

West Virginia University Hospital  
Jon Michael Moore Trauma Center  
June 29, 2005  
11:45 am

AGENDA

POLYHEME® TRAUMA TRIAL COMMUNITY MEETING

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

- |          |                                 |
|----------|---------------------------------|
| 11:45 am | Welcome and Introductions       |
| 12:00 pm | Federal regulations and the IRB |
| 12:15 pm | Explanation of PolyHeme® trial  |
| 12:45 pm | Questions and Answers           |
| 1:00 pm  | Adjourn                         |

Handouts are available at the back of the room.

Polyheme Clinical Trial Media Plan  
Jon Michael Moore Trauma Center  
West Virginia University

MESSAGES

Key points to emphasize in the campaign should include:

- (1) That WVU needs their help in completing a research project that can save lives after severe traumatic accidents.
- (2) That the research involves giving some severely injured patients in need of transfusions a blood substitute for a limited period of time.
- (3) That the substitute has been tested extensively for effectiveness & safety.
- (4) That such research can only be done in emergency situations.
- (5) That the potential benefit is that injured people who today face the possibility of dying because of lack of blood, could receive a blood substitute that carries needed oxygen into their system.
- (6) That WVU considers the risk in this research to be minimal, but the potential to be far reaching.

TARGET AREA:

The research will involve EMS personnel in Harrison, Marion and Monongahela counties. The goal for the outreach project would be to conduct a public informational campaign based in these three counties.

MEDIA

WVU Health Sciences Communications will provide information to the news media and arrange interviews for Lawrence Roberts, M.D., F.A.C.S. Dr. Roberts will also talk with as many newspaper editors and broadcast news managers as possible to interest them in assisting in informing the community.

Press Release – Week of May 16, with phone follow-up from Communications office offering interviews. The suggested media files from PolyHeme will serve as templates for press releases and other materials. The IRB will review all materials prior to use.

- Newspapers: (Daily) Morgantown Dominion Post, Fairmont Times West-Virginian, Clarksburg Exponent, and (Weekly) Morgantown Times, Bridgeport News, Shinnston News and Harrison County Journal
- Television: Stations WBOY in Clarksburg, and WDTV in Clarksburg.
- Radio stations: WVHF-FM in Clarksburg, WOBG-AM in Clarksburg, WHAR-AM in Clarksburg, WVUC-FM in Fairmont, WMMN-AM in Fairmont, WAJR-AM in Morgantown, WCLG-AM in Morgantown, and West Virginia Public Radio.

Editor contact:

During the week of May 23, Bill Case from Communications will make personal contact with the key editors of the three daily newspapers listed above and suggest a meeting with Dr. Roberts to seek newspaper assistance in informing the community. The approach in each community will vary depending in part upon response from the editor(s) – it may include op-ed column written by Dr. Roberts; a newspaper editorial based on information we supply, or a community meeting or meeting with public officials

Contacts: Geri Ferrara, Editor, Dominion Post

Hope Stephan, managing editor or Bill Byrd, Times-West Virginian  
John Miller, managing editor, Exponent-Telegram

Broadcast programming

During late May or early June, Dr. Roberts will appear as a guest on the half-hour health talk show carried by WAJR radio in Morgantown, which is sponsored by WVU.

In early June, the Polyheme study will be the subject of a report by Dr. Bob D'Alessandri, WVU VP for Health Sciences, who serves as a medical reporter for four television stations in WV, including WBOY-TV. The segment will include an interview with Dr. Roberts, video of the product, and basic information about the study.

WVU HSC communications will encourage other reporters who regularly contact us for story ideas to do pieces on Polyheme.

EVENTS:

WVU Trauma Services will arrange for Dr. Roberts to attend scheduled meetings of Rotary, Kiwanis, or other civic groups in each county to explain the research to local leaders and the public. Whenever possible, he will be accompanied by leaders of the local ambulance/EMT agencies. Media will be invited to cover any local forums arranged with the newspapers, or any public speaking events associated with the project.

Additional community forums will be scheduled if the researchers or the communications staff are contacted by interested individuals or groups in any or all of the target counties.

ASSESSMENT:

- (1) The questionnaire developed by PolyHeme should be given to those who attend any of the forums. Researchers also should recruit a cross-section of target area residents from these forums to conduct three focus groups at the end of the campaign.
- (2) The focus groups – one for each county – will be the final public assessment of attitudes about the project. The facilitator of these groups should collect attitudes in relation to the campaign conducted, and the project itself.

**Participant Feedback Form**

Kiwanis Fairmont  
Fairmont Field Club  
June 29, 2005

*Please circle your answers*

1. Would you support a study such as the one described at this meeting being conducted in this community, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?

Yes            No

2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?

Yes            No

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?

Yes            No

4. Do you have any comments or concerns you wish to share with the investigators?

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Age: \_\_\_\_\_ Ethnic background: \_\_\_\_\_

Gender: Male \_\_\_\_\_ Female \_\_\_\_\_

Thank you for your participation today. Please call Dr. Lawrence H. Roberts or Elizabeth Wooster RN at 598-4659 if you have any other questions.

## PolyHeme® Trauma Trial

Community Consultation

West Virginia University  
Hospitals  
Hon Michael Moore Trauma  
Center

## Clinical Investigator

- Dr. Lawrence H. Roberts, MD, FACS

Director

Jon Michael Moore Trauma Center

## Study Sponsor

Northfield Laboratories Inc.

- Developer of the oxygen-carrying resuscitative fluid called PolyHeme®
- Conducted multiple studies with PolyHeme over the past decade
- Most studies have been with injured trauma patients
- Company website: [www.northfieldlabs.com](http://www.northfieldlabs.com)

## Study Purpose

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

## What is Hemorrhagic Shock?

**Hemorrhagic:** massive loss of blood

**Shock:** 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*

#### *In the Ambulance*

The patient receives  
salt water  
(blood is not available)

#### *In the Hospital*

The patient receives  
salt water  
and donated blood

## Standard of Care Limitations

### *In the Ambulance*

- 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

### *In the Hospital*

- Risks associated with large infusions of donated blood in trauma patients have been identified
- Increase in immune function, which may cause failure of vital organs and death, observed in some patients who have received transfusions<sup>1</sup>

<sup>1</sup>A. Sauaia et al., *Archives of Surgery* (1994),  
Volume 129:39-45

## What is PolyHeme®?

*A temporary red  
blood cell  
substitute  
that carries oxygen*

*In the acute setting, 1  
unit (pint) of  
PolyHeme is given in  
place of 1 unit (pint)  
of blood*



## What is PolyHeme®?

- Made from human blood
- Compatible with all blood types
- Immediately available
- Manufactured with steps to reduce the risk of viral transmission



## Why Use PolyHeme®?

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

### Why Use PolyHeme®?

- There are risks associated with large infusions of donated blood in trauma patients<sup>1</sup>
- In a controlled Phase II trial in hospitalized trauma patients, higher levels of immune markers were seen in patients who received blood transfusions as compared to those who received PolyHeme<sup>2</sup>

<sup>1</sup>A. Sauaia et al., *Archives of Surgery* (1994), Volume 129:39-45

<sup>2</sup>E. E. Moore, *Journal of American College of Surgeons* (2003), Volume 196 (1)

### Why Use PolyHeme®?

*To evaluate a potential improvement in survival of severely injured and bleeding patients*

### PolyHeme® Experience: Past

- Administered to patients with acute blood loss in the hospital setting
- Patients have received up to 20 units (pints) or 1,000 gm of PolyHeme®
  - Normal volume of blood in a human is 10 units (pints) or 500 gm of hemoglobin
- Some of these patients kept alive while losing virtually all of their own blood during ongoing bleeding and receiving only PolyHeme® as replacement.

### PolyHeme® Experience: Past

- Observations in these patients have suggested the life-sustaining potential of PolyHeme® in the treatment of urgent life-threatening blood loss and life-threatening hemoglobin levels

*[Gould et al, Journal of American College of Surgeons (2002), Volume 195 (4)]*

### PolyHeme® Experience: Past

- During the course of evaluation of any investigational product, both adverse experiences and serious adverse experiences can occur. These may be due to either:
  - the underlying condition of the patient
  - the treatment setting or
  - the investigational product itself
- Both adverse experiences and serious adverse experiences have occurred in prior studies.

### PolyHeme® Experience: Past

- One trial conducted in older patients undergoing elective surgery for abdominal aortic aneurysm that involved a non-routine procedure where up to 60% of their own blood was removed and later replaced.
  - Serious adverse events, including cardiovascular, were observed.
  - It cannot be determined whether due to experimental procedure or PolyHeme itself.
- Patients in this study were older with more cardiovascular risk factors than those in the trials in trauma patients.

### PolyHeme® Experience: Past

- In trauma patients, PolyHeme® has been rapidly infused during urgent life-threatening blood loss in sufficiently large quantities, up to 20 units (pints), to be considered well-tolerated in this patient population.

*[Gould et al, Journal of American College of Surgeons (2002), Volume 195 (4)]*

### PolyHeme® Experience: Current Trial

- 720 patients will be enrolled:
  - 360 patients in the control group
  - 360 patients in the PolyHeme® group
- Currently, enrollment underway at a 17 Level I trauma centers across the United States
  - A list of centers is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- The FDA has approved the study
- 22 Institutional Review Boards have approved the study. 1 IRB has not approved the study

### PolyHeme® Experience: Current Trial

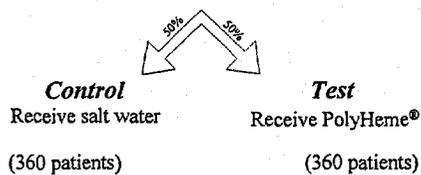
- An Independent Data Monitoring Committee set up to review mortality and serious adverse experiences after 60, 120, 250 and 500 patients have been enrolled and followed for 30 days
- Committee has reviewed the safety data on the first 60, 120 and 250 patients
- Committee has recommended that the study continue without any change

### PolyHeme® Experience: Current Trial

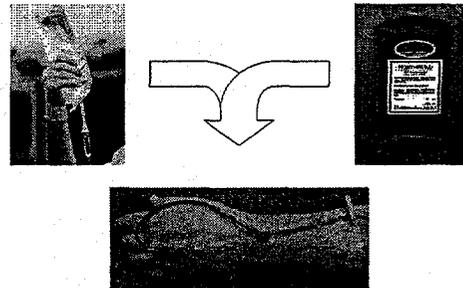
- At the 250 patient look, Committee conducted an adaptive sample size determination.
- Assessment was based on a comparison between the mortality rate predicted in the protocol and the observed mortality rate in the trial to date.
- Committee has concluded that no adjustment in the number of patients to be enrolled in the study is required.

### 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

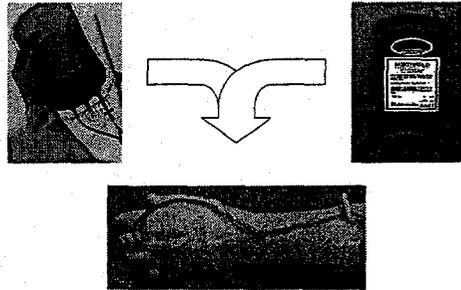
### *Control*

- Salt water for hydration
- Donated blood to boost oxygen levels

### *Test*

- 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
- Patient with visible or identifiable method of objection (e.g. wearing exclusion bracelet)

## 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

## Consent Safeguards

- If consent cannot be obtained before enrollment, frequent attempts will be made to contact the patient's LAR and family to describe the study
- The patient, family members, or a legally authorized representative may decide to withdraw the patient at any time

### Potential Benefits of PolyHeme®

- Can enhance the amount of vital oxygen in the patient's blood (prehospital setting)
- May avoid failure of vital organs (prehospital and hospital settings)
- Might increase the likelihood of survival
- Is compatible with all blood types
- Is immediately available
- Manufactured with steps to reduce the risk of viral transmission

### 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 is overseeing the trial to monitor the safety of the product
- The FDA is being 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?

## QUESTIONS AND ANSWERS POLYHEME® TRAUMA TRIAL

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

*To evaluate the safety and efficacy of PolyHeme® in treating severely injured and bleeding patients, starting at the scene of injury, and to assess a potential survival benefit.*

### **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*

### **What is PolyHeme®?**

*PolyHeme® is a temporary oxygen-carrying red blood cell substitute made from human blood. PolyHeme® requires no cross-matching, and therefore is compatible with all blood types. PolyHeme® is manufactured using steps to reduce the risk of viral transmission. It has a shelf-life of over 12 months.*

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

*Patients in "hemorrhagic shock" will begin to receive either saline (salt water), which is the standard of care (control), or PolyHeme (investigational treatment). Treatment will begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during a 12 hour postinjury period in the hospital.*

*In the hospital, patients in the control group will receive saline for hydration and blood if necessary to boost oxygen levels. Unlimited doses of each are allowed.*

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

### **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*

**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 that does not carry oxygen such as saline (salt water). Therefore, when blood is not immediately available, use of an oxygen carrier such as PolyHeme® may restore sufficient circulating levels of hemoglobin and potentially improve patient survival.*

*There are also risks associated with large infusions of donated blood in trauma patients, including an increase in immune function which may cause failure of vital organs and death in some patients who receive transfusions [A. Sauaia et al., Archives of Surgery (1994), Volume 129:39-45]. In a controlled Phase II trial in hospitalized trauma patients, higher levels of immune markers were seen in patients receiving blood transfusions as opposed to those who received PolyHeme® [E. E. Moore, Journal of American College of Surgeons (2003), Volume 196 (1)].*

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

*Bleeding patients are given a solution, such as saline, at the scene or in the ambulance to raise blood pressure. When patients arrive at the hospital, they are given Type O blood, if needed immediately, and later receive cross-matched blood, when available, if they continue to need blood transfusion.*

**Who is 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 sustained severe injuries*

**Who will 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*

**How many patients will be enrolled in the study?**

*A total of 720 patients will be enrolled in the study; 360 patients in the control group and 360 patients in the PolyHeme® group.*

**Has enrollment begun anywhere?**

*Currently, enrollment is underway at a 17 Level I trauma centers across the United States. A list of those centers is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). The FDA has approved this study as well as a total of 22 Institutional Review Boards. One IRB did not approve the study.*

**How will patient safety be assured in this trial?**

*An Independent Data Monitoring Committee, consisting of independent medical and statistical experts, is responsible for periodically evaluating the safety data from the trial and making recommendations relating to the continuation or modification of the trial protocol to minimize any risks to patients. The protocol includes four planned evaluations that occur after the first 60, 120, 250 and 500 patients have been enrolled and monitored for a 30-day follow-up period.*

**What has been the experience with the study since it has begun?**

*The Independent Data Monitoring Committee (IDMC) has reviewed the safety data on mortality and serious adverse events from the ongoing trauma study after the first 60, 120 and 250 patients were enrolled and followed for 30 days. After these three safety looks, the Committee recommended that the study continue without any change. In addition, at the 250 patient look, the IDMC conducted an adaptive sample size determination as specified in the protocol. A blinded power analysis was performed to determine if any increase in the sample size of the study was necessary. The assessment was based on a comparison between the mortality rate predicted in the protocol and the observed mortality rate in the trial to date. The IDMC has concluded that no adjustment in the number of patients to be enrolled in the study is required.*

**How many units of PolyHeme® have been given to patients previously?**

*Northfield has experience with PolyHeme® in patients with acute blood loss in trauma and elective surgery in the hospital setting, including those who have received up to 20 units (pints) containing 1,000 gm of PolyHeme®. The normal volume of blood in a human is 10 units (pints) containing 500 gm of hemoglobin. This means that up to two times the normal volume of blood in a human has been replaced by PolyHeme®. Some of these patients were kept alive while losing virtually all of their own blood during ongoing bleeding and receiving only PolyHeme® as replacement. Observations in these patients have suggested the life-sustaining potential of PolyHeme® in the treatment of urgent life-threatening blood loss and life-threatening hemoglobin levels [Gould et al, Journal of American College of Surgeons (2002), Volume 195 (4)].*

**What has been the safety experience with PolyHeme® in prior studies?**

*During the course of evaluation of any investigational product, both adverse experiences and serious adverse experiences can occur. These may be due to either the underlying condition of the patient, the treatment setting, or the investigational product itself. Both adverse experiences and serious adverse experiences have occurred in prior studies.*

*PolyHeme® was studied in one trial in patients experiencing planned acute blood loss while undergoing elective surgery for abdominal aortic aneurysm. The trial included a non-routine procedure called acute normovolemic hemodilution (ANH) in which a large quantity of the patient's own blood, up to 60%, is removed prior to the surgery, and is later replaced. The procedure in this study resulted in the infusion of large volumes of blood in addition to up to 6 units of PolyHeme® in the experimental group, while smaller overall volumes of blood alone were administered in the control group. Serious cardiovascular adverse experiences occurred more frequently in the PolyHeme® group. The patients in this study were older with more cardiovascular risk factors than those in the trials in trauma patients. It cannot be determined whether these findings are due to the more extensive ANH in the PolyHeme® group, to the reinfusion of more blood following surgery in the PolyHeme® group or to PolyHeme® itself.*

*In trauma patients, PolyHeme® has been rapidly infused during urgent life-threatening blood loss in sufficiently large quantities, up to 20 units (pints), to be considered well-tolerated in this patient population [Gould et al, Journal of American College of Surgeons (2002), Volume 195 (4)].*

#### **What is an exception from informed consent?**

*Patients are enrolled in a clinical study without giving informed consent before being enrolled.*

#### **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 safety and effectiveness of particular interventions.*

*Participating in the study has the potential for of direct benefit to the enrolled patients, defined as an increase in survival, because:*

- *Patients are in a life-threatening situation that necessitates intervention*
- *Previous studies support the potential to provide 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 therapy, and the risks and benefits of the proposed intervention*

*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.*

*It is unlikely that there will 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's enrollment before beginning treatment.*

**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.*

**What if I don't want to participate in this study?**

*Members of the public can object to participating in the study by wearing or displaying an exclusion bracelet (offered by the clinical site or from the manufacturer). Patients enrolled in the study may withdraw from the study, without prejudice, at any time by notifying the investigator.*

**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.*

**What are the potential benefits of PolyHeme®?**

*PolyHeme® may increase the likelihood of survival after traumatic injury  
The need for blood transfusion might be reduced  
Patients might avoid a reduction in the function of internal organs that sometimes follows blood transfusion*

**What are the potential risks of PolyHeme®?**

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

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

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

**Will patients get paid to participate?**

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

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

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

April 8, 2005



Dear \_\_\_\_\_

LETTER to  
COMMUNITY

I am the Director of Trauma at West Virginia University Morgantown, WV. I am writing to ask your help in promoting understanding regarding a research study using a blood substitute in severely injured patients.

The product is called *Polyheme*®. It is a "blood substitute." When people are severely injured and have lost a great deal of blood, paramedics at the scene of the accident currently cannot administer blood but instead give salt water. Once the patients arrive at the hospital however, they can receive human blood. This study will compare using *Polyheme*® instead of salt water by paramedics at the accident site, to determine if the risk of dying from severe trauma is changed. Only patients in dire need of blood from injury will be potential recipients of *Polyheme*®. This *Polyheme*® blood substitute has already been studied in animals and in small groups of humans. *Polyheme*® functions like human blood to carry oxygen to the vital organs. *Polyheme*® however has not previously been studied in trauma patients starting in the field immediately after injury. The study is nationwide and involves about 25 other trauma centers. Trauma is the leading cause of death among Americans under the age of 45. One out of 5 such patients currently die of their injuries.

Patients who qualify for this study are, by definition, in shock, and are not able to provide the standard informed consent. Federal regulations (21 CFR 50.24 Exception from Informed Consent) allow studies such as the *Polyheme*® study to continue with informed consent being obtained afterwards by patient or family. One of the requirements of these regulations is that we consult with the communities in which the research will be conducted, and disclose the research plan and the risks and expected benefits. This is the purpose of my letter.

Two weeks ago, WVU announced its interest to participate in this study and there was a press release followed by local TV and radio news spots as well as a Dominion Post article on May 19. The community must be well informed and understand this clinical trial before it begins.

If there is additional information you would like on this subject, or you would like me to present to your group, I would be delighted to do so and answer any questions. My point of contact for this study is Elizabeth Wooster, RN at 304-598-4659.

In the spirit of providing the best of medical care to those who live in our community, I look forward to working with you to inform your community about this study.

Sincerely,

Lawrence H. Roberts MD FACS  
Director, Jon Michael Moore Trauma Center  
West Virginia University Ruby Memorial Hospital &  
The Robert C. Byrd School of Medicine

Jon Michael Moore Trauma Center  
Ruby Memorial Hospital  
West Virginia University Children's Hospital  
Jon Michael Moore Trauma Center  
Medical Center Drive  
PO Box 8229  
Morgantown, WV 26506-8229

**West Virginia University Jon Michael Moore Trauma Center set to embark on a clinical study in severely injured patients to evaluate the possible benefit of a blood substitute for standard salt water**

PolyHeme® is an oxygen-carrying blood substitute. The study currently involving 25 trauma centers, PolyHeme® is being compared to standard salt water for replacement of blood in severely injured patients in shock. This study is aimed at evaluating the effect of PolyHeme® on patient survival as compared to salt water. Trauma patients in the field at the accident site by the paramedics and all patients are carefully evaluated throughout the study period of three months.

Trauma is the leading cause of death among Americans under the age of 45, and in severe trauma with shock, one out of 5 patients currently die.

Blood is not available in ground ambulances. PolyHeme®, a blood substitute, can however be available, and will be studied.

Because critically injured patients in shock cannot give informed consent, federal regulations (Exception to Informed Consent 21 CFR 50.24) allow consent to be given by the patient or family member afterwards in emergency situations like this. One of the requirements of these regulations is that we consult with the communities in which the research will be conducted, and disclose the research plan and the risks and expected benefits.

The study will be conducted in Monongalia, Harrison and Marion counties and involves severely injured patients who are in shock and will be transported to the Jon Michael Moore Trauma Center of West Virginia University Hospitals, Morgantown.

PolyHeme® is manufactured by Northfield Laboratories Inc., of Evanston, Illinois. Website: <http://www.northfieldlabs.com/PolyHeme.html>

For additional information, questions, or concerns, or to learn how you may elect to not participate in this study, please contact Elizabeth Wooster, RN at 304-598-4659

Dear \_\_\_\_\_

I am the Director of Trauma at West Virginia University Ruby Memorial Hospital, in Morgantown, WV. I am writing to ask your help in promoting community awareness and understanding regarding a research study using a blood substitute product in severely injured patients.

The product is called *Polyheme*®. It is a "blood substitute." When people are severely injured and have lost a great deal of blood, paramedics at the scene of the accident currently cannot administer blood but instead give salt water. Once the patients arrive at the hospital however, they can receive human blood. This study will compare using *Polyheme*® instead of salt water by paramedics at the accident site, to determine if the risk of dying from severe trauma is changed. Only patients in dire need of blood from injury will be potential recipients of *Polyheme*®. This *Polyheme*® blood substitute has already been studied in animals and in small groups of humans. *Polyheme*® functions like human blood to carry oxygen to the vital organs. *Polyheme*® however has not previously been studied in trauma patients starting in the field immediately after injury. The study is nationwide and involves about 25 other trauma centers. Trauma is the leading cause of death among Americans under the age of 45. One out of 5 such patients currently die of their injuries.

Patients who qualify for this study are, by definition, in shock, and are not able to provide the standard informed consent. Federal regulations (21 CFR 50.24 Exception from Informed Consent) allow studies such as the *Polyheme*® study to continue with informed consent being obtained afterwards by patient or family. One of the requirements of these regulations is that we consult with the communities in which the research will be conducted, and disclose the research plan and the risks and expected benefits. This is the purpose of my letter.

Two weeks ago, WVU announced its interest to participate in this study and there was a press release followed by local TV and radio news spots as well as a Dominion Post article on May 19. The community must be well informed and understand this clinical trial before it begins.

If there is additional information you would like on this subject, or you would like me to present to your group, I would be delighted to do so and answer any questions. My point of contact for this study is Elizabeth Wooster, RN at 304-598-4659.

In the spirit of providing the best of medical care to those who live in our community, I look forward to working with you to inform your community about this study.

Sincerely,

Lawrence H. Roberts MD FACS  
Director, Jon Michael Moore Trauma Center  
West Virginia University Ruby Memorial Hospital &  
The Robert C. Byrd School of Medicine

**West Virginia University Jon Michael Moore Trauma Center set to embark on a clinical study in severely injured people – trial to evaluate the possible benefit of a blood substitute fluid instead of salt water**

PolyHeme® is an oxygen-carrying blood substitute. In a nationwide study currently involving 25 trauma centers, PolyHeme® will be compared to standard salt water for replacement of blood loss in critically injured patients in shock. This study is aimed at evaluating whether PolyHeme® changes patient survival as compared to salt water. The study begins in the field at the accident site by the paramedics and all patients are carefully evaluated throughout the study period of three months.

Trauma is the leading cause of death among Americans under the age of 45, and in severe trauma with shock, one out of 5 patients currently die.

Blood is not available in ground ambulances. PolyHeme®, a blood substitute, can however be available, and will be studied.

Because critically injured patients in shock cannot give informed consent, federal regulations (Exception to Informed Consent 21 CFR 50.24) allow consent to be given by the patient or family member afterwards in emergency situations like this. One of the requirements of these regulations is that we consult with the communities in which the research will be conducted, and disclose the research plan and the risks and expected benefits.

The study will be conducted in Monongalia, Harrison and Marion counties and involves severely injured patients who are in shock and will be transported to the Jon Michael Moore Trauma Center of West Virginia University Hospitals, Morgantown.

PolyHeme® is manufactured by Northfield Laboratories Inc., of Evanston, Illinois. Website: <http://www.northfieldlabs.com/PolyHeme.html>

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