

Study Title: “Effect of personal shadow boxes in ICU rooms on patient and family satisfaction”

A. Study Purpose and Rationale

The term “ICU” generally invokes images of very ill patients connected to a multitude of life-supporting machines, IV medications, and monitoring devices. Advancements in science and technology have enabled physicians and nurses to better care for patients with increasing acuity, but at the potential expense of *how* care is provided. Such a sterile and technological environment may promote impersonal interaction with laboratory values and monitors instead of humanistic interaction with the patient and/or family [1]. Many ICU patients are also unable to communicate due to their critical illness or high level of sedation, which further depersonalizes the patient and threatens therapeutic caring and empathy. Together, the ICU environment and lack of direct patient communication facilitate the creation of physical and emotional barriers between the ICU team and the patient and/or family, which can negatively impact patients’ and family members’ sense of feeling valued, acknowledged, and cared about. These psychological detriments may further manifest as increased pain, discomfort, and anxiety [2]

The importance of the ICU environment is highlighted by studies that suggest factors such as noise and light levels, color schemes, presence of artwork and photographs, and access to window views can impact patient comfort, recovery, and satisfaction [1]. Even the quality of the ICU waiting area plays a significant role in family satisfaction [3]. We were particularly interested in the use of personal photographs because they have the potential to not only mitigate the coldness and unfamiliarity of the ICU room, but also emphasize the patient as a person to improve communication and care. A few studies have examined nurse responses to patient photographs in the ICU setting. Overall responses were positive, and most nurses felt that photos helped them relate to the patient as an individual though had no impact on the care they provided [2, 4-5]. However, no studies to date have examined the effect of photographs on patient and family experience in the ICU. We hypothesize that the placement of personal shadow boxes containing meaningful photographs, artwork, and memorabilia, in patient rooms will not only improve the ICU environment, but also increase patient and family satisfaction with care through improved relationships and communication with the ICU team.

B. Study Design and Statistical Analysis

We will use a prospective pre-post study design to evaluate the effect of personal shadow boxes on patient and family satisfaction. We calculated our sample size based on available data for the validated, 24-item Family Satisfaction in the ICU (FS-ICU) questionnaire. Based on prior studies we assumed that family satisfaction with overall ICU experience would be rated 75% [6-8], and hypothesized that placement of personal shadow boxes could increase satisfaction to 80% (relatively small effect). Therefore, assuming a standard deviation (SD) = 15 [8-10], to achieve 80% power with a 5% type I error rate, we would need 143 patients in each study period. With 50-60 discharges from each MICU in one month and a conservatively estimated non-response rate of 50% (also taking into account patients with family members who may not wish to or are unable to bring in personal objects), we plan for 3 months of data collection per study period. The novel 11-item patient and family questionnaires designed for the purpose of our study has an estimated SD = 2.8 based on extrapolated data from Neto *et al* [4]. If we assume even a small improvement in mean total score from 30 to 31, we would require only 125 patients in each study period to achieve 80% power.

The pre- and post-intervention phases will each last for 3 months based on the power calculations. The primary outcome will be patient and family satisfaction with their ICU experience before and after the

shadow boxes are placed in patient rooms. The secondary outcome will be staff perception of how the intervention influences patient care. These will be assessed using a total of four questionnaires described in greater detail in section F.

Descriptive analyses will be used to summarize demographic characteristics of patients (age, gender, admission diagnosis, APACHE II score, mechanical ventilation, length of ICU stay, survival status) and of family respondents (age, gender, relation to patient). Admission diagnoses will be broadly categorized as cardiovascular, respiratory, gastrointestinal, or trauma/sepsis/other.

Total scores on the novel patient and family questionnaires will be calculated by adding individual item scores and will range from 11 to 44, with a higher number indicating a more positive response. Total FS-ICU scores will be calculated by averaging individual items, provided that $\geq 70\%$ of questions were answered [6], and will range from 0% to 100%, with 100% representing highest satisfaction. Scores on the subscales "satisfaction with care" and "satisfaction with decision-making" will also be calculated.

Differences between mean pre- and post-intervention satisfaction scores (both individual items and total scores) will be assessed using two-sample *t* tests since data is normally distributed. Linear regression analyses will be used to adjust for possible confounding given increased age, male gender, higher severity of illness, longer LOS, and need for mechanical ventilation have been associated with higher satisfaction rates. Subgroup analyses will also be performed to determine whether differences are more pronounced with higher severity of illness and longer LOS due to longer exposure to the intervention.

Although we are also interested in potential effects on staff perception of patient care, it is not possible to blind ICU staff to the intervention. Any measured changes would be biased by knowledge of the intended project. As a result, we will administer the survey developed by Neto and colleagues [4], to members of the ICU team at the end of the study to gauge overall response to the intervention. Members with significant patient interaction, such as day and night RNs, respiratory therapists, resident physicians, and attending physicians, will be asked to participate. Descriptive analyses will be used to summarize findings.

C. Study Procedure

During the 3-month pre-intervention phase, all eligible patients and family members (see exclusion criteria below) will be approached on the day of anticipated discharge by the unit assistant. They will be asked to complete the questionnaires prior to leaving the unit as part of an effort to assess and improve quality of care in the ICU. Depending on whether the IRB deems the study to involve human subjects, informed consent may or may not be obtained. If the family member is not present, a member from the study team will contact the family member and administer the questionnaire on the floor or mail the questionnaire.

During the 3-month study phase, the RN in charge of any patient with anticipated LOS > 48h will ask family members, as early as deemed appropriate once the patient is stable, if they would like to bring in personal photographs, meaningful artwork, or memorabilia, to be displayed in the shadow box. The items will be displayed for the entire duration of the patient's ICU stay and returned to a family member when the patient leaves the ICU. Questionnaires will be administered at the time of discharge as earlier described.

D. Study Drugs

N/A

E. Medical Device

N/A

F. Study Questionnaires

All prior studies involving the use of patient photographs in the ICU setting examined nurse and physician responses. Since there have been no studies looking at the effect of photographs or personal shadow boxes on patient and family experience, no validated questionnaires have been developed for this purpose. As such, we adapted 8 items from the validated questionnaire used to assess staff responses that we felt most directly related to patient care [4]. We additionally added 3 items to assess patient comfort and overall satisfaction. A similar questionnaire was created for family members. Both questionnaires consist of 11 statements that seek to capture the potential effect of photographs and personal objects on patient care, communication, and comfort. Using a 4-point Likert scale, the statements range from strongly disagree (1) to strongly agree (4).

To improve the validity and statistical rigor of our study, we also chose to administer the 24-item FS-ICU, a validated questionnaire, originally developed by Heyland and later refined by Wall, assessing overall family satisfaction in the ICU [6, 11]. A number of researchers have developed questionnaires to measure family satisfaction with care [11-13], a reliable and useful proxy for patient satisfaction. We chose the FS-ICU questionnaire because it focuses on communication and decision making, areas we feel will be most strongly influenced by our intervention.

To assess staff perception of the project, we will administer the previously described questionnaire developed by Watson and adapted by Neto [4-5]. Minor wording changes were made to make the questionnaire specific to this study and appropriate for both physicians and nurses.

*All questionnaires are attached to the end of this protocol, with the exception of the FS-ICU questionnaire that can be found at http://www.thecarenet.ca/docs/fss/FS_ICU_24.pdf

G. Study Subjects

All patients in MICU A and MICU B of the Columbia University Medical Center who are discharged during the study periods will be eligible. Exclusion criteria for patients are: non-survivors, LOS<48h, inability to read or understand English, or severe cognitive/visual/hearing impairment that would prevent completion of the questionnaire. Family members of patients with the latter three exclusion criteria will still be eligible to participate.

H. Recruitment of Subjects

Patients and family members will be recruited from MICU A and MICU B of the Columbia University Medical Center. They will be informed of the study and provided with questionnaires (and consent forms, if necessary) at the time of discharge from the ICU.

I. Confidentiality of Study Data

All data will be de-identified and stored securely.

J. Potential Conflict of Interest

There are no potential conflicts of interest.

K. Location of the Study

The study will be conducted in MICU A and MICU B at New York-Presbyterian Hospital/Columbia University Medical Center.

L. Potential Risks

The study poses no potential risks and discomforts to patients or family members, with the exception of release of confidential medical information or the loss of valuable items. All efforts will be made to maintain patient confidentiality and to protect patient information. Similarly, the items contributed by family members will be secured inside the shadow box to prevent loss or theft.

M. Potential Benefits

Patients and family may benefit from improvement in any or all of the outcome measures. These include increased comfort and subjective feeling of being care about, decreased pain and anxiety, improved relationship and communication with the ICU team, and overall improved satisfaction with care received in the ICU.

N. Alternative Therapies

N/A

O. Compensation to Subjects

There will be no compensation to recruited subjects.

P. Costs to Subjects

There will be no costs other than the possibility of lost items, addressed above in L.

Q. Minors as Research Subjects

N/A

R. Radiation or Radioactive Substances

N/A

References

1. Rubert R, Long LD, Hutchinson ML. "Chapter 3: Creating a Healing Environment in the ICU." *Crit Care Nursing* 2007.
2. Andersson M, Hall-Lord ML, Wilde-Larsson B, et al. "Patient photographs-A landmark for the ICU staff: A descriptive study." *Intensive and Critical Care Nursing* 2013; 29:193-201
3. Kutash M and Northrop L. "Family members' experiences of the intensive care unit waiting room." *J Adv Nurs* 2007; 60:384-88
4. Neto C, Shalof R, and Costello J. "Critical care nurses' responses to patient photographs displayed at bedside." *Heart Lung* 2006; 35:198-204
5. Watson C. "Portrait study . . . dehumanization of patients in an intensive care unit having a photograph." *Nurse Times* 1987; 24:64-67
6. Wall RJ, Engelberg RA, Downey L, et al. "Refinement, scoring, and validation of the Family Satisfaction in the Intensive Unit (FS-ICU) survey." *Crit Care Med* 2007; 35:271-79
7. Wall RJ, Curtis JR, Cooke Cr, et al. "Family satisfaction in the ICU: differences between families of survivors and nonsurvivors." *Chest* 2007; 132:1425-33
8. Stricker KH, Kimberger O, Schmidlin K, et al. "Family satisfaction in the intensive care unit: what makes the difference?" *Int Care Med* 2009; 35:2051-59
9. Jongerden IP, Slooter AJ, Peelen LM, et al. "Effect of intensive care environment on family and patient satisfaction: a before-after study." *Int Care Med* 2013; 39:1626-34
10. Schwarzkopf D, Behrend S, Skupin H, et al. "Family satisfaction in the intensive care unit: a quantitative and qualitative analysis." *Int Care Med* 2013; 39:1071-79
11. Heyland DK and Tranmer JE. "Measuring Family Satisfaction with Care in the Intensive Care Unit: The Development of a Questionnaire and Preliminary Results." *J Crit Care* 2001; 16:142-49
12. Wasser T, Pasquale MA, Matchett S, et al. "Establishing reliability and validity of the critical care family satisfaction survey." *Crit Care Med* 2001; 29:192-96
13. Azouley E, Pochard F, Chrevret S, et al. "Meeting the needs of intensive care unit patient families." *Am J Respir Crit Care Med* 2001; 163:135-39

Patient Experience Questionnaire (11 items)

	Strongly Disagree	Disagree	Agree	Strongly Agree
My ICU room was a comfortable space that promoted healing	1	2	3	4
I felt that the ICU team could relate to me as an individual	1	2	3	4
I felt that the ICU team respected me and cared about me	1	2	3	4
The ICU team offered empathetic touch when I appeared to be in pain or distress	1	2	3	4
The ICU team addressed me by my name	1	2	3	4
I developed an emotional tie with the ICU nurses and physicians who cared for me	1	2	3	4
There was good communication between me, my family, and the ICU team	1	2	3	4
Members of the ICU team took the time to provide teaching and emotional support to me and my family	1	2	3	4
Overall, my pain was well controlled	1	2	3	4
Overall, my anxiety was well controlled	1	2	3	4
Overall, I had a positive experience and was satisfied with the care I received	1	2	3	4

Family Experience Questionnaire (11 items)

	Strongly Disagree	Disagree	Agree	Strongly Agree
The ICU room was a comfortable space that promoted healing	1	2	3	4
I felt that the ICU team could relate to my family member as an individual	1	2	3	4
I felt that the ICU team respected and cared about my family member	1	2	3	4
The ICU team offered empathetic touch to my family member when he/she appeared to be in pain or distress	1	2	3	4
The ICU team addressed my family member by his/her name	1	2	3	4
I developed an emotional tie with the ICU nurses and physicians who cared for my family member	1	2	3	4
There was good communication between me and the ICU team	1	2	3	4
Members of the ICU team took the time to provide teaching and emotional support	1	2	3	4
Overall, my family member's pain appeared to be well controlled	1	2	3	4
Overall, my family member's anxiety appeared to be well controlled	1	2	3	4
Overall, I had a positive experience and was satisfied with the care my family member received	1	2	3	4

ICU Staff Questionnaire (15 items)

	Strongly Disagree	Disagree	Agree	Strongly Agree
The patient's personality and character are emphasized by the photographs and objects.	1	2	3	4
Photographs and personal objects help me relate to the patient as an individual.	1	2	3	4
In my practice, it is important to me to get to know the patient as an individual.	1	2	3	4
Having photographs in the room increases the frequency with which I call the patient by name when I'm providing direct care.	1	2	3	4
I tend to offer empathetic touch more frequently to patients who have photographs than to patients without photographs.	1	2	3	4
The unit looks less clinical with the personal shadow boxes.	1	2	3	4
Photographs and personal objects facilitate communication with the patient.	1	2	3	4
Photographs and personal objects facilitate communication with the family.	1	2	3	4
I tend to spend more time providing teaching and emotional support to patients who have photographs.	1	2	3	4
Seeing photos of the patient in normal health helps me to visualize goals to aim for in my care.	1	2	3	4
The comparison between the photograph and the patient can be upsetting.	1	2	3	4
In general, photographs and personal objects make a difference to the care a patient receives.	1	2	3	4
Photographs and personal objects interfere with my ability to care for the patient.	1	2	3	4
Photographs and personal objects make me feel more emotionally involved with patients than I usually wish to.	1	2	3	4
Personal photographs and objects help make my work more rewarding.	1	2	3	4

IRB Protocol
Jessica Yang, PGY1