

SUPPORTING A CLINICAL TRIAL IN A PEDIATRIC PACU

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Background Information: Pediatric PACU RN staff in this academic medical center was presented with the opportunity to support a randomized, controlled clinical trial of an investigational drug in a pediatric population with a genetic lysosomal storage disorder, Mucopolysaccharidosis type III A (Sanfilippo syndrome). The PACU setting is appropriate because the patients may require sedation or anesthesia, at the discretion of the investigator, for delivery of the investigational product.

Objectives of Project: The primary objective of the trial is to assess the potential clinical efficacy of an investigational drug administered via a surgically implanted indwelling intrathecal drug delivery device or via lumbar puncture. Efficacy will be measured as a meaningful amelioration in the typical progression of cognitive decline due to the disease, and will be measured using the Bayley Scales of Infant and Toddler Development, 3rd Edition.

Process of Implementation: The investigational drug is administered every 2 weeks or every 4 weeks according to the protocol. The Pediatric PACU nurses work closely with the team to prepare for each encounter, to provide patient care, and to support the patient, family, physicians and the study team during each 4-hour episode.

Statement of Successful Practice: Participation, collaboration, and support of a clinical trial in the PACU setting presents a unique opportunity for clinical nursing staff in an academic medical center. Accommodations made in PACU provide a safe and private location and dedicated PACU RN staff. Perianesthesia leadership has provided integral support to the investigators to ensure consistent conditions for the trial.

Implications for Advancing the Practice of Perianesthesia Nursing: This successful practice demonstrates a unique opportunity for creative collaboration by PACU leaders and nursing staff in support of clinical research in an academic medical center.