THE USE OF PATIENT DIARIES IN THE CVICU TO PREVENT POST INTENSIVE CARE SYNDROME AND IMPROVE FAMILY SATISFACTION WITH CARE

A Scholarly Project

Submitted to the

Faculty of Liberty University

In partial fulfillment of

The requirements for the degree of

Doctor of Nursing Practice

By

Denise M. Goodberlet

Liberty University

Lynchburg, VA

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Scholarly Project Chair Approval: _____

Lynne' S. Sanders, EdD, MSN, RN, CNE. Date

ABSTRACT

Patients in the ICU are at risk for adverse physiological and psychological symptoms including anxiety, depression and confusion common with post intensive care syndrome. The presence of these symptoms is correlated with poor satisfaction with care and decreased quality of life. This creates stress for patients as well as the families of these patients. This evidence-based practice (EBP) project sought to answer the clinical question: For patients and families in the cardiovascular intensive care unit (CVICU), can participating in an intensive care diary program, when compared to standard of care, decrease the symptoms and incidence of post-intensive care syndrome in patients in the CVICU along with improving family satisfaction with the care and involvement in decision making at discharge from the hospital? Patients and family members in the intervention group received a bound notebook with written suggestions for its use after baseline satisfaction scores were obtained prior to the implementation of the diary program. At the time of the patient's transfer from the CVICU, participants in both groups completed the Family Satisfaction with Care in the Intensive Care Unit survey (FS-ICU-24) as well as a demographic questionnaire. The groups did not differ significantly in age, gender, relationship to the patient, living arrangements, or previous experience as a family member of a patient in an ICU. Although mean scores of the FS-ICU-24 were higher in the intervention group, only the overall satisfaction achieved statistical significance ($p=.02$). While only five patients were discharged to the medical surgical units, no one experienced symptoms of PICS. This EBP project, while not achieving statistical significance in its results, it did achieve clinical significance, and served as a pilot for a larger, multiunit study.

Keywords: Post-intensive care syndrome, PICS, critical care, intensive care unit (ICU), patient diaries, intensive care diary, and ICU diary

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List of Abbreviations

American Association of Critical Care Nurses (AACN)

Cardiothoracic Intensive Care Unit (CVICU)

Collaborative Institutional Training Initiative (CITI)

Coronary Artery Bypass Graft (CABG)

Cumulative Index to Nursing and Allied Health Literature (CINAHL)

Doctor of Nursing Practice (DNP)

Evidence Based Practice (EBP)

Extra Corporeal Membrane Oxygenation (ECMO)

Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)

Institutional Review Board (IRB)

Intensive Care Unit (ICU)

Medical Intensive Care (MICU)

National Teaching Institute (NTI)

Post Intensive Care Unit Syndrome (PICS)

Richmond Agitation and Sedation Scale (RASS)

Social Behavioral Education (SBE)

Society of Critical Care Medicine (SCCM)

United States (US)

SECTION ONE: INTRODUCTION

It is well known that patients who survive a critical illness often do not return to their original state of health, as a result of long-term sequelae of critical illness. Post-intensive care syndrome (PICS) is a frequently encountered phenomenon that includes physical, neurological, cognitive, and emotional issues affecting patients long after they leave the intensive care unit (ICU) (Petrinec, & Martin, 2018). The prevalence of this syndrome can be as high as 50 percent of the patients that survive the ICU (Wang, et al., 2019).

Intensive care units have designed a variety of interventions to reduce the emergence of PICS in ICU survivors, including early mobility, screening daily for readiness to wean from the ventilator, assessing and controlling delirium, and engaging families in many aspects of daily care (Roberts, et al., 2018). One of the destressing symptoms of PICS is the gap in memories or delusional memories of the ICU stay (Locke, et al., 2016). Patient diaries have been found to serve as a medium to distinguish between what was real and what was a delusional memory by recording the experiences of both the patient and family during an ICU admission (Wang et al., 2019). These diaries allow the patients and the families to reflect on their stay and provide clarity to the event, eventually moving past the barriers that are inhibiting their return to a normal state of health (Wang et al., 2019).

Background

Each year, millions of patients are admitted to the ICU and approximately one-third of these patients are mechanically ventilated (Locke, et al., 2016). Given the improved survival rates of critically ill patients, stakeholders have broadened the outcome focus from short-term mortality to long-term mortality and morbidities that are often underrecognized by ICU clinicians. The Society of Critical Care Medicine (SCCM) has defined PICS as a new or

worsening decline in mental, cognitive, or physical health following critical illness that persists beyond the acute hospitalization (McPeake & Mikkelsen, 2018; Wang et al., 2019). PICS affects 50% to 70% of ICU survivors, and the effects can persist for many years after ICU hospitalization (Wang et al., 2019). Untreated PICS causes distress for patients and families and may affect the long-term outcomes which concern stakeholders.

Weakness acquired in the ICU is a physical sequela that occurs in 25% to 80% of patients who are mechanically ventilated for more than four days and in over half of septic patients (Davidson & Harvey, 2018). Cognitive function derangements occur in 30% to 80% of ICU survivors and encompass memory, planning, problem-solving, visual-spatial, and processing issues (Davidson & Harvey, 2018). Anxiety, depression, and sleep disturbances are encountered in up to 50% of ICU survivors which can last for many years after discharge (Davidson & Harvey, 2018). Together these physical, cognitive, and mental changes affect socioeconomic status, quality of life, and patient satisfaction (Davidson & Harvey, 2018; McPeake & Mikkelsen, 2018; Wang, et al., 2019).

Problem Statement

Patients in the ICU are at risk for adverse physiological and psychological symptoms including anxiety, depression, sleep disturbances and post intensive care syndrome. The presence of these symptoms is correlated with poor satisfaction with care and decreased quality of life. If these symptoms are ongoing, they may contribute to difficulties in the patients' ability to adjust to being at home and leading normal lives. This creates stress for patients as well as the families of these patients.

Purpose of the Project

Intensive care patient diaries are a simple, yet valuable instrument aimed at helping patients and family members come to terms with the critical care experience. The main purpose of this project was to pilot the introduction of a patient diary program in the CVICU and assess if using the diaries indeed decreased the incidence of PICS as the literature suggested. The other purpose of this project was to assess if the introduction of the diary program had any effect on family satisfaction with care received and their perceived involvement in decision making while their family member was in the ICU.

Clinical Question

For patients and families in the cardiovascular intensive care unit (CVICU), can participating in an intensive care diary program, when compared to standard of care, decrease the symptoms and incidence of post-intensive care syndrome in patients in the CVICU along with improving family satisfaction with the care and involvement in decision making at discharge from the hospital?

SECTION TWO: LITERATURE REVIEW

The purpose of this literature review is to provide a synthesis of the published current body of knowledge for the problem of PICS in the ICU and how patient diaries help to minimize the occurrence and improve satisfaction. The literature review will discuss the search strategy, critical appraisal of the literature, and the conclusions drawn about the findings. A discussion on the conceptual framework used in the implementation of ICU diaries will conclude the literature review.

Search Strategy

A literature review was conducted using the Cumulative Index to Nursing and Allied Health Literature (CINAHL), OVID, Cochrane Database of Systematic Reviews, and Medline Plus to locate English-language, full text articles. The following key words and phrases were used: post-intensive care syndrome, PICS, critical care, intensive care unit (ICU), patient diaries, intensive care diary, and ICU diary. Parameters of the search included English-language literature published within the past five years and was narrowed to academic journals that focused on adults to support the population that will be the recipient of the intervention for this project. Literature was used from outside of the United States (US) due to the paucity of published reports of ICU diaries in the US. Several more articles were found during a review of the bibliographies of the selected articles.

The results of the key words and phrases yielded 5,280 studies between 2014 and 2019 and when limited to English-language, academic journals, and the adult population, the number decreased to 1,202 studies. The search was further narrowed to include only critical care patients further reducing the total to 143 articles (45 were exclusive to US geographical area). The final selection of 26 articles was made after focusing on evidence based practice projects, qualitative and quantitative studies, systematic reviews and primary sources to arrive at the highest quality of evidence. Editorials, dissertations, and informational articles were reviewed though not included in the critical appraisal or synthesis but were utilized for background information instead.

Critical Appraisal

A critical appraisal was completed utilizing the Hierarchical Levels of Evidence for Literature (Melnyk & Fineout-Overholt, 2011). There are seven hierarchical levels which

include systematic reviews or meta analyses as level one to respectable though low level of evidence such as opinions of authorities and/or reports of expert committees, quality improvement reports and evidence based projects as level seven. Levels of evidence are assigned to studies based on the methodological quality of their design, validity, and applicability to patient care (Melnyk & Fineout-Overholt, 2011). The vigor of the appraisal supports the strength of the recommendation.

Two thirds of the articles reviewed for the critical appraisal were qualitative and included evidence-based practice projects, single descriptive or qualitative studies, or systematic reviews of qualitative or descriptive studies. The remaining one third of the articles were comprised of systematic reviews of quantitative studies, randomized control trials, non-randomized controlled trials or mixed method studies.

Although small, the systematic reviews and meta analyses had strengths in their methodology. McIlroy, et al. (2019) and Ullman, et al. (2015) utilized structured tools to assess the methodological quality of the studies with at least two independent reviewers. Two authors also assessed the risk of bias and when there was a discrepancy with the analysis, a third blinded author resolved the discrepancies thus enhancing the credibility of the review (McIlroy, et al., 2019). Although the number of studies included in the review were small, heterogenous, and had a substantial risk of bias, they were of moderate quality overall and demonstrated improvements in anxiety and depression (McIlroy et al., 2019; Ullman et al., 2015).

McIlroy et al. (2019) found a significant improvement in patients' anxiety which is contrary to what Ulman et al. (2015) found in their review. This could be explained by the difference in the publication dates. The topic of patient diaries had little controlled studies early

in the conception period of this intervention which many of the early scholars noted in their conclusions and recommendations for further research (Nedder, Levine, Ryan-Avery, 2017).

Krednester, et al. (2018) found in a randomized controlled trial that patients who received the patient diary had significantly lower anxiety and depression. The evidence supports the efficacy of ICU diaries in reducing psychological morbidity following discharge from a critical illness (Krednester, et al., 2018). The limitations of this study include small sample size, use of self-report symptom measures (screening tools and not diagnostic instruments), and many patients did not meet the inclusion criteria limiting the generalizability of findings (Krednester, et al., 2018). Using diagnostic interview methods and multiple sites to increase numbers would yield a better study (Krednester, et al., 2018).

Quasi experimental and single non-experimental studies, mid-level strength, represented one third of the articles reviewed here. All of these studies utilized reliable, validated tools to measure multiple aspects of psychological health as well as possessing appropriate and strong statistics (Aitken et al., 2016; Akerman, Ersson, Fridlund, & Samuelson, 2013; Fukuda, Inoue, Kinoshita, & Yukawa, 2015). All of these studies were conducted outside the United States which is a major weakness as it relates to this project.

Although Aitken et al. (2016) had high attrition rates, patients valued the diary and viewed it to be a therapeutic tool to promote memory and recall of the ICU and their progress. Aitken et al. (2016) noted an important strength was the investigation of the issue of perception of diaries by both patients and relatives with a separate analysis of the two groups suggesting that patients and relatives require different interventions. In addition to the high attrition rates, another limitation was the small sample size of the participants. Although small, the sample was adequate to answer the aim of the study (Aitken et al., 2016). Like Aitken et al. (2016), Fukuda,

Inoue, Kinoshita, and Yukawa (2015) also had a small sample size which was a limitation to that study as well.

Akerman et al. (2013), using a descriptive, exploratory cohort design found benefits from using the diary to fill in memory gaps of critical care patients. The two strengths of this study were interviews were conducted by a critical care nurse who specialized in interview techniques and the choice of mixed method which provided a deeper insight into the question which provided dimensions on the findings (Akerman et al., 2013). Weaknesses found with this study were 1) patients with longer length of stays may have different experiences and be more prone to hallucinations or delusions that may affect their survey answers and 2) the questionnaire was not pilot tested prior to use (Akerman, et al., 2013). Fukuda, Inoue, Kinoshita, and Yukawa (2015) found similar distorted memories during ICU admissions that cleared with diary use as well as relieved acute stress symptoms.

The largest number of studies reviewed were all qualitative in nature. Two of the articles were qualitative systematic reviews (Roberts, et al., 2018; Teece & Baker, 2017), three articles were evidence-based practice projects (Blair, Eccleston, Binder, & McCarthy, 2017; Huynh, et al., 2017; Locke, et al., 2016) and seven were qualitative studies (Ewens, Chapman, Tulloch, & Hendricks, 2014; Garrouste-Orgeas, et al., 2014; Johansson, Hanson, Runeson, & Wahlin, 2015; Levine, Reilly, Nedder, & Ryan-Avery, 2018; Nielsen & Angel, 2016; Petersson, Ringsal, Apelqvist, & Bergbom, 2015; Strandberg, Vesterlund, & Engstrom, 2018). The three evidence-based practice projects were the lowest level of evidence though they still contributed support to the implementation of diaries in the ICU with good outcomes and provided clinical significance. While each qualitative systematic review has strengths in the methodology and analysis, some

limitations did exist. The limitations common to all the articles included small sample sizes and single sites.

Blair, et al. (2017) reported that small sample sizes have a concern for bias. Garrouste, et al. (2014) had a unique limitation in that there existed a large percentage of higher education in participants which has the potential to limit generalizability. Ewens et al. (2014) also had a unique limiting factor with a low number of responders in an already low sample size. Further detail on individual article analysis can be found in Appendix A.

Synthesis

Amalgamating all the finding from the literature review, there is support that ICU diaries introduced early in the length of stay, within 2 days, has a profound impact on the incidence of psychological morbidity, patient and family satisfaction, and health related quality of life post discharge from the ICU. Taking the diaries home and reviewing and sharing with others has shown to improve memory gaps and humanize their experience in a highly technological environment. Although there is a scarcity of literature, especially US literature, that is statistically significant along with the fact that the majority of the articles are on the lower spectrum of the hierarchy of evidence, there is clinical significance for the patients and for their recovery from a critical illness.

Conceptual Framework/Model

The conceptual framework that guided this project was the Iowa Model of Evidence-Based Practice (EBP) (Iowa Model Collaborative, 2017). The Iowa Model is based on Roger's 1983 theory of diffusions of innovation and is a commonly used framework for the implementation of EBP (Iowa Model Collaborative, 2017). Since 2001, more than 3,900

requests for permission to use the model has come from clinicians, educators, administrators, and researchers nationally and internationally (Iowa Model Collaborative, 2017).

This model allows clinicians to center on knowledge and problem-focused triggers while enticing clinicians to question current practice and investigate if there is opportunity for improvement (Doody & Doody, 2011). The model has seven steps and initiates with a clinical "trigger" that identifies a clinical problem. The remaining phases are interprofessional team formation; evidence review, critique, and synthesis; change implementation through piloting; ongoing evaluation; and outcomes dissemination.

The application of the model to this project began with the identification of an opportunity to improve care in the ICU patient population. Patient and family satisfaction were deemed an organizational priority and after reviewing the literature there was sufficient evidence to design and implement an evidence based practice change. This evidence based project was a pilot in a single unit and after evaluating if the change is appropriate for adoption, it is hopeful that the project will then progress to the other ICUs within the facility and eventually to other hospitals within the health system. Permission to use the model can be found in Appendix B.

Summary

The findings of this literature review, although low on the hierarchy of evidence, supports the use of diaries in the critical care patient population. There are many psychological and physiological sequelae that affect patients who have spent time in the intensive care unit which can be alleviated by the implementation of patient diaries. Patient diaries help both patients and families overcome anxiety, depression, memory gaps and correct hallucinations and delusional memories. Overcoming these problems facilitate speedy recovery and improve health related quality of life. Keeping an ICU patient diary has been shown to improve communication,

decrease anxiety, fill memory gaps, maintain cognition, humanize the experience and improve overall satisfaction with the care that was provided.

SECTION THREE: METHODOLOGY

Design

The ICU diary program was implemented as a scholarly evidence-based project to fulfill the requirements of the Doctor of Nursing Practice program objectives. The project utilized the Iowa Model of Evidence-Based Practice as a guide (Iowa Model Collaborative, 2017). According to the Iowa Model, a practice change is evaluated with a pilot study (Iowa Model Collaborative, 2017). This evidenced-based project was a quantitative, prospective two group, time series design in the quasi-experimental category using a convenience sample.

Time series designs attempt to detect whether an intervention has had an effect significantly greater than the underlying secular trend and are useful in quality improvement projects for evaluating the effects of interventions when it is difficult to randomize or identify an appropriate control group (Eccles, Grimshaw, Campbell, & Ramsay, 2003). Data is collected at multiple time points before and after the intervention is implemented which allow the underlying trend and cyclical effects to be estimated (Eccles, et al., 2003). Well-designed time series evaluations increase the confidence with which the estimated of effect can be accredited to the intervention that was implemented (Eccles, et al., 2003)

Measurable Outcomes

The measurable outcomes for this project was the occurrence of anxiety or confusion which are major symptoms of PICS along with how the family rated their satisfaction with care and decision making while in the ICU.

Setting

The setting for this project was in the CVICU within a 470 bed short term acute care hospital in Northeastern United States. The CVICU is a 12 bed unit that recovers and cares for post-operative cardiothoracic surgical patients as well as patients with cardiovascular issues, such as pulmonary embolisms or deep vein thromboses requiring catheter directed thrombolytics, myocardial infarctions, coronary artery disease or cardiogenic shock necessitating invasive assist devices (intra-aortic balloon pumps, ventilatory support, Impella devices or extracorporeal membrane oxygenation [ECMO]). The CVICU is a major part of the revenue generating cardiovascular service-line which has been recognized as one of America's best hospitals for cardiac surgery and is a five star recipient for quality by Healthgrades for coronary artery bypass grafts (CABG). Blue Cross and Blue Shield has designated this hospital as a Blue Distinction Center for Cardiac Care.

When patients no longer require critical care, they are transferred out of the CVICU to the medical-surgical floors. Many of the cardiac patients are transferred to the step down unit on the seventh floor which is a 40 bed telemetry unit. All of the cardiothoracic surgery patients go there to continue the recovery from surgery as these nurses' focus is on the care of the cardiac patient. Patients from the CVICU who are not cardiothoracic surgical patients may go to other floors but an attempt is made to cohort them on the cardiac floor.

Population

The target population for the scholarly project implementation was the adult patient population in the CVICU. As the literature suggested, the diary program was especially effective for patients who were mechanically ventilated for more than 24 hours, have been in the intensive care arena for over 24 hours, or those that have a negative two score on the Richmond Agitation

- Sedation Scale (RASS) (Blair, Eccleston, Binder, & McCarthy, 2017). The sample of the population was a purposive, convenience sample from the service line in which this scholar is an active clinician. The inclusion criteria consisted of adult patients who have been in the CVICU for more than 24 hours or who had a qualifying RASS score. Excluded in the pilot were those patients with a diagnosis of dementia, other underlying psychological diagnoses, a zero RASS score, cannot communicate with assessor (deaf or non-English speaking) or refuse to participate.

Ethical Considerations

The Collaborative Institutional Training Initiative (CITI) was completed at the beginning of the process. This served as a review of the protection of human subjects in biomedical research concepts. The Biomedical Basics course offered historic and current information on regulatory and ethical issues important to the conduct of research involving human subjects. The Social-Behavioral-Educational (SBE) Basic course introduced social-behavioral-educational research with a focus on the protection of human subjects. The curriculum offered historic and current information on regulatory and ethical issues important to the conduct of research involving human subjects. These courses provided completion certificates which are located in Appendix C.

After completing the CITI training, approval was requested from Liberty University Internal Review Board (IRB). After approval from Liberty University, approval was obtained from Catholic Health System's IRB. Both of these approvals were obtained before the project was introduced to the staff and once obtained, the was implemented. Copies of the approvals are located in Appendix G.

Patients and family members were approached and provided information on the project upon meeting inclusion criteria while in the CVICU. Further consent was assumed if the survey

was returned. If the survey was not returned, then it was assumed they declined to participate. The coordinator recused herself from the care of patients in the CVICU who have been there for more than 48 hours to minimize conflict of interest. As she is a nurse practitioner for the Cardiothoracic Surgery group, many of her patients were not in the CVICU for more than 48 hours but in the event that some were, another colleague assumed their care. Many of the patients invited to participate in this project were critical care patients on the medical service with cardiac problems. Example of the informed consent is located in Appendix E.

To further protect the confidentiality of the participants, surveys were returned in a sealed envelope and only the coordinator opened the envelopes. None of the doctors or nurses had access to the surveys which allowed the participants to be a candid as they wish. All project records were kept in a locked office off site from the hospital. Participants were assigned a pseudonym that was logged on a spreadsheet that was kept separate from the surveys.

It was noted on the consent form that participation was completely voluntary, and they were able to decline to participate at any time. It was also noted that participants may choose to not answer any question for any reason. Declining to participate in the project, withdraw from the project, or omit any questions did not inhibit the relations between the participants or the hospital, provider, or university now or in the future.

Data Collection

Patient characteristics were collected such as demographics (sex, age), reason for admission to the CVICU, use and duration of mechanical ventilation or non-invasive ventilation, and length of stay in the intensive care unit. Family characteristics was also collected and included age, gender, relationship to the patient, previous ICU exposure, and educational level. Serial assessments of anxiety and confusion were collected and recorded in the electronic

medical record three times a day as is per policy in the institution. Patient and family satisfaction scores were collected utilizing the Family Satisfaction with Care in the Intensive Care Unit (FS-ICU-24) survey (www.fsicu.com). The data collection was carried out by the DNP student when a transfer order has been placed or within 24 hours of being transferred to the floor.

Once on the medical-surgical unit the patients had continued serial assessments of anxiety and confusion as per standard of care. A chart review was performed looking at nursing documentation from days two, four, six and day of discharge. If patients were discharged before day six, then only days two and four and day of discharge were noted in data collection. The patients and families were encouraged to continue to write in the diary.

Tools

The tool that was utilized to measure satisfaction in care while in the ICU was the FS-ICU-24 (Appendix E). The FS-ICU-24 is available for use free of charge providing the source of the tool is acknowledged and no modifications to the tool without permission (CARENET, 2019). The project coordinator received written permission from the author to use the questionnaire in the project (Daren Heyland, written communication, February 22, 2019). The conformation email from the author is in Appendix F along with a copy of the permission statement from the website.

It is common practice in this facility for administration to use data garnered from Press Ganey surveys and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) to guide practice changes targeted at improving patient outcomes and experiences. Because these extensively used surveys do not directly measure patient and family satisfaction with the care received in the ICU, the FS-ICU-24 was used and after administration reviewed the tool it was determined that it would not produce bias with the Press Ganey surveys.

The FS-ICU-24, a 24 item questionnaire, is a reliable and valid tool used to measure family satisfaction with care and decision-making in the ICU (Clark, Milner, Beck, & Mason, 2016). The FS-ICU-24 has 14 questions aimed at satisfaction with care and 10 questions aimed at decision-making and reported to take approximately 15 minutes to complete (Clark, et al., 2016). As decision-making is not part of this project, this data will be reserved for future use. Each question was answered using a five-point Likert scale: 1 = poor, 2 = fair, 3 = good, 4 = very good, and 5 = excellent. There was a sixth answer for not applicable. According to Clark, et al. (2016), this questionnaire has well established reliability with a Cronbach alpha of 0.92 for satisfaction with care.

Intervention

Identification of the triggering issue marked the beginning of the project. After the concept of PICS prevention via the patient diary had been approved by the project chairperson, a literature review and synthesis were completed, and the proposal was written. While the proposal was being written, permission to use the tools and models was obtained from the authors. Simultaneous to the writing of the proposal, an informed consent was drafted and submitted for approval as well. Once the proposal and consent were approved by the project chair, the proposal was submitted to the Liberty University Internal Review Board (IRB). After the Liberty IRB approved the project, it was submitted to Catholic Health IRB which ensures human protection in the institution where the project took place.

Once all approvals were obtained, the project was ready to start and kicked off with educational sessions for the staff (nurses, nursing assistants and providers) of the CVICU. Several educational sessions were conducted by the project coordinator on the purpose of the project, benefits of the project, and what should be included in the patient diary from the

healthcare providers. Samples of diary entries were available for the staff to reference. While the educational sessions were in process, baseline data was collected to establish a baseline level of satisfaction in the CVICU prior to the start of the diary project. After baseline data was collected, participant enrollment began. A daily review of the CVICU census took place to identify potential participants utilizing the inclusion and exclusion criteria previously discussed. When a patient was identified, the project coordinator approached the families and had face to face discussions about the project, the benefits of participation, the process and concluded with signed consents. The primary nurse for that patient obtained a diary from the dedicated diary binder, wrote the first entry, and reinforced the diary project to the family (if present). The nurse encouraged the family members and/or friends to write in the diary as well. The diary was left in the patient's room.

The patients are evaluated three times a day for signs and symptoms of delirium, anxiety, depression using preset questions in the electronic charting system. This data was collected via chart review by the project coordinator. Once the patient was transferred from the CVICU, the FS-ICU-24 survey was given to the family member of the patient with instructions to seal the self-addressed envelope and sign along the seal then return to it the coordinator. The majority of the surveys were handed directly to the family members while in the CVICU and the coordinator rounded on the family members once transferred and collected the sealed envelopes. Several of the patients were discharged or passed away before the questionnaire was directly handed to the family. In that case the FS-ICU-24 questionnaire was mailed to the families with a self-addressed envelope.

In order to complete this project by the end of the doctoral program, survey distribution was conducted for one month. It was anticipated that there would be a minimum of 10 pre-diary

patients and 10 to 20 diary participants in the project. After all surveys were collected, the data was analyzed using the SPSS software.

Once the data has been analyzed and synthesized, the proposal was transformed into a manuscript for dissemination of the project results. The climax of the dissemination will be the defense of the project and acceptance into the Liberty University's Scholarly Crossing.

Timeline. Figure 1 is the proposed timeline for this scholarly project developed at the time of proposal writing. Figure 2 is the actual timeline for this scholarly project that was kept during the conduction of the project. Many action items took much longer than anticipated.

Feasibility Analysis. As the literature states, this is a simple intervention to implement. The resources that were needed was support from hospital administration, specifically the CVICU nurse manager's support, diaries to deliver to the patients, paper for the printing of brochures and surveys, poster boards for educational sessions, and time allotted for staff to attend the educational session. The hospital agreed to support the project and the printing of materials. The cost of purchasing the diaries from the SCCM was privately donated. Data collection and analysis was done as part of the practicum hours allotted for scholarly project and the remaining time required to analyze the data was completed by the student on her own time.

Data analysis

Demographic and clinical characteristics of the study population will be summarized using the appropriate descriptive statistics. As this is an evidence based pilot project, statistical significance was not needed to be achieved rather notation of clinical significance (Social Science Statistics, 2019). It was determined that if the question could be answered then there was enough data.

Figure 1. Proposed Scholarly Project Timeline

February	March	April	May	June	July	August	September	October
CITI Training Write Proposal Develop Partnerships with facility Develop Timeline Obtain quotes for printing diaries and brochures Obtain permissions to use Iowa Model. (1/2019) Obtain permission to use FS-ICU tool (2/21/2019)	Obtain proposal approval (2/21-3/1/19) Print diaries and brochures Liberty University IRB approval (3/8/19) Mercy Hospital IRB (3/22/19)	Initiate Project (3/29-4/5/19) Inservice Staff Collect baseline data distributing FS-ICU and FS-SDU surveys (goal 20 surveys) Implement Diary Program and enroll patients/families (4/21/19) Distribute FS-ICU surveys to eligible families.	Collect Data	Analyze Data (6/1/19) Synthesize Data (6/7/19) Draft of project to chair by 6/16/19 Update and submit scholarly project work plan to maintain timeline by 6/28/19	Submit updated draft to chair by 7/21/19	Request defense appointment by 8/19/19 Submit final draft of project by 8/31/19	Present and defend scholarly project Submit final written report	Submit manuscript to Liberty University Digital Commons

Figure 2. Actual Scholarly Project Timeline

February	March - June	July	August	September	October	November	December
CITI Training Write Proposal Develop Partnerships with facility Develop Timeline Obtain quotes for printing diaries and brochures Obtain permissions to use Iowa Model. (1/2019) Obtain permission to use FS-ICU tool. (2/21/2019)	Obtain proposal approval (2/21-3/1/19) Print brochures Order Diaries Liberty University IRB approval (5/17/19) Draft of project to chair (6/16/19) Mercy Hospital IRB (6/21/19)	Initiate Project (7/15/19) Collect baseline data by distributing FS-ICU (goal 20 surveys)	Implement Diary Program and enroll patients/families (8/1/2019) Develop Code Book Distribute FS-ICU surveys to eligible families follow transferred patients to assess for PICS symptoms, chart reviews	Collect Data Continue to recruit subjects and follow those that were already enrolled Enrollment closed (9/30/19)	Relearn SPSS and start entering data into program	Analyze data Synthesize data Transition proposal into final manuscript for submission	Submit updated draft to chair by 7/21/19 Request defense appointment Submit final draft of project by Present and defend scholarly project Submit final written report Submit manuscript to Liberty University Digital Commons

SECTION FOUR: RESULTS

Descriptive Statistics

There were 19 patients in the CVICU included in the project, 13 were men (mean age was 57.69), six were female (mean age was 68.83) and the mean length of stay in the CVICU was five days and ranged between two and 42 days. All patients were intubated and had at least one comorbidity. The majority of the patients who received diaries were male (78%) as well as the majority who were discharged to the floor (80%). Of the nine patients who were in the intervention group, four died in the unit before they were able to be transferred and thus were not included in the PICS assessment. Their families were given a FS-ICU-24 questionnaire and they were returned and therefore were included in the satisfaction analysis.

Table 1. *Descriptive Demographic Statistics*	n	%
Patients (N=19)		
Male	13	68
Female	6	32
Age ≤ 50	2	10
Age > 50	17	89
Medical Admission	6	31.6
Surgical Emergent Admission	6	31.6
Surgical Elective Admission	7	36.8
Family (N=14)		
Male	2	14.2
Female	12	85.7
Age < 50	4	28.6
Age > 50	10	71.4
Lives with patient	8	57.1
Previous ICU experience	3	21.4
High School degree	2	14.3
2 yr college degree	6	42.9
4 yr college degree	4	28.6
Graduate degree	2	14.3

A total of 19 families were approached to participate in the project, 10 families for baseline data and nine families who received diaries. Of the 19 families approached, 14 (73.6%) completed the satisfaction surveys, five (35.7%) were from the baseline group and nine from the diary group (64.2%). Five family satisfaction baseline surveys were not returned and assumed to have withdrawn from participation. Table 1 highlights the demographics of the patients and the family participants.

Inferential Statistics

Independent-samples t-tests were conducted to compare the overall family satisfaction, family satisfaction with care and satisfaction for decision making for the baseline group (preintervention) and the diary group (post intervention). There was a significant difference in scores for the preintervention group for overall family satisfaction (M = 76.3, SD = 18.45) and the postintervention group (M = 94.75, SD = 2.09; $t(12) = -2.799$, $p = .02$). When analyses were conducted on the individual subcategories there were no significant differences for preintervention group for family satisfaction with care or with decision making (M = 76.2, SD = 15.94; M = 77.0, SD = 24.07) and the diary group (M = 95.11, SD = 7.89; t (5.1) = -2.49, p = .05; M = 94.56, SD = 6.88; $t(4.3) = -1.59$, $p = .18$). It was further determined that a large effect size existed.

Post Intensive Care Syndrome Symptoms

There were five patients that were transferred out of the CVCU to the medical-surgical units. Not one patient exhibited signs or symptoms of PICS such as anxiety, depression, or confusion during the remainder of their admission. Two patients were discharged before the sixth day and those that were still in the hospital past the sixth day did not have any symptoms of PICS on discharge day.

Family Satisfaction with Care

FS-ICU-24 baseline survey data were collected during a two week period prior to diary implementation. A total of five baseline surveys were collected (50 percent return rate). Scores were converted from the Likert responses to a 1-100 scale with 100 indicating the most satisfied (Heyland, et al, 2002). The CVICU baseline data had a composite score of 76 in part one (satisfaction with care) and 78 in part two (satisfaction with decision making).

A total nine surveys were collected during the intervention period. A goal of 10 to 20 diary participants was originally set but that was not recognized due to time constraints of completing the project in time for graduation. As this was a pilot study the nine surveys were deemed sufficient as it answered the questions. All surveys returned had been filled out completely; only questions that were not completed were those related to death if the patient did not die. For the post intervention period, the CVICU had average scores of 95 on part one and 96 on part two.

During the intervention phase there were four patient deaths. Of the nine surveys collected during the post intervention phase, four surveys contained the addition 3 questions about the final hours before death. Scores for the additional questions were also converted to a 0-100 scale, with 100 indicating the best. Of the families whose loved one died, 50 percent felt that their life was slightly prolonged, and the other 50 percent felt that it was neither prolonged nor shortened. The second question about comfort during the final hours had an average score of 87 and the question about support during the final hours had an average score of 95.

Embedded at the end of the FS-ICU were open-ended questions that allowed written comments by family members. The majority of the comments were positive, and they spoke highly of the nursing staff. The amount of positive comments increased by 19 percentage points

after the diary program was implemented and the amount of negative comments significantly decreased from 22 percent to 3 percent (19 percent).

SECTION FIVE: DISCUSSION

Implication for Practice

Patient care diaries have shown to be clinically significant to both patients and families during their time in the CVICU. Consistent with the literature, while there was no statistical significance, the diary program was clinically significant (Aitkens, et al, 2017). This was especially noted when the patient died in the CVICU. One family member of a patient that died commented that reading the tributes to her loved one helped with the difficult decision that had to be made and appreciated the care and love the staff demonstrated (personal communication, October 7, 2019).

The diary program was well received by both staff and patients and while the numbers were small no one who used the diaries demonstrated evidence of PICS. When speaking with the first diary patient transferred to the medical-surgical unit, he reported that reviewing the diary helped him to piece together what he missed during his time in the CVICU (personal communication, September 14, 2019). This was congruent with what Ackerman, et al. (2013) reported in their study.

One of the limitations identified in this project was the small number of participants. In the critical care arena there is a small population and when exclusion criterion is added the numbers are further reduced. Blair, et al. (2017) and Ewens, et al. (2014) also shared this same concern that small sample sizes have a concern for bias. This places a bias and increases the chance for coincidence as the effect size was found to be large. This also limits the

generalizability to other populations. This EBP project, while not achieving statistical significance in its results, served as a pilot for a larger, multiunit study. Additional research, with clear communication of the methodology and results, will contribute to the growing body of evidence related to the use of ICU diaries.

Another limitation or possible alternative explanation was when the participants were approached for enrollment, the coordinator discussed that this was part of a doctoral project. Participants may have answered the FS-ICU-24 survey with a more positive light to aid in the success of the project. This gives further support for an ongoing analysis with the diary program implemented as a standard of care. The analysis period should also be extended for two reasons. First would be to obtain a larger baseline sample and second to increase participant size as the short duration, while sufficient for a pilot, could not eliminate that the results obtained were by chance (Pallant. 2013)

Sustainability

Patient outcomes and satisfaction scores continue to be a priority for this facility as is for most health care facilities across the nation. With reimbursement tied to outcomes in a financially constricted time most institutions keep satisfaction and outcomes as a top priority. This project has shown to impact satisfaction positively. As several authors noted, the diary is a simple and inexpensive initiative to implement and one that is easily sustainable (Fukuda, et al., 2015; Locke, et al., 2016).

This project has been opened up to the CVICU as a standard of care for all patient who have been in the unit for more than 48 hours or mechanically ventilated for more than 24 hours. It has been extended to the medical intensive care unit (MICU) and presented at a town meeting

where all nurse leaders, managers, directors and senior leadership attend. The idea has been well accepted and leaders of the other ICUs are anxious to implement this project as well.

The coordinator received a donation for the purchase of the Thrive ® diaries from the Society of Critical Care Medicine (SCCM) that will be used until they are depleted. Through the assistance of inhouse marketing department, similar diaries could be easily reproduced if the other ICUs do not want to incur the cost. The foundation of the hospital could also be approached for financial assistance for the purchase of the diaries from the SCCM. Other plain notebooks could be used and can be purchased in bulk thus minimizing the cost burden.

Dissemination Plan

The results are continuously discussed at leadership rounds and staff meetings as a means of sustaining the initiative as a standard of care. As part of the requirements for the degree of Doctor of Nursing Practice (DNP) graduation, this project will be submitted to Liberty University's Digital Commons repository. A poster presentation will be submitted during nurses week within the health system. The same poster will be submitted for acceptance at the AACN's National Teaching Institute (NTI) symposium in May 2020. A manuscript for journal publication is in the process of development and is being considered for submission.

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Appendix A

Evidence Table

Clinical Question: Can providing a diary to patients and their families help decrease the symptoms and incidence of post-intensive care syndrome (PICS) in cardiovascular patients and their families during and after their admission to the CVICU?

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
Aitken, L. M., Rattray, J., Kenardy, J., Hull, A. M., Ullman, A. J., LeBrocque, R., … & Macfarlane, B. (2017). Perspectives of patients and family members regarding psychological support using intensive care diaries: An exploratory mixed methods study.	To identify whether distress post-intensive care influencing patients' and relatives' choice as to whether they would likely to	Most of the patients were male (63%) and had a mean age of 54 years. 91% were mechanically ventilated with a median Acute Physiology and Chronic Health Evaluation (APACHE) III score of 60.0.	Exploratory mixed methods study. Interviews were conducted 3-5 months after discharge. Psychological distress was assessed using Kessler-10 and PTSD symptom	57 patients and 22 relatives consented to participate, with 22 patients and relatives interviewed before data saturation. Psychological distress was evident in 47% of the patients	Single non experimental study – Level 4	Attrition rates between recruitment at the end of ICU admission and follow-up were high although they were like other	Yes – still showed that diaries made a positive impact if not statistically then clinically.

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
Journal of Critical Care, 38, 263-268. DOI: 10.1016/j.jcrc.2016.12.003	receive a diary and what information delivery method is preferred.	Family members were predominantly female (82%) with a mean age of 50. Main reason for ICU admission was medical followed by trauma making up 70 % of the patients. Remaining 30% were admitted because of surgery (elective, cardiac and emergency). Of the family members, 64% were spouse or partner.	checklist-5. Perceptions of benefit of diaries were assessed using a 4 point Likert scale. Differences were examined using Fisher exact test (P<.05).	and 23% of the relatives. Participants' psychological health was similar for those who perceived diaries as beneficial, and those who did not. Themes included memory, process, and impact, although opinions were diverse.		ICU longitudinal studies. Study was completed at a single site which could limit generalizability. The sample size was small but adequate to answer the question. The data collected during the interviews was	

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
						limited to information gained by prompted questions.	
Akerman, E., Ersson, A., Fridlund, B., & Samuelson, K. (2013). Preferred content and usefulness of photo diary as described by ICU patients – A mixed methods analysis. *Australian Critical Care, 26*(1), 29-35. DOI:10.1016/j.aucc.2012.04.002	The purpose of this study was to identify the preferred content and usefulness of an ICU-diary as described by ICU-patients.	320 total patients from a previous study. 115 patients received a diary and 205 patients did not. Of the 115 included in this study the mean age was 61 (SD±15), 38% were women, no significant demographic difference between the	A descriptive, exploratory cohort design with a mixed method approach. The patients answered a questionnaire (n=115) and participated in an interview (n=15) six months after the ICU-stay. Data analysis	84% had an ICU diary covering the entire time in the ICU and 90% read the whole diary. The majority felt that the written content met with their expectations. The patients explained that detailed information	A single non experimental study – Level 4	Patients with longer LOS can have different experiences and be more prone to hallucinations or delusions which can affect answers to	Yes – gave good information to include in diaries, supported the benefit of ICU diaries

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
		diary group and non-diary group though the diary group had a slightly longer LOS and ventilator days.	was carried out in three stages; the questionnaire was analyzed by descriptive statistics and categorized by content (four open-ended questions) and the interviews were analyzed by manifest content analysis.	about daily activities and medical facts had to be included to understand and give a sense of coherence of what had happened. The content in the ICU-diary had to be chronological to follow the process in which photos were an important part. 91% of the patient stated that they could follow changes		the surveys/interviews. Questionnaire was not pilot tested before being used which questions validity. The interview might induce a bias as they were interviewed in the hospital and may recall	

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
				in their condition and felt it was important to have photos. The patients re-read the ICU-diary during the recovery which helped them to fill in the memory gaps and used it as a tool for communication.		different experiences and memories than the other interviews.	
Blair, K. T. A., Eccleston, S. D., Binder, H. M., & McCarthy, M. S. (2017). Improving	To investigate how the use of an ICU diary in	Patients' family members in an ICU, 36 staff members	Diary was provided to the patient's identified as being at risk,	Team work improved, communication between patient and	Evidenced Based project – Level 7	This was an evidenced based project	Yes – supports the fact that it is a tool to help

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
the patient experience by implementing an ICU diary for those at risk of post-intensive care syndrome. *Journal of Patient Experience*, *4*(1), 4-9. DOI: 10.1177/2374373517692927	patients who scored positive for the CAM-ICU or who have been intubated longer than 24 hours compare with the nonuse of an ICU diary, of the same population, impact patient, family and staff engagement and satisfaction	(RN/MD) of the same unit	RN made the first entry explaining the purpose for ICU admission and diary use. RN champion rounded every day assessing the completeness of the entries and encouraging the use; surveys/interviews were conducted with staff on the barriers/benefits/improvement	staff improved. 50 diaries were initiated but a small percentage offered thoughts/feelings		and is low on the pyramid	mitigate PICS and PICS-F as well as a tool to enhance communication.

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
	throughout the admission episode.		s needed of the project,				
Ewens, B., Chapman, R., Tulloch, A., & Hendricks, J. M. (2014). ICU survivors' utilization of diaries post discharge: A qualitative descriptive study. *Australian Critical Care*, *27*(1), 28-35. DOI: 10.1016/j.aucc.2013.07.001	To explore patients and family members perceptions and utilization of diaries following discharge from hospital after a critical illness.	18 adult patients who were admitted to an ICU and ventilated over 24 hours.	Diaries were given to eligible patients and their families. Education sessions were provided to the staff on the appropriate entries to make, families were encouraged to write in the diaries as well. When the patient was	Many of the patients used and often read their diaries but few made entries after discharge. Reading the diaries elicited mixed feelings but most of the patients felt it had a positive initiative in their recovery. Diaries filled in the memory gaps and make	Single center, qualitative descriptive study - Level 6	Single center, low response rate in an already small number of participants	Yes, as the study demonstrated a positive experience for the patient and the family. Although there was no statistical significance given, there is clinical significance

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
			getting ready for transfer the diary would be reviewed the with patient and questions answered and the patient was encouraged to take it with them and continue their journaling. Follow up was conducted every 2-3 days after discharge from the ICU until discharge to home then a survey was sent to the patients at 3, 6,	sense of the experience and reinforce the human connection when immersed in a technical environment.			

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
			and 12 months after hospital discharge. Data collection and analysis was done using a descriptive, qualitative framework.				
Fukuda, T., Inoue, T., Kinoshita, Y., & Yukawa, T. (2015). Effectiveness of ICU diaries: Improving "distorted memories" encountered during ICU admission. *Open Journal of Nursing, 5*, 313-324. DOI: 10.4236/ojn.2015.54034	To assess improving distorted memories by providing information during ICU admission to patients to relieve the acute stress symptoms	The control group had 23 participants 12 of which were male; the median age was 76 (45-89), the ICU length of stay was 3-19 days and the main reason for admission was cardiovascular in	Non randomized controlled trial was conducted. The control group was provided normal care in the ICU and the intervention group was provided an	The ICU diary group had statistically significant reduction in HADS-anxiety, HADS – depression and ASDS when compared to the control group.	Non randomized control trial – Level 3	Study sample was small, single site	Yes = supported the concept of improving memories and alleviating stress. Tool for patients to reflect over and over when

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
	after ICU discharge.	nature. The intervention group had 17 participants, 14 of which were males with a median age of 72 (54-85), length of stay ranged from 3-17 days and the main reasons were ties between cardiovascular and gastrointestinal in origin.	ICU diary and normal care in the ICU. Patients were visited 1 week after discharge from the ICU for interview and scoring on the ICU memory tool, Hospital Anxiety and Depression Scale (HADS) and Acute Stress Disorder Scale (ASDS). The participants were scored on the HADS and ASDS 10 days	Interviews also showed that the diary was helpful in putting the pieces together, memories could not be restored through the diary alone and needed help from others, perception that nurses provided intensive care when the individual was experiencing difficulties. Nurses			delusional memories or nightmares happen.

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
			after ICU discharge and prior to discharge from the hospital. The interview at one week also included a survey on how the participants in the intervention group felt about the diary.	comments not only informed patient about reality but also encouraged them.			
Garrouste-Orgeas, M., Perier, A., Mouricou, P., Gregoire, C., Bruel, C., Brochon, S., … & Misset, B. (2014). Writing in and	To investigate the families' experiences with reading and writing in patient	Family member mean age was 54.6 +/- 13.0, patient mean age was 71+/- 11 yrs. Patients that were included	Qualitative study was conducted involving 32 semi-structured in-depth interviews of	Communicative, emotional, and humanizing experiences emerged from the data.	Qualitative study – Level 6	General applicability of the findings may be limited secondary	Yes – this study demonstrated the positive effects of the diaries

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
reading ICU diaries: Qualitative study of families' experience in the ICU. *PLoS ONE, 9*(10), e110146. DOI:10.1371/journal.pone.0110146	ICU diaries that were kept by both the family and the staff.	were primarily there for medical complication, 8 had unscheduled surgery and 2 had scheduled surgery. Shock was the main reason for admission with respiratory distress second and 10 were admitted because of COPD/COMA/ARF/monitoring. 73% of the patients were male and 84 % of the family members were female. 60% of	relatives of 26 patient who met ICU-diary criteria (vent>48hr). Grounded theory was used to conceptualize the interview data via a three step coding process (open, axial and selective coding)	Families used the diaries to access, understand and assimilate the medical information written in the diaries by staff members, and then to share this information with other family members. The diaries enabled family members to maintain a connection with the patient by		to the participation of both family members and all ICU staff members in the diaries, the instructions given to diary writers and inclusion of medical information in the diaries. The high educationa	on family members. The study showed that diaries serve as a powerful tool to deliver holistic patient- and family-centered care despite the dehumanizing environment.

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
		the family members had 3 or more years of higher education, 34% were spouse and 31% were grown children.		documenting their presence and expressing their love and affection. Families confided in the diaries to maintain hope. The family members felt the diaries humanized the medical staff and patient.		l level of the sample may limit the general applicability. Family dynamics were not considered.	
Huynh, T. G., Covalesky, M., Sinclair, S., Gunter, H., Norton, T., Chen, A., & Yi, C. (2017). Measuring outcomes of an intensive care	1. To improve family satisfaction with patient care within the ICU	107 families of patients who were in the ICU>48 hrs., had procedures that required sedation,	Family Satisfaction with Care in the intensive care unit (FS-ICU) was distributed to	93 baseline surveys were collected prior to implementation of the ICU diary project.	Evidenced Based Project – Level 7	Not all patients who met criteria received diaries, timing of	Yes – diaries have shown to have a positive influence on patient

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unit family diary program. *AACN Advanced Critical Care, 28*(2), 179-190. DOI:10.4037/aacnacc2017862	2. To increase the number of referrals made to the post-ICU recovery clinic.	intubated/sedated or scored positive on the Confusion Assessment Method in the ICU (CAM-ICU), had a Richmond Agitation-Sedation scale (RASS) -2 or greater, or had the potential for memory lapses from MICU and CVICU	family members at the time of discharge from the ICU pre and post diary implementation	No significant increase in satisfaction was noted however a significant increase (43%) in referrals to the Post ICU recovery clinic was noted.		the project rollout was initiated just prior to the opening of a new inpatient tower which may have skewed the results as staff were overwhelmed and did not focus on project. Revisions were	families. Nurses are in a unique position to identify patients at risk of PICS. The ICU diary can be used a s a communication tool during an ICU stay and to debrief their patients about their ICU experiences.

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						made to survey may not have been validated.	
Johansson, M., Hanson, E., Runeson, I., & Wahlin, I. (2015). Family members' experiences of keeping a diary during a sick relative's stay in the intensive care unit: A hermeneutic interview study. *Intensive and Critical Care Nursing, 31*, 241-249. DOI: 10.1016/j.iccn.2014.11.002	The aim of the study was to explore family members' experiences with keeping a diary during a sick relative's stay in an ICU.	11 patients (7 female/4 male) ranging in age from 19-63 in a general ICU. Inclusion criteria for family members were: blood relative or close friend who had an ICU diary, willing to share their experiences, 18 years or older.	A qualitative method with a hermeneutic approach that was inspired by Gadamer was used. Purposeful sampling was used to gain as broad an understanding as possible. Interviews were conducted 6-10	Meta-theme emerged – it felt like contact. The diary served an important purpose – to convey the attempt to sustain a connection with the patient who often was unconscious. The diary became a link to the patient,	Level 6 – single qualitative study	Role confusion as the interviewer was new to qualitative research and more familiar to her role as a nurse, small sample, single site	Yes – this study supports the concept that the diary was instrumental in meeting the needs of many family members, served as an important and useful source of information

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			weeks after the patient was discharged from the ICU. Interviews were conductive as a participative conversation between the interviewer and the interviewee and each participant spoke about their experience with the diary. Interviews were	it sustained and strengthened their relationship with the patients, the diary helped the participants express their experiences whilst the patients were in the icu. Meta-theme had two themes (feeling of togetherness and made communication possible) and 6 sub-themes (we were there,			for both patients and family members, involving family members in diary writing is therapeutic.

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			transcribed verbatim.	we had a task, they cared, all is well at home, how it felt, so that you can really understand)			
Kredentser, M. S., Blouw, M., Marten, N., Sareen, J., Bienvenu, O. J., Ryu, J., … & Olafson, K. (2018). Preventing posttraumatic stress in icu survivors: A single-center pilot randomized controlled trial of icu diaries and psychoeducation. Critical Care Medicine, 46(12),	The goal was to assess the feasibility and acceptability of ICU diaries in a Canadian context and to provide foundational information comparing ICU diaries	58 (35 male/23 female) critically ill adult patients (mean age of 55) with a median ICU stay of 12 days, median hospital stay of 24 days, median ventilator duration of 8 days and coma duration of 4 days. 10 had	Patients were randomized 1:1 in blocks of 20, using computer-generated randomization to one of four arms.	They were able to enroll 1.9 patients per month in a 10 bed ICU which was in line with other ICU trials. The study completion rate was above the 60% goal despite high ICU mortality. More than	Four arm pilot randomized controlled trail – level 2	Small sample size and use of self-report symptom measures. Many icu patients did not meet eligibility criteria which may limit	Yes – diary intervention supports the value of diaries especially in reducing anxiety and depression at 90 days post discharge. This study supports the feasibility

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1914-1922. DOI: 10.1097/CCM.0000000000003367	with psychoeducation to inform a larger, multicenter trial.	previous ICU admissions.		three entries per day were noted in the diary groups. Delivery of the diary and psychoeducation interventions took longer than allotted 30 days post ICU discharge. All ICU survivors randomized to diary intervention completed the study suggesting increased engagement		generalizability of intervention.	of implementation.

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				and perceived high value.			
Levine, S. A., Reilly, K. M., Nedder, M. M., & Avery, K. R. (2018). The Patient's Perspective of the Intensive Care Unit Diary in the Cardiac Intensive Care Unit. *Critical Care Nurse*, *38*(4), 28–36. DOI:10.4037/ccn2018970	To describe implementation of an intensive care unit diary in the cardiac intensive care unit and to describe the patient's perspective of the diary.	English speaking, adult CCU patients who were intubated for a minimum of 24 hours and who were without any preexisting dementia or history of posttraumatic stress disorder or PICS to participate in the study. Almost two-thirds of the participating patients were men (62%). The	Consent for participation in the study was given by the patient health care proxy or a family member. The study consisted of 3 phases: writing in the diary about the patient's events in the cardiac intensive care unit, a follow-up visit with the patient within 1 week	Of 26 patients, 13 completed all phases of the study. Four themes were identified from the transcripts of the patients' responses: (1) The diary allowed patients to correlate memories to actual events, (2) it enabled patients to read about their families' experiences	Qualitative/descriptive study – Level 6	The study was completed in a single unit within a single institution. The themes identified may not be reflective of cultural differences. Small number -	Yes - The intensive care unit diary can help patients gain clarity of their time in the cardiac intensive care unit.

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		age of the participants ranged from 43 years to 82 years; male participants were generally older. The mean hospital length of stay was 19.9 days; the mean CCU length of stay was 12.1 days. The number of days intubated ranged from 3 to 27 (mean, 7.6 days).	of cardiac intensive care unit transfer, and a follow-up telephone call 2 months after hospital discharge.	during their critical illness, (3) recovery was an emotional process that affected the patient's readiness to read the diary, and (4) patients expressed a desire for more entries by caregivers.		A total of 26 patients enrolled in the study; however, only 13 completed all 3 phases of the study. Many staff nurses described difficulty finding time to complete diary entries in the	

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						context of competing clinical obligations. This time limitation presented a barrier to the completion of comprehensive entries in each diary. Some families did not feel comfortab	

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						le writing in the diary because they did not know what to include. The researcher conducting the telephone interviews was part of the research team, which may have influenced	

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						participant responses.	
Locke, M., Eccleston, S., Ryan, C. N., Byrnes, T. J., Mount, C., & McCarthy, M. S. (2016) Developing a Diary program to minimize patient and family post-intensive care syndrome. *AACN Advanced Critical Care, 27*(2), 202-220. DOI:10.4037/aacnacc2016467	To the evaluate the process and outcomes of the project in terms of feasibility, sustainability and staff/patient satisfaction within the facility.	Nurses and patients in a 20 bed mixed medical-surgical ICU. Patients were included if they were intubated for longer than 24 hours, and/or rated positive for delirium on the Confusion Assessment Method for the ICU (CAM-ICU) tool.	Patient were chosen, nurses contributed the initial diary entry to tell why the patient was admitted to the ICU. Subsequent entries were written throughout the stay by primary nurse, physician team, and/or ancillary services. Participation was voluntary.	50 diaries with feedback were received from patient/family members and staff via surveys and informal interviews. Over 200 stakeholders were educated. Interviews suggested that the diaries provided an outlet for thoughts and emotions, showing	Single qualitative study – Level 6	Qualitative, non-randomized, no comparison group. Voluntary so unclear as to how many people completed the program.	Yes – supports the benefit of the diary that has been reported for decades by the European and Australian healthcare providers.

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			Diaries were sent with the patient to the stepdown unit and on discharge to home/rehab. The team maintained tracking tool.	genuine care and concern by staff. They also enhanced communication between healthcare team and patient-family unit.			
McIlroy, P. A., King, R. S., Garrouste-Orgeas, M., Tabah, A., & Ramanan, M. (2019). The effect of icu diaries on psychological outcomes and quality of life of survivors of critical illness and their relatives: A systematic review	The objective of this study was to evaluate the effect of ICU diaries on posttraumatic stress disorder symptoms	1208 patients who were admitted to an ICU for 48 hours and their family members, regardless of age, illness, severity or admission category.	Two authors independently searched the online databases PubMed, Embase, PsycINFO, and the Cochrane Central Register of Controlled	The search identified 1,790 articles and retained eight studies for inclusion in the analysis. Pooled results found no significant reduction in patients'	Level 1 – Systematic Review and Meta-Analysis	Quality of studies – overall were of moderate quality with substantial risk of bias. Many were	Yes – despite the lack of statistical significance in relation to the reduction of PTSD, this review supports the use of

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and meta-analysis. *Critical Care Medicine, 47*(2), 273-279. DOI:10.1097.CCM.0000000000003547	in ICU survivors and their relatives. Secondary objectives were to determine the effect on anxiety, depression, and health-related quality of life in patients and their relatives.		Trials. Search was supplemented by reviewing all references of relevant articles, consulting with leaders in the field and by searching clinical trials registries. Reasons for exclusion were recorded and disputes were resolved by discussion or review by a third author. A structured template was	posttraumatic stress disorder symptoms with ICU diaries (risk ratio, 0.75 [0.3–1.73]; p = 0.5; n = 3 studies); however, there was a significant improvement in patients' anxiety (risk ratio, 0.32 [0.12, 0.86]; p = 0.02; n = 2 studies) and depression (risk ratio, 0.39 [0.17–0.87]; p = 0.02;		observational and included small patient numbers. Although several studies reported significant findings, they were unable to pool some results due to differing reporting methods. There was a high risk of bias	diaries to improve anxiety, depression, and HRQoL.

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			used for the extraction of data form the included studies and was independently extracted by the two authors. Structured tools were used to assess the methodological quality of included studies. Two authors independently assessed the risk of bias, discrepancies were resolved	n = 2 studies) symptoms. Two studies reported significant improvement in posttraumatic stress disorder symptoms of relatives of ICU survivors; however, these results could not be pooled due to reporting differences. One study reported no significant improvement in either		and inaccurate conclusions. The length of follow-up ranged from hospital discharge to 36 months post discharge and all results were pooled together which is a cause of	

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			by blinded independent evaluation by a third author. Data was analyzed	anxiety (risk ratio, 0.94; 95% [0.66–1.33]; p = 0.72) or depression (risk ratio, 0.98; 95% [0.5–1.9]; p = 0.95) in relatives. There was a significant improvement in health-related quality of life of patients with a mean increase in the Short Form-36 general health score by 11.46		heterogeneity.	

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				(95% CI, 5.87–17.05; $p \leq 0.0001$; n = 2 studies). No studies addressed health-related quality of life of relatives.			
Nielsen, A. H. & Angel, S. (2016). Consolation or confrontation when interacting through an ICU diary – A phenomenological-hermeneutical study. *Intensive and Critical Care Nursing, 34*, 4-10. DOI: 10.1016/j.iccn.2016.06.002	Explore relatives' experience of interacting with other relative when writing a diary for the critically ill patient.	Seven relatives of 6 patients (4 male in /2 female; 50-79, with sepsis or MOF; 5/6 ventilated) a 6 bed ICU of a Danish regional hospital.	Qualitative interview data were analyzed using a phenomenological-hermeneutical approach building on the theory of Ricoeur.	Three themes evolved: 1) Authorship means the responsibility and power to determine how the story should be told, 2) relationships between relative determine	Qualitative study – Level 6	Data primarily consisted of female informants, possible differences related to gender could not be elaborated.	This article does not support the change I am proposing.

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				authorship and content of the diary narrative, 3) crating the story in the diary together influenced relationships between relatives.		Differences due to the relation to the patient could not be clarified as the sample yielded too little variation.	
Petersson, C. G., Ringdal, M., Apelqvist, G., & Bergbom, I. (2015). Diaries and memories following an ICU stay: a 2-month follow-up study. *British Association of*	To describe and compare patients' memories and PTSD in relation to having received and	Patients ≥18 years with a Length of Stay (LOS) of 3 days or more who had received a diary or not at a general nine-bed ICU	Patients received their diaries at ICU discharge. After 2 months patients answered the ICU Memory Tool, a	Of the 96 patients, 52(54%) received a diary, 44 did not. Patients with diaries had significantly	Single descriptive study – Level 6	Limitations of the present study are the small sample size and two groups	Yes - Diaries seem to be valuable in understanding what happened, giving a feeling of

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Critical Care Nurses, 23(6), 299-307. DOI: 10.1111/nicc.12162	read or not received a diary and patients' experiences of having received and read their diary, without having discussed the contents with ICU staff.		screening instrument for PTSD (PTSS-14) and a questionnaire including space for own comments about the diaries.	longer stay and more mechanical ventilation. Of these, 40 patients responded to PTSS-14 and had evaluated and read the diary and 34 patients served as controls. No significant differences were found in presence/absence of memories between these groups. In the diary-group patients with emotional		which are not completely comparable as they were not randomized to the intervention.	trust and for talking about their ICU-stay. As many patients described stressful memories, sessions should be offered with ICU staff.

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				memories had lower APACHE. Feelings of being anxious or frightened were more common in the diary-group. At 2 months, 12% scored above cut-off on the PTSS14 with no difference between groups. The diaries were helpful for understanding the ICU-stay.			

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Roberts, M. B., Glaspey, L. J., Mazzarelli, A., Jones, C. W., Kilgannon, H. J., Trzeciak, S., & Roberts, B. W. (2018). Early interventions for the prevention of posttraumatic stress symptoms in survivors of critical illness: A qualitative systematic review. *Critical Care Medicine, 46*(8), 1328-1333. DOI: 10.1097/CCM.0000000000003222	The objective was to collate the world's literature on interventions aimed at preventing posttraumatic stress disorder (PSDS) among survivors of critical illness.	Adult human subjects, treated in an icu setting, intervention arm aimed at reducing PSDS. Final inclusion articles numbered at 17 and covered 2023 subjects. Majority of studies were RCT and two used historical controls.	Authors performed a search of CENTRAL, MEDLINE, EMBASE, CINAHL, and clinical trials registry platforms, with no restriction to language using a comprehensive strategy.	All the studies had concern for bias as per the Cochrane tool for assessing risk of bias, none of the studies reported any adverse events due to the study intervention. There was heterogeneity in interventions tested. Two studies evaluated ICU Diaries which started on day 3 or 4 and were	Level 5 – Systematic review of qualitative studies	Small number of interventional trials have reported data on interventions to reduce PTDS and those that did were small trials, and all had concern for bias according to Cochrane Collaboration tool.	While this study had a lot of limitations and a small number of studies specifically directed to diaries, the information was useful.

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				maintained by family members and hospital staff and were given to the patients to read after discharge. Both studies found the diaries reduced PTSD symptoms on at least one measure		There were varying clinical scenarios, interventions studied, high degree of heterogeneity.	
Strandberg, S., Vesterlund, L., & Engström, Å. (2018). The contents of a patient diary and its significance for persons cared for in	The objective of this study was to describe the contents of a patient	9 persons (5 women/4 men between 30-78 [M=55]) previously treated in an icu who were given	An empirical study with a qualitative design. 8 telephone interviews and one face-to-	One main theme of gaining understanding emerged. There were four categories	Level 6-single qualitative study	Most interviews were done over the phone, purposeful sample	Yes – helps patients to understand what happened to them, this study

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an ICU: A qualitative study. *Intensive & Critical Care Nursing, 45*, 31-36. DOI:10.1016/j.iccn.2017.12.004	diary and its significance for persons cared for in an ICU.	a diary. Patients were Swedish adults (over 18). Length of stay in the ICU varied from 11-83 days with a mean of 38 days and the reason for icu admission included respiratory failure, sepsis and trauma.	face interview were conducted. Data were analyzed using qualitative content analysis as described by Graneheim and Lundman	that made up the main theme and included: the diary is written for me, to create memories from the time of care, who writes in the diary, to be able to return to the diary.		and people who may have not wanted to remember their stay in the icu may inflict a bias. Lack of evidence for the effect of this intervention.	provides guidelines for what and when a diary should be written. Connects staff to patients and families.
Teece, A. & Baker, J. (2017). Thematic analysis: How do patient diaries affect	This review aims to use a thematic analysis to	The literature was predominantly qualitative in	A search was conducted using MEDLINE,	Three themes arose: Reclaiming ownership of	Level 5 – Systematic review of	Scarcity of studies eligible for	Yes – high level of evidence, supports the

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survivors' psychological recovery? *Intensive and Critical Care Nursing, 41*, 50-56. DOI:10.1016/j.iccn.2017.03.002	explore and synthesis evidence of the actual or potential reported effects of diaries on the psychological rehabilitation and recover of discharge critical care patients.	nature. 10 primary studies were selected – four quantitative and 6 were qualitative	Embase, CINAHL, and the Cochrane Library using the key words: critical care ICU, intensive care, patient diary, follow up, psychological, emotional, rehabilitation, post-traumatic stress disorder, and memory loss. The articles included were from 2006-2016 and were focused on adult patients	lost time, emphasizing personhood, fear and frustration. Diary intervention was shown to have a largely positive impact on survivors' psychological recovery however caution should be exercised as recipients may find contents painful and emotional. Diaries should be embedded	descriptive studies.	inclusion and small cohort sizes. Majority of studies were qualitative.	concept that patients benefit from their use and recover is aided by the use.

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			who survived a critical care stay. The quality of the studies was appraised using the Scottish Intercollegiate Guidelines Network (SIGN) grading system. Data abstraction was via the deductive generation of codes relative to the effect of diaries on	within a robust critical care follow up plan.			

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			psychological recovery. The codes were then grouped into common themes.				
Ullman, A. J., Aitken, L. M., Rattray, J., Kenardy, J., Le Brocque, R., MacGillivray, S., & Hull, A. M. (2015). Intensive care diaries to promote recovery for patients and families after critical illness: A cochrane systematic review. *International Journal of Nursing Studies, 52*, 1243-1253.	To assess the effect of an intensive care unit (ICU) diary, when compared to no use of an ICU diary, on patient and their caregivers or families during the patient's recovery	Included were all randomized controlled trials (RCTs) and controlled clinical trials (CCTs) that evaluated the effectiveness of patient diaries for their impact on recovery after admission to ICU. Excluded were non-randomized	A search of the Cochrane Central Register of Controlled Trials (CENTRAL2014, Issue 1), Ovid MEDLINE (1950 to January 2014), Ovid EMBASE (1980 to January 2014),	We identified three eligible studies; two describing ICU patients (N = 358), and one describing relatives of ICU patients (N = 30). No study adequately reported on risk of PTSD as described using a clinical	Systematic review – Level 1	None of the included studies adequately described the multi-dimensionality of the patient diary intervention, in terms of its characteristics as a	Yes - Though there is minimal evidence from RCTs of the benefits or harms of patient diaries for patients and their caregivers or family members, a

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DOI:10.1016/j.ijnurstu.2015.03.020	from an admission to the ICU.	studies such as cohort studies because of the increased potential for bias. Also excluded were cross-over trials as this methodology is not suitable for evaluating an intervention that must be given at a specific time point.	PsycINFO (1950 to January 2014), Published International Literature on Traumatic Stress (PILOTS) database (1971 to January 2014); EBSCOhost CINAHL (1982 to January 2014) and Web of Science Conference Proceedings Citation Index – Science and Social Science	interview, family or caregiver anxiety or depression, health-related quality of life or costs. Within a single study there was no clear evidence of a difference in risk for developing anxiety (RR 0.29, 95% CI 0.07–1.19) or depression (RR 0.38, 95% CI 0.12–1.19) in participants who received		complex intervention. The manner and time in which the patient diary was provided, the skills and qualification of the clinician providing the patient diary and the co-interventions that these entail have not	small study described the potential to reduce post-traumatic stress symptomatology in family members.

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			and Humanities (1990 to January 2014) was performed without restrictions on the basis of date, language or publication status. Two review authors (AU and LA) independently assessed titles and abstracts of retrieved studies for relevance. After initial assessment	ICU diaries, in comparison to those that did not receive a patient diary. Within a single study there was no evidence of difference in median post-traumatic stress symptomatology scores (diaries 24, SD 11.6; no diary 24, SD 11.6) and delusional ICU memory recall (RR 1.04, 95% CI 0.84–1.28) between the		been adequately explored. These elements may have an important contribution to the effectiveness of a patient diary to improve, or worsen, patient and family member recovery. While publicatio	

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
			they retrieved full versions of all potentially eligible studies. The same two review authors then independently checked the full papers for eligibility. Discrepancies between review authors were resolved through mutual discussion and, where required, consulted a third independent	patients recovering from ICU admission who received patient diaries, and those who did not. One study reported reduced post-traumatic stress symptomatology in family members of patients recovering from admission to ICU who received patient diaries (median 19;		n bias, indirectness and inconsistency were not established, the methodologic quality and precision of the effect estimates was low to very low.	

Article Title, Author, etc. (Current APA Format)	**Study Purpose**	**Sample (Characteristics of the Sample: Demographics, etc.)**	**Methods**	**Study Results**	**Level of Evidence (Use Melnyk Framework)**	**Study Limitations**	**Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.**
			review author (RB). Data was extracted and analyzed. A meta-analysis was not conducted due to the small number of studies eligible for inclusion in the review. There were no unit of analysis issues as the patient and caregivers were the unit of analysis for all included studies.	range 14–28), in comparison to no diary (median 28; range 14–38).			

Appendix B

Permission Letter

On January 12, 2019 Kimberly Jordon from the University of Iowa Hospitals and Clinics wrote to Denise Goodberlet via Liberty University email. Below is a true and exact copy of the email received on the Liberty University account:

You have permission, as requested today, to review and/or reproduce *The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care.* Click the link below to open.

The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care

Copyright is retained by University of Iowa Hospitals and Clinics. **Permission is not granted for placing on the internet.**

Citation: Iowa Model Collaborative. (2017). Iowa model of evidence-based practice: Revisions and validation. *Worldviews on Evidence-Based Nursing, 14(3), 175-182. doi:10.1111/wvn.12223*

In written material, please add the following statement:
Used/reprinted with permission from the University of Iowa Hospitals and Clinics, copyright 2015. For permission to use or reproduce, please contact the University of Iowa Hospitals and Clinics at 319-384-9098.

Please contact UIHCNursingResearchandEBP@uiowa.edu or 319-384-9098 with questions.

Appendix C

CITI Training Certificates

Course Completion for Denise Goodberlet

Congratulations on your recent course completion!

Name:	**Denise Goodberlet** (ID: 7794049)
Institution:	**Liberty University** (ID: 2446)
Course:	**Biomedical & Health Science Researchers**
Stage:	**1 - Basic Course**
Completion Date:	**27 Jan 2019**
Expiration Date:	**26 Jan 2022**
Completion Record ID:	**30185393**

To share the **Completion Report** for this course, use the following link:

citiprogram.org/verify/?k61e6b6ee-0112-4308-9d5f-1f19ce81e0bf-30185393

Note that this link will share the full two-part report, which includes all quiz scores.

To share the **Completion Certificate** for this course, use the following link:

citiprogram.org/verify/?w4fb6b04f-430c-4395-b28a-85882e952113-30185393

Note that this link will share only the certificate, which does not include quiz scores.

These links are permanent and may be used to access or share your Completion Report and Completion Certificate at any time. It is not necessary to log in to the CITI Program site to view these links.

We suggest you retain this email for your records.

Course Completion for Denise Goodberlet

Congratulations on your recent course completion!

Name:	**Denise Goodberlet** (ID: 7794049)
Institution:	**Liberty University** (ID: 2446)
Course:	**Biomedical Responsible Conduct of Research**
Stage:	**1 - RCR**
Completion Date:	**27 Jan 2019**
Expiration Date:	**26 Jan 2023**
Completion Record ID:	**30185394**

To share the **Completion Report** for this course, use the following link:

citiprogram.org/verify/?k8b53fa24-543e-4b5c-a7ea-0011f9dbc689-30185394

Note that this link will share the full two-part report, which includes all quiz scores.

To share the **Completion Certificate** for this course, use the following link:

citiprogram.org/verify/?w3d337079-eac5-4947-b20a-3aa3dad975d2-30185394

Note that this link will share only the certificate, which does not include quiz scores.

These links are permanent and may be used to access or share your Completion Report and Completion Certificate at any time. It is not necessary to log in to the CITI Program site to view these links.

We suggest you retain this email for your records.

Appendix D

CONSENT FORM

The Use of Patient Diaries in the CVICU to prevent Post-intensive Care Syndrome and Improve Patient and Family Satisfaction with Care

Denise M. Goodberlet

Liberty University

School of Nursing

You are invited to be part of an evidence based scholarly project using patient diaries in the intensive care unit (ICU) as a means to decrease the incidence of post intensive care syndrome, abbreviated PICS, (characterized by anxiety, confusion, and weakness) and increase family satisfaction with care received in the ICU. You and your family were selected as possible participants because you have been in the intensive care unit for over 48 hours, have been on a mechanical ventilator, have loved ones visiting your, speak and understand English, are over the age of 18 and may have scored positive on the ICU delirium screen. Please read this form and ask any questions you may have before agreeing to be in the study.

Denise Goodberlet, a doctoral candidate in the School of Nursing at Liberty University, is conducting this project.

Background Information: The purpose of this project is to help patients and family members come to terms with the critical care experience. Keeping an ICU patient diary has been shown to improve communication, decrease anxiety, fill memory gaps, maintain cognition, humanize the experience and improve overall satisfaction with the care that was provided.

Procedures: If you agree to be in this project, I would ask you to do the following things:

1. Write in the journal provided about the day to day activities and world events while your loved one is in the ICU
2. Complete a 24 item survey on family satisfaction with care in the ICU.

Risks: The risks involved in this study are minimal, which means they are equal to the risks you would encounter in everyday life. Risks and discomforts you might encounter may include

uncomfortable memories that resurface when reading the entries into the diary of the ICU stay and remembering your loved one/family member in such a critical condition.

Benefits: The direct benefits participants should expect to receive from taking part in this study are minimizing the occurrence of PICS and improved family satisfaction with care in the ICU.

Compensation: Participants will not be compensated for participating in this study.

Confidentiality: The records of this study will be kept private. In any report I might publish, I will not include any information that will make it possible to identify a subject. Patients will be assigned a pseudonym that will be kept secured in a separate area from the records. Research records will be stored securely, and only the researcher will have access to the records. Surveys will be collected on a daily basis and none of the doctors or nurses will have access to the answers on your surveys so you may be as candid as you like. I may share the data I collect from you for use in future projects, research studies or with other researchers; if I share the data that I collect about you, I will remove any information that could identify you, if applicable, before I share the data.

Conflicts of Interest Disclosure: The coordinator serves as a provider in the Cardiothoracic Surgery Service which covers many, but not all, of the patients in the CVICU. To limit potential conflicts, the coordinator will not care for patients in the CVICU who have been there for more than 48 hours. This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study. No action will be taken against an individual based on his or her decision to participate in this study.

Voluntary Nature of the Project: Participation in this project is voluntary. Your decision whether or not to participate will not affect your current or future relations with Liberty University or Catholic Health. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

How to Withdraw from the Project: If you choose to withdraw from the project, please contact the researcher at the email address/phone number included in the next paragraph. Should you choose to withdraw, data collected from you will be destroyed immediately and will not be included in the project results.

Contacts and Questions: The coordinator of this project is Denise Goodberlet. You may ask any questions you have now. If you have questions later, **you are encouraged** to contact her at 1-585-409-3072 or at dgoodberlet@liberty.edu. You may also contact the researcher's faculty chair, Dr. Lynne' Sanders at lsanders@liberty.edu.

If you have any questions or concerns regarding this project and would like to talk to someone other than the coordinator or faculty chair, **you are encouraged** to contact the Institutional Review Board, 1971 University Blvd., Green Hall Ste. 2845, Lynchburg, VA 24515 or email at irb@liberty.edu.

Please notify the coordinator if you would like a copy of this information for your records.

Statement of Consent: I have read and understood the above information. I have asked questions and have received answers. I consent to participate in the project.

☐ The researcher has my permission to photograph me as part of my participation in this study.

_____

Signature of Participant Date

_____

Signature of Investigator Date

Appendix E

Family Satisfaction with Care in the Intensive Care Unit Survey

FAMILY SATISFACTION WITH ICU

Family Satisfaction with Care in the Intensive Care Unit©: FS-ICU 24R
How are we doing?

We would like to hear your opinions about your family member's recent admission to the Intensive Care Unit (ICU)

Your family member was a patient in this ICU. The questions that follow ask **YOU** about your family member's **most recent ICU admission**. We understand that there were probably many doctors and nurses and other staff involved in caring for your family member. We know that there may be exceptions but we are interested in **your overall assessment** of the quality of care we delivered. We understand that this was probably a very difficult time for you and your family members. We would appreciate you taking the time to provide us with your opinion. Please take a moment to tell us what we did well and what we can do to make our ICU better. **Please be assured that all responses are confidential.** The Doctors and Nurses who looked after your family member will not be able to identify your responses.

PART 1: SATISFACTION WITH CARE

Please check one box that best reflects your views. If the question does not apply to your family member's stay then check the 'Not Applicable' box (N/A).

HOW DID WE TREAT YOUR FAMILY MEMBER (THE PATIENT)? HOW SATISFIED ARE YOU WITH…

	Poor	Fair	Good	Very Good	Excellent	N/A
1. **Concern and Caring by ICU Staff?** The courtesy, respect and compassion **your family member (the patient)** was given.	☐1	☐2	☐3	☐4	☐5	☐
2. **Symptom Management?** How well the ICU staff assessed and treated your family member's symptoms.						
a. How well the ICU staff assessed and treated your family member's pain.	☐1	☐2	☐3	☐4	☐5	☐
b. How well the ICU staff assessed and treated your family member's breathlessness.	☐1	☐2	☐3	☐4	☐5	☐
c. How well the ICU staff assessed and treated your family member's agitation.	☐1	☐2	☐3	☐4	☐5	☐

Appendix F

Permission to Use FS-ICU-24

Thank you for your interest in the **Family Satisfaction in the Intensive Care Unit (FS-ICU) questionnaire**. The questionnaire was originally developed in 2003 using a rigorous methodology as outlined in our original publication in the Journal of Critical Care, and then refined and shortened in 2006. Recently, we published a review article that summarizes the psychometric properties and clinical utility of FS-ICU and the other related tools that measure family satisfaction.
For a link to the abstract, click here.
For a copy of the summary table produced in this article, click here.

FS-ICU is now available in a number of formats and languages (click here for a complete list).

1. Original, Long Form: FS-ICU 34
This 34-item questionnaire comprehensively captures all the domains relevant to the needs of families with loved ones cared for in a critical care environment.

View the original questionnaire here
Read a paper about using the data to improve care in the ICU here

2. Revised, Shortened Form: FS-ICU 24
The 24-question version was developed in 2006 in collaboration with researchers at Harborview Medical Center (Seattle, Washington) and was validated for use in the United States.

View the 24-item questionnaire here.
Read how and why we shortened the questionnaire here.
Review the entire publication here.

These questionnaires available for you to use free of charge as long as you acknowledge their source and you do not modify without permission. Both versions can be used for local quality improvement processes but if you are using them in a research project, the scaled FS-ICU 24 would have greater validity.

Database analysis and Benchmarking
We can also provide you with a database to which you can enter the data (right-click and "Save As": FS-ICU 24, FS-ICU 34) and SPSS program codes to facilitate your analysis (right-click and "Save As": here). For variable name key click here. For instructions on how to code and score the questionnaire, please click here.

Interested in a benchmarked report that compares your site's performance to others in our database?

Click here to learn more.

* Please note that for repeated reporting on your site's performance there will be a charge.

We hope you find the questionnaire useful in defining and improving care provided to critically ill patients and their families. If you have any comments, questions, or suggestions for improvements, please contact us.

Sincerely,

Daren Heyland
dkh2@queensu.ca

Shawna Froese
froeses@kgh.kari.net

Retrieved from: www.thecarenet.ca/resource-center/family-satisfaction-survey

Email conformation of permission to use:

From: Daren Heyland <dkh2@queensu.ca>

Date: 2/22/2019, 3:50 AM

To: Goodberlet, Denise

Hi,

Yes, you have my permission.

You can find current versions of the tool on our new website, www.fsicu.com

Please just cite the website,

Thanks

Daren

Appendix G

IRB Approval Documentation

LIBERTY UNIVERSITY.
INSTITUTIONAL REVIEW BOARD

May 17, 2019

Denise M. Goodberlet
IRB Application 3811: The Use of Patient Care Diaries in the CVICU to Prevent Post-Intensive Care Syndrome and Improve Family Satisfaction with Care

Dear Denise M. Goodberlet,

The Liberty University Institutional Review Board has reviewed your application in accordance with the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) regulations and finds your study does not classify as human subjects research. This means you may begin your research with the data safeguarding methods mentioned in your IRB application.

Your study does not classify as human subjects research because evidence-based practice projects are considered quality improvement activities, which are not considered "research" according to 45 CFR 46.102(d).

Please note that this decision only applies to your current research application, and any changes to your protocol must be reported to the Liberty IRB for verification of continued non-human subjects research status. You may report these changes by submitting a new application to the IRB and referencing the above IRB Application number.

If you have any questions about this determination or need assistance in identifying whether possible changes to your protocol would change your application's status, please email us at irb@liberty.edu.

Sincerely,

[redacted]

G. Michele Baker, MA, CIP
Administrative Chair of Institutional Research
Research Ethics Office

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Liberty University | Training Champions for Christ since 1971

Catholic Health

Legal Services Department
Institutional Review Board
Ph: (716) 821-4477
Fax: (716) 821-4465

June 21, 2019

Denise Goodberlet
c/o Cardiothoracic Surgery/Critical Care
Mercy Hospital of Buffalo
585 Abbott Road
Buffalo, New York 14220

RE: CHS/IRB/1911- The Use of Patient Care Diaries in the CVICU to Prevent Post-Intensive Care Syndrome and Improve Family Satisfaction with Care

Ms. Goodberlet,

Thank you for submitting the necessary documentation for review of your proposed research study referenced above. The following documents were submitted and reviewed:

CHS IRB Application form
Study Protocol
Data Collection Sheet/ Survey Sheets
Belmont Report Signature Statements from Principal Investigator(s)
Letter Requesting Review
C.V. for Principal Investigator(s)
Recruitment Information

Following an expedited review on June 21st, 2019, you have approval to proceed with the above mentioned study for one year at Catholic Health. The annual follow-up/expiration date for your study is June 20th, 2020. Please find enclosed a stamped approved copy of the protocol, consent and data collection forms that shall be used for your research, if applicable.

The Board expects a progress report from the principal investigator every twelve months or at the end of this study, whichever comes first. There are to be no changes made in the procedures being followed. In the event of any adverse events or mishaps, these must be reported to the IRB within 5 business days. The IRB members may request you to appear at the next scheduled IRB meeting to discuss the incidence. Please take note that you must submit a follow-up report and request for continuation of the study before the expiration date noted above or your study will be terminated.