

# Serum biomarker for stratifying patients in septic shock clinical trials



Center for Technology Commercialization

## TECHNICAL FIELD

Diagnostic: Septic shock (2007-0406)

## BACKGROUND

Sepsis is a severe medical condition resulting from the immune system's response to an infection. It is usually developed by people who are very young or very old, have weakened immune systems, are wounded or injured, have addictive habits, or are receiving certain invasive treatments or examinations. It has become more common in hospitals because of the advances associated with medical treatments, the increased number of elderly and cancer patients, and the widespread use of antibiotics. Septic shock is sepsis complicated by a low blood pressure that does not respond to standard treatment. Also associated are problems with one or more organs, including the heart, lungs, kidneys, and liver. As a result, the body does not get enough oxygen. The death rate for patients with septic shock is 50%.

Currently, there exists no method for stratifying clinical trials for potential treatments of septic shock. As a result, patients that would respond well to standard treatment are exposed to high-risk therapeutics that would add no benefit to their recovery. This technology provides a marker that identifies patients that will benefit from the current standard of care, thus excluding them from clinical trials. This also provides a more accurate test group for trial medications.



## TECHNOLOGY

Currently, there exists no method for stratifying pediatric septic shock clinical trial candidates. Specifically, there is no way to eliminate patients that would have a high likelihood of a positive outcome with standard care from these trials. Dr. Wong at CCHMC has demonstrated that there is a marked increase in a specific protein in the serum of a non-survivor cohort of septic shock patients. Studies have also established a threshold value for serum levels of this protein, such that patients below this value will likely have a good outcome with respect to septic shock (95% certainty).

The strategy would involve exclusion of patients that would otherwise qualify for trials, except that they have an admission marker serum level below the threshold value. This would improve the risk-to-benefit ratio of the study compound by prospectively eliminating patients that would otherwise have a high likelihood of doing well with standard care alone.

Recently, Dr. Wong received additional validation of the marker after examining a cohort of patient samples collected by an outside group. The samples from this cohort had their marker serum levels measured using a different method than patients at CCHMC. The results, however, were remarkably similar to those identified previously. A predictive value for a positive outcome was determined to be 94%.

Our goal is to develop this technology into a rapid screening kit that would be used at admission to determine whether or not a patient will respond to standard septic shock therapy and we are seeking collaborators to help us accomplish this.

## APPLICATIONS

Stratifying septic shock clinical trials for pediatric, and potentially adult, patients

## ADVANTAGES

- Excludes patients that would do well without the trial compound
- Improves risk-to-benefit ratio of studies
- Easy to measure
- Eliminates unnecessary exposure to trial medications

## INVESTIGATOR

Hector Wong, MD  
Critical Care  
Cincinnati Children's Hospital Medical Center

## STATUS

Patent applications pending.

## CONTACT

Korie Counts, PhD  
Technology Manager  
[korie.counts@cchmc.org](mailto:korie.counts@cchmc.org)  
513-636-6736

# Serum biomarker for stratifying patients in septic shock clinical trials

## THE INVENTOR

Hector Wong, MD  
Critical Care

## BACKGROUND

**MD:** University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School, Piscataway, NJ, 1989.

**Residency:** Department of Pediatrics, George Washington University School of Medicine, Children's National Medical Center, Washington, DC, 1990-1992.

**Fellowship:** Clinical Fellow, Department of Anesthesiology, Division of Pediatric Critical Care Medicine, University of Pittsburgh School of Medicine, Children's Hospital of Pittsburgh, Pittsburgh, PA, 1992-1995;  
Research Fellow, Department of Pharmacology, University of Pittsburgh School of Medicine, Pittsburgh, PA, 1992-1995.

**Certification:** Diplomate, National Board of Medical Examiners, 1990;  
Diplomate, American Board of Pediatrics, 1993;  
Diplomate, American Board of Pediatrics: Sub-Board of Pediatric Critical Care Medicine, 1996.



## AWARDS AND HONORS

Awarded "2005 Best Doctors"  
Awarded "2004 Best Doctors"  
Phi Eta Sigma (Academic Honor Society), 1982  
Honorable Mention, Academic Collegiate All-America in Baseball, 1984  
Honorable Mention, Academic Collegiate All-America in Baseball, 1985  
Alpha Omega Alpha, 1988  
Society of Critical Care Medicine Educational Scholarship, 1994  
Society of Critical Care Medicine Educational Scholarship, 1995  
Society of Critical Care Medicine Specialty Award (Pediatrics), 1997  
Mentored Clinical Scientist Development Award, National Institutes of Health, 1997  
Presidential Citation, Society of Critical Care Medicine, 2000  
Presidential Citation, Society of Critical Care Medicine, 2001  
Research Citation, Society of Critical Care Medicine, 2001  
Presidential Citation, Society of Critical Care Medicine, 2002  
Best Doctors selection, 2002  
Presidential Citation, Society of Critical Care Medicine, 2003  
Best Doctors selection, 2003

## PROFESSIONAL ORGANIZATION MEMBERSHIPS

Diplomat, National Board of Medical Examiners  
Diplomat, American Board of Pediatrics  
Member, Society of Critical Care Medicine  
Member, Shock Society  
Diplomat, American Board of Pediatrics, Sub-Board of Pediatric Critical Care Medicine  
Member, Cell Stress Society International  
Member, American Thoracic Society  
Member, Society for Pediatric Research