Title: The Effects of Expectation Setting and Bundle Consent on Caregiver Stress in the Pediatric ICU

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The Effects of Expectation Setting and Bundle Consent on Caregiver Stress in the Pediatric ICU

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Protocol synopsis	
Study identifier	Bundle Consent and Caregiver Stress
Type of study	Prospective Cluster Randomized Control Trial
Background	Having a child admitted to the Pediatric Intensive Care Unit (PICU) is a challenging and stressful experience for parents and caregivers. Despite the high survival when compared to adult ICUs[1], a PICU admission can have meaningful long term negative health consequences for adult caregivers including symptoms of depression, anxiety and PTSD[2]. There is little known in regards to what specific factors impact the mental health of caregivers of PICU patients. However, research into stress and anxiety has suggested that uncertainty is a significant contributor to stress when faced with a new environment.[3] This uncertainly is palpable in the PICU for many reasons. First, few caregivers are medically savvy enough to appreciate the diversity and scope of pathology that is routinely treated in the PICU. They may not know that PICU is an acronym for Pediatric Intensive Care Unit or that the sickest children in the hospital are cared for in that unit.[4] They may have no experience with pediatric illness beyond a simple viral process. Therein lies a major source of stress and uncertainty and basis of a question intensivists often field, “Have you ever seen a child this sick?” Intensivists can and often do attempt to mitigate this uncertainty with illness specific anticipatory guidance. However, providing that guidance, and often re-assurance, in the PICU can be challenging due to the uncertain trajectory of pediatric illness. It is frequently difficult to counsel caregivers on what to expect during their hospitalization without becoming too hypothetical or presenting conflicting possible scenarios.[5] Prior research suggests that invasive procedures can be a significant source of immediate stress for caregivers. This uncertainty is compounded by the fact that it is common practice to introduce the idea of invasive procedures, and subsequently obtain consent, only when that procedures is likely to be required. This leads to obtaining informed consent, a concept with legal significance, in the setting of a deteriorating child and subsequently a caregiver under significant duress.

	This forces us to consider the question, are we obtaining morally and legally valid informed consent or, despite our best efforts, are we obtaining coerced consent? To further illustrate the possibility of coerced consent, one can consider how often parents or guardians refuse to give consent for invasive procedures? In general practice, and the experience of the PICU in which I currently practice, caregiver refusal is a very rare occurrence. This my because in pediatric critical care practice there are few good alternatives to the types of invasive procedures that we commonly perform (intubation, central venous catheterization, arterial catheterization, and procedural sedation). However, it maybe be because intensivists are, unintentionally, overwhelming caregivers who are in acutely stressful and emotionally vulnerable states. The complex landscape of the PICU described above presents a unique opportunity to simultaneously obtain consent under less stressful circumstances and set realistic expectations as to the nature of a PICU admission, a means of alleviating some of the uncertainly of a PICU stay by introducing the types of procedural support we can offer and obtaining informed consent prior to their immediate necessity. In this study we will use a prospective cluster randomized design to compare caregiver stress level via the Short Stress Overload Scale (SOS-S) in a control arm our current model of obtaining ad-hoc for invasive procedures. In the experimental arm, employing a scripted bundle consent upon admission to the PICU, which will serve the dual purpose of consenting parents and/or legal guardians for 5 commonly performed invasive procedures as well as general expectation setting for the PICU)
Hypothesis	Caregivers that are consented for invasive procedures via a bundle consent at the time of admission to the PICU will report less stress at 48-72 hours post admission and at the time of discharge than those consented via the current ad-hoc model of consent.
Study objectives	1. To quantify caregiver stress and determine if a bundle consent and expectation setting can decrease that stress. 2. To determine the change in the proportion of procedures performed without appropriate and documented written consent, between the current ad-hoc model of consent and a bundle consent process.
Study population	Parents or caregivers of patients admitted to a PICU during the designated study period

Main inclusion criteria	Parents or caregivers of critically ill children admitted to the Pediatric ICU during the designated study period.
Main exclusion criteria	Anticipated length of PICU stay < 24 hours, Non-English speaking patients
Study intervention	Scripted consent for the following invasive procedures (central venous catheter, arterial catheter, intubation, procedural sedation) by a PICU Attending, Fellow, or Nurse Practitioner within 12 hours of admission to the Pediatric ICU.
Data collection	Patient and caregiver demographic, as well as patient diagnostic, therapeutic and procedural data will be collected as well as caregiver self-reported stress scores via the Short Stress Overload Scale (SOS-S)
Clinical endpoints	Discharge from the Pediatric ICU or if interim analysis dictates that harm is being done as discussed under Ethical Considerations heading.
Confounding variables	• Patient demographic data (age) • Patient PELOD-2 Score • Type of admission (planned, direct from ED, transfer from floor, transfer from outside Hospital) • Prior NICU or PICU stay admission • Caregiver demographic data (Age, Sex, Ethnic background, highest education level) • Caregiver assessment of “Life-threatening” nature of illness using a Likert scale
Ethical considerations	As this study evaluates consent, and particularly the possibility of coerced consent, it is not possible to create a design that involved consent for participation that does not jeopardize the integrity of the study. Furthermore, our experimental intervention, a bundled consent process, is currently being utilized at various pediatric and adult ICUs in the United States and will meet all of the legal requirements for informed consent in the state of Virginia. We will therefore ask for a waiver of individual informed consent for randomization. We will be asking for caretaker consent for the collection of demographic data and measurement of caretaker stress. The scripted bundle consent process will add no risk of physical harm to the Pediatric ICU patient. We recognize the possibility that our intervention may result in an increase in stress and/or anxiety to parents and/or caregivers in the experimental group and therefore plan to conduct interim analyses (after the first 50 and 100 patients) to ensure that no harm is being done, with the intent of terminating our study if we show an increase in caregiver stress of 20% or more in the experimental group. Furthermore, for the study participants in both groups, we plan to use caregiver stress scores as a basis for referral to already existing internal mechanism for caregiver stress mitigation,

	including but not limited to: Social Work, Case Management and Child Life services if a caregiver's score fall in the "High Stress" quadrant (High Personal Vulnerability and High Event Load Scale)
Methodology	Control and Experimental groups will be created using a cluster randomization design in alternating periods beginning of the 1st and 15th of each month. Caregivers included in the control group will be admitted to the PICU and undergo consent for invasive procedures as is indicated by the clinical needs of their children as per current unit practices. Caregivers included in the experimental group will, within 12 hours of admission, be consented for: central venous catheter, arterial catheter, intubation, and procedural sedation via a scripted bundled consent by an PICU Attending, Fellow, or Nurse Practitioner. Then, for both groups, at 48-72 hours after admission and at the time of discharge from the PICU, they will receive and complete the SOS-S, either electronically or on paper, to measure stress, which will then be collected and recorded. Any caregiver in the experimental or control group identified to fall into the "High Stress" group as per the SOS-S will be referred to pre-existed support services within the PICU/VCUHS infrastructure. All data recorded will be completely de-identified and collected within REDCap.
Statistical plan	First, we will identify the confounding factors using a bivariate regression model between each of the following factors and the primary outcome: patient age, type of admission, prior ICU admissions, caregiver demographic data, and caregiver assessment of life-threatening illness. Second, the association between the bundle consent process and the outcome (caregiver stress) will be investigated using logistic regression models, adjusting for the confounding factors identified in step one. Third, a multivariable logistic regression will be performed with all variables (full model). The simplification of this full model will be done using another multivariable logistic regression with backward selection at the level $p = 0.05$.
Sample size	After examining prior studies which used the SOS-S to quantify pathologic stress reactions, We estimate a mean SOS-S score of 19.9 and a standard deviation of 11.3. We anticipate a 20% reduction in SOS-S score in the experimental group (i.e. from

	19.9 to 15.9). Setting an alpha of 0.05 and power of 0.8. We anticipate requiring a sample size of 266 caregivers to sufficiently test the null hypothesis.
Location	Pediatric Intensive Care Unit at the Children's Hospital of Richmond, VCUHS
Study duration	We admit an average of 1000 patients per year, 83 patients per month. We anticipate at participation rate of 80%. Therefore we anticipate a study duration of 4 month to enroll the necessary number of patients.
Anticipated results	A scripted consent bundle signed at the time of admission will lead to decrease in measured caregiver stress at 48-72 hours of PICU stay and at the time of discharge from the ICU.
Future perspectives	This will be the another step in create a Pediatric ICU environment that will be able to minimize the emotional and psychologic stress on the parents and caregivers Pediatric ICU patients.
References	1. Society of Critical Care Medicine, *Critical Care Statistics.* Society of Critical Care Medicine, https://www.sccm.org/Communications/Critical-Care-Statistics. Retrieved 2020. 2. Rodrı´guez-Rey R, Alonso-Tapia J, Colville G. Prediction of parental posttraumatic stress, anxiety and depression after a child's critical hospitalization. J Crit Care. 2018;45:149-155. 3. Durette, M. (2013). *Uncertainty and Primary Appraisal as Predictors of Acute Stress Uncertainty and Primary Appraisal as Predictors of Acute Stress Disorder in Parents of Critically Ill Children: A Mediational Model.* (Doctoral Thesis) 4. Butler, A., Copnell B., Willetts, G., Family Centered care in the paediatric intensive care unit: an integrative review of the literature. Journal of Clinical Nursing, 2013. 23, 2086-2100: 10.1111/jocn.12498. 5. Gill, M. PICU Prometheus: Ethical issues in the treatment of very sick children in Paediatric Intensive Care. Mortality, November 2005; 10(4): 262-275