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Contacts: **Leni Kirkman, University Hospital**
210-358-2335
Dewey Mitchell, BAMC
210- 916-3016

S.A. trauma centers release blood substitute study results *-Researchers find comparable survivability in both PolyHeme and Control groups-*

San Antonio (November 7, 2007) — Every second counts for severely injured and bleeding patients, so finding the safest and quickest way to stabilize those suffering from massive blood loss is a top priority for emergency responders and trauma surgeons. For this reason, University Hospital and Brooke Army Medical Center (BAMC) were two of 32 Level I trauma Centers across the United States taking part in a study involving the use of PolyHeme[®], an investigational blood substitute, in trauma patients suffering shock due to massive blood loss. Today, The University of Texas Health Science Center and U.S. Army trauma surgeons, heading up the San Antonio arm of this national study, released results which indicate that patients receiving PolyHeme did about the same as patients who received the current standard of care for shock – saline solution given intravenously. However, after analyzing the national data, they conclude PolyHeme may have some increased risks when compared to blood.

There were 714 total trauma patients treated at all 32 U.S. study sites. Of this figure, 19 were from the South Texas trauma region. (14 enrolled at University Hospital, 5 at BAMC). Nationally, 46 of the 349 patients who were treated with PolyHeme died, and 36 of the 365 patients who received saline solution died. Over the course of the study, there were three deaths among patients enrolled at University Hospital (2 received PolyHeme, 1 was given saline solution) and there were two deaths at BAMC, both in the PolyHeme group. Researchers agree the difference in deaths between the two groups of patients is not statistically significant, that is, it's not greater than what would be expected by chance. Nationally, a greater number of heart attacks were reported in patients who received PolyHeme (11) than those who received saline (3).

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POLYHEME STUDY RESULTS

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At University Hospital two patients suffered heart attack, one in the PolyHeme group and one in the saline group.

STUDY DESIGN

The study was conducted under a federal regulation that allows research in certain emergent, life-threatening situations using a community consultation plan.

This federal regulation allows an Institutional Review Board (IRB) to approve a clinical trial without requiring initial informed patient consent provided specific criteria are met. These criteria include:

- Patients must be in a life-threatening situation.
- The experimental treatment must offer patients the potential for direct clinical benefit in the form of increased survival.
- The risks are reasonable.
- Without an exception from informed consent the research could not be conducted.
- The community in which the study is being conducted is consulted and the findings from the study are reported back to the community.

This study enrolled only patients suffering hemorrhagic shock (massive blood loss), who were at risk of dying. Hemorrhagic shock causes the patient's blood pressure to become dangerously low. The lack of blood-carrying oxygen to the body's organs causes them to have difficulty functioning and can eventually cause a total shut-down.

PolyHeme is a universally compatible, immediately available oxygen-carrying resuscitative fluid designed to treat hemorrhagic shock where blood transfusion is required, but blood is not available.

Treatment began in the helicopter by San Antonio AirLife crews, either at the scene of the injury or while in flight to University Hospital or BAMC. Treatment continued through a 12-hour post-injury period in the hospital.

The AirLife patients enrolled in this study were randomly selected to receive either PolyHeme or IV saline solution. Patients, and their legally authorized representatives or family members, were notified at the earliest opportunity.

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WHO WAS ENROLLED?

Table 1
National Study Patient Characteristics

	PolyHeme®	%	Saline Control	%
Age	36.3	---	37.9	---
Gender				
Male	272	78%	289	79%
Female	78	22%	75	21%
Race				
Caucasian	160	46%	170	47%
African American	124	35%	120	33%
Hispanic	53	15%	61	17%
Asian	10	3%	7	2%
Other	3	<1%	6	2%

Table 2
University Hospital
Study Patient Characteristics

14 subjects	PolyHeme®	%	Saline Control	%
Age	18-63	---	23-62	---
Gender				
Male	5	71%	7	100%
Female	2	29%	0	0%
Race				
Caucasian	4	71%	1	14%
African American	0	0%	0	0%
Hispanic	3	29%	6	86%
Asian	0	0%	0	0%
Other	0	0%	0	0%

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**Table 3
Brooke Army Medical Center
Study Patient Characteristics**

5 subjects	PolyHeme®	%	Saline Control	%
Age	15-49	---	19-49	---
Gender				
Male	2	67%	2	100%
Female	1	33%	0	0%
Race				
Caucasian	1	33%	2	100%
African American	1	33%	0	0%
Hispanic	1	33%	0	0%
Asian	0	0%	0	0%
Other	0	%	0	0%

WHY STUDY TRAUMA PATIENTS?

This type of groundbreaking clinical research is vitally important to improve injury prevention efforts, as well as survival and quality of life for trauma patients. Injuries destroy the health, lives and livelihoods of millions of people:

- Trauma-related injuries are the leading cause of death among all Americans under the age of 45.
- In Bexar County and South Texas, more children die from injury than from all other causes of death – combined.
- Each year, trauma accounts for 37 million ER visits and 2.6 million hospital admissions.
- Injuries in a single year cost the U.S. \$406 billion - \$326 billion in lost productivity and \$80. 2 billion in medical costs.

CONSULTING THE COMMUNITY

Fourteen community meetings were held in San Antonio and throughout the 22-county

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trauma region, to inform and consult the community, before the study was given final approval by the UT Health Science Center and BAMC IRBs. Notices were made of meetings so all individuals interested in learning more about this study, and who wished to offer feedback, could do so.

Now that the study has been completed, and the results have been analyzed and presented at the annual American College of Surgeons meeting last month, local researchers are providing the results of the study to this participating community, as required by the exception to informed consent regulation.

Additional information is also available by contacting the UT Health Science Center project coordinator at the UT Health Science Center Department of Surgery, MC: 7740, 7703 Floyd Curl, San Antonio, Texas 78229-3900 or by phone at (210)567-3623 or the BAMC project coordinator at the Institute of Surgical Research, 3400 Rawley E. Chambers Ave, Fort Sam Houston, TX 78234, or by phone at (210)916-8192.