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Christiana Care chosen for new clinical study to benefit trauma patients

Landmark clinical study: Treatment to begin at accident scene

WILMINGTON, DE (Sept. 23, 2003) Christiana Care's Trauma Center at Christiana Hospital is participating in a national clinical trial to evaluate the effectiveness of PolyHeme®, an oxygen-carrying blood substitute. The study tests Polyheme's efficacy in increasing the survival of critically injured and bleeding patients. Under the study protocol, treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during a 12-hour post injury period in the hospital. Since blood is not presently carried in ambulances, the use of PolyHeme in these settings has the potential to address a critical unmet medical need for an oxygen-carrying solution where blood is currently not available. The study will compare the survival rate of patients receiving PolyHeme to that of patients who receive the current standard of care, which is saline solution.

"We are excited to be included in this groundbreaking clinical trial," commented Gerard Fulda, M.D., the principal investigator. "Trauma-related injuries are a leading cause of death among Americans under 45 years old, according to the CDC's National Center for Injury Prevention and Control. In fact, almost one in five trauma patients die from their injuries. If we can begin to treat these patients very early with an oxygen-carrying solution and keep their hemoglobin levels up, we may see more survivors," he added.

Because the patients eligible for this study are unlikely to be able to provide prospective informed consent due to the extent and nature of their injuries, the study will be conducted under federal regulations that allow for clinical research in emergency settings using an exception from the requirement for informed consent (21 CFR 50.24).

The treatment under study, PolyHeme®, is a universally compatible, immediately available, oxygen-carrying resuscitative fluid designed for use in urgent blood loss when blood is not immediately available. It has been studied extensively in trauma trials in the hospital setting. PolyHeme is manufactured by Northfield Laboratories Inc., of Evanston, Illinois.

To learn more about this trial, Christiana Care will sponsor the following community meetings:



Tues., Sept. 23, 7 p.m., Christiana Hospital, Room 1100, 4755 Ogletown-Stanton Rd., Newark

Thurs., Sept. 25, 7 p.m., Hockessin Memorial Hall, 1225 Old Lancaster Pike, Hockessin

About Christiana Care

Christiana Care Health System, which traces its roots back to 1888, is one of the region's largest not-for profit health care providers, serving the people of Delaware as well as neighboring Maryland, Pennsylvania and New Jersey. A teaching hospital, Christiana Care is recognized as a regional center for excellence in cardiology, cancer and women's health services, as well as Level-I trauma care and Level-3 neonatal intensive care (both highest intensity). Christiana Care operates two hospitals, long-term and transitional care services and an extensive range of outpatient and home health services. Last year, Christiana Care provided \$42.8 million of charity care.

About Northfield Laboratories

Northfield Laboratories is a leading developer of an oxygen-carrying blood substitute. Its product, PolyHeme, is the only blood substitute that has been rapidly and safely infused in clinical trials in sufficiently massive quantities to be considered useful in the treatment of large volume blood loss in trauma and surgical settings. PolyHeme requires no cross matching, making it immediately available and compatible with all blood types, and has an extended shelf life of over 12 months.