

Table 4: Intensive Care Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Anesthesia/sedation	#Ketamine	Safety	PK, PD and safety studies of short- and long-term effects	Preclinical studies completed with the FDA/ National Center for Toxicological Research (NCTR) via Inter-Agency Agreement https://bpcanichd.nih.gov/prioritization/clinicaltrials/Pages/pediatric-trials-network.aspx Pediatric PK, PD and safety study underway by the PTN
	Inhaled anesthetics	Toxicity of inhaled anesthetics in developing brains	Identification of markers of apoptosis	Preclinical studies completed with the FDA/ National Center for Toxicological Research (NCTR) via Inter-Agency Agreement https://bpcanichd.nih.gov/prioritization/clinicaltrials/Pages/pediatric-trials-network.aspx Publication: Journal of Applied Toxicology 09/2013; 33(9). DOI:10.1002/jat.2857
	#Lorazepam	Dosing, safety	PK, safety, and efficacy trial comparing lorazepam with midazolam for sedation	WR received from the FDA Clinical trial completed; No label change anticipated.
	Dexmedetomidine	Adjunctive use in pediatric anesthesia	Long-term follow up	Pediatric opportunistic study by the PTN ongoing
Shock	Hydrocortisone	Dosing, duration of treatment, weaning process	PK and comparative effectiveness studies	Collaboration with the NICHD Collaborative Pediatric Critical Care Network in development
Analgesia	Hydromorphone	PK and safety of pain medications in children	PK, PD, and safety of analgesics in obese and non-obese children	Pediatric PK, PD and safety study underway by the PTN
Respiratory secretions and drooling	Glycopyrrolate	PK parameters and side effect profile in infants up to 3 years of age	Hybrid trial design	Under consideration

Drug and indications **in bold** have been identified by the NICHD as a priority and are newly added to the BPCA list.

#Drugs listed twice for different indications or populations.

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