April 2022 Updates on ED Clinical Trials

We are now two years into the pandemic and have developed new workflows and new normals. What is not new is your continued willingness to serve our community through both clinical and academic excellence. Thank you—this work cannot be done without you. Our research staff who come from multiple departments are also an integral part of our mission. They may ask for your assistance with study needs and, if busy, please let them know graciously or see if they can come back another time or have someone else help (reminder: many hope to grow up and work in your shoes). We welcome feedback and your involvement to ensure high-quality studies that integrate into our clinical workflow.
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

COVID-19 STUDIES

- Binax COVID + Flu Combo Card
- BinaxNOW
- Covid PreVent Trial (on hold)
- ACTIV-3 (TICO)
- ACTIV-4a (AC-INPT)
- ACTIV-4d (NECTAR)
- IVY-4

ACTIVE STUDIES

- STRATIFY
- AF CDS
- GUIDED-HF
- PACT
- KCENTRA (on hold)
- Fentalog (ToxIC)
- ICECAP
- BOOST-3
- HydraSense
- SAVE-O2
- FAST Exam
- Compartment Syndrome
- REASON3

OHSU & ADVENTIST STUDIES

- Binax COVID + Flu Combo Card
- BinaxNOW
- ICECAP

COVID-19 STUDIES

Clinical Evaluation of the BinaxNOW® COVID-19 Ag / Flu A & B Combo Card
Objective: To estimate the clinical sensitivity and specificity of the BinaxNOW® Ag Combo card against the reference method, Abbott RealTime SARS-CoV-2/Flu A & B, in patients suspected of COVID-19/Flu A & B infection by *any* healthcare provider (RN, NP, PA, *or* MD) using nasal swabs. Staff will collect 2 nasal swabs from each subject. One of the swabs will be shipped to the Sponsor's central laboratory for reference testing, while the other will be tested within 5 minutes of collection on the rapid AG COMBO card.

Launch: TBD **Sites: OHSU & Adventist**

Study coordinators will check with clinical staff on suspected COVID-19/Flu A & B patients between Monday – Thursday from 8:00-2:00 PM.

- **PI**: Bory Kea; **Coordinator**: Keeley McConnell
- **Inclusion**: Subject is suspected of COVID-19/FLU A & B infection by a healthcare provider.
- **Exclusion**: Subject is ≥ eight (8) days from symptom onset, Subjects with active nose bleeds or acute facial injuries/trauma, use of topical nostril treatments within 24 hours, nasal wash within the last 2 hours, currently enrolled in a study to evaluate an investigational drug, already participated in this study, unable/unwilling to provide informed consent, vulnerable populations (prisoners and pregnant woman).
- **Status**: Pre-Launch **Enrolled**:
- **Contact:** Keeley McConnell, Senior Clinical Research Coordinator: mcconnke@ohsu.edu

Clinical Evaluation of the BinaxNOW® COVID-19 Antigen (Ag) Card

Objective: To estimate the clinical sensitivity and specificity of the BinaxNOW® COVID-19 Ag card against the reference method, Abbott RealTime SARS-CoV-2, in patients suspected of COVID-19 infection by *any* healthcare provider (RN, NP, PA, *or* MD) using nasal swabs. Staff will collect 2 nasal swabs from each subject. Swabs will be shipped to the Sponsor's central laboratory for reference testing.

Launched: August 2020 Sites: OHSU & Adventist

Study coordinators will check with clinical staff on suspected COVID-19 patients (there is no time limit on symptom duration) between Monday – Friday from 9:00-4:00 PM.

- **PI**: Bory Kea; **Coordinator**: Keeley McConnell
- **Inclusion**: Subject is suspected of COVID-19 infection by a healthcare provider.
- **Exclusion**: Subjects with active nose bleeds or acute facial injuries/trauma, currently enrolled in a study to evaluate an investigational drug, already participated in this study, unable/unwilling to provide informed consent, vulnerable populations (prisoners and pregnant woman).
- **Status**: Enrolling; **Enrolled: 312**
- **Contact:** Keeley McConnell, Senior Clinical Research Coordinator: mcconnke@ohsu.edu

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

ACTIV-3 (Therapeutics for Inpatients with COVID-19 [TICO])

A platform designed for testing therapeutic monoclonal antibody agents for adults hospitalized for COVID-19

Launched: August 4, 2020
Study Duration: July 2022

- **PI**: Akram Khan, MD; **Coordinators**: PRISM Research Team
- **Inclusion**: > 18 yo, COVID + and symptomatic (< 12 days)
- **Exclusion**: received convalescent plasma, serious condition(s) present at enrollment (i.e. stroke, meningitis, encephalitis, congestive heart failure, DVT or PE)
- **Status**: ACTIVE, **Enrolled: 11**
- **Contact**: Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912

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:** ACTIVE, **Enrolled**: **20**
- **Contact**: Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912

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: 10**
- **Contact**: Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@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

- **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: 129**
- **Contact**: Akram Khan, khana@ohsu.edu ; Olivia Krol, krolo@ohsu.edu ; page 11912

ACTIVE STUDIES

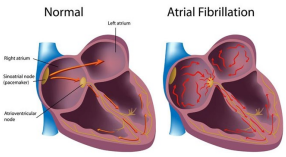
Tailored Dissemination and Implementation of Emergency Care Clinical Decision Support to Improve Emergency Department Disposition (STRATIFY)

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.

The Vanderbilt team leading the study will be on-site on the following dates:
OHSU: Thursday, April 14
HMC: Friday, April 15

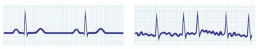
You are invited for a 20-30 min group session or individually as it fits your schedule. Food and drinks will be provided for you to eat on your own per OHSU guidelines, and we will have a Yeti travel mug for you too!

- **PI:** Bory Kea; **Study Coordinator**: Joy Kim
- **Status:** Conducting on-site visits
- **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).



Launched: **OHSU - January 11, 2022; HMC – April 4, 2022**

- **PI:** Bory Kea; **Study Coordinator**: Joy Kim
- **Inclusion:** >18 years, OAC naïve
- **Status:** Enrolling; **Enrolled: Quantitative – 15; Qualitative – 2 patients, 4 providers**
- **Contact:** Joy Kim, kimjoy@ohsu.edu

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**

- **PI:** Bory Kea; **Study Coordinator**: Joy Kim
- **Inclusion:** Diagnosed with HF and/or received loop diuretics in ED.
- **Status:** Enrolling; **Enrolled: 5**
- **Contact:** Joy Kim, kimjoy@ohsu.edu

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: 54**
- **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, **Coordinators**: 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**: Joy Kim
- **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:** Resuming in Feb. 2022; **Enrolled: 35**
- **Contact:** Joy Kim, kimjoy@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: 41; All site total: 456**
- **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: 20; All site total: 308**
- **Contact:** Michael Seigneur, seigneum@ohsu.edu

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

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**: Sheridan; **Coordinator**: Jordan Gillespie
- **Status**: Enrolling; **Enrolled**: **524**; Enrollment Goal: 600
- **Contact**: Jordan Gillespie, gillesjo@ohsu.edu

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**: Sheridan; **Coordinator**: Jordan Gillespie

- **Status**: Enrolling; **Enrolled**: **524 total, 110 sepsis enrollments**
- **Contact:** Jordan Gillespie; gillesjo@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
- **Contact**: Samantha Underwood, underwos@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

- **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:** Active
- **Contact:** Nikolai Schnittke, schnittk@ohsu.edu

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

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:** Active
- **Contact:** Nikolai Schnittke, schnittk@ohsu.edu ; Bryson Hicks, hicksbr@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:** Active
- **Contact:** Nikolai Schnittke, schnittk@ohsu.edu

CLOSED STUDIES

Beckman Heart Failure

The purpose of this study is to collect blood samples for the evaluation of the Access Natriuretic Peptide assay as an aid in the diagnosis of acute HF and assessment of severity of individuals suspected of having HF.

Launched: May 6, 2021

- **PI**: Bory Kea, **Coordinator**: Joy Kim
- **Inclusion:** ≥21 years, presenting with a suspicion of acute HF
- **Exclusion**: Dyspnea not secondary to HF (lung disease, trauma, etc.), Stage 4 or 5 CKD, chronic dialysis, participation in a clinical study that may interfere with participation in this study.
- **Status**: Closed; **Enrolled: 4**