Learning to Care for Those in Harm's Way

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COVID-stripping Blood Filters May Prove Effective Treatment for Sepsis, other Blood-borne Pathogens
Uniformed Services University researchers enter cooperative agreement for clinical testing

Bethesda, Md. – Two new blood filters, proven to safely and quickly remove a range of pathogens, including COVID-19, from blood during pre-clinical testing, will now be further evaluated to determine their efficacy in patients under a new cooperative agreement between the Uniformed Services University (USU) and the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF).

USU and HJF researchers, led by Army Col. (Dr.) Kevin Chung and Danielle Clark, Ph.D., respectively, will begin clinically testing these technologies -- the Seraph® 100 manufactured by ExThera Medical of California, and the GARNET, developed by BOA Biomedical Inc., of Boston. The agreement will expand on the Defense Advanced Research Projects Agency's $150 million Dialysis-Like Therapeutics research program that previously helped develop a pathogen agnostic extracorporeal blood cleansing medical countermeasure capable of responding to any infectious outbreak. The success of that program has opened the door for multiple clinical studies evaluating blood purification using the two filters.

Chung, who is professor and chair of USU's Department of Medicine, will serve as the principal investigator. The study will build upon data from Chung's oversight of two patients who received ExThera's Seraph® 100 therapy in April 2020, along with more than 200 patients who were treated under an FDA Emergency Use Authorization after that time. The agreement calls for expansion on the earlier trial to research effectiveness and impact and is designed to take advantage of USU's unique nationwide faculty and campus.

"We already know both filters remove COVID-19 from pre-clinical studies. Now, we will evaluate both for COVID patients treated under the EUA to see if that translates into clinical benefit," said Chung.

Simultaneously, the researchers are planning a randomized controlled trial in general sepsis for both technologies to move towards FDA approval, if shown to be effective. The first step is a feasibility study. If one or both turn out to be efficacious, the team will look at conducting a pivotal trial that would be required for FDA approval to treat sepsis from any pathogen.

The cooperative agreement is also a result of the Defense Health Agency-approved DoD COVID RESPONSE Consortium (Rapid Evaluation and Study of the Pandemic Outbreak Nationally by Sustaining and leveraging prolonged field care research Efforts), proposed by Chung. USU's The American Genome Center (TAGC) will provide support under the agreement, as will the HJF-administered Austere Environments Consortium for Enhanced Sepsis Outcomes (ACESO).

"Broad spectrum pathogen removal as an adjunct to standard therapy to help achieve source control in the bloodstream could represent paradigm shift in the way we manage sepsis," Chung said. "These

devices do not care how often COVID mutates or if we are dealing with the next emerging pathogen. We are looking forward to systematically evaluating these novel technologies to determine clinical efficacy."

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About the Uniformed Services University of the Health Sciences: The Uniformed Services University of the Health Sciences, founded by an act of Congress in 1972, is the nation's federal health sciences university and the academic heart of the Military Health System. USU students are primarily active duty uniformed officers in the Army, Navy, Air Force and Public Health Service who receive specialized education in tropical and infectious diseases, TBI and PTSD, disaster response and humanitarian assistance, global health, and acute trauma care. USU also has graduate programs in oral biology, biomedical sciences and public health committed to excellence in research. The University's research program covers a wide range of areas important to both the military and public health. For more information about USU and its programs, visit *www.usuhs.edu*.