

October 2022 Updates on ED Clinical Trials

Happy Halloween, Fall, Diwali, Dia de los Muertos, y de mas! We have a couple of exciting new pediatric studies starting up in the Peds ED at OHSU, as well as the launch of new and old studies at Adventist. As always, let me or the PIs of the studies know if you have questions, comments, or feedback on ways to improve studies through the ED. And thank you for all that you do for our patients, and contribution to our triple mission of patient care, education, and research.

Bory Kea, MD, MCR, Director of Clinical Trials

For the interested reader, more details on the below research studies can be found at:

<http://www.ohsu.edu/cprem>



OREGON
HEALTH & SCIENCE
UNIVERSITY

- PediDOSE
- P-ICECAP
- PREOXI
- IVY-4
- GUIDED-HF
- ACTIV-4d (NECTAR)

- STRATIFY
- AF CDS
- FAST Exam
- REASON3
- Compartment Syndrome
- PACT

- KCENTRA
- Fentanyl (Toxic)
- Save-O2
- ICECAP
- BOOST-3
- Covid PreVent Trial (on hold)

ACTIVE STUDIES

Pediatric Dose Optimization for Seizures in EMS (PediDOSE)

This study is a multi-center, stepped wedge trial of midazolam dosing for seizures in pediatric patients in the Emergency Medical Services (EMS) setting. It randomizes the timing of each of the participating EMS agencies at 20 different sites to switch from conventional, weight-based dosing to standardized, age-based dosing so that every EMS agency switches from conventional to standardized dosing over a 4-year enrollment period in this 5-year study. The primary outcome is seizing on ED arrival measured by the Ceribell Device. Federal exception from informed consent (EFIC) procedures will be used for enrollment.



Launching: October 17, 2022

- **PI:** Matthew Hansen, **Coordinators:** Keeley McConnell, Jordan Taboada
- **Inclusion:** Patient is Age ≥ 6 months to ≤ 13 years AND had a paramedic-witnessed seizure AND Require transport to any hospital; Ceribell Placement on patients age ≥ 2 years.
- **Exclusion:** Patient has a prior history of a benzodiazepine allergy; OR has known or presumed pregnancy; OR Has severe growth restriction based on the paramedic's assessment.
- **Status:** Launching November 1!

- **Contact:** cprem@ohsu.edu
- **24-hour line:** 503-494-1777



P-ICECAP

P-ICECAP – Pediatric Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients

This study is a multicenter, randomized, adaptive allocation clinical trial to identify the optimal duration of induced hypothermia for neuroprotection in comatose survivors of cardiac arrest.

Launched: October 2022 Site: Doernbecher Children’s Hospital

- **PI:** Serena Kelly, **Co-I:** Aileen Kirby, Cydni Williams, Beech Burns, Mo Daya, Bory Kea
- **Coordinator:** Keeley McConnell
- Registered with ClinicalTrials.gov: NCT05376267
- FDA IDE: William Meurer, G210126
- **Status:** Enrolling; **Enrolled: 0; All site total: 5**
- **Contact:** Kelley McConnell, mcconnke@ohsu.edu

PREOXI: Pragmatic Trial Examining Oxygenation prior to Intubation

PREOXI aims to evaluate the efficacy of oxygen masks with or without positive pressure in improving patient outcomes with low oxygen levels during intubation

Launched: July 2022

Study Duration: February 2023

Sites: OHSU & Vanderbilt University Medical Center

- **PI:** Akram Khan, MD ; **Coordinators:** PRISM Research Team
- **Inclusion:** Patient is located in a participating unit and tracheal intubation using a laryngoscope and sedation is planned
- **Exclusion:** Patient receive positive pressure ventilation by a mechanical ventilator, bag-mask device, or laryngeal mask airway; less than 18 years old; pregnant; prisoner; immediate need for tracheal intubation precludes safe performance of study procedures; patient is hypopneic or apneic; operator determined that preoxygenation with non-invasive positive pressure ventilation or preoxygenation with facemask oxygen required
- **Status:** ACTIVE, **Enrolled: 9**
- **Contact:** Akram Khan, khana@ohsu.edu ; Minn Oh, ohmi@ohsu.edu ; page 11912

IVY-4: Influenza and Other Viruses in the Acutely Ill

Assessing the clinical validity of SARS-CoV-2 RT-PCR results and vaccine effectiveness

Launched: February 2022

Study Duration: February 2023

Sites: OHSU & Vanderbilt University Medical Center

- **PI:** Akram Khan, MD ; **Coordinators:** PRISM Research Team
- **Inclusion:** acute symptom onset within 14 days of admission; positive or negative SARS-CoV-2, influenza, or RSV test after onset of symptoms
- **Exclusion:** test > 14 days of onset of symptoms, previously enrolled in surveillance program
- **Status:** ACTIVE, **Enrolled:** 373
- **Contact:** Akram Khan, khana@ohsu.edu ; Minn Oh, ohmi@ohsu.edu ; page 11912

Implementation of a Self-Care Plan for Patients with Acute Heart Failure Discharged from the ED (GUIDED-HF)

GUIDED-HF is a multi-site project with implementation of a self-care plan for acute heart failure (HF) at OHSU and Hillsboro Medical Center. This project aims to provide self-care coaching (x3 virtual visits) for patients discharged from the Emergency Department (ED) with HF.

Launched: February 1, 2022

Sites: OHSU & HMC

- **PI:** Bory Kea; **Study Coordinator:** Joy Kim
- **Inclusion:** Diagnosed with HF and/or received loop diuretics in ED.
- **Status:** Enrolling; **Enrolled:** 18
- **Contact:** Joy Kim, kimjoy@ohsu.edu

ACTIV-4d (Novel Experimental COVID Therapies Affecting Host Response [NECTAR])

Evaluating therapies targeting host tissue and the renin-angiotensin-aldosterone system (RAAS) in hospitalized patients with COVID-19.

Launched: January 2022

Study Duration: January 2023

- **PI:** Akram Khan, MD ; **Coordinators:** PRISM Research Team
- **Inclusion:** > 18 yo., COVID + and symptomatic, requiring oxygen support or SpO2 < 92, hospitalization period < 72 hours
- **Exclusion:** pregnant, breastfeeding, prisoners, end-stage renal team on dialysis, DNR/DNI
- **Status:** ACTIVE, **Enrolled:** 24
- **Contact:** Akram Khan, khana@ohsu.edu ; Minn Oh, ohmi@ohsu.edu ; page 11912

Tailored Dissemination and Implementation of Emergency Care Clinical Decision Support to Improve Emergency Department Disposition (STRATIFY)

STRATIFY is a study on the development and dissemination/implementation of a clinical decision support tool for heart failure risk stratification and disposition. This project aims to examine ED workflow at OHSU and Hillsboro Medical Center (HMC) to determine how to best integrate it into a clinical decision support (CDS) tool for patient and provider shared-decision making, specifically for acute heart failure patients.

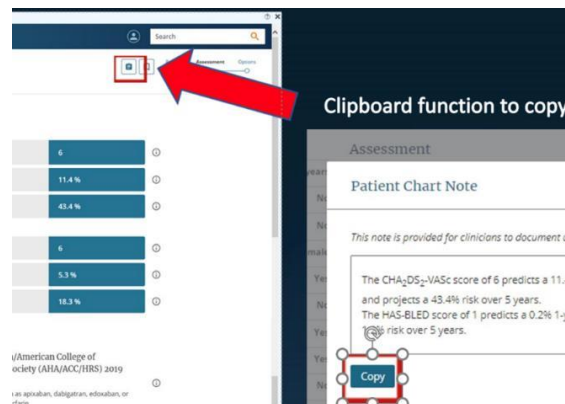
- **PI:** Bory Kea; **Study Coordinator:** Joy Kim
- **Status:** Analyzing retrospective EHR data using the STRATIFY risk factors to understand and address data challenges in STRATIFY implementation

- **Contact:** Joy Kim, kimjoy@ohsu.edu

Atrial Fibrillation (AF) Clinical Decision Support (CDS) Tool

A stepped-wedge clinical trial of an electronic clinical decision support tool to improve stroke prevention in patients with atrial fibrillation. Patients and providers will be recruited for qualitative interviews at 3 sites (OHSU, AHP, HMC).

Please use the clipboard function to copy documentation from the tool:



Launched: OHSU – January 11, 2022; HMC – April 4, 2022
Launching: AHP – February, 2023

- **PI:** Bory Kea; **Study Coordinator:** Joy Kim
- **Inclusion:** : >18 years, OAC naïve
- **Status:** Enrolling; **Enrolled: Quantitative – 73; Qualitative – 4 patients, 8 providers**
- **Contact:** Joy Kim, kimjoy@ohsu.edu

Automated Ultrasound Image Analysis of the Abdominal FAST Exam

Purpose of this study is to attain a library positive and negative abdominal ultrasound images of the standard Focused Assessment with Sonography for Trauma (FAST) imaging protocol, which can be subsequently annotated to train a machine learning algorithm.

Launched: October 13, 2021

Sites: OHSU, Medstar, Brook Army Medical Center, Tripler Army Medical Center, Womack Army Medical Center

- **PI:** Nikolai Schnittke; **Coordinators:** Samantha Underwood and Michael Fleming
- **Inclusion:** Adults ED trauma patients who either have a positive FAST exam performed and saved by the clinical team, or have a CT scan of the abdomen/pelvis performed as part of the trauma workup, with follow-up research FAST performed by the study team. Non-trauma patients with peritoneal fluid are also eligible for a research FAST exam performed by the study team.
- **Exclusion:** Skin disease and/or wounds that would preclude transducer placement, prisoners.
- **Status:** Enrolling; **Enrolled: 88; All site total: 156**
- **Contact:** Nikolai Schnittke, schnittk@ohsu.edu

For potential enrollment please call or page TRG: 4-5939 pager: 11502

REASON3: Bedside Cardiac Ultrasound in Cardiac Arrest

The objective is to measure survival rates associated with different presenting rhythms as assessed by ultrasound versus ECG strip in patients presenting in cardiac arrest.

Launched: August 17, 2021

- **PI:** Nikolai Schnittke
- **Inclusions:** Adult ED patients in nontraumatic cardiac arrest
- **Exclusions:** Resuscitation ended due to end-of-life decisions, ultrasound images or rhythm strip not saved.
- **Status:** Enrolled; **Enrolled: 6; All site total: 289**
- **Contact:** Nikolai Schnittke, schnittk@ohsu.edu

Observational Study of Extremity Compartment Syndrome Using SWE and MFI

An observational study to evaluate the utility of two ultrasound modes (shear wave elastography and microvascular flow imaging) in the diagnosis of compartment syndrome related to lower and/or upper extremity traumatic injury.

Launched: May 5, 2021

- **PI:** Kenton Gregory
- **Inclusions:** Adult ED patients with suspected (clinical suspicion and/or high-risk injury requiring scheduled compartment checks) single or multiple acute compartment syndrome of the lower and/or upper extremity.
- **Exclusions:** Prior fasciotomy of affected extremity, Skin disease and/or wounds that would preclude transducer placement, Prisoners.
- **Status:** Enrolling; **Enrolled: 16; All Site total: 43**
- **Contact:** Nikolai Schnittke, schnittk@ohsu.edu ; Bryson Hicks, hicksbr@ohsu.edu

For potential enrollment please call or page TRG: 4-5939 pager: 11502

PACT- Prehospital Airway Control Trial

PACT is an open-label, multi-site, stepped wedge randomized trial comparing a standard strategy of airway management with a strategy of first attempt with supraglottic airway (SGA) for trauma patients in a prehospital setting. The primary outcome is 24-hour mortality. It is assessed 24 hours after hospital arrival. Eight local agencies in the Clackamas and Washington counties are participating including AMR Clackamas, Clackamas County Fire District 1, Lake Oswego Fire, Molalla Fire, Canby Fire, Tualatin Valley Fire & Rescue, Hillsboro Fire & Rescue, and Metro West Ambulance.

Launched: April 1, 2021

- **PI:** Mo Daya, **Co-I:** Marty Schreiber **Coordinator:** Nancy Le, Sam Underwood
- **Inclusion:** Trauma requiring advanced airway management. Indicators of the need for advanced airway management include: a) GCS < 8, b) SpO2 < 90 despite supplemental oxygen, c) ETCO2 > 60 despite supplemental ventilation, or d) provider discretion. **Transport to LITES Trauma Center – OHSU ONLY.**
- **Exclusion:** <15 years of age, pregnant, prisoner, initial advanced airway attempted by a non-PACT agency, in cardiac arrest without ROSC at time of intervention, caustic substance ingestion, airway burns, objection to enrollment voiced by subject or family members at the scene.
- **Status:** Enrolling; **Enrolled: 64**
- **Contact:** Nancy Le, lena@ohsu.edu

****OHSU Team- please remember to document: (1) Date & Time of Airway Exchange and (2) Reason for Airway Exchange (hypoxia, inadequate ventilation, etc).****

KCENTRA

A multicenter, pre-hospital pilot trial to determine the feasibility and safety of Kcentra administration for the early treatment of patients with traumatic shock, compared to placebo, in the field. This study will be conducted under EFIC (Exception from Informed Consent).

Launched: March 2021 Sites: OHSU and sites at Houston (2) and Seattle (1)

- **PI:** Schreiber, **Coordinator:** Samantha Underwood
- Registered with ClinicalTrials.gov: NCT04019015
- FDA IND: Martin Schreiber, 18153
- Inclusion: 18 years and older, SBP <70 or no palpable pulse, suspicion of hemorrhagic shock, transport to participating hospital
- **Status:** On Hold
- **Contact:** Sam Underwood, underwos@ohsu.edu

Predicting medical consequences of novel fentanyl analog overdose using the Toxicology Investigators Consortium (ToxIC)

Purpose of this multi-center study is molecular identification and quantitation of fentanyl analogues (fentalogs) in a prospective cohort of 1000 Emergency Department (ED) patients with opioid overdose (OD) from the established ToxIC hospital network. The number of subjects to be enrolled at each ToxIC site is approximately between 25-100. As an Exploratory Sub-Aim, we will characterize psychostimulant drug co-ingestions with fentalogs (e.g. synthetic cannabinoids, cocaine, cathinones, etc.) to provide confirmatory identification and quantitation.

Please use "poisoning by opioids" in your impression for all opioid overdoses.

Launched: November 2020

- **PI:** Adrienne Hughes; **Study Coordinator:** Keeley McConnell
- **Inclusion:** ED patient Opioid OD. Availability of waste blood or urine specimens for analysis.
- **Exclusion:** Age < 18 years. Non-toxicological diagnosis. Prisoners. Trauma/Burns.
- **Status:** Enrolling (resumed Feb 2022); **Enrolled: 50**
- **Contact:** Keeley McConnell, mconnke@ohsu.edu

SAVE-O2 - Strategy to Avoid Excessive Oxygen for Critically Ill Trauma Patients

SAVE-O2 will be a multicenter cluster randomized, stepped wedge implementation trial of a multimodal educational intervention to target normoxia in adult trauma patients admitted to the intensive care unit (ICU). The goal is to improve oxygenation to >90% of eligible patient-hours spent in the desired normoxia range, excluding time without supplemental oxygen or time on FiO2 100% and below the normoxia range.

Launched: October 15, 2020

- **PI:** Schreiber, **Coordinator:** Samantha Underwood
- **Inclusion:** Patients who meet criteria for entry into the OHSU trauma registry
- **Exclusion:** Age <18 years, Prisoners, Known pregnancy, Transferred patients not admitted through the emergency department
- **Status:** Active (Will close on October 15, 2022)
- **Contact:** Samantha Underwood, underwos@ohsu.edu



ICECAP – Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients (a SIREN Network study)

This study will enroll comatose adult survivors of out of hospital cardiac arrest that have already been rapidly cooled using a definitive temperature control method.

Launched: September 2020 Site: Portland Adventist ED

- **ICECAP PI:** Daya, **ICECAP Co-I:** Julia Durrant (OHSU), Miko Enomoto (OHSU), Josh Lupton (OHSU & Portland Adventist), Marwan Mouammar (Portland Adventist), Matthew Neth (Portland Adventist), William Spurlock (Portland Adventist), **Coordinator:** Keeley McConnell
- Registered with ClinicalTrials.gov: NCT 04217551
- FDA IDE: William Meurer, G160072
- **Status:** Enrolling; **Enrolled: 48; All site total: 573**
- **Contact:** Keeley McConnell, mcconnke@ohsu.edu

For more information: <https://siren.network/clinical-trials/icecap>



BOOST-3 Brain Oxygen Optimization in Severe TBI Phase-3 Trial (a SIREN Network study)

BOOST 3 is a trial run through the nationwide SIREN Network. This study is comparing two strategies currently used for monitoring and treating patients with severe traumatic brain injury in the ICU. BOOST 3 allows for EFIC (Exception from Informed Consent) if an LAR is not present (within 6 hours).

Launched: March 16, 2020

- **BOOST-3 PI:** David Zonies, **SIREN PI:** Daya, **Coordinators:** Michael Seigneur (TRG), Jenny Cook EM Coordinator
- Registered with ClinicalTrials.gov: NCT03754114
- **Status:** Enrolling; **Enrolled: OHSU: 25; All site total: 406**
- **Contact:** Michael Seigneur, seigneum@ohsu.edu

For more information: <https://www.ohsu.edu/school-of-medicine/emergency/boost-3-study>

Covid PreVent Trial

Purpose: Evaluating a single treatment of very low dose thoracic radiation in patients with s/sx of severe COVID, but prior to intubation, to determine whether intubation can be avoided. Can be on other trials, get normal meds.

- **PI:** Ravi Chandra, Radiation Medicine
- **Inclusion:** >50 yo, s/sx severe COVID (fever, tachypnea, oxygen requirement), hospitalized and sx for less than 9 days
- **Exclusion:** Mechanical ventilation, prior RT or intrinsic pulmonary disease, CHF exacerbation within 6 months
- **Status:** On hold
- **Contact:** Ravi Chandra, chandrav@ohsu.edu

CLOSED STUDIES

ACTIV-4a (Antithrombotic Strategies in Hospitalized Adults with COVID-19 [AC-INPT])

Evaluating the effects of combining a P2Y12 inhibitor with anticoagulants for adults hospitalized for moderate to severe COVID-19. This is a continuation of the ACTIV-4 study, which evaluated prophylactic vs. therapeutic anticoagulation in adults hospitalized with COVID-19.

Launched: September 4, 2020
Study Duration: December 2021

- **PI:** Akram Khan, MD ; **Coordinators:** PRISM Research Team
- **Inclusion:** > 18 yo., COVID + and symptomatic, expected to require hospitalization for > 72 hours
- **Exclusion:** comfort care, ICU level of care (including high flow), ventilated, pregnant, low platelet or hemoglobin counts, contraindication to anticoagulation (i.e. recent stroke, bleeding disorder)

- **Status:** Closed, **Enrolled:** 24
- **Contact:** Akram Khan, khana@ohsu.edu ; Minn Oh, ohmi@ohsu.edu ; page 11912

HydraSense for Sepsis

A novel device for distal perfusion: currently enrolling in patients 6mo-65yo with fever, sepsis, and ESI 2-3.

Launched: June 24, 2019

- **PI:** David Sheridan
- **Status:** Completed; **Enrolled:** 563 total, 123 sepsis enrollments
- **Contact:** David Sheridan; sheridda@ohsu.edu

Digital Capillary Refill with HydraSense

Using a novel device (Hydrasense) to compare manual vs digital capillary refill: currently enrolling in patients 6mo-65yo.

This study requires NO work or input from RNs or MDs. The study team will work around staff with any patients they enroll to make sure and prioritize your time with them over the study.

Launched: September 12, 2018

- **PI:** David Sheridan
- **Status:** Completed; **Enrolled:** 563; Enrollment Goal: 600
- **Contact:** David Sheridan; sheridda@ohsu.edu

