

**St. Luke's Medical Center**  
**Bethlehem, PA**



REGIONAL  
RESOURCE-LEVEL I  
**TRAUMA**  
CENTER

A member of the University of Pennsylvania Trauma Network

RECEIVED  
MEDICAL AFFAIRS DEPT.  
DEC 16 2004

**RE: A Phase III, Randomized, Controlled, Open-Label, Multicenter, Parallel Group Study Using Provisions for Exception from Informed Consent Requirements Designed to Evaluate the Safety and Efficacy of Poly SFH-P Injection [Polymerized Human Hemoglobin (Pyridoxylated), PolyHeme®] When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries Beginning in the Prehospital Setting (SLHN 2004-20)**

Mr. Manny Changalis,

December 15, 2004

Attached is a report documenting proof of our communication to the community as previously described at the July 13, 2004 IRB meeting. In addition, we have attached copies of letters from the Medical Advisory Committees at the state and regional level. We have been granted approval by all three committees to conduct the PolyHeme study in the Eastern Region which includes Lehigh and Northampton County as well as the Bucks County Region.

We greatly appreciate your consideration of this important study and welcome any questions or comments you may have regarding our efforts.

Sincerely,

James Cipolla, MD

cc: GAW

## PolyHeme Community Consultation/Public Disclosure (CC/PD) Activity Report

List of Completed Activities	Date	Result, if applicable
Comprehensive article appeared in Network Pulse	September/October Issue	
Information posted on network Intranet	September 7, 2004 and ongoing	
Met with Jehovah's Witnesses Liason to discuss study details	September 22, 2004	Made aware by Joseph Brazil (liasion) that JW community is well informed of this study due to Lehigh Valley Hospital's participation. Reviewed details of study. Bracelets distributed (to deny participation).
Public Notice was placed in local print news publications including time and location of public meeting and investigator contact information	<i>Express Times</i> 9/12, 9/22, and 9/26, 2004 <i>East Penn Press</i> ** 9/15, 9/22, 9/29, 2004	
Public Meeting Held in Laros Auditorium, St. Luke's Hospital	October 5, 2004	Attended by 5 community members including representatives from the Jehovah's Witness community. Satisfaction was confirmed regarding our CC/PD efforts on behalf of their community and encouragement was received to conduct the study at our hospital. They offered and will be presenting at our TRIMM ( <u>T</u> R <u>A</u> uma <u>I</u> nterdisciplinary <u>M</u> orbidity and <u>M</u> ortality) Conference on Dec 16, 2004.
Contact with local city and county government via letter to inform officials of St. Luke's participation in PolyHeme Ambulance Study	November 14, 2004	

## PolyHeme Community Consultation/Public Disclosure (CC/PD) Activity Report

List of Completed Activities	Date	Result, if applicable
Link placed on St. Luke's Hospital and Health Network website to distribute information and create a forum for comments and questions via email	September 7, 2004 and ongoing	
Posters and fact sheets containing general information about the trial developed and distributed to all lectures, presentations, health fairs, blood pressures and other public community functions sponsored or attended by SLHHN (approx. 150 to 200 events per year)	September 2004 and ongoing	
Posters displayed and fact sheets distributed at three malls in the Lehigh Valley where St. Luke's has permanent presence and provides services/screening/learning opportunities as described above (Palmer Park, Westgate, and South Malls)	September 7, 2004 and ongoing	
Posters displayed and fact sheets distributed at all network-owned physician practices (approx. 40) throughout the Lehigh Valley	September 7, 2004 and ongoing	
A public notice with voice over was broadcast during Talk With Your Doctor (TWYD), St. Luke's locally produced health information program	September 23, 2004	
Posters displayed and fact sheets distributed via St. Luke's mobile health and dental services, HealthStar I and HealthStar II where and when appropriate	September 7, 2004 and ongoing	
News releases distributed to all regional major and minor media	September 8, 2004	
Interviews by Channel 69 for broadcast that evening with the principal investigator	September 9, 2004	
4 hour educational Train the Trainer session for participating EMS squads	October 13, 2004	Participants attended from 9 EMS squads + PennStar. Education continues and is going very well at each site. Refresher courses will be held periodically as needed with the first set of refreshers to occur in January, 2005.

**The Future Is Here**  
Continued from page 1

In addition, St. Luke's was the first hospital in Pennsylvania to perform robotically-assisted surgery. "It's our one goal to provide the best possible patient care that we can," says Marc Granson, MD, chief of Surgery, St. Luke's Hospital & Health Network. "This kind of advanced surgical system, and the expertise to use it effectively, puts us at the forefront of technology for patient care. We do more procedures with the da Vinci system than any other hospital in the state, and we have the most experience with a wide variety of surgeries. In fact, we are the only hospital in the region to perform heart surgery with the da Vinci system. It is the best available, and it enhances the ability of our surgeons to do their very best work for the benefit of our patients. Today, there is very little we can't do at St. Luke's."

"That goes for all of our clinical areas of excellence," adds Schantz. "We are the region's most honored heart program with 11 national awards; Dr. Riley and the St. Luke's Cancer Center are leading the way in research and clinical trials for a solid tumor vaccine; our Trauma Center has been chosen to participate in a national trial to evaluate an oxygen-carrying blood substitute called PolyHeme®; and we have the busiest obstetrical program in the region with more than 4,200 annual births.

"These are all facts you will find in our new image campaign. At St. Luke's, the future really is here." | end

Thank you for your contributions to the new *Pulse*.

Please continue to submit story and suggestions for publication to: suggestions@networkpulse.com. Although we can't be held liable for any errors, even the gravest, we'll use all feedback as possible.

Thank you

**Prize winners from the Family Picnic – congratulations!**

Monika Berger, Bethlehem	\$25 Gift Card, Wal-Mart/Sam's
Betty Benulis, Miners	\$25 Gift Card, Wal-Mart/Sam's
Steve Schaffer, Bethlehem	\$25 Gift Card, Wal-Mart/Sam's
Luz H. Herrera, Bethlehem	\$50 Gift Card, Wal-Mart/Sam's
Denise Hulbert, Allentown	\$75 Gift Card, Best Buy
Eileen Catino, Bethlehem	\$75 Gift Card, Best Buy
Doris Bersch, Physician Group	\$75 Gift Card, Home Depot
Vicki Mayk, VNA/Quakertown	\$75 Gift Card, Home Depot
Linda Leschinger, Bethlehem	\$75 Gift Card, Target
Elizabeth Engler, VNA	\$75 Gift Card, Target
Donna Green, Bethlehem	\$75 Gift Card, Target
Ervin Kessler, Allentown	\$75 Gift Card, Target
Dennis J. Steckenburg, Bethlehem	\$100 Gift Certificate, Lehigh Valley Mall
Kathy Lentz, VNA	\$100 Gift Certificate, Lehigh Valley Mall
Matthew Martinez, Bethlehem	\$200 Gift Certificate, Lehigh Valley Mall
Peggy Stiely, Miners	\$300 Gift Certificate, Lehigh Valley Mall

**Services**

**St. Luke's chosen to study investigational blood substitute in trauma patients**

St. Luke's Hospital is one of a select number of Level I trauma centers in the United States chosen to participate in a groundbreaking national clinical trial to evaluate the safety and efficacy of PolyHeme®, an oxygen-carrying blood substitute, in treating critically injured and bleeding patients.

"We are excited to be included in this groundbreaking clinical trial," says James Cipolla, MD, the principal investigator. "Nationally, almost one in five trauma patients die from their injuries. If we can begin to treat patients very early with an oxygen-carrying solution and keep their hemoglobin levels up, we may see more survivors."

Although St. Luke's is not the only trauma center in the Valley to participate in this study, it is the only trauma center to utilize area EMS ground transport in addition to air transport. "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," explains Cipolla. "This has the potential to help many seriously injured patients in the Lehigh Valley."

Under the study protocol, treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance/aircraft, and continue during a 12-hour post-injury period in the hospital. 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.

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).

Use of this provision in a study protocol is granted by the Institutional Review Board (IRB) responsible for the initial and continuing review and approval of the research study. Such a decision is based on the finding and documentation that, among other things, patients are in a life-threatening situation requiring emergency medical intervention, currently available treatments are | continued on page 4

## United Way mobilizes community around critical issues

by Peter Carpino, president, United Way of the Greater Lehigh Valley

Thank you for your very generous support of United Way's efforts to improve the Lehigh Valley's quality of life. In what follows, I hope to give you a sense of *how differently this United Way is doing business* and how other United Ways and United Way of America increasingly are viewing it as a model.

Three years ago, your United Way made a strategic decision to *move beyond being simply a conduit* that raises and distributes funds and to *take a proactive leadership role* in mobilizing the community around critical issues like early childhood education and services for the aging... issues that touch us all.

While United Way certainly will continue to fund agency programs -- this year, it maintained program funding at the prior year's level of \$5.5 million... no small feat, given the nominal increase in the campaign -- it's also earmarking funds for some special initiatives. Here are three examples:

♦ **Early Childhood Education.** National research shows that the quality of childcare is higher in those centers that are accredited. When United Way learned that only 18 of the 115 local, non-profit childcare centers were accredited, it decided to invest \$200,000 so more centers could earn accreditation. Last year, 13 centers began the accreditation process; eight more were added this year. By helping these centers become accredited, United Way is playing a direct role in helping improve the overall quality of the Lehigh Valley's early care and education system. This added investment is over and above the \$700,000 that United Way currently provides to nine local centers to help children of the working poor receive supervised day care so their parents can hold a job. | continued on page 6

## VNA's Nurse-Family Partnership program holds first recognition ceremony

The Nurse-Family Partnership (NFP) program of the Visiting Nurse Association of St. Luke's recently held its first recognition ceremony. Twenty-seven young mothers were honored for their participation in the program that offers education and support to first-time, at-risk mothers. The young women were recognized for having healthy babies, for navigating the first two years of motherhood with success and for making life changes that include continuing their educations or getting jobs.

The NFP changes the lives of first-time, low-income mothers, children and families through a long-term home visitation program by registered nurses. The program emphasizes changing behavior and its impact is felt for generations. Nurses visit families for a 30-month period, beginning in early pregnancy, with visits continuing until babies are two years old. Through regular visits, nurses teach and support new families by implementing a national, research-based program with proven positive outcomes.

The NFP Program serves families in the City of Bethlehem, parts of Northampton County, Lehigh County (excluding the City of Allentown) and lower Carbon County. The program began in October 2001 with a four-year prevention grant from the Pennsylvania Governor's Partnership for Children. The Nurse-Family Partnership has received strong support from the business community, private individuals and local churches. | end

## Blood Substitute Continued from page 2

unproven or unsatisfactory, obtaining informed consent is not feasible, potential risks are reasonable in relation to what is known of the condition, participation in the study could provide a direct benefit to the patients enrolled, and the research could not be practicably conducted without an exception from informed consent requirements.

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 in trauma trials in the hospital setting. PolyHeme® is manufactured by Northfield Laboratories Inc., of Evanston, Illinois.

### PolyHeme® at a glance:

- ♦ If you are at least 18 years old and injured, not obviously pregnant AND have lost a large amount of blood you might receive an experimental blood substitute in the ambulance called PolyHeme®
- ♦ You have the right to refuse participation in this study by obtaining a bracelet (call 1-800-755-1626 to obtain a bracelet)

There are potential risks of this study:

- ♦ risk of hepatitis and HIV
- ♦ risk of kidney or liver damage
- ♦ risk of rash
- ♦ risk of increased blood pressure

There are potential benefits of this study:

- ♦ there is a possible benefit that receiving PolyHeme® in the ambulance might increase your likelihood of survival
- ♦ your participation in this study may help patients in the future

If you have any questions, please call 1-800-755-1626, email [polyheme@slhn.org](mailto:polyheme@slhn.org) or log on to [www.slhnn.org](http://www.slhnn.org). | end



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## PolyHeme Trauma Trial

- [At-a-Glance Facts](#)
- [Community Meeting](#)
- [Exception from Informed Consent](#)
- [Frequently Asked Questions](#)
- [Study Backgrounder](#)
- [Express Your Opinion](#)

St. Luke's Hospital is one of a select number of Level I trauma centers in the United States chosen to participate in a groundbreaking national clinical research trial to evaluate the life-saving ability of PolyHeme®, an oxygen-carrying blood substitute, in treating severely injured and bleeding patients.

Under the study procedures, treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance/aircraft, and continue for 12 hours after the injury in the hospital. 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 (salt water).

Because the patients who meet the study requirements are unlikely to be able to give his/her informed consent in advance 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).

Use of this exception in a study procedure is granted by the Institutional Review Board (IRB) responsible for the initial approval of the research study. Such a decision is based on the finding that, patients are in a life-threatening situation requiring emergency medical care, currently available treatments are unproven or unsatisfactory, obtaining informed consent is not possible, potential risks are reasonable in relation to what is known of the condition, participation in the study could provide a direct benefit to the patients participating, and the research could not be practicably conducted without an exception from informed consent requirements. PolyHeme® is a universally compatible (it can be given to any patient regardless of blood type), immediately available, oxygen-carrying blood substitute made from human blood. It is designed for immediate treatment when blood is not available. PolyHeme® is manufactured

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**BEST PLACE to work i**

by Northfield Laboratories Inc., of Evanston, Illinois.

**PolyHeme® at-a-glance**

- If you are at least 18 years old and injured, not obviously pregnant **AND** have lost a large amount of blood you might receive an experimental blood substitute in the ambulance/aircraft called PolyHeme®
- You have the right to refuse participation in this study by obtaining a bracelet (call 1-800-755-1626 to obtain a bracelet)
- There are potential risks of this study
  - Risk of hepatitis and HIV
  - Risk of kidney or liver damage
  - Risk of rash
  - Risk of increased blood pressure
- There are potential benefits of this study
  - There is a possible benefit that receiving PolyHeme® in the ambulance/aircraft might increase your likelihood of survival
  - Your participation in this study may help patients in the future

If you have any questions, please call 1-800-755-1626. A public meeting regarding PolyHeme® is scheduled for October 5, 2004 at 7 pm in Laros Auditorium, St. Luke's Hospital – Bethlehem Campus.

Principal Investigator: James Cipolla, MD  
Contact Information: 1-800-755-1626, [polyheme@slhn.org](mailto:polyheme@slhn.org)  
Sponsor: [Northfield Laboratories Inc.](#)

***Click on any of the subjects below for more information.***

<a href="#">At-a-Glance Facts</a>	<a href="#">Community Meeting</a>	<a href="#">Exception from Informed Consent</a>
<a href="#">Frequently Asked Questions</a>	<a href="#">Study Backgrounder</a>	<a href="#">Express Your Opinion</a>

**Community Meeting**

October 5, 2004  
7 – 8 pm  
Laros Auditorium  
Doctors' Pavilion  
St. Luke's Hospital  
801 Ostrum Street  
Bethlehem, PA 18015

**Exception From Informed Consent**

The U.S. Food and Drug Administration (FDA) under regulations called 21 Code of Federal Regulations 50.24 specifies the conditions under which an exception from informed consent may be obtained. The Institutional Review Board (IRB) associated with each hospital approves its use locally.

[Click here for more information from the U. S. Food and Drug Administration about the exception from informed consent.](#)

## **Frequently Asked Questions**

### **1. Why is this study being conducted?**

To evaluate the lifesaving ability of PolyHeme® when given to severely injured and bleeding patients starting at the scene of injury.

### **2. What is the title of this study?**

A Phase III, Randomized, Controlled, Open-Label, Multicenter, Parallel Group Study Using Provisions for Exception from Informed Consent Requirements Designed to Evaluate the Safety and Efficacy of Poly SFH-P Injection [Polymerized Human Hemoglobin (Pyridoxylated) PolyHeme®] When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries Beginning in the Prehospital Setting.

### **3. What is hemorrhagic shock?**

A condition in which a patient has experienced massive blood loss.

Shock is a life-threatening condition that might include:

- Dangerously low blood pressure
- Internal organs not receiving enough oxygen and have difficulty functioning, which could lead to death

### **4. What is the design of this study?**

Patients in hemorrhagic shock will begin to receive either salt water (saline), which is the standard of care (control), or PolyHeme® (investigational/experimental treatment). Treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance/aircraft, and continue for 12 hours after the injury in the hospital.

In the hospital, patients in the standard of care/control group will receive salt water (saline) for hydration and blood if necessary to boost oxygen delivery levels. Unlimited doses of each are allowed.

Patients in the treatment group will receive salt water (saline) for hydration and PolyHeme® to boost oxygen delivery levels. The maximum dose of PolyHeme® will be six units during the first 12 hours. Blood will be used thereafter if oxygen delivery levels need to be increased.

**5. Why is there a need for improvement in the way trauma patients are treated now?**

Trauma is the leading cause of death among Americans under the age of 45. Currently the only available treatment for hemorrhagic shock, when blood is not available, is the infusion of a solution such as saline, which does not carry oxygen. Therefore, when blood is not immediately available, use of an oxygen carrier such as PolyHeme® may restore adequate circulating levels of hemoglobin (the oxygen-carrying protein in blood) and potentially improve patient survival.

**6. What is the current standard of care? How are trauma patients usually treated?**

Patients are given salt water (saline) at the scene or in the ambulance/aircraft. When they arrive at the hospital, they are given blood after typing and cross-matching is accomplished.

**7. Who would be eligible for the study?**

- Patients who have lost a large amount of blood and are in shock
- Patients who are at least 18 years old
- Patients who have severe injuries

**8. Who would be excluded from the study?**

- Women who are obviously pregnant
- Patients with severe brain injuries
- Patients who require CPR to maintain their heartbeat
- Patients with "unsurvivable" injuries
- Patients who are known to object to blood transfusions
- Patients who are known to refuse resuscitation

**9. What is PolyHeme®?**

PolyHeme® is an oxygen-carrying blood substitute made from human blood.

PolyHeme® requires no cross-matching, and therefore is compatible with all blood types. It could provide an immediate treatment alternative when blood is not available. PolyHeme® is highly purified/rid of contaminants to reduce the risk of viral disease

transmission. It can safely be stored for more than 12 months.

**10. Has PolyHeme® been tested on humans before?**

Yes, there have been five human clinical trials of PolyHeme®.

In the Phase II hospital trauma trial, PolyHeme® significantly increased survival compared with historical controls.

**11. How many patients have been treated with PolyHeme®?**

More than 300 patients have been treated, including patients in a hospital-based trauma research trial.

**12. What is known about the safety of PolyHeme®?**

In clinical trials to date, PolyHeme® has demonstrated no relevant adverse medical effects.

**13. What is an exception from informed consent?**

Patients will automatically participate in a clinical research study without giving informed consent before participating.

**14. Why was such an exception granted in connection with this study?**

Patients are in a life-threatening situation, available treatments are unproven or unsatisfactory and the collection of valid scientific evidence is necessary to determine the lifesaving ability of particular alternative treatments.

Taking part in the study has the possibility for direct benefit to the enrolled patients because:

- Patients are in life-threatening situations and require immediate medical treatment.
- Previous studies support the possibility of providing a direct benefit to enrolled patients.
- Risks associated with the use of the PolyHeme® are reasonable in relation to what is known about the patients' medical condition, the risks and benefits of standard medical care, if any, and the risks and benefits of the proposed treatment.

It is expected that patients will be unable to give informed consent because of the extent of their injuries and the fact that they are in shock. There will not be time to find and ask for consent from the patient's legally authorized representative (LAR) or to provide an opportunity for a family member to object to the patient participating in the study before beginning treatment.

**15. Who grants such exceptions?**

The U.S. Food and Drug Administration (FDA) under regulations called 21 Code of Federal Regulations 50.24 specifies the conditions under which an exception from informed consent may be obtained. The Institutional Review Board (IRB) associated with each hospital approves its use locally.

**16. What if patients do not want to participate in this study?**

Patients can withdraw from the study at any time by notifying the investigator.

**17. Will patients still receive treatment if they don't want to participate in the study?**

Patients still will receive the standard of care if they decline to participate in this study.

**18. What are the potential benefits of participating in the study?**

- PolyHeme® may increase the likelihood of survival after traumatic injury
- Patients might avoid the risks of blood transfusion
- Patients might avoid a reduction in the function of internal organs that sometimes follows blood transfusion

**19. What are the potential risks of participating in the study?**

- Rash
- Increased blood pressure
- Kidney or liver damage
- Transmission of hepatitis and HIV viruses
- Unforeseen happenings

**20. How much will it cost patients to participate?**

There is no charge to the patient to participate in this study. The cost of certain laboratory tests that are required will be paid for by the study sponsor.

**21. Will patients get paid to participate?**

No, patients will not be paid to participate in this study.

**22. Who is the manufacturer of PolyHeme®?**

Northfield Laboratories Inc., Evanston, IL. For more information, visit [www.northfieldlabs.com](http://www.northfieldlabs.com).

**PolyHeme® Study Backgrounder**

The PolyHeme® Ambulance Study is a landmark Phase III clinical trial

- This is the first U.S. trial of a blood substitute in which treatment will begin at the scene of injury, and continue in the ambulance during transport to the hospital.
- The trial will be conducted in approximately 20 Level I trauma centers throughout the U.S. – the centers of influence in trauma—selected for their excellence.
- It is expected that 720 patients will be enrolled in the trial.
- The goal of the research trial is to improve survival for seriously injured trauma patients.
- Patients who meet the study requirements will be randomized/assigned by chance to receive either the standard of care (saline/salt water) or PolyHeme®.
- Because the patients who meet the study requirements are unlikely to provide his/her informed consent due to the extent and nature of their injuries, the research trial will be conducted under federal regulations that allow clinical research in emergency settings using an exception from the requirement for informed consent (21 CFR 50.24).
- This clinical research trial would not be possible without Northfield's extensive trauma research study in the hospital setting.

PolyHeme® is the only oxygen-carrying blood substitute that has been rapidly and safely administered in clinical research trials.

- PolyHeme® replaces both lost blood volume and hemoglobin which are associated with traumatic injury.
- Patients in the hospital trauma trial received up to 20 units, replacing double the average adult's blood volume.

PolyHeme's unique characteristics make it the ideal oxygen-carrying blood substitute in both civilian and military settings:

- Universally compatible
- Immediately available
- Favorable safety profile
- Safely stored from more than 12 months
- Reduced chance of disease transmission

**Express Your Opinion / Contact the Study Coordinator**

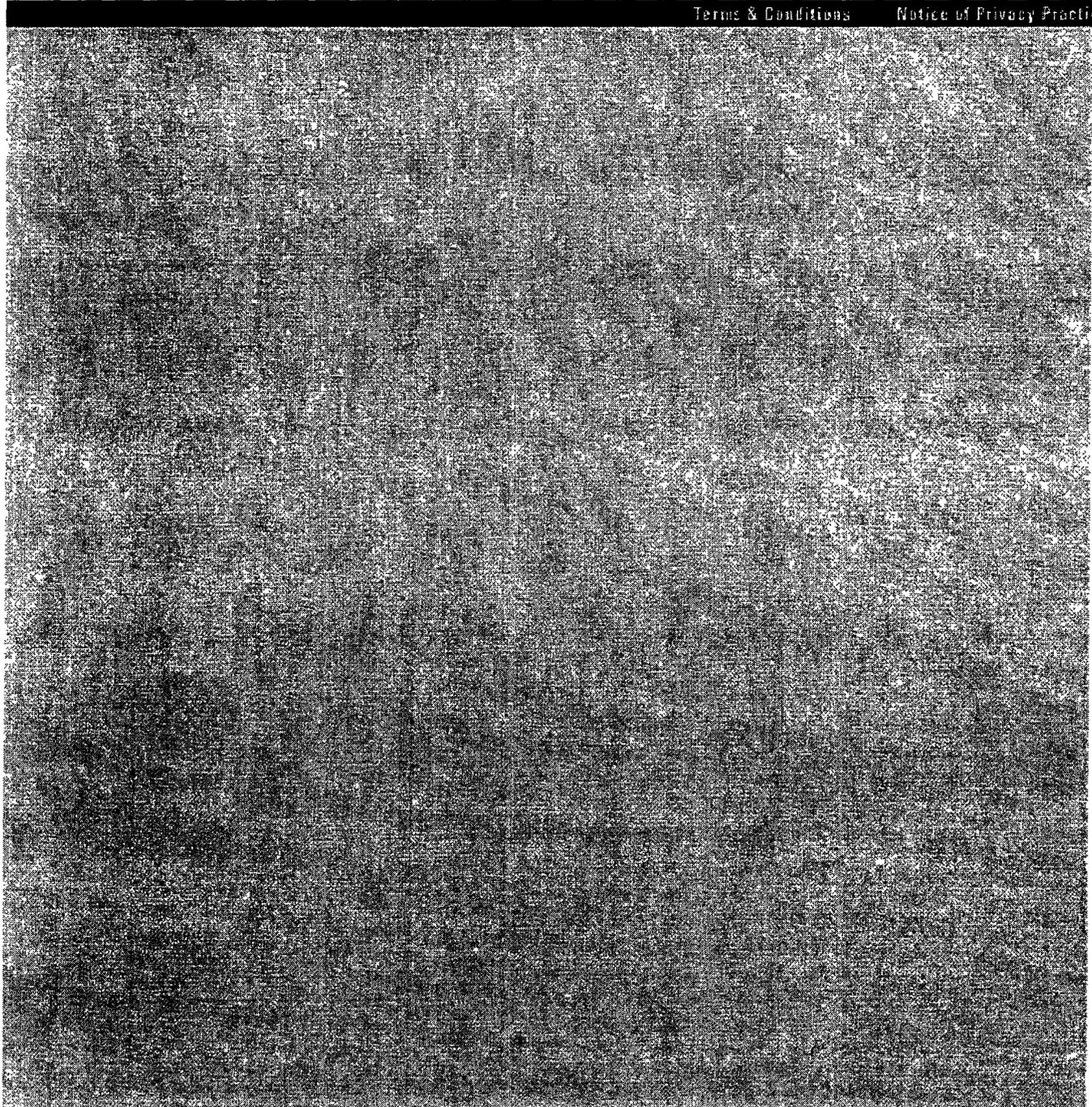
Send your email to: [polyheme@slhn.org](mailto:polyheme@slhn.org)  
Please include the phrase "Polyheme Info" in the subject

line.

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**Category** Lectures

**Facility** St. Luke's Hospital - Allentown Campus, St. Luke's Hospital - Bethlehem Campus, St. Luke's Quakertown Hospital, St. Luke's North, St. Luke's Hospital & Health Network, St. Luke's Miners Memorial Hospital, Visiting Nurse Association of St. Luke's

### PolyHeme® - Community Event

**Date** 10/05/2004

**Start Time** 7:00 pm

**End Time** 8:00 pm

**Location** Laros Auditorium, Doctors' Pavilion, 701 Ostrum Street, Bethlehem

St. Luke's Hospital is one of a select number of regional resource (Level I) trauma centers in the United States chosen to participate in a groundbreaking national clinical research trial to evaluate the safety and efficacy of PolyHeme®, an oxygen-carrying blood substitute, in treating critically injured and bleeding patients.

**Description**

Join us for a special opportunity to learn more about this exciting study and the clear benefits to trauma patients.

For more information about PolyHeme®, please visit the [PolyHeme®](#) page on this site.

**Contact #** 1-800-755-1626

**Cost/Fee** Free

[Register Online](#)

To Whom It May Concern:

Regarding the Community Consultation and Public Disclosure (CCPD) performed by St. Luke's Hospital and detailed in the regulatory documents submitted to Northfield Labs, please note the following additional points.

- While developing the CCPD plan, it was decided to reference Lehigh Valley Hospital's previous CCPD efforts and to supplement it with our outreach efforts. Together, we feel we adequately reached those communities that would be most likely to receive PolyHeme in a trauma as well as to simply educate the community of this unique clinical trial and the fact that it was being conducted utilizing waiver of informed consent.
- In addition to meeting with and targeting our CCPD to the general public, special effort was made to reach the Jehovah Witness population as they generally do not accept whole blood products and their presence in the Lehigh Valley is significant. I, Gail Wainwright, met extensively with several representatives of the Jehovah Witness community, specifically Mr. Joseph Brazil. He specifically stated to me after several of our meetings and after his attendance at our public meeting on October 5, 2004, that we satisfied all questions and concerns regarding the study and that he spoke on behalf of his entire community. We confidently believe that we have reached our designated communities and have satisfied questions and concerns by providing information and education.
- Low attendance was noted at our public meeting. Again, we anticipated a large number of Jehovah Witnesses to be present at the meeting, however, it became noted at the meeting that the Jehovah's Witnesses were having a congregational service that night and it was also noted that many of the Jehovah Witnesses reviewed the details of this specific study during Lehigh Valley Hospital's CCPD. Joseph Brazil stated that he represented their group and by bringing their questions to the meeting. The questions were all specific to ensuring that the study they were already aware of was indeed the same study that would be conducted at our site utilizing the same product. He felt the questions were answered to his satisfaction by Dr. Cipolla and stated he would relay the results back to his congregation. He later spoke at our Trauma Interdisciplinary Morbidity and Mortality monthly conference to educate our hospital about their beliefs and how it affects this PolyHeme study.
- Regarding our press releases, please note that the submitted press release was utilized and the same release repeated in every print article that went out to the communities.

Sincerely,

Gail Wainwright, RN  
Trauma Research Coordinator  
St. Luke's Hospital

Protocol Approval
Start Date: 9-7-04
End Date: 7-12-05
Initials: JBB
St. Luke's Hospital, IRB
Bethlehem, PA 18015

DRAFT

**FOR IMMEDIATE RELEASE (Issued 7/7/04)**

Contact: Steve Andrews, Network Marketing & Communications, 610-954-4178

**ST. LUKE'S HOSPITAL CHOSEN TO STUDY INVESTIGATIONAL  
BLOOD SUBSTITUTE IN TRAUMA PATIENTS**  
St. Luke's Is Only Trauma Center in Valley To Utilize Ground Transport In Study

BETHLEHEM – St. Luke's Hospital is one of a select number of Level I trauma centers in the United States chosen to participate in a groundbreaking national clinical research trial to evaluate the safety and efficacy of PolyHeme®, an oxygen-carrying blood substitute, in treating critically injured and bleeding patients.

"We are excited to be included in this groundbreaking clinical research trial," says James Cipolla, MD, the principal investigator. "Nationally, almost one in five trauma patients die from their injuries. If we can begin to treat patients very early with an oxygen-carrying solution and keep their hemoglobin levels up, we may see more survivors."

Although St. Luke's is not the only trauma center in the Valley to participate in this study, it is the only trauma center to utilize area EMS ground transport in addition to air transport. "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," explains Cipolla. "This has the potential to help many seriously injured patients in the Lehigh Valley."

Under the study protocol, treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance/aircraft, and continue during a 12-hour post-injury period in the hospital. 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.

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

- more -

**St. Luke's - Polyheme Study**  
**Page 2**

federal regulations that allow for clinical research in emergency settings using an exception from the requirement for informed consent (21 CFR 50.24).

Use of this provision in a study protocol is overseen by the Institutional Review Board (IRB) responsible for the initial and continuing review and approval of the research study. Such a decision is based on the finding and documentation that, amongst other things, patients are in a life-threatening situation requiring emergency medical intervention, currently available treatments are unproven or unsatisfactory, obtaining informed consent is not feasible, potential risks are reasonable in relation to what is known of the condition, participation in the study could provide a direct benefit to the patients enrolled, and the research could not be practicably conducted without an exception from informed consent requirements.

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 in trauma trials in the hospital setting. PolyHeme® is manufactured by Northfield Laboratories Inc., of Evanston, Illinois.

**PolyHeme at a glance:**

- If you are at least 18 years old, not obviously pregnant and injured AND have lost a large amount of blood you might receive an experimental blood substitute in the ambulance called PolyHeme®
- You have the right to refuse participation in this study by obtaining a bracelet (call 1-800-755-1626 to obtain a bracelet)
- There are potential risks of this study
  - risk of hepatitis and HIV
  - risk of kidney or liver damage
  - risk of rash
  - risk of increased blood pressure
- There are potential benefits of this study
  - there is a possible benefit that receiving PolyHeme® in the ambulance might increase your likelihood of survival
  - your participation in this study may help patients in the future

If you have any questions, please call 1-800-755-1626, email [polyheme@sltn.org](mailto:polyheme@sltn.org) or visit us on the web at [www.sltn.org](http://www.sltn.org). A public meeting regarding PolyHeme® is scheduled for October 5, 2004 at 7 pm in Laros Auditorium,

- more -

**St. Luke's - Polyheme Study**  
**Page 3**

St. Luke's Hospital - Bethlehem Campus.

**About Northfield Laboratories**

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

###

DRAFT

Protocol Approval
Start Date: 9-7-04
End Date: 7-12-05
Initials: [Signature]
St. Luke's Hospital, IRB
Bedlehem, PA 18015

**St. Luke's Chosen to Study Investigational Blood Substitute in Trauma Patients**

St. Luke's Hospital is one of a select number of Level I trauma centers in the United States chosen to participate in a groundbreaking national clinical trial to evaluate the safety and efficacy of PolyHeme®, an oxygen-carrying blood substitute, in treating critically injured and bleeding patients.

"We are excited to be included in this groundbreaking clinical trial," says James Cipolla, MD, the principal investigator. "Nationally, almost one in five trauma patients die from their injuries. If we can begin to treat patients very early with an oxygen-carrying solution and keep their hemoglobin levels up, we may see more survivors."

Although St. Luke's is not the only trauma center in the Valley to participate in this study, it is the only trauma center to utilize area EMS ground transport in addition to air transport. "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," explains Cipolla. "This has the potential to help many seriously injured patients in the Lehigh Valley."

Under the study protocol, treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance/aircraft, and continue during a 12-hour post-injury period in the hospital. 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.

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 312.64).

Use of this provision in a study protocol is granted by the Institutional Review Board (IRB) responsible for the initial and continuing review and approval of the research study. Such a decision is based on the finding and documentation that, amongst other things, patients are in a life-threatening situation requiring emergency medical intervention, currently available treatments are unproven or unsatisfactory, obtaining informed consent is not feasible, potential risks are reasonable in relation to

what is known of the condition, participation in the study could provide a direct benefit to the patients enrolled, and the research could not be practicably conducted without an exception from informed consent requirements.

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 in trauma trials in the hospital setting. PolyHeme® is manufactured by Northfield Laboratories Inc., of Evanston, Illinois.

**PolyHeme® at a glance:**

- If you are at least 18 years old and injured, not obviously pregnant AND have lost a large amount of blood you might receive an experimental blood substitute in the ambulance called PolyHeme®
- You have the right to refuse participation in this study by obtaining a bracelet (call 1-800-755-1626 to obtain a bracelet)
- There are potential risks of this study:
  - risk of hepatitis and HIV
  - risk of kidney or liver damage
  - risk of rash
  - risk of increased blood pressure
- There are potential benefits of this study:
  - there is a possible benefit that receiving PolyHeme® in the ambulance might increase your likelihood of survival
  - your participation in this study may help patients in the future

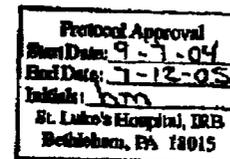
If you have any questions, please call 1-800-755-1626, email [polyheme@slhn.org](mailto:polyheme@slhn.org) or visit us on the web at [www.slhn.org](http://www.slhn.org). A public meeting regarding PolyHeme® is scheduled for October 5, 2004 at 7 pm in Laros Auditorium.

A public meeting regarding PolyHeme® is scheduled for October 5, 2004 at 7 pm in Laros Auditorium, St. Luke's Hospital – Bethlehem Campus.

<ad>

Community Meeting  
PolyHeme: What You Need to Know

October 5, 2004  
7-8 pm  
Laros Auditorium  
Doctors' Pavilion  
St. Luke's Hospital  
801 Ostrom Street  
Bethlehem, PA 18015



Open to all members of the community interested in learning more about this research study and to offer feedback to representatives of the St. Luke's Regional Resource Trauma Center.

The PolyHeme<sup>®</sup> Study is a landmark phase III clinical research trial:

- This is the first U.S. trial of a blood substitute in which treatment will begin at the scene of injury, and continue in the ambulance during transport to the hospital
- The goal of the trial is to evaluate improved survival for seriously injured accident victims
- Because the patients eligible for the study are unlikely to be able to provide consent due to the extent and nature of their injuries, the trial will be conducted under federal regulations that allow clinical research in emergency settings using an exception from the requirement for informed consent (21 CFR 31.24)

PolyHeme<sup>®</sup> has been rapidly and safely infused in clinical research trials in sufficiently massive quantities to be useful in the treatment of large volume blood loss.

Have a question? Ask it.  
Have a comment? Make it.  
Have a concern? Voice it.

<St. Luke's Trauma Center logo>  
801 Ostrom Street  
1-800-755-1626  
Bethlehem, PA 18015  
polyheme@slhn.org  
www.slhn.org

Protocol Approval
Start Date: 9-7-04
End Date: 7-12-05
Initials: <i>hm</i>
St. Luke's Hospital, IRB
Bethlehem, PA 18015

<link>  
 PolyHeme® Trauma Trial Information  
 </link>

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St. Luke's Hospital is one of a select number of Level I trauma centers in the United States chosen to participate in a groundbreaking national clinical research trial to evaluate the life-saving ability of PolyHeme®, an oxygen-carrying blood substitute, in treating severely injured and bleeding patients.

Under the study procedures, treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance/aircraft, and continue for 12-hours after the injury in the hospital. 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 (salt water).

Because the patients who meet the study requirements are unlikely to be able to give his/her informed consent in advance 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 312.64).

Use of this exception in a study procedure is granted by the Institutional Review Board (IRB) responsible for the initial approval of the research study. Such a decision is based on the finding that, patients are in a life-threatening situation requiring emergency medical care, currently available treatments are unproven or unsatisfactory, obtaining informed consent is not possible, potential risks are reasonable in relation to what is known of the condition, participation in the study could provide a direct benefit to the patients participating, and the research could not be practicably conducted without an exception from informed consent requirements.

PolyHeme® is a universally compatible (it can be given to any patient regardless of blood type), immediately available, oxygen-carrying blood substitute made from human blood. It is designed for immediate treatment when blood is not available. PolyHeme® is manufactured by Northfield Laboratories Inc., of Evanston, Illinois.

#### PolyHeme® at a glance:

- If you are at least 18 years old and injured AND have lost a large amount of blood you might receive an experimental blood substitute in the ambulance/aircraft called PolyHeme®
- You have the right to refuse participation in this study by obtaining a bracelet (call 1-800-755-1626 to obtain a bracelet)
- There are possible risks of this study
  - risk of hepatitis and HIV
  - risk of kidney or liver damage
  - risk of rash
  - risk of increased blood pressure
- There are possible benefits of this study
  - there is a possible benefit that receiving PolyHeme® in the ambulance/aircraft might increase your chances of survival

- your participation in this study may help patients in the future

If you have any questions, please call 1-800-755-1626 or visit the web at [www.slhln.org](http://www.slhln.org). A public meeting regarding PolyHeme® is scheduled for October 5, 2004 at 7 pm in Laros Auditorium, St. Luke's Hospital – Bethlehem Campus.

Principal Investigator: James Cipolla, MD  
 Contact Information: PHONB, [polyheme@slhln.org](mailto:polyheme@slhln.org)  
 Sponsor: Northfield Laboratories Inc.  
 <content>

<links>  
 Click here for information about community meeting  
 Click here for regulations permitting an exception from informed consent  
 Click here for frequently asked questions about the study  
 Click here for a PolyHeme® study backgrounder  
 Click here to provide your opinion about the study or contact the study coordinator  
 </links>

**Community Meeting**

October 5, 2004  
 7 – 8 pm  
 Laros Auditorium  
 Doctors' Pavilion  
 St. Luke's Hospital  
 801 Ostrum Street  
 Bethlehem, PA 18015

**Exception From Informed Consent**

The U.S. Food and Drug Administration (FDA) under regulations called 21 Code of Federal Regulations 50.24 specifies the conditions under which an exception from informed consent may be obtained. The Institutional Review Board (IRB) associated with each hospital approves its use locally.

(Click here for more information on exception from informed consent)  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfifr/CFRSearch.cfm?fr=50.24>

**Frequently Asked Questions**

1. Why is this study being conducted?

To evaluate the live-saving ability of PolyHeme® when given to severely injured and bleeding patients starting at the scene of injury.

2. What is the title of this study?

A Phase III, Randomized, Controlled, Open-Label, Multicenter, Parallel Group Study Using Provisions for Exception from Informed Consent Requirements Designed to Evaluate the Safety and Efficacy of Poly SFEI-P Injection [Polymerized Human Hemoglobin (Pyridoxylated) PolyHeme®] When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries Beginning in the Prehospital Setting.

3. What is hemorrhagic shock?

A condition in which a patient has experienced shock, as a result of massive blood loss. Shock is a life-threatening condition that might include:

- Dangerously low blood pressure
- Internal organs may not receive enough oxygen and therefore may not function well enough
- Might lead to death

4. What is the design of this study?

Patients in hemorrhagic shock will begin to receive either salt water (saline), which is the standard of care (control), or PolyHeme® (investigational/experimental treatment). Treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance/aircraft, and continue for 12 hours after the injury in the hospital.

In the hospital, patients in the standard of care/control group will receive salt water (saline) for hydration and blood if necessary to boost oxygen delivery levels. Unlimited doses of each are allowed.

Patients in the treatment group will receive salt water (saline) for hydration and PolyHeme® to boost oxygen delivery levels. The maximum dose of PolyHeme® will be 6 units during the first 12 hours. Blood will be used thereafter if oxygen delivery levels need to be increased.

5. Why is there a need for improvement in the way trauma patients are treated now?

Trauma is the leading cause of death among Americans under the age of 45. Currently the only available treatment for hemorrhagic shock, when blood is not available, is the infusion of a solution such as salt water (saline), which does not carry oxygen. Therefore, when blood is not immediately available, use of an oxygen-carrier such as PolyHeme® may restore adequate circulating levels of hemoglobin (the oxygen-carrying protein in blood) and possibly improve patient survival.

6. What is the current standard of care? How are trauma patients usually treated?

Patients are given salt water (saline) at the scene or in the ambulance/aircraft. When they arrive at the hospital, they are given blood after typing and cross-matching is accomplished.

7. Who would be eligible for the study?

- Patients who have lost a large amount of blood and are in shock
- Patients who are at least 18 years old
- Patients who have severe injuries

8. Who would be excluded from the study?

- Women who are obviously pregnant
- Patients with severe brain injuries
- Patients who require CPR to maintain their heartbeat
- Patients with "unsurvivable" injuries
- Patients who are known to object to blood transfusions
- Patients who are known to refuse resuscitation

9. What is PolyHeme®?

PolyHeme® is an oxygen-carrying blood substitute made from human blood. PolyHeme® requires no cross-matching, therefore it is compatible with all blood types. It could provide an immediate treatment alternative when blood is not available. PolyHeme® is highly purified/rid of contaminants to reduce the risk of viral disease transmission. It can be safely stored for over 12 months.

10. Has PolyHeme® been tested on humans before?

Yes, there have been 5 human clinical research trials of PolyHeme®.

In the Phase II hospital trauma trial, PolyHeme® significantly increased survival compared with historical controls.

11. How many patients have been treated with PolyHeme®?

Over 300 patients have been treated, including patients in a hospital-based trauma research trial.

12. What is known about the safety of PolyHeme®?

In clinical trials to date, PolyHeme® has demonstrated no relevant medical adverse effects.

13. What is an exception from informed consent?

Patients will automatically participate in a clinical research study without giving informed consent before participating.

14. Why was such an exception granted in connection with this study?

Patients are in a life-threatening situation, available treatments are unproven or unsatisfactory and the collection of valid scientific evidence is necessary to determine the life-saving ability of particular alternative treatments.

Taking part in the study has the possibility for direct benefit to the enrolled patients because:

- Patients are in a life-threatening situation that require immediate medical treatment
- Previous studies support the possibility of providing a direct benefit to enrolled patients
- Risks associated with the use of the PolyHeme® are reasonable in relation to what is known about the patients' medical condition, the risks and benefits of standard medical care if any, and the risks and benefits of the proposed treatment

It is expected that patients will be unable to give informed consent because the extent of their injuries and the fact that they are in shock. There won't be time to find and ask for consent from the patient's legally authorized representative (LAR) or to provide an opportunity for a family member to object to the patient participating in the study before beginning treatment.

15. Who grants such exceptions?

The U.S. Food and Drug Administration (FDA) under regulations called 21 Code of Federal Regulations 50.24 specifies the conditions under which an exception from informed consent may be obtained. The Institutional Review Board (IRB) associated with each hospital approves its use locally.

16. What if patients don't want to participate in this study?

Patients can withdraw from the study at any time by notifying the investigator.

17. Will patients still receive treatment if they don't want to participate in the study?

Patients will still receive the standard of care if they decline to participate in this study.

18. What are the possible benefits of participating in the study?

- PolyHeme® may increase the chances of survival after traumatic injury
- Patients might avoid the risks of blood transfusion

- Patients might avoid a reduction in the function of internal organs that sometimes follows blood transfusions

19. What are the possible risks of participating in the study?

- Rash
- Increased blood pressure
- Kidney or liver damage
- Transmission of hepatitis and HIV viruses
- Unforeseen happenings

20. How much will it cost patients to participate?

There is no charge to the patient to participate in this study. The cost of certain laboratory tests that are required will be paid for by the study sponsor.

21. Will patients get paid to participate?

No, patients will not be paid to participate in this study.

22. Who is the manufacturer of PolyHeme®?

Northfield Laboratories Inc., Evanston, IL. For more information, visit [www.northfieldlabs.com](http://www.northfieldlabs.com)

#### **PolyHeme® Study Background**

The PolyHeme® Ambulance Study is a landmark Phase III clinical trial

- This is the first U.S. clinical research trial of a blood substitute in which treatment will begin at the scene of injury, and continue in the ambulance during transport to the hospital
- The trial will be conducted in approximately 20 Level I trauma centers throughout the U.S. — the centers of influence in trauma—selected for their excellence
- It is expected that 720 patients will participate in the research trial
- The goal of the research trial is to improve survival for seriously injured trauma patients
- Patients who meet the study requirements will be randomized/assigned by chance to receive either the standard of care (saline/salt water) or PolyHeme®
- Because the patients who meet the study requirements are unlikely to be able to provide his/her informed consent in advance due to the extent and nature of their injuries, the research trial will be conducted under federal regulations that allow clinical research in emergency settings using an exception from the requirement for informed consent (21 CFR 50.24)
- This clinical research trial would not be possible without Northfield's extensive trauma research study in the hospital setting

**PolyHeme® is the only oxygen-carrying blood substitute that has been rapidly and safely administered in clinical research trials.**

- PolyHeme® replaces both lost blood volume and hemoglobin which are associated with traumatic injury
- Patients in the hospital trauma research trial received up to 20 units, replacing double the average adult's blood volume

**PolyHeme's unique characteristics make it the ideal oxygen-carrying blood substitute in both civilian and military settings:**

- universally compatible
- immediately available
- favorable safety report
- safely stored for over 12 months
- reduced chance of disease transmission

**Express Your Opinion / Contact the Study Coordinator**

Send your email to: [polyheme@slm.org](mailto:polyheme@slm.org) or call 1-800-755-1626  
Please include the phrase "polyheme info" in the subject line.

Protocol Approval
Start Date: 7-7-04
End Date: 7-12-05
Initials: hm
St. Luke's Hospital, TRS Bethlehem, PA 18015

**PolyHeme® Phase III Clinical Research Trial**

- This is the first U.S. trial of a blood substitute in which treatment will begin at the scene of injury and continue in the ambulance during transport to the hospital
- The goal of the trial is improved survival for seriously injured accident victims
- Eligible patients will be randomized to receive either the standard of care (salt water / saline solution) or PolyHeme®
- Because the patients eligible for the study are unlikely to be able to provide consent due to the extent and nature of their injuries, the trial will be conducted under federal regulations that allow clinical research in emergency settings using an exception from the requirement for informed consent (21 CFR 50.24)

**PolyHeme® has been rapidly and safely infused in clinical trials and may be useful in the treatment of large volume blood loss.**

- PolyHeme® replaces both lost blood volume and hemoglobin which are associated with traumatic injury
- Patients in the hospital trauma trial received up to 20 units, replacing double the average adult's blood volume

**PolyHeme's® unique characteristics make it a potential resuscitative fluid.**

- universally compatible
- immediately available
- favorable safety profile
- extended shelf life of over 12 months

**PolyHeme® at a glance:**

- If you are at least 18 years old, not obviously pregnant and injured AND have lost a large amount of blood you might receive an experimental blood substitute in the ambulance called PolyHeme®
- You have the right to refuse participation in this study by obtaining a bracelet (call 1-800-755-1626 to obtain a bracelet)
- There are *potential risks* of this study
  - risk of hepatitis and HIV
  - risk of kidney or liver damage
  - risk of rash
  - risk of increased blood pressure
- There are *potential benefits* of this study
  - there is a possible benefit that receiving PolyHeme® in the ambulance might increase your likelihood of survival
  - your participation in this study may help patients in the future

2005/FEB/01/TUE 09:42 AM ST LUKES TRAUMA

FAX No. 61095422020

P. 017/017

If you have any questions, please call 1-800-755-1626 or visit the web at [www.albim.org](http://www.albim.org).  
A public meeting regarding PolyHeme® is scheduled for October 5, 2004 at 7 pm in  
Laros Auditorium, St. Luke's Hospital - Bethlehem Campus.



## PolyHeme<sup>®</sup> Trauma Trial

St. Luke's Regional Resource  
Trauma Center  
[www.slhn.org](http://www.slhn.org)

## Clinical Investigator

- James Cipolla, MD, is a trauma surgeon at St. Luke's Hospital
- Contact Info for PolyHeme Study:
  - Phone: 1-800-755-1626
  - Email: [polyheme@slhn.org](mailto:polyheme@slhn.org)

## Study Sponsor

Northfield Laboratories Inc.

- Developer of the oxygen-carrying blood substitute called PolyHeme<sup>®</sup>
- Conducted multiple studies with PolyHeme over the past decade
- Most studies have been with injured trauma patients
- Company website: [www.northfield.com](http://www.northfield.com)

## Study Purpose

*To evaluate the life-saving potential of PolyHeme<sup>®</sup> when given to severely injured and bleeding patients in "hemorrhagic shock," starting at the scene of injury*

## What is Hemorrhagic Shock?

massive loss of blood  
life-threatening condition

- Dangerously low blood pressure
- Internal organs don't receive enough oxygen and have difficulty functioning
- Might lead to death

## Need for Improved Outcome

- The Center for Disease Control (CDC) lists trauma as the leading cause of death among Americans under age 45
- Thousands of trauma patients die each year
- Many of these patients die because the "standard of care" cannot reverse the damaging effects of hemorrhagic shock

## What is the Standard of Care?

*Represents the current treatment*

*Standard of Care*

	
The patient receives salt water (blood is not available)	The patient receives salt water and donated blood

## Standard of Care Limitations

- Standard of Care*
- Salt water does not carry oxygen, unlike blood
  - Without enough oxygen, the body and its internal organs have difficulty functioning and can stop working (organ failure)

## Standard of Care Limitations

- Standard of Care*
- Donated blood takes time (45-60 minutes) to be matched for each patient
  - Patients who receive more than 6 units of donated blood in the first 12 hours have an increased risk of organ failure

## What is PolyHeme®?

*A blood substitute  
that carries oxygen*

1 unit of PolyHeme  
=  
1 unit of blood



## What is PolyHeme®?

- Made from human blood
- Compatible with all blood types
- Immediately available
- Reduced risk of viral disease (viral load reduced over a billion times)



## Why Use PolyHeme®?

- PolyHeme was developed to treat blood loss when blood is not available
  - Blood is not available in the ambulance
  - PolyHeme will be immediately available in the ambulance and carries oxygen
- PolyHeme can reduce the use of donated blood in the first 12 hours after injury, and might avoid potential organ failure

## Why Use PolyHeme®?

*To improve survival  
of severely injured and bleeding  
patients*

## PolyHeme® Experience

- PolyHeme has been studied in more than 300 individuals and 5 different clinical trials
- PolyHeme has been extensively studied in hospitalized trauma patients
- *PolyHeme has kept trauma patients alive when they have lost all of their own blood*

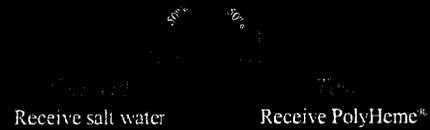
## PolyHeme® Experience

Past studies have shown that PolyHeme

- Carries as much oxygen as blood (1 unit of PolyHeme = 1 unit of blood)
- Reduces need for donated blood
- Has not caused organ damage
- Has replaced up to two times a person's entire blood volume (2 x 10 units = 20 units)

## Trial Design: Before the Hospital

*Severely injured trauma patients will be  
assigned to either one of two groups  
by chance*



## Ambulance Infusion



## Trial Design: At the Hospital

- Salt water for hydration
- Donated blood to boost oxygen levels
- Salt water for hydration
- PolyHeme® to boost oxygen levels
- Maximum dose of 6 units during first 12 hours
- Donated blood will be used thereafter

## Hospital Infusion



## Who Would Be Included?

### *Patients at risk of dying*

- Who have sustained severe injuries
- Who have lost a large amount of blood and are in shock
- Who are at least 18 years old
- Who are of either gender (male or female)

## Who Would Be Excluded?

- Patients who are obviously pregnant
- Patients who have severe head or brain injuries
- Patients who have "unsurvivable" injuries
- Patients who require CPR
- Patients with known objections to blood transfusions
- Patients with known orders not to resuscitate

## FDA Review

- Northfield Laboratories received clearance to proceed with this study from the Food and Drug Administration (FDA)
- The FDA authorized the use of an exception from informed consent requirements for this study

## What is Informed Consent?

A process by which patients make informed decisions about participating in research studies

- Traditionally required for all research studies
- Research studies compare 2 treatments (standard vs. investigational)
- Doctors describe each of these potential treatments

## What is Informed Consent?

A process by which patients make informed decisions about participating in research studies

- Patients are informed of the potential risks and potential benefits associated with each of these treatments
- Patients choose whether to participate in the study

## What is Exception from Informed Consent?

*Patients are enrolled in a research study without giving their informed consent*

## How Can That Be?

A federal regulation (21 CFR 50.24), created in 1996, allows certain studies that meet the following criteria to use this exception

- *Patients' lives must be at risk*
- Available treatments are not satisfactory
- Patients are unable to give consent
- Potential risks are reasonable

## How Can That Be?

A federal regulation (21 CFR 50.24), created in 1996, allows certain studies that meet the following criteria to use this exception

- Participation in the research could provide a direct benefit (*increased survival*) to the patient
- The research could not be practicably carried out without an exemption

## Consent Safeguards

- If possible, the patient or a legally authorized representative (LAR) can give consent before the patient is enrolled in the study
- If consent cannot be obtained before enrollment, frequent attempts will be made to contact the patient's LAR and family to describe the study

## Consent Safeguards

*The patient, family members, or a legally authorized representative may decide to withdraw the patient at any time*

## Potential Benefits of PolyHeme®

- *Might increase the likelihood of survival*
- Can enhance the amount of vital oxygen in the patient's blood
- Is compatible with all blood types
- Is immediately available
- Has reduced risk of viral disease (viral load reduced over a billion times)

## Potential Risks of PolyHeme®

- Rash
- Increased blood pressure
- Kidney or liver damage
- Viral infection (HIV, hepatitis, etc.)
- Unforeseen happenings

## Patient Protection

The Institutional Review Board (IRB) is a group of medical, scientific, and nonscientific members of the community

- Reviews all proposals for research on humans
- Assures patient safety
- Monitors community feedback

## Patient Protection

- The IRB will decide whether or not to allow this hospital to participate in the PolyHeme® trial
- An independent data monitoring committee will oversee the trial
- The FDA will be kept informed of the trial's progress

## If We Participate...

- The results of the study will be revealed to the community after the trial has been completed
- Those who do not want to participate in the study can [wear a special bracelet] to exclude themselves

Questions  
or  
Comments?

Protocol Approval  
Start Date: 9-7-04  
End Date: 7-12-05  
Initials: JRM  
St. Luke's Hospital, IRB  
Bethlehem, PA 18015

Dear Colleague:

As you well know, trauma-related injuries are a leading cause of death in Americans under 45 years old, affecting more than 2 million persons annually. Nearly one in five trauma victims dies as a result of his/her injuries.

St. Luke's Regional Resource Trauma Center is participating in a national clinical study to evaluate a new blood substitute in severely injured and bleeding patients who are in shock. Treatment would begin before arrival at the hospital, either at the scene of injury or in the ambulance, and continue through a 12-hour post-injury period in the hospital. Only persons over 18 years of age who meet specific study criteria will be eligible for inclusion.

This groundbreaking study is being conducted in accordance with federal regulations permitting an exception from informed consent requirements under 21 CFR 50.24. As such, we are asking for your help.

It is of paramount importance that we inform as many residents of the Lehigh Valley as possible about this study. Enclosed you will find an informational poster and a supply of flyers. Please consider displaying the poster in your waiting room and distributing the flyer to your patients.

In addition, we have established a special toll-free phone number and email address specifically for this study. If you or your patients have any questions or concerns, please do not hesitate to call me at 1-800-755-1626 or email me at polyheme@alho.org.

Thank you in advance for your support.

With Regards,

James Cipolla, MD  
Principal Investigator  
St. Luke's Regional Resource Trauma Center

2005/FEB/01/TUE 09:41 AM ST LUKES TRAUMA

FAX No. 61095422020

P. 007/017

**DEPARTMENT OF  
HEALTH**

... in pursuit of good health

(717) 787-8740

December 14, 2004

Gail A. Wainwright, BSN, RN  
Trauma Research Coordinator  
801 Ostrum Street  
St. Luke's Hospital  
Bethlehem, PA 18015

Dear Ms. Wainwright:

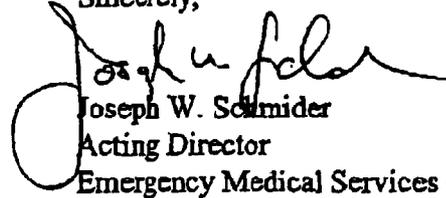
The EMS Office approves initiation of the Phase III proposal submitted to the Department on behalf of Saint Luke's Hospital and Health System entitled: "A Randomized, Controlled, Open Label, Multicenter, Parallel Group Study Using Provisions for Exception of Informed Consent Requirements Designed to Evaluate the Safety and Efficacy of Poly SFH-P Injection When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries, Beginning the Prehospital Setting" with the following conditions:

1. The study is restricted to those prehospital patients who meet the criteria for exception of informed consent since it will be impossible to provide the full informed consent in a reasonable time in the prehospital setting.
2. The study is restricted to patients cared for and transported by City of Bethlehem EMS, Bethlehem Township EMS, City of Allentown EMS, St. Luke's EMS, Quakertown, Easton EMS, Suburban EMS, Medic 9 EMS, Nazareth EMS, Centronia EMS and PENNStar Air Ambulance or EMS units enrolled in the study by Lehigh Valley Hospital. Any possibility of extending additional EMS units would require an additional request with supporting documentation to the Department prior to expanding the program.
3. The study is restricted to patients whose destination is Saint Luke's Hospital or Lehigh Valley Hospital **as defined** by the statewide trauma destination protocol by licensed ambulances participating in this study. The EMS Office requests notification in the event a patient is enrolled in the study and must be withdrawn based on a failure of this requirement.
4. The EMS Office is to receive a semi-annual report on this project, including number of patients enrolled in the study an overview of preliminary results and issues that have been encountered during the study.

Should you encounter problems in implementing the study, let me know and we will provide assistance if possible. If the study implementation produces unexpected negative impact on the EMS system or the patients it serves, the study must be stopped and the EMS Office notified immediately. Please provide this office with a summary and findings report within 60 days of the completion of the Phase III study.

You may contact me at (717) 787-8740 with any further questions in this regard.

Sincerely,



Joseph W. Schmider  
Acting Director  
Emergency Medical Services Office

cc Eastern PA EMS Council, Inc.  
Buck's County EMS Council

Enc: Triage Protocol

FROM :

FAX NO. : 2152817955



# County of Bucks

## EMERGENCY HEALTH SERVICES



911 Ivyglenn Circle, Ivyland, PA 18974  
 (215) 215-340-8735 Fax (215) 957-0765  
 email: bcpaeh@verizonetg.net

*County Commissioners*

**CHARLES H. MARTIN, Chairman**  
**MICHAEL G. FITZPATRICK, ESQ**  
**SANDRA A. MILLER**

December 2, 2004

**EMS Office**

Pennsylvania Department of Health  
 P.O. Box 90  
 Harrisburg, PA 17108

**To Whom It May Concern:**

The Bucks County Medical Advisory Committee met with representatives of St. Luke's Hospital at our November meeting to discuss their planned phase III prehospital trial of Polyheme. This blood substitute, made by Northfield Laboratories, is a cross linked glutaraldehyde - polymerized human hemoglobin. The purpose of the study is to determine the efficacy of Polyheme in the treatment of patients with hemorrhagic shock secondary to trauma.

Present at the meeting was one of the study investigators from St. Luke's Hospital - Bethlehem along with Dr. Darwin Kencpp, ALS Service Medical Director for the EMS service based at St. Luke's Hospital - Quakertown. A presentation was made about the purpose, scope, design, eligibility, and exclusion criteria for the trial.

The following points were made clear to the members of the MAC:

- 1) The investigators are utilizing a waiver of informed consent.
- 2) Only one Bucks County EMS service, St. Luke's Quakertown - M-108, is participating in this phase of the trial.
- 3) The Polyheme intervention is in "addition to" all current prehospital protocols for trauma resuscitation in Bucks County. Patients will still have at least one large bore access initiated with a crystalloid infusion during their prehospital treatment phase even when entered in the Polyheme trial.

The MAC unanimously approved the involvement of St. Luke's Quakertown M108 in the Polyheme prehospital trial. The only request was that the Bucks County Regional EMS office be informed of all prehospital administrations of Polyheme by M-108. The MAC wants to assure EMS personnel are continuing to follow all trauma protocols and that on-scene times are not adversely affected by Polyheme administration. The MAC would also like an annual update from the investigators as to the status of the trial.

Thanks for your time in this matter. Please contact me with any further questions that you may have.

Sincerely,

Gerald Wydro, MD  
 Regional Medical Director  
 Bucks County Emergency Health Services



*James Conrad*  
President

*Everitt F. Binns, Ph.D.*  
Executive Director

October 26, 2004

Dr. Douglas Kupas,  
EMS Office  
Room 1032  
Health and Welfare Building  
Harrisburg, PA 17120

Dear Doug,

At the October 11, 2004, meeting of the Eastern PA EMS Council Medical Advisory Committee, representatives from St. Luke's Hospital presented their research proposal for Polyheme use on ground based ALS units. This presentation also included the amended information for the Lehigh Valley Hospital Center study.

After a brief discussion, the committee members present voted unanimously to support the St. Luke's research project as written and the amendment to the current Lehigh Valley Hospital Center project..

Thank you for the opportunity to participate in this process. If you have any questions, please do not hesitate to contact me at the EMS Council office.

Respectfully yours,

Everitt F. Binns, Ph.D.  
Executive Director

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St. Luke's Hospital - Allentown Campus, St. Luke's Hospital - Bethlehem Campus, St. Luke's Quakertown Hospital, St. Luke's North, St. Luke's Hospital & Health Network, St. Luke's Miners Memorial Hospital, Visiting Nurse Association of St. Luke's

## **PolyHeme® - Blood Substitute Study**

07 Sep 2004

### **St. Luke's Hospital chosen to study investigational blood substitute in trauma patients**

*St. Luke's is only trauma center in Valley to utilize ground transport in study*

St. Luke's Hospital is one of a select number of regional resource (Level I) trauma centers in the United States chosen to participate in a groundbreaking national clinical research trial to evaluate the safety and efficacy of PolyHeme®, an oxygen-carrying blood substitute, in treating critically injured and bleeding patients.

"We are excited to be included in this groundbreaking clinical research trial," says James Cipolla, MD, the principal investigator. "Nationally, almost one in five trauma patients die from their injuries. If we can begin to treat patients very early with an oxygen-carrying solution and keep their hemoglobin levels up, we may see more survivors."

Although St. Luke's is not the only trauma center in the Valley to participate in this study, it is the only trauma center to utilize area EMS ground transport in addition to air transport. "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," explains Cipolla. "This has the potential to help many seriously injured patients in the Lehigh Valley."

Under the study protocol, treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance/aircraft, and continue during a 12-hour post-injury period in the hospital. 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.

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).

Use of this provision in a study protocol is overseen by the Institutional Review Board (IRB) responsible for the initial and continuing review and approval of the research study. Such a decision is based on the finding and documentation that, amongst other things, patients are in a life-threatening situation requiring emergency medical intervention, currently available treatments are unproven or unsatisfactory, obtaining informed consent is not feasible, potential risks are reasonable in relation to what is known of the condition, participation in the study could provide a direct benefit to the patients enrolled, and the research could not be practicably conducted without an exception from informed consent requirements.

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 in trauma trials in the hospital setting. PolyHeme® is manufactured by Northfield Laboratories Inc., of Evanston, Illinois.

PolyHeme® at a glance:

- If you are at least 18 years old, not obviously pregnant and injured AND have lost a large amount of blood you might receive an experimental blood substitute in the ambulance called PolyHeme®
- You have the right to refuse participation in this study by obtaining a bracelet (call 1-800-755-1626 to obtain a bracelet)

There are potential risks of this study: risk of hepatitis and HIV, risk of kidney or liver damage, risk of rash and risk of increased blood pressure.

There are potential benefits of this study: there is a possible benefit that receiving PolyHeme® in the ambulance might increase your likelihood of survival and your participation in this study may help patients in the future.

If you have any questions, please call 1-800-755-1626, email [polyheme@slhn.org](mailto:polyheme@slhn.org) or visit us on the [PolyHeme®](#) page of this site. A public meeting regarding PolyHeme® is scheduled for October 5, 2004 at 7 pm in Laros Auditorium, St. Luke's Hospital – Bethlehem Campus.

#### **About Northfield Laboratories**

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

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