)

Date: __ / __ / __
(for internal use only)

Study ID:
2 6 0

15452

4. Index ICU (Setting):

- (1) TICU = Transplant
- (2) 4G = Neuro Trauma
- (3) 4F/5F = Neuro ICU
- (4) 6FG = Trauma ICU
- (5) U3E1 = Mercy Cardiovascular ICU
- (6) U4F2 = Mercy Medical ICU

5. Admitting Diagnosis (upon admission to Index ICU): (Choose ONE response per item.)

	Primary Dx 1	Secondary Dx 2	N/A (-2)
a. Pulmonary disease/infection/respiratory failure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Renal or liver failure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Neurological disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Heme-onc or onc disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. CHF, Cardiomyopathy, MI, arrhythmia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Sepsis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Cardio/thoracic/vascular surgery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. Transplant	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. Other surgery (ortho/abdominal/etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j. GI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
k. Trauma	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
l. Post-operative complication	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
m. Other diagnosis; <i>please specify:</i> _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

(for office use only)

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6. Was admission/first available Braden score documented within 72 hours?

- 1 Yes ---->
- 2 No

a. Enter score:

7. Was admission/first available Skin Tool score documented within 72 hours?

- 1 Yes ---->
- 2 No

a. Choose one:

- 1 None
- 2 S
- 3 Sk
- 4 Ski
- 5 Skin

8. Community-acquired pressure ulcer (ST II or greater)?

- 1 Yes
- 2 No
- 3 Unsure

9. Functional assessment:

	Independent 1	Needs Assistance 2	Dependent 3	Missing (-1)
a. Eating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Grooming	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Bathing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Dressing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Toileting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Transfers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Cooking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. Cleaning	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. Laundry	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j. Grocery shopping	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
k. Money Management	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
l. Home ambulation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
m. Community ambulation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
n. Driving	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
o. Medication administration	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. ICU-acquired pressure ulcer occurrence (ST II or greater)?

- 1 Yes ----->
- 2 No
- 3 Unsure

a. Number of ICU-acquired pressure ulcers (ST II or greater):

b. Comment: _____

11. Arrival in ICU ----->

12. Departure from ICU ---->

a.	b.
Date	Time
<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (month) (day) (year)	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
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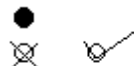
13. APACHE III score (first 24 hours of Index ICU stay):

Instrument Number:

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Study ID:

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16268



DAILY MEDICAL RECORD AUDIT (Part 1)

[Physical Restraint Use]

Case Number:

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Hospital Admission Date:

		/			/				
(month)			(day)			(year)			

Abstraction Date:

		/			/				
(month)			(day)			(year)			

Collector ID Number:

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		/			/				
(month)			(day)			(year)			

Physical Restraint Use

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
A. Physical restraint use (any portion of the day in restraint) <i>(Choose all that apply.)</i>														
1) None	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>
2) 1 wrist	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>
3) 2 wrist	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>
4) 1 lower extremity	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>
5) 2 lower extremity	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>
6) Vest	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>
7) Waist	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>
8) Other(s); specify:	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>
(coding)														
_____	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>
_____	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>



Physical Restraint Use

(continued)

	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28
A. Physical restraint use (any portion of the day in restraint) <i>(Choose all that apply.)</i>														
1) None	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>
2) 1 wrist	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>
3) 2 wrist	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>
4) 1 lower extremity	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>	4 <input type="radio"/>
5) 2 lower extremity	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>	5 <input type="radio"/>
6) Vest	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>	6 <input type="radio"/>
7) Waist	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>	7 <input type="radio"/>
8) Other(s); specify:	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>	8 <input type="radio"/>
_____ (coding)	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>	a. <input type="radio"/>
_____	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>	b. <input type="radio"/>

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48501



DAILY MEDICAL RECORD AUDIT (Part 2)

[Neuro Assessment]

Case Number:

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		/			/					
(month)			(day)			(year)				

Neuro Assessment

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B1. Did the patient spend any period during the day sedated?

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
1 Yes	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○
2 No	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○
3 Procedural /OR sedation	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○

B2. Did the patient spend at least 8 out of a 12-hour block awake?

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
12 am - 12 pm														
1 Yes	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○
2 No	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○
3 Patient spent < 4 hrs of this timeframe in the ICU	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○

B3. Did the patient spend at least 8 out of a 12-hour block awake?

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
12 pm - 12 am														
1 Yes	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○	1 ○
2 No	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○	2 ○
3 Patient spent < 4 hrs of this timeframe in the ICU	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○	3 ○

Neuro Assessment

(continued)

	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28
B1. Did the patient spend any period during the day sedated?	1 Yes	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>
	2 No	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>
	3 Procedural /OR sedation	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>
B2. Did the patient spend at least 8 out of a 12-hour block awake?	12 am - 12 pm													
	1 Yes	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>
	2 No	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>
3 Patient spent < 4 hrs of this timeframe in the ICU	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	
B3. Did the patient spend at least 8 out of a 12-hour block awake?	12 pm - 12 am													
	1 Yes	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>	1 <input type="radio"/>
	2 No	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>	2 <input type="radio"/>
3 Patient spent < 4 hrs of this timeframe in the ICU	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	3 <input type="radio"/>	

Instrument Number:

0	0	3
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Study ID:

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49714



DAILY MEDICAL RECORD AUDIT (Part 3)

[Pain Assessment]

Case Number:

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		/			/					
(month)			(day)			(year)				

Pain

C. Did patient experience pain?	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1 Yes -----> 2 Yes, but no score documented 3 No 4 Not assessed	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: [][] . []	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: [][] . []	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: [][] . []	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: [][] . []	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: [][] . []	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: [][] . []	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: [][] . []
D. Use of "Unable to Communicate" descriptor	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No



Pain

(continued)

C. Did patient experience pain?	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
1 Yes -----> 2 Yes, but no score documented 3 No 4 Not assessed	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>
D. Use of "Unable to Communicate" descriptor	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No



Pain

(continued)

C. Did patient experience pain?	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
1 Yes -----> 2 Yes, but no score documented 3 No 4 Not assessed	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>
D. Use of "Unable to Communicate" descriptor	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No



Pain

(continued)

C. Did patient experience pain?	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28
1 Yes -----> 2 Yes, but no score documented 3 No 4 Not assessed	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>	1 ○ 2 ○ 3 ○ 4 ○ Highest pain score: <input type="text"/> <input type="text"/> . <input type="text"/>
D. Use of "Unable to Communicate" descriptor	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No	1 ○ Yes 2 ○ No

Instrument Number:

0 0 4

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Study ID:

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19737



DAILY MEDICAL RECORD AUDIT (Part 4) [Respiratory Assessment]

Case Number:

[] [] [] [] [] [] [] [] [] []

Respiratory Assessment

[] [] / [] [] / [] [] [] []
(month) (day) (year)

E. Intubated?

[]

[]

[]

[]

[]

[]

Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
Yes	No	Bipap	Yes	No	Bipap	Yes	No	Bipap	Yes	No	Bipap	Yes	No	Bipap	Yes	No	Bipap	Yes	No	Bipap
1	2	3	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
a. Method:			a. Method:			a. Method:			a. Method:			a. Method:			a. Method:			a. Method:		
<input type="radio"/> 1 ET			<input type="radio"/> 1 ET			<input type="radio"/> 1 ET			<input type="radio"/> 1 ET			<input type="radio"/> 1 ET			<input type="radio"/> 1 ET			<input type="radio"/> 1 ET		
<input type="radio"/> 2 Trach			<input type="radio"/> 2 Trach			<input type="radio"/> 2 Trach			<input type="radio"/> 2 Trach			<input type="radio"/> 2 Trach			<input type="radio"/> 2 Trach			<input type="radio"/> 2 Trach		
b. Ventilated:			b. Ventilated:			b. Ventilated:			b. Ventilated:			b. Ventilated:			b. Ventilated:			b. Ventilated:		
<input type="radio"/> 1 Yes			<input type="radio"/> 1 Yes			<input type="radio"/> 1 Yes			<input type="radio"/> 1 Yes			<input type="radio"/> 1 Yes			<input type="radio"/> 1 Yes			<input type="radio"/> 1 Yes		
<input type="radio"/> 2 No			<input type="radio"/> 2 No			<input type="radio"/> 2 No			<input type="radio"/> 2 No			<input type="radio"/> 2 No			<input type="radio"/> 2 No			<input type="radio"/> 2 No		
c. Unplanned extubation:			c. Unplanned extubation:			c. Unplanned extubation:			c. Unplanned extubation:			c. Unplanned extubation:			c. Unplanned extubation:			c. Unplanned extubation:		
<input type="radio"/> 1 Yes			<input type="radio"/> 1 Yes			<input type="radio"/> 1 Yes			<input type="radio"/> 1 Yes			<input type="radio"/> 1 Yes			<input type="radio"/> 1 Yes			<input type="radio"/> 1 Yes		
<input type="radio"/> 2 No			<input type="radio"/> 2 No			<input type="radio"/> 2 No			<input type="radio"/> 2 No			<input type="radio"/> 2 No			<input type="radio"/> 2 No			<input type="radio"/> 2 No		



Respiratory Assessment

(continued)

E. Intubated?

Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>
<p>↓</p> <p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>	<p>↓</p> <p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>	<p>↓</p> <p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>	<p>↓</p> <p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>	<p>↓</p> <p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>	<p>↓</p> <p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>	<p>↓</p> <p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>
<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>
<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>



Respiratory Assessment

(continued)

E. Intubated?

Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
<p>Yes No Bipap 1 2 3 <input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap 1 2 3 <input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap 1 2 3 <input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap 1 2 3 <input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap 1 2 3 <input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap 1 2 3 <input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap 1 2 3 <input type="radio"/> <input type="radio"/> <input type="radio"/></p>
<p>↓</p> <p>a. Method: <input type="radio"/> 1 ET <input type="radio"/> 2 Trach</p> <p>b. Ventilated: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p> <p>c. Unplanned extubation: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p>	<p>↓</p> <p>a. Method: <input type="radio"/> 1 ET <input type="radio"/> 2 Trach</p> <p>b. Ventilated: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p> <p>c. Unplanned extubation: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p>	<p>↓</p> <p>a. Method: <input type="radio"/> 1 ET <input type="radio"/> 2 Trach</p> <p>b. Ventilated: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p> <p>c. Unplanned extubation: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p>	<p>↓</p> <p>a. Method: <input type="radio"/> 1 ET <input type="radio"/> 2 Trach</p> <p>b. Ventilated: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p> <p>c. Unplanned extubation: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p>	<p>↓</p> <p>a. Method: <input type="radio"/> 1 ET <input type="radio"/> 2 Trach</p> <p>b. Ventilated: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p> <p>c. Unplanned extubation: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p>	<p>↓</p> <p>a. Method: <input type="radio"/> 1 ET <input type="radio"/> 2 Trach</p> <p>b. Ventilated: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p> <p>c. Unplanned extubation: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p>	<p>↓</p> <p>a. Method: <input type="radio"/> 1 ET <input type="radio"/> 2 Trach</p> <p>b. Ventilated: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p> <p>c. Unplanned extubation: <input type="radio"/> 1 Yes <input type="radio"/> 2 No</p>

Respiratory Assessment

(continued)

E. Intubated?

Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28
<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>	<p>Yes No Bipap</p> <p>1 2 3</p> <p><input type="radio"/> <input type="radio"/> <input type="radio"/></p>
<p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>	<p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>	<p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>	<p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>	<p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>	<p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>	<p>a. Method:</p> <p><input type="radio"/> 1 ET</p> <p><input type="radio"/> 2 Trach</p>
<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>b. Ventilated:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>
<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>	<p>c. Unplanned extubation:</p> <p><input type="radio"/> 1 Yes</p> <p><input type="radio"/> 2 No</p>

APPENDIX B

[IRB APPROVALS]

Seaman, Jennifer Burgher

From: irb@pitt.edu
Sent: Tuesday, July 02, 2013 2:12 PM
To: Seaman, Jennifer Burgher
Subject: PI Notification: Your requested study-team modification has been approved



University of Pittsburgh *Institutional Review Board*

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
<http://www.irb.pitt.edu>

Memorandum

To: Amber Barnato MD MPH
From: Christopher Ryan PHD Vice Chair
Date: 7/2/2013
IRB#: [MOD09060348-07](#) / PRO09060348
Subject: SPEACS-2: Improving Patient Communication and Quality Outcomes in the ICU

The University of Pittsburgh Institutional Review Board reviewed and approved the requested modifications by the expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 7/2/2013
Expiration Date: 2/18/2014

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

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

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

Seaman, Jennifer Burgher

From: irb@pitt.edu
Sent: Monday, June 23, 2014 2:34 PM
To: Seaman, Jennifer Burgher
Subject: PI Notification: Your requested expedited modification has been approved



University of Pittsburgh *Institutional Review Board*

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
<http://www.irb.pitt.edu>

Memorandum

To: Amber Barnato
From: Christopher Ryan Vice Chair
Date: 6/23/2014
IRB#: [MOD09060348-09](#) / PRO09060348
Subject: SPEACS-2: Improving Patient Communication and Quality Outcomes in the ICU

The University of Pittsburgh Institutional Review Board reviewed and approved the requested modifications by expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 6/23/2014
Expiration Date: 2/18/2015

For studies being conducted in UPMC facilities, no clinical activities that are impacted by the modifications can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

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

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

APPENDIX C

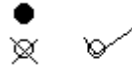
[PALLATIVE CARE DATA COLLECTION FORMS]

Instrument Number:

0 7 8

Shade circles like this: ●

Not like this: ○



Please use **BLACK** Pen Only!

Study ID:

2 6 0 1

Palliative Care Consultation

Case Number:

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Hospital Admission Date:

		/			/				
(month)			(day)			(year)			

Abstraction Date:

		/			/				
(month)			(day)			(year)			

Collector ID Number:

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A. Does the patient have a palliative care consultation?

1 Yes ----->

1. Date of initial consultation:

		/			/				
(month)			(day)			(year)			

2 No ----->

2. **STOP HERE!**

Instrument Number:

0 7 9

Shade circles like this:



Not like this:



Please use **BLACK** Pen Only!

Study ID:

2 6 0 1

Palliative Care Consultation Data Collection Form

Case Number:

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Hospital Admission Date:

Grid for Hospital Admission Date: (month) / (day) / (year)

Abstraction Date:

Grid for Abstraction Date: (month) / (day) / (year)

Collector ID Number:

Grid for Collector ID Number: 2 empty boxes

1. Reason(s) for consult:

(Select all that apply ...)

	Yes (1)
a. Pain and Symptom Management	<input type="radio"/>
b. Clarification of Goals of Care	<input type="radio"/>
c. EOL Goal Planning	<input type="radio"/>
d. Family Support	<input type="radio"/>
e. Inpatient Hospice Evaluation	<input type="radio"/>
f. Unknown	<input type="radio"/>
g. Other; specify:	<input type="radio"/>

(office use only)

Grid for office use only: 4 empty boxes

2. Requesting Physician/Provider:

Last, First

a.) Role:

b.) Specialty/Service:

(office use only)

Requestor ID Code:

Grid for Requestor ID Code: 2 empty boxes

(office use only)

Role Code:

Grid for Role Code: 2 empty boxes

(office use only)

Specialty/Service Code:

Grid for Specialty/Service Code: 2 empty boxes

60877



3. Consultation Visit Notes:

(a.) Date of Visit			Provider Name	Provider Role		
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(b.) (office use only) Provider Codes:
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(Continued on the next page)



3. Consultation Visit Notes: (continued)

(a.) Date of Visit			Provider Name	Provider Role	(b.) (office use only) Provider Codes:			
month	day	year						
16.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
17.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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27.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
28.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

4. Comments:

(office use only)

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J. Seaman, University of Pittsburgh School of Nursing. Adapted from MB Happ, University of Pittsburgh School of Nursing, 2012.



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