

October 7, 2005

Western Institutional Review Board
3535 7th Ave. SW
Olympia, WA 98502

Review Item: Public Consultation and Public Disclosure Activities

Sponsor: Northfield Laboratories, Inc.

Protocol NR: RTBSE-11- (N)

Reviewed Item: POLY SFH-P

WIRB PR NR: 20030927/1066482

PI: Carl Rosati, MD
Surg. Crit. Care Med. MC-162
47 New Scotland Ave.
Albany, NY 12208

Study Coordinator: Susan Rauch, RN
Pul. Div. Crit. Care Med. MC-91
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rauch@mail.amc.edu

Protocol NR : RTBSE-11-(N)

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Sponsor : Northfield Laboratories, Inc.

Drug : POLY SFH-P

**PI : Carl Rosati, MD
Surg. Crit. Care Med. MC-162
47 New Scotland Ave.
Albany, NY 12208**

**Study Coordinator : Susan Rauch, RN
518-262-6608**

Public Consultation and Public Disclosure Activities

September 12, 2005

Prior to the Press Release scheduled for September 7th, our public relations department notified a number of public official of the study and planned public consultation. Since Albany is the state capital, our PR Department wishes to allow several weeks to allow them to voice any questions or concerns. We received no contact from our local political figures. Listed below are those to whom notification was sent.

Name	Address	City	State	Zip
Senator Neil Breslin		Albany	NY	12247
Senator Joseph Bruno		Saratoga Springs	NY	12866
Senator Hugh Farley		Amsterdam	NY	12010
Senator Kemp Hannon		Garden City	NY	11530
Assemblyman Ronald Canestrari		Albany	NY	12247
Assemblyman Richard N. Gottfried		Albany	NY	12248
Assemblyman John McEnery		Albany	NY	12247
Assemblyman Paul Tonko		Amsterdam	NY	12010
Senator Hillary Clinton		Albany	NY	12207
Senator Charles Schumer		Albany	NY	12207
Congressman John Sweeney		Clifton Park	NY	12065
Congressman Michael McNulty		Albany	NY	12207
County Executive, Michael Breslin		Albany	NY	12207
Mayor Gerald Jennings		Albany	NY	12207
Albany County Commissioner of Health, James Crucetti		Albany	NY	12202

Community Out Research Process

- 1) Press Conference - September 7, 2005
- 2) Saratoga Community Meeting- September 12, 2005
with distribution of information brochures in Saratoga and Skidmore College.
- 3) Albany Medical Center Community Meeting – September 14, 2005
- 4) Empire State Plaza Concourse – September 15, 20, 26, and 27, 2005
- 5) Colonie Family Day – September 17, 2005
- 6) Nursing Education Teaching Day – September 18, 2005
- 7) The Schoharie Health Fair – September 21, 2005
- 8) Albany Medical Center Community Meeting - October 5, 2005
- 9) Website- Live September 7, 2005 and will continue through study.
- 10) Study Phone Line –518-262-2828
- 11) Local Colleges- I have also contacted several local colleges in the hope of getting information on the student's web site with a link to the Polyheme site. Unfortunately, only one college was willing to permit it. Please see attached emails.
- 12) Public shopping areas
 - A brochure on the bulletin board in some of our larger grocery stores was permitted.
 - I also attempted to have an information table in both of our largest malls and was denied. Not even allowed to leave brochures!
 - Some local business did allow me to leave small batches of informational brochures (subway& starbucks).
- 13) Polyheme Question & Answer Brochures – Used them at every event and distributed approximately 1000.
- 14) Letters sent to every Jehovah's Witnesses Congregation (10) in the TriCity area. The PI and Study Coordinator met the Hospital Liaison Committee for Jehovah's Witnesses.

The majority of responses that we received came from personal contact either through a community meeting or an information table.

Media Coverage

September 7, 2005 – Press Conference

TV

- **WNYT**
- **WTEN**
- **FOX Capital News 9**
- **WRGB**
- **WXXA**

Newspaper

- **Business Review**
- **Troy Record**
- **Times Union**
- **Dailey Gazette**
- **Saratogian**

Radio

- **WGY**
- **WAMC**
- **NPR**

AMC Community Meetings 9/14/05 & 10/05/05

Newspapers

- **Times Union**
- **Gazette**
- **Troy Record**
- **Post Star**
- **Saratogian**
- **Spotlights**
- **Jewish World**

Albany Medical Center Publications

- **The Page**
- **Groupwise email system (Community Meetings – reaches anyone with a computer in the college or hospital)**

News clipping that I was able to obtain have been included.



PRESS CLIP

THE DAILY GAZETTE ♦ THURSDAY, SEPTEMBER 8, 2005 ♦ B7

ALBANY

Albany Med will join blood substitute trial

BY JILL BRYCE
Gazette Reporter

Albany Medical Center is one of 20 trauma centers in the nation chosen to participate in national clinical trials to evaluate the safety and efficiency of a red blood cell substitute that could increase the survival rates of trauma patients.

Although there is no substitute for real blood, this could be used when there's a major blood loss in a shooting or motor vehicle accident, for example.

"We are excited to be included in the ground-breaking clinical trial," said Dr. Carl Rosati principal investigator of the study.

Trauma-related injuries are a leading cause of death among Americans under 45 years old. One in five trauma patients dies from their injuries, said Rosati.

"If we can begin to deliver an oxygen-carrying solution very early and keep these patients' hemoglobin levels up, we may see more survivors," said Rosati.

The red blood cell substitute is PolyHeme, a universally compatible, oxygen-carrying resuscitative fluid derived from human blood. Ambulances do not carry blood because it is such a fragile substance, so researchers are searching for a product that can be used at the scene of an accident to save lives.

Under the study, PolyHeme would be administered before a patient arrives at the hospital, either at the scene of the injury or in the ambulance. It then would be administered for 12 hours in the hospital. Northfield Laboratories of Evanston, Ill., which makes PolyHeme, is funding the study.

The study will compare the survival rate of patients receiving PolyHeme to patients who receive standard care, which is saline solution, followed in the hospital by donated blood if needed.

To be eligible for the study, patients must be at least 18 years old, critically injured, in an emergency situation where they are losing a large amount of blood, and in a state of shock.

Albany Medical Center spokeswoman Sue Ford said the hospital is in the "public disclosure phase" and is obligated to inform the public about the clinical trial and will also host several meetings.

If the public is not supportive, the hospital will not proceed, said Ford, but if there's positive feedback the program could begin by November.

Patients with severe brain injuries or irreparable injuries, those known to object to blood transfusions due to religious reasons and women who are pregnant will be excluded from the study.

Only patients transported to Albany Medical Center by the LifeNet "MedFlight" helicopter or by ground ambulance by emergency medical services agencies within Albany, Schenectady and Rensselaer counties will be considered for the study.

Because patients who are eligible for the study will probably not be able to provide consent due to the extent of their injuries, the hospital will not seek their permission, as allowed by federal regulations for clinical research in emergency settings.

A series of public meetings will be held and residents can ask questions, or obtain a bracelet that allows them to opt out of the study. Meetings will be take place at 7 p.m. Wednesday, Sept. 14, and at 7 p.m. Wednesday, Oct. 5, at the Huyck Auditorium at Albany Medical Center. Also, a representative will be at the Empire State Plaza concourse level Sept. 15, 20, 21, 26 and 27. Information is available by calling the PolyHeme response line at 262-2828.

PRESS CLIP

TIMES UNION

CAPITAL REGION



THURSDAY, SEPTEMBER 8, 2005

This hospital test could prove to be a lifesaver

Albany Med joins nationwide study of blood substitute that could help trauma victims survive

By **MATT PACENZA**
Staff writer

ALBANY — Patients unlucky enough to be in a serious accident in the next few months may receive a new product with the potential to revolutionize emergency medicine while a helicopter or ambulance rushes them to the hospital.

The liquid coursing into their veins could be a new substitute for blood called PolyHeme. Soon to

be tested at Albany Medical Center, it may transform how paramedics and physicians treat trauma victims — and save lives.

The benefit of PolyHeme, which is made from human blood, is that it can be stored much longer — it has a shelf life of 12 months, compared with 42 days for blood — and can be given to anyone regardless of blood type, saving critical minutes when each second matters. Currently, emergency

FIND OUT MORE

Albany Medical Center will hold a pair of public meetings about the PolyHeme study, at the hospital's Huyck auditorium at:

■ 7 p.m. Wed., Sept. 14

■ 7 p.m. Wed., Oct. 5

For information, call Albany Med at 262-2828

personnel rarely give a trauma victim blood on the way to the hospital because they don't know the person's blood type.

"This will be a great help to us," said Walter Gould, a flight nurse with Albany MedFlight, which transports trauma patients by helicopter to Albany Med.

Albany Med is one of about 20 hospitals in the study, which is being paid for by Northfield Laboratories of Evanston, Ill., PolyHeme's maker. Researchers hope to test the product on 720 patients across the country, a big enough sample to draw conclusions about its effectiveness and safety.

The study, likely to begin at Albany Med within a month or two, raises ethical questions be-

cause most trauma victims will not be capable of offering informed consent — a requirement for nearly all medical research — before they get PolyHeme.

There are federal regulations that allow for research in emergency settings where consent is difficult to obtain. Albany Med officials are pledging to do everything they can to get permission from the victim or a family member. They're also holding two community meetings to let people know about the research and PolyHeme.

Please see **BLOOD 12** ▶

BLOOD: Product holds promise of saved lives

▼ CONTINUED FROM B1

Officials recognize, however, that those meetings will be of dubious utility — no one plans, after all, to become a trauma victim. "We've been struggling with how to tap into our community," said Susan Rauch, a registered nurse and a coordinator of the study.

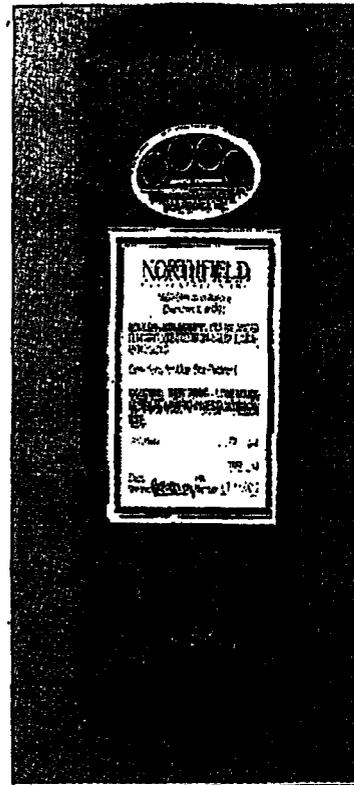
The study's principal investigator, Dr. Carl Rosati, said he is confident that PolyHeme is safe. It has already been tested on 171 people as part of the initial clinical trials.

"The risk profile of this product is less than for blood itself," said Rosati, director of the trauma section of Albany Med's surgery division. The biggest risk for blood is that someone is given the wrong type, an error that can be fatal — not a concern for PolyHeme.

There are several settings in which PolyHeme could be invaluable, Rosati said: during long transports, for a mass casualty event where blood supplies might run low and on the battlefield. The Pentagon has been involved in the research.

PolyHeme is made from hemoglobin extracted from blood. Like blood — and unlike saline, often given when blood can't be, as in an ambulance — PolyHeme is capable of carrying oxygen.

Anyone 18 or older who is critically injured and has suffered major blood loss is eligible for the study. During transport, nurses and paramedics will decide whether any given patient is eligible. The trial will be randomized, meaning only some of the selected patients will get PolyHeme. The others will get saline or whatever other standard



POLYHEME, a blood substitute, holds the promise of being a lifesaver for victims of trauma.

of care they would otherwise normally receive.

PolyHeme could also be useful once the patient gets to the emergency department. It takes a hospital about 45 minutes to figure out someone's blood type. That time period is critical for someone who has suffered major trauma, Rosati said.

"We're looking to limit the shock phase — that's our major killer," he said.

▶ **Matt Pacenza can be reached at 454-5533 or by e-mail at mpacenza@timesunion.com.**

THE BUSINESS REVIEW

SERVING NEW YORK'S CAPITAL REGION

LATEST NEWS
September 7, 2005

Albany Med hospital part of blood substitute study

Albany Medical Center Hospital is one of 16 Level 1 trauma centers in the United States chosen to participate in a national clinical trial to evaluate the safety and efficacy of a temporary oxygen-carrying red blood cell substitute and its ability to increase survival of trauma patients.

PolyHeme is a universally compatible, oxygen-carrying resuscitative fluid derived from human blood and designed for use in cases of major blood loss, when blood is not immediately available.

"We are excited to be included in this groundbreaking clinical trial," said Dr. Carl Rosati, the director of the section of trauma, division of general surgery at Albany Medical Center and principal investigator of the study. "Almost one in five trauma patients die from their injuries. If we can begin to administer an oxygen-carrying solution very early and keep these patients' hemoglobin levels up, we may see more survivors."

Rosati said that because of its fragility, ambulances are unable to carry blood, so researchers are looking for a product that can be used at the scene of an accident. 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 followed in the hospital by donated blood, if needed.

Under the study protocol, PolyHeme would be administered before arrival at the hospital, either at the scene of the injury or in the ambulance, and would continue during a 12-hour post-injury period in the hospital.

Because the patients eligible for the 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. The Institutional Review Board at Albany Med -- which must approve the hospital's participation in the study -- requires the investigators to hold public meetings to educate the public and answer their questions about the study in lieu of informed consent. Members of the public may receive bracelets allowing them to opt out of the study.

Public meetings will take place at 7 p.m. Wednesday, Sept. 14 and at 7 p.m. and Wednesday, Oct. 5 at the Huyck Auditorium at Albany Med. In addition, a representative will be at the Empire State Plaza concourse level on Sept. 15, 20, 21, 26 and 27. For additional information, call (518) 262-2828.

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9-7 10:30 AM News Update - Crown Point Man Faces Murder Indictment in Toddler's Death

CROWN POINT MAN FACES MURDER INDICTMENT IN TODDLER'S DEATH



An Essex County grand jury has indicted Greggory L. Varmette on three charges, including murder, in the death of a boy he was babysitting.

Varmette, who is from Crown Point, was indicted Tuesday on two counts of second-degree murder, first-degree manslaughter and endangering the welfare of a child in conjunction with the death of 3-year-old Stephen McKay.

Varmette was arrested on an assault charge Aug. 3 after the child was admitted to the emergency room at Moses-Ludington Hospital in Ticonderoga. The toddler was flown to Fletcher Allen Health Care in Burlington, where he died early on Aug. 4.

An autopsy done by the Vermont Chief Medical Examiner's Office found that Stephen's death was attributable to head injuries; swelling of the brain; blunt trauma of the torso and extremities, including contusions and a broken left forearm; and cardiopulmonary arrest.

Varmette is being held in the Essex County Jail. An arraignment date in Essex County Court has not been set. (pressrepublican.com)

SYRACUSE'S ROBINSON SEES SOME GOOD IN SEASON-OPENING DEBACLE



It wasn't exactly the outcome Greg Robinson envisioned for his first game on the Syracuse sideline.

The first-year coach watched his punchless offense sputter and fizz out in Sunday's 15-to-7 season-opening home loss to West Virginia, but in the aftermath of the loss, Robinson says there were some positive signs, including several plays

that could have gone for big gains if Syracuse had executed properly.

Junior quarterback Perry Patterson had an erratic game leading the Orange's new West Coast offense for the first time.

Overall, he was 15-for-32 for 85 yards and two interceptions, one of which was returned for West Virginia's only touchdown. The Syracuse offense produced just 103 yards, the lowest total since the Orange managed just 93 against Iowa in 1976. (Associated Press)

POTSDAM/CANTON POLICE STEP-UP ENFORCEMENT



Potsdam and Canton Police Departments have begun their stepped-up fall law-enforcement campaigns with dozens of arrests in each community. The crackdown again this fall coincides with back-to-school and back-to-college efforts designed to rein in rowdy behavior. In the past three days, Canton police arrested 34 people of 42 charges and Potsdam police arrested numerous more. Charges ranged from vehicle and traffic charges, the most being seat-belt and cell-phone violations, to unnecessary noise, underage drinking, marijuana counts and public urination. (1340WMSA)

STATE ANALYSIS A MIXED REVIEW ON CHARTER SCHOOLS



A state analysis has found that charter schools are making academic gains, but also causing fiscal drains on neighboring traditional schools.

The report on the innovative public charter schools will be presented to the State Board of Regents Thursday and Friday.

Charter schools operate privately on public funds free from much of the bureaucracy of traditional public schools. After six years, they remain the subject of heated debate among education officials and the Legislature.

The schools operate on five-year renewable charters that end if the school isn't successful.

Among the State Board of Regents findings is that charter schools drain student aid from traditional schools to pay for the charter school students' educations. (Associated Press)

NEW YORK EXPECTING FIRST HURRICANE EVACUEES THIS WEEK



Several hundred Hurricane Katrina evacuees are expected to make their way to New York as early as this week.

Social service, religious and education leaders are arranging for housing, school and jobs.

State emergency officials have asked several counties, including Erie and Onondaga, to accommodate about 150 people each.

New York is one of roughly 30 states that have offered to take in those left homeless by the devastating Gulf Coast hurricane.

Buffalo Common Council Member Antoine Thompson says the city has 200 units of public housing and 500 units in city-owned property available for evacuees.

Syracuse officials have reserved 120 hotel rooms for the expected influx. The rooms will provide temporary housing until more permanent arrangements are made.

Officials expect the new arrivals to be in their communities for 18 to 24 months, although some are expected to make New York their permanent home.
(Associated Press)

NORTH COUNTRY KIDS RETURN TO SCHOOL



Class was underway for most parochial school children across the North Country yesterday, although a handful of students got a head start last week with freshman or junior-high orientations. Summer construction projects in some districts did not have any impact on the start of classes. A safety reminder for motorists: be alert for stopped school buses and children on the street during morning and afternoon bus runs to prevent needless injuries or tragedy. Local police agencies will also be stepping up traffic surveillance with the opening of school. (1340WMSA)

HIGH GAS PRICES COULD COST NEW YORKERS EXTRA \$600 MILLION A MONTH



Senator Charles Schumer says that if gas prices don't start declining, they will cost New York drivers an extra 600 million dollars a month.

If the high prices continue for a year, Schumer says it will cost the entire state some 7.2 billion dollars, and New York City drivers would fork over nearly one billion dollars more than they paid last year.

The figures are based on state gas-consumption statistics and triple-A fuel cost calculators. The statewide average yesterday for a gallon of unleaded was \$3.25.

In New York City, 3-dollar gas would mean the average driver pays an extra 45-dollars a month, or 548-dollars more per year compared to the cost last year.

Most industry experts believe the recovery from Hurricane Katrina will bring the cost of gas back down, but politicians including Schumer are calling for an investigation of possible price gouging.

Lawmakers also have called for state and federal governments to suspend their taxes on gas. (Associated Press)

SEN. CLINTON CHARGES BUSH HAS WEAKENED DISASTER AGENCY



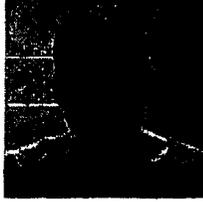
Senator Hillary Clinton says federal emergency planning under President Bush has become "a recipe for disaster." Clinton says FEMA ran far more effectively under her husband's watch.

The Democratic senator is pushing legislation to take FEMA back out of the Department of Homeland Security. It's one of a number of signals a political fight is brewing over what many complain has been a bungled government response to Hurricane Katrina.

Senators Susan Collins and Joe Lieberman said they would hold hearings into the federal response, but Clinton is pushing for an independent commission, modeled on the nine-eleven commission, to investigate government lapses and gaps.

The apparent failings of the federal response led The Times-Picayune, Louisiana's largest newspaper, to call for the firing of every federal official involved in the Katrina response. (Associated Press)

MICHAUD PLEADS NOT GUILTY TO WIFE'S BLUDGEONING DEATH



Another not guilty plea from St. Lawrence County murder suspect Michael Michaud.

Yesterday he was in county court answering an indictment for second-degree murder for July's bludgeoning death of his wife Christine in Norwood. With his not guilty plea recorded, Michaud was returned to county jail where he's being held without bail. State Police say Michaud confessed to killing his wife.

MAN CHARGED IN CRASH THAT KILLED HIS WIFE



A central New York man has been charged with felony vehicular manslaughter after a weekend crash that left his wife dead.

Authorities say 50-year-old Danny Reed of Andes was driving a pickup truck that went off a Delaware County roadway early Saturday.

Investigators say 52-year-old Kathryn Reed was thrown from the vehicle after it hit a guard rail. She was pronounced dead at the scene.

State Police say Danny Reed sustained minor injuries. He was treated at a local hospital and released.

Officials say they expect Reed will face more charges in connection with the fatal crash. The case is expected to be presented to a Delaware County grand jury. (Associated Press)

ALBANY MED TO PARTICIPATE IN STUDY OF BLOOD SUBSTITUTE



Albany Medical Center is among a select group of trauma centers chosen to participate in a national clinical trial of a blood substitute.

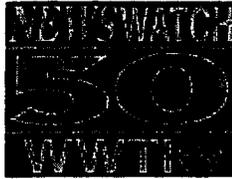
The study will evaluate the safety and effectiveness of PolyHeme, and its ability to increase the survival of trauma patients. PolyHeme is a temporary oxygen-carrying red blood cell substitute.

Under the study protocol, PolyHeme would be administered prior to arrival at the hospital, either at the scene of an accident or in the ambulance. It would continue to be given during a 12-hour post-injury period at the hospital.

PolyHeme is derived from human blood and is designed for use in cases of major blood loss, including shootings or car accidents. It can be used when blood is urgently needed but isn't immediately available.

Trauma-related injuries are a leading cause of death among Americans under 45 years old, affecting more than two million people a year. (Associated Press)

INTERNATIONAL FREEDOM CENTER NAMES FAMILY ADVISORY GROUP



The controversial Freedom Center proposed for the World Trade Center site, yesterday named a seven-member advisory of September 11th family members.

The International Freedom Center still needs to submit more detailed plans about its content by September 23rd to the Lower Manhattan Development Corporation. Chairman John Whitehead has said that if the detailed plans don't satisfy the rebuilding agency it will look for another tenant.

A group of 9-11 family members has objected to the Freedom Center, saying it would detract from the planned memorial and it may host anti-American exhibits.

The family advisory group will advise the center's board and staff on all aspects of center programming. (Associated Press)

UNION OFFERS REWARD IN MEMBER'S DEATH



Colleagues of a nursing home aide killed by a stray bullet that pierced her home are offering 10-thousand dollars to anyone who can put the shooter behind bars.

Catholic Health System and the upstate chapter of the Service Employees International Union offered the reward yesterday with the hope of bringing Lottie Matos' killer to justice.

Matos was cleaning her Buffalo home last month when a masked assailant barged into the house next door and opened fire on a man in a wheelchair. The bullets missed the man and his two nephews, but one of the bullets pierced Matos' window and struck her in the stomach.

Police have said they have no leads or suspects.

Matos worked as a nurse's aide at Nazareth Nursing Home, part of Catholic Health's network of hospitals and other facilities. (Associated Press)

US AIRWAYS TO RESTORE SOME UPSTATE SERVICE TO PITTSBURGH



US Airways is planning to restore some service to Pittsburgh from an upstate airport.

The financially-strapped carrier ended service from the Binghamton Regional Airport to Pittsburgh last November. That prompted complaints from many frequent fliers who wound up traveling through the more congested Philadelphia airport.

Broome County executive Barbara Fiala says US Airways has decided to start two daily flights from Binghamton to Pittsburgh. She says the new service will start November 9th.

Fiala says she's pleased US Airways has responded to the request by local officials to restore direct service to Pittsburgh. The airline will continue to provide seven daily flights from the Binghamton airport to Philadelphia. (Associated Press)

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back 

This hospital test could prove to be a lifesaver

Albany Med joins nationwide study of blood substitute that could help trauma victims survive

By MATT PACENZA, Staff writer

First published: Thursday, September 8, 2005

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The liquid coursing into their veins could be a new substitute for blood called PolyHeme. Soon to be tested at Albany Medical Center, it may transform how paramedics and physicians treat trauma victims -- and save lives.

The benefit of PolyHeme, which is made from human blood, is that it can be stored much longer -- it has a shelf life of 12 months, compared with 42 days for blood -- and can be given to anyone regardless of blood type, saving critical minutes when each second matters. Currently, emergency personnel rarely give a trauma victim blood on the way to the hospital because they don't know the person's blood type.

"This will be a great help to us," said Walter Gould, a flight nurse with Albany MedFlight, which transports trauma patients by helicopter to Albany Med.

Albany Med is one of about 20 hospitals in the study, which is being paid for by Northfield Laboratories of Evanston, Ill., PolyHeme's maker. Researchers hope to test the product on 720 patients across the country, a big enough sample to draw conclusions about its effectiveness and safety.

The study, likely to begin at Albany Med within a month or two, raises ethical questions because most trauma victims will not be capable of offering informed consent -- a requirement for nearly all medical research -- before they get PolyHeme.

There are federal regulations that allow for research in emergency settings where consent is difficult to obtain. Albany Med officials are pledging to do everything they can to get permission from the victim or a family member. They're also holding two community meetings to let people know about the research and PolyHeme.

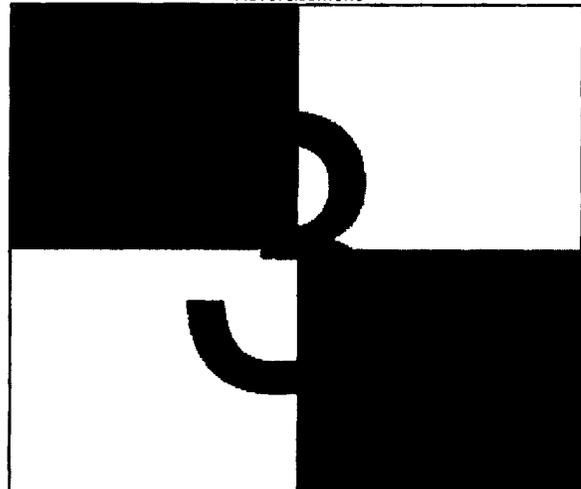
Officials recognize, however, that those meetings will be of dubious utility -- no one plans, after all, to become a trauma victim. "We've been struggling with how to tap into our community," said Susan Rauch, a registered nurse and a coordinator of the study.

The study's principal investigator, Dr. Carl Rosati, said he is confident that PolyHeme is safe. It has already been tested on 171 people as part of the initial clinical trials.

"The risk profile of this product is less than for blood itself," said Rosati, director of the trauma section of Albany Med's surgery division. The biggest risk for blood is that someone is given the wrong type, an error that can be fatal -- not a concern for PolyHeme.

There are several settings in which PolyHeme could be invaluable, Rosati said: during long transports, for a mass casualty event where blood supplies might run low and on the battlefield. The Pentagon has been involved in the research.

Advertisement



PolyHeme is made from hemoglobin extracted from blood. Like blood -- and unlike saline, often given when blood can't be, as in an ambulance -- PolyHeme is capable of carrying oxygen.

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PolyHeme could also be useful once the patient gets to the emergency department. It takes a hospital about 45 minutes to figure out someone's blood type. That time period is critical for someone who has suffered major trauma, Rosati said.

"We're looking to limit the shock phase -- that's our major killer," he said.

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AMC News Release

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ALBANY MEDICAL CENTER

Albany Medical Center Chosen to Participate in National Study of Blood Substitute in Trauma Patients

Questions & Comments

Contact: Sue Ford

(518) 262-3421

fords@mail.amc.edu

ALBANY, N.Y., September 7, 2005 – The Albany Medical Center is one of a select number of Level 1 trauma centers in the U.S. chosen to participate in a groundbreaking national clinical trial to evaluate the safety and efficacy of PolyHeme—a temporary oxygen-carrying red blood cell substitute—and its ability to increase survival of trauma patients.

"We are excited to be included in this groundbreaking clinical trial," said Carl Rosati, M.D., director, section of trauma, division of general surgery, and principal investigator of the study. "Trauma-related injuries are a leading cause of death among Americans under 45 years of age. In fact, almost one in five trauma patients die from their injuries. If we can begin to administer an oxygen-carrying solution very early and keep these patients' hemoglobin levels up, we may see more survivors."

PolyHeme is a universally compatible, oxygen-carrying resuscitative fluid derived from human blood and is designed for use in cases of major blood loss such as shootings, motor vehicle or construction-site accidents when blood is urgently needed but is not immediately available.

Under the study protocol, PolyHeme would be administered before arrival at the hospital, either at the scene of the injury or in the ambulance, and would continue during a 12-hour post-injury period in the hospital. Because of its fragility, ambulances are unable to carry blood, so researchers are looking for a product that can be used at the scene of an accident to save lives. 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, followed in the hospital by donated blood, if needed.

To be considered eligible for this study, patients must be at least 18-years old, critically injured, and in an emergency situation where they are losing a large amount of blood and are in a state of shock. Patients with severe brain injuries or irreparable injuries, those who are known to object to blood transfusions due to religious reasons and women who are obviously pregnant will be excluded from the study. Only patients who are transported to Albany Med by LifeNet "MedFlight" helicopter or by ground ambulance by participating emergency medical services agencies within Albany, Saratoga, Schoenectady and Rensselaer counties will be considered for this study.

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

The Institutional Review Board (IRB) at Albany Medical Center requires the study investigators to hold public meetings to educate the public and answer their questions about the study in lieu of informed consent. Albany Med's participation in this study is

contingent upon the IRB's approval.

A series of public meetings at which citizens can ask additional questions or obtain a bracelet allowing them to opt out of the study will take place at 7 p.m. Wednesday, September 14 and at 7 p.m. Wednesday, October 5 at the Huyck Auditorium at Albany Medical Center. In addition, a representative will be at the Empire State Plaza concourse level on September 15, 20, 21, 26 and 27. For additional information, individuals can call (518) 262-2828.

"Our top priority is the safety of our patients, so we want to hear any concerns that the public might have," said Rosati. "It's important that people ask questions and voice their opinions before the study begins. That way, we can help them understand the importance of this study and how it could positively impact trauma care or issue them a bracelet to wear during the duration of the study that allows them to opt out in the event that they are confronted with a medical emergency and need a blood substitute."

Research published in 2002 in the Journal of the American College of Surgeons showed that 171 patients who received PolyHeme during trauma or urgent surgery had a 30-day death rate of 25 percent, compared with 65 percent in a control group.

The PolyHeme study is a multi-center trial currently underway at 16 trauma centers in the U.S., including the Mayo Clinic in Rochester, MN and the University of California at San Diego Medical Center. Approximately 20 hospitals will eventually participate in the study, which is expected to enroll 720 patients. Northfield Laboratories, Inc., of Evanston, Ill., manufacturer of PolyHeme, is funding the study.

The Albany Medical Center is northeastern New York's only academic health sciences center. It consists of one of the nation's oldest medical schools, Albany Medical College; one of New York's largest teaching hospitals, Albany Medical Center Hospital; and one of the Capital Region's most active fundraising organizations, the Albany Medical Center Foundation, Inc.

-30-

New Scotland Avenue, Albany, New York 12208 - (518) 262-3421 - FAX (518) 262-3880

[<<Back](#)



Albany Med to participate in study of blood substitute

ALBANY, N.Y. Albany Medical Center is among a select group of trauma centers chosen to participate in a national clinical trial of a blood substitute.

The study will evaluate the safety and effectiveness of PolyHeme, and its ability to increase the survival of trauma patients. PolyHeme is a temporary oxygen-carrying red blood cell substitute.

Under the study protocol, PolyHeme would be administered prior to arrival at the hospital -- either at the scene of an accident or in the ambulance. It would continue to be given during a 12-hour post-injury period at the hospital.

PolyHeme is derived from human blood and is designed for use in cases of major blood loss, including shootings or car accidents. It can be used when blood is urgently needed but isn't immediately available.

Trauma-related injuries are a leading cause of death among Americans under 45 years old, affecting more than two (m) million people a year.

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LEGAL NOTICE

Albany Medical Center
Polyheme Trauma Study
Albany Medical Center of
Albany, New York is one of a
selected number of Level I
trauma centers in the United
States considering participa-
tion in a clinical study of a
new, potentially life-saving
treatment for severely in-
jured patients who are bleed-
ing and in shock. The study
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proval by the Western Insti-
tutional Review Board
(WIRB) of Albany Medical
Center. This study uses a
provision for an exception
from informed consent re-
quirements in accordance
with federal regulations
(21CFR 312.61) since it is
anticipated that patients will
not be able to provide con-
sent due to the nature and
extent of their injuries. Pa-
tients, their legally autho-
rized representative, or a
family member will be noti-
fied at the earliest opportu-
nity and their inclusion and the
details of the research study
will be discussed at a commu-
nity meeting which will be
held at Albany Medical
Center, 43 New Scotland
Ave., Albany, NY 12208 in
the Huyck Auditorium on
Wednesday, September 14,
2005 from 7 pm to 9 pm. For
all members of the commu-
nity who are interested in
learning more about this
study and to offer feedback
to representatives of Albany
Medical Center, www.amc.edu/polyheme
(518) 282-2828

ALBANY TIMES UNION
News Plaza
Box 15000
Albany, New York 12212

**STATE OF NEW YORK
COUNTY OF ALBANY**

T. Dollard / I predict of the City of Albany, being duly sworn, says th
is Principal C ES UNION, a daily newspaper printed in the County of
of Colonie, and he County of Albany, Town of Colonie and the City of
aforsaid and t which a printed copy is annexed has been regularly pu
the said ALBANY the following dates:

- 09-08-2005
- 09-11-2005
- 09-13-2005

T. Dollard

Sworn to before me, this 13th day of September 2005

John M. Kelly
Notary Public
Albany County

Acct. #070075003



Jodi M. (Kelly) Burick
Notary Public, State of New York
Qualified in Albany County
Commission Expires Oct. 16
No. 4898040

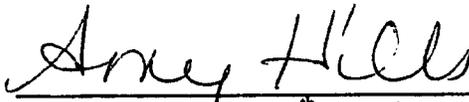
State of New York,
City and County of Schenectady

ss.:

Albany Medical Center Polyheme Trauma Study
Albany Medical Center of Albany, New York is one of a select number of Level-I trauma centers in the United States considering participation in a clinical study of a new, potentially life-saving treatment for severely injured patients who are bleeding and in shock. The study is being considered for approval by the Western Institutional Review Board (WIRB) of Albany Medical Center. This study uses a provision for an exception from informed consent requirements in accordance with federal regulations (21CFR 50.24) since it is anticipated that patients will not be able to provide consent due to the nature and extent of their injuries. Patients, their legally authorized representative, or a family member will be notified at the earliest opportunity and their inclusion and the details of the research study. A community meeting will be held at Albany Medical Center, 43 New Scotland Ave., Albany, NY 12208 in Huyck Auditorium on Wednesday, September, 14, 2005 from 7pm to 9pm, for all members of the community who are interested in learning more about this study and to offer feedback to representatives of Albany Medical Center. www.amc.edu/polyheme (518) 262-2828 9-8,11,13 4737

Amy Hills of the City of Schenectady, being duly sworn, says that he/she is Principal Clerk in the office of the Daily Gazette Co., published in the City of Schenectady and that the notice/advertisement, of which the annexed is a printed copy, has been regularly published in the Daily Gazette and/or Sunday Gazette as follows:

3 insertions Sept. 8,11,13 2005



Sworn to me on this 14th day of September 2005

LISA J. BALDWIN NOTARY PUBLIC
COMMISSIONER OF DEEDS

My commission expires 6-28-06



**Albany Medical Center
Polyhep Trauma Study**

Albany Medical Center of Albany, New York is one of a selected number of Level I trauma centers in the United States considering participation in a clinical study of a new potentially life-saving treatment for severely injured patients who are bleeding and in shock. The study is being considered for approval by the Western Institutional Review Board (WIRB) of Albany Medical Center. This study uses a provision for an exception from informed consent requirements in accordance with federal regulations (21CFR 50.24) since it is anticipated that patients will not be able to provide consent due to the nature and extent of their injuries. Patients, their legally authorized representative, or a family member will be notified at the earliest opportunity and their inclusion and the details of the research study.

A community meeting will be held at Albany Medical Center, 43 New Scotland Ave., Albany, NY 12208 in Huyck Auditorium on Wednesday, September 14, 2005 from 7 pm to 9 pm for all members of the community who are interested in learning more about this study and to offer feedback to representatives of Albany Medical Center.
www.amc.edu/polyhep
(518)262-2828

9/8, 11, 13, 3x

STATE OF NEW YORK, COUNTY OF SARATOGA

Ashleigh Robinson BEING DULY SWORN, DEPOSES AND SAYS: THAT SHE IS THE PRINCIPAL CLERK OF THE SARATOGIAN, THE OFFICIAL NEWSPAPER; THAT THE FOREGOING LEGAL ADVERTISING WAS PUBLISHED IN SAID NEWSPAPER ON

September 8, 11, 13, 2005

SUBSCRIBED AND SWORN TO BEFORE ME:

Ashleigh Robinson

THIS 14th DAY OF September, 2005

Pamela Foote

NOTARY

PAMELA FOOTE
NOTARY PUBLIC, State of New York
Qualified in Washington County
My Commission Expires 10/21/05
Reg. # 01FC4099149

LEGAL NOTICE

Albany Medical Center
PolyHeme Trauma Study
PolyHeme Medical Center, of
Albany, New York is one of
several Level I trauma cen-
ters in the United States
considering participation in a
clinical study of a new, po-
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for severely injured patients
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Patients, their legally autho-
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fied at the earliest opportuni-
ty and their inclusion and the
details of the research study
will be discussed at a commu-
nity meeting. A community meeting
will be held at Albany Medical
Center, 43 New Scotland
Ave., Albany, NY 12208 on
Wednesday, October 27, 2005
from 7 pm to 9 pm. For
all members of the commu-
nity who are interested in
learning more about this
study and to offer feedback
to representatives of Albany
Medical Center, www.amc.edu/polyheme
(518) 262-2828 TU 4t (14219)

ALBANY TIMES UNION
News Plaza
Box 15000
Albany, New York 12212

**STATE OF NEW YORK
COUNTY OF ALBANY**

T. Dollard is Principal of Colonie, aforesaid and the said ALBANY TIMES UNION, a daily newspaper printed in the County of Albany, Town of Colonie and the City of Albany, which a printed copy is annexed has been regularly published in the following dates:

- 09-25-2005
- 09-29-2005
- 10-02-2005
- 10-04-2005

T. Dollard

Sworn to before me, this 4th day of October 2005

Jodi M. Kelly Burick
Notary Public
Albany County

Acct. #070075003



Jodi M. (Kelly) Burick
Notary Public, State of New York
Qualified in Albany County
Commission Expires Oct. 19, 2005
No. 4898040

State of New York,
City and County of Schenectady

ss.:

**Albany Medical Center
PolyHome Trauma Study**
Albany Medical Center of Albany, New York is one of a select number of Level I trauma centers in the United States considering participation in a clinical study of a new, potentially life-saving treatment for severely injured patients who are bleeding and in shock. The study is being considered for approval by the Western Institutional Review Board (WIRB) of Albany Medical Center. This study uses a provision for an exception from informed consent requirements in accordance with federal regulations (21CFR 50.24) since it is anticipated that patients will not be able to provide consent due to the nature and extent of their injuries. Patients, their legally authorized representative, or a family member will be notified at the earliest opportunity and their inclusion and the details of the research study. A community meeting will be held at Albany Medical Center, 43 New Scotland Ave., Albany, NY 12208 in Huyck Auditorium on Wednesday, October 5, 2005 from 7 pm to 9 pm for all members of the community who are interested in learning more about this study and to offer feedback to representatives of Albany Medical Center.
HYPERLINK: "http://www.amc.edu/polyhome"
www.amc.edu/polyhome (518) 262-2828
9-25-29;10-2,4 7804

Amy Hills of the City of Schenectady, being duly sworn, says that he/she is Principal Clerk in the office of the Daily Gazette Co., published in the City of Schenectady and that the notice/advertisement, of which the annexed is a printed copy, has been regularly published in the Daily Gazette and/or Sunday Gazette as follows:

4 insertions Sept. 25, 29 Oct. 2, 4 2005

Amy Hills

Sworn to me on this 5th day of October 2005

LISA J. BALDWIN

NOTARY PUBLIC

COMMISSIONER OF DEEDS

My commission expires 6-28-06

Lisa Baldwin

Albany Medical Center
PolyHeme Trauma Study

Albany Medical Center of Albany, New York is one of several Level I trauma centers in the United States considering participation in a clinical study of a new, potentially life-saving treatment for severely injured patients who are bleeding and in shock. The study is being considered for approval by the Western Institutional Review Board (WIRB) of Albany Medical Center. This study uses a provision for an exception from informed consent requirements in accordance with federal regulations (21CFR 50.24) since it is anticipated that patients will not be able to provide consent due to the nature and extent of their injuries. Patients, their legally authorized representative, or a family member will be notified at the earliest opportunity and their inclusion and the details of the research study.

A community meeting will be held at Albany Medical Center, 43 New Scotland Ave., Albany, NY 12208 in Huyck Auditorium on Wednesday, October 5, 2005 from 7 pm to 9 pm, for all members of the community who are interested in learning more about this study and to offer feedback to representatives of Albany Medical Center.

(518) 262-2828

9/25, 29; 10/2, 4, 4x

PATRICIA REED BEING DULY SWORN, DEPOSES AND SAYS: THAT SHE IS THE PRINCIPAL CLERK OF THE SARARTOGIAN, THE OFFICIAL NEWSPAPER; THAT THE FOREGOING LEGAL ADVERTISING WAS PUBLISHED IN SAID NEWSPAPER ON

Sept- 25, 29 Oct 2, 4 2005

SUBSCRIBED AND SWORN TO BEFORE ME:

THIS 4 DAY OF October, 2005

Sandra J Pellock
NOTARY

Patricia Reed

SANDRA J. PELLOCK
NOTARY PUBLIC, State Of New York
No. 01PE4883493
Qualified in Saratoga County
My Commission Expires 7-6-07

From: Sue Ford
To: Rauch, Susan
Date: 9/13/05 3:40:06 PM
Subject: Other Outlets

Hi Susan,

- The Times Union and Capital News 9 said they'll post the forum for us tomorrow. I also made calls to the Saratogian and Spotlight newspapers to see if there is anything additional they can do for us.

~~✗~~ Rick Cook says that the SUNY Albany School of Public Health has presentations almost daily and that this would be a good forum for you. You might want to give them a call.

Also, I did learn that the RPI research is part of our ethics department's research. No need to call Liva if you haven't already.

Sue

From: Sue Ford
To: Rauch, Susan
Date: 9/15/05 1:04:30 PM
Subject: PolyHeme

Hi Susan,

Here's the list of media outlets that I know have definitely covered PolyHeme:

Business Review, Troy Record, Times Union, Daily Gazette, WRGB, WNYT, WXXA, WTEN, Capital News 9, WGY, WAMC, and the Saratogian has said that they will at some point this week.

The Times Union also mentioned the community forum in their calendar listing.

If you do a Google search, you will see many more.

I plan to reach out to the YMCA VP this afternoon.

Sue

Sue Ford
PR Specialist
Albany Medical Center
43 New Scotland Avenue
Albany, NY 12203
518-262-3421
518-262-3880 (fax)
fords@mail.amc.edu

From: Nicole Harte
To: Rauch, Susan
Date: Fri, Sep 16, 2005 8:56 AM
Subject: Fwd: Public Notices

Heard you were looking for the run dates.
Nicole

>>> Nicole Harte 8/26/2005 9:31:48 AM >>>
Susan,

Here's my public notice plan for the two public forums being planned in Huyck.

Run dates for the 9/14 forum:

TU, Gazette, Troy Record, Post Star, Saratogian- 9/8, 9/11, 9/13

Spotlights - 9/14

Jewish World - 9/8

Run Dates for the 10/5 public forum:

TU, Gazette, Troy Record, Post Star, Saratogian - 9/25, 9/29, 10/2, 10/4

Spotlights - 9/28, 10/5

Jewish World - 9/15, 9/22, 9/29

Let me know if you have any questions.
Nicole

CC: Ford, Sue

From: Susan Rauch
To: jerrygordan@juno.com
Subject: Polyheme Study Information

Dear Mr. Gordan,

Albany Medical Center is one of several Level I trauma centers in the US considering participation in a clinical study to evaluate the life sustaining potential of an investigational product in the treatment of severely injured patients who are bleeding and in shock.

Under federal regulations, a prerequisite for such an emergency medicine study is a period of public disclosure/community consultation due to the probable inability to obtain prestudy consent.

Carl Rosati, MD, Director of Trauma, Dept. of Surgery is the principal investigator at Albany Medical Center. Thus far, we have used community meetings, TV, Radio and newspaper notices in order to inform the tri-city area.

We also want to offer the opportunity to community organization to have a presentation, a chance to ask questions and voice their opinions.

Our information/opinion line and web site are listed below.

Information Line: 262-2828

Web Page: www.amc.edu/polyheme

Please let me know if any local Lions Club organizations would be interested. Thank you again for your help!

Susan Rauch
Study Coordinator
rauchs@mail.amc.edu
262-6608

From: Jerry Gordon <jerrygordon@juno.com>
To: <RauchS@mail.amc.edu>
Date: 9/19/05 1:16:50 PM
Subject: Re: Polyheme Study

Susan,

Below is a list of whom I forwarded your email to. I selected the clubs in the immediate Capital District, and wrote to the president, if s/he has email. (But for the Troy club, I sent it right to our Program Chair.)

Albany Lion Club: Larry Krug, Acting Pres, 438-3273, lkrug1@hotmail.com
Ballston Spa Lions Club: Christopher Jackson, Pres, 584-1337, whiteskates44@hotmail.com
Bethlehem Lions Club: Jeff Buenau, Secretary, 283-3736, buenausopticians@aol.com
Guilderland Lions Club: Jean Mann, Pres, 452-1237, jean.mann@dfa.state.ny.us
Rotterdam Lions Club: Paul Andrews (only one I've got email for), andrewsp@knick.net
Saratoga Springs Lions Club: Peter Brown, Pres, 583-9439, PBrown@citynatlbank.com
Scotia/Glenville Lions Club: Nancy Larson, Pres, 885-0968, ejnalanson@msm.com
Shenedehowa Lions Club: , Bob Chatelain, Pres, 371-2664, rchatelain@aol.com
Troy Lions Club: Joann Beach, Program Chair, 489-7606, jbeach@lionseyebankalbany.com
Waterford Lions Club: Carl Klossner, Pres, 664-6726, cklossner@hotmail.com
I hope you get some speaking engagements.
Best regards,
Jerry

PolyHeme® Trauma Trial

Community Consultation

ALBANY MEDICAL CENTER
www.amc.edu/polyheme
518-262-2828

Clinical Investigator

- Carl Rosati MD, FRCSC, FACS
- Co-Investigators Albany Medical Center
Emergency Dept. and Trauma Surgery
Service

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

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 transfusions¹

¹A. 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 patients¹
- 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 PolyHeme²

¹A. Sznajda et al., *Archives of Surgery* (1994), Volume 129:39-45

²E. 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
- 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

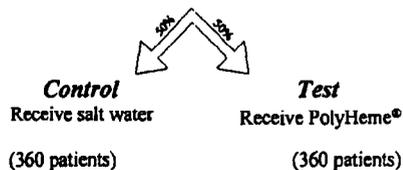
- An Independent Data Monitoring Committee set up to review mortality and serious adverse experiences after 60, 120, 250 and 500 patients have been enrolled and followed for 30 days
- Committee has reviewed the safety data on the first 60, 120 and 250 patients
- Committee has recommended that the study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

PolyHeme® Experience: Current Trial

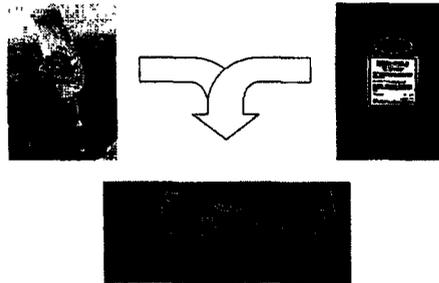
- At the 250 patient look, Committee conducted an adaptive sample size determination.
- Assessment was based on a comparison between the mortality rate predicted in the protocol and the observed mortality rate in the trial to date.
- Committee has concluded that no adjustment in the number of patients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

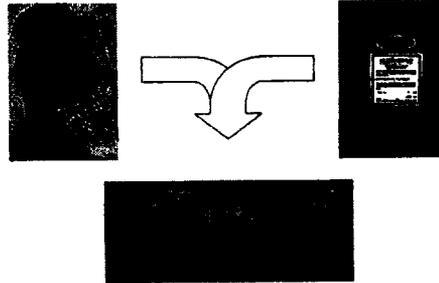
Control

- 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?

Survey
Responses

Community Meetings Summary

9/17/05				Colonie Family Safety Day				Web responses listed as "none" corresponding to date
9/21/05				Schoharie Health Fair				Web responses
9/18/05				Community Teaching Day/Nursing				
	Caucasian	F	57	CTD	yes	yes	yes	
	Caucasian	F	47	CTD	yes	yes	yes	
	Caucasian	F	53	CTD	yes	yes	yes	
	American	F	50	CTD	yes	yes	yes	
	Caucasian	F	48	CTD	yes	yes	yes	Why not hand out to out patients at our hospital
	Caucasian	F	28	CTD	yes	yes	yes	
	Asian	F	40	CTD	yes	yes	yes	
	Caucasian	F	39	CTD	yes	yes	yes	Good luck on the study! Move forward!
	Irish American	F	48	CTD	yes	yes	yes	
	Non Hispanic	F	None given	CTD	yes	yes	yes	
	Caucasian	F	32	CTD	yes	yes	yes	Would be beneficial to children in field as well, hope to see that done as soon as this is proven effective
	Italian American	F	29	CTD	yes	yes	yes	
	Caucasian	F	61	CTD	yes	yes	yes	
	Caucasian	M	55	CTD	yes	yes	yes	
	Caucasian	F	35	CTD	yes	yes	yes	
	Caucasian	F	31	CTD	yes	yes	yes	More research regarding cardiovascular risk factors
	Caucasian	F	40	CTD	yes	yes	yes	
	Caucasian	F	51	CTD	yes	yes	yes	
	Caucasian	F	48	CTD	yes	yes	yes	
	Caucasian	F	41	CTD	yes	yes	yes	
	Caucasian	F	46	CTD	yes	yes	yes	
	Caucasian	F	40	CTD	yes	yes	yes	

Community Meetings Summary

	Caucasian	F	50	CTD	yes	yes	yes	
	Caucasian	F	51	CTD	yes	yes	yes	
	Caucasian	F	37	CTD	yes	yes	yes	
	Caucasian	F	52	CTD	yes	yes	yes	Sounds like there are only positive reasons to move forward.....esp. since the EMS team is unable to provide treatment for shock other than fluids.
	Caucasian	F	47	CTD	yes	yes	yes	
	Caucasian	F	47	CTD	yes	yes	yes	I have a concern about the risk of transmission of hepatitis and HIV viruses
	None given	F	56	CTD	yes	yes	yes	
	Caucasian	F	35	CTD	yes	yes	yes	
	Caucasian	F	49	CTD	yes	yes	yes	Great!
	Caucasian	F	51	CTD	yes	yes	yes	
	Caucasian	F	56	CTD	yes	yes	yes	
	Caucasian	F	37	CTD	yes	yes	yes	
	Caucasian	F	46	CTD	yes	yes	yes	
	None given	F	48	CTD	yes	yes	yes	
	Caucasian	F	22	CTD	yes	yes	yes	
	Caucasian	F	42	CTD	yes	yes	yes	
	Caucasian	F	49	CTD	yes	yes	yes	Present in high risk areas- bars, colleges
	Caucasian	F	44	CTD	yes	yes	yes	Great idea-and much needed
	Caucasian	F	52	CTD	yes	yes	yes	Are you going out to the local/rescue squads with this program? & to fire companies & EMT courses (captive audiences)
	Caucasian	F	51	CTD	yes	yes	yes	
	Caucasian	F	36	CTD	yes	yes	yes	
	None given	F	50	CTD	yes	yes	yes	

Community Meetings Summary

	Caucasian	F	46	CTD	yes	yes	yes	
	Caucasian	F	48	CTD	yes	yes	yes	
	Caucasian	F	37	CTD	yes	yes	yes	
	Caucasian	F	27	CTD	yes	yes	yes	
	Caucasian	F	43	CTD	yes	yes	yes	
	European American	F	57	CTD	yes	yes	yes	
10/05/05				Hospital Liaison Committee				Liaison Committee for Jehovah's Witnesses Preceding AMC Meeting
10/05/05				AMC Community Meeting				Community Meeting Minutes
	Caucasian/Mohawk	M	57	AMC	yes	yes	yes	
	Caucasian	F	62	AMC	yes	yes	yes	
	None Given	M	56	AMC	yes	yes	yes	
	Caucasian	M	70	AMC	yes	yes	yes	Excellent presentation
	Caucasian	M	37	AMC	yes	maybe	maybe	Very informative- appreciate the doctor's simple explanation to those of us who are not trained in the medical field. This product may very well not only be a life saver for those in a trauma situation, but also to those who would not accept a blood transfusion involving red blood cells or whole blood.
	Caucasian	M	57	AMC	no	yes	yes	
	Caucasian	M	48	AMC	yes	yes	yes	

September 12, 2005

Saratoga Library Community Meeting

Activity: Study presentation by Carl Rosati, MD

Arrangement made on September 7th and placed on library events calendar.

NO ATTENDANCE

The study coordinator spent part of the afternoon distributing brochures to the town hall, library, and Starbucks (reading table). I also when to the student union of Skidmore College to post copies of the brochure on bulletin boards and left about 25 copies.



Saratoga Springs Public Library
49 Henry St. Saratoga Springs, NY 12866 584-7860

Meeting Room
Request

Date(s) of Event	Day of the Week	Actual Time Meeting Starts	Beginning & Ending Times-Allow for setup & cleanup.
9/12/05	Monday	7pm -	6 ³⁰ - 9 ⁰⁰ pm.

Please be advised of the following:

- Meeting room users may not enter the building prior to opening, and meetings must end 45 minutes after the library closes.
- Attendees should also be advised that there is a strictly enforced 2-hour parking limit in the library parking lot.
- Please contact us if you need to cancel your meeting.
- Setup of chairs and tables is the responsibility of the meeting room users, not library staff.

Bad Weather: Please call the library for any announcements of closing due to inclement weather.

Organization: Albany Medical Center

Contact Person for This Meeting: Susan Rauch

Contact Person Phone Number: 518-262-6608

Address, City, State, and Zip: AMC Pul. Div. MC-91, 47 New Scotland Ave., Albany, NY 12208

(The name & number of the contact person will be made available to anyone inquiring about a meeting)

Email Address (if any): rauch.s@mail.amc.edu

Please check one of the three rooms below. Note: The occupancy limits reflect the fire code and may not be exceeded. If you expect more people, please plan for a larger room.

Community Room
120 people maximum

Comes With:
120 chairs-setup & breakdown by group
15 tables-setup & breakdown by group
kitchen & large coffee maker
platform stage (24' by 14')
lectern
public address system
data projector & screen
piano (on the stage)
vacuum for cleanup

Susman Room
30 people maximum

Comes With:
30 chairs
3 tables
sink
15-cup coffee maker
white board/markers
tack board
data projector & screen

Glasby Room
20 people maximum

Comes With:
20 chairs
2 tables
sink
15-cup coffee maker
white board/markers
tack board
data projector & screen

Additional equipment may be available. Please contact Sue Pettit at (518) 584-7860 ext. 264, fax- 584-7866 or email address: susanp@sspl.org. Please contact us 72 hours in advance of your meeting to discuss any equipment needs or connection requirements you may have. Also be aware that we may not always be able to repair equipment during your meeting.

The library provides Hearing assistance equipment for use in meeting rooms. Please help make this equipment available as needed.

Confirmed by:	Date Confirmed:
---------------	-----------------

**SARATOGA SPRINGS PUBLIC LIBRARY**

49 Henry Street, Saratoga Springs, NY 12866-3271

(518) 584-7860 • FAX (518) 584-7866

www.sspl.org**Meeting Rooms Policy**

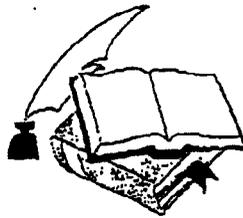
Article six of the *American Library Association Bill of Rights*, which has been endorsed by the Saratoga Springs Public Library, reads as follows:

Libraries which make exhibit space and meeting rooms available to the public they serve should make such facilities available on an equitable basis, regardless of the beliefs or affiliations of individuals or groups requesting their use.

The Saratoga Springs Public Library maintains three meeting rooms which may be used by community groups and agencies (not individuals) when not being used for library purposes, subject to the following guidelines approved by the library board:

1. Rooms are available to groups with headquarters in or that provide substantial services to the citizens of the Saratoga Springs Enlarged City School District.
2. Meeting rooms may not be used for commercial and/or for profit purposes. This includes such programs as investment seminars, sales/service demonstrations, demonstrations by private for-profit health care practitioners, etc.
3. All meetings and programs shall be free and open to the public, and rooms may not be used for fund-raisers such as garage sales, bake sales, etc.
4. The library reserves the right to cancel a reservation for library purposes.
5. All groups are responsible for damage and are required to leave facilities in a clean and orderly condition.
6. When scheduled for use by minors, an adult supervisor must be present at all times.
7. No alcoholic beverages may be consumed on library property.
8. No smoking is allowed in the library building.
9. The library encourages use of meeting rooms for diverse events and groups and seeks to give all eligible organizations an opportunity to use our services. For these reasons, no group may reserve a room more than 12 months in advance. All groups are encouraged to find other facilities for regularly scheduled meetings when possible. Meeting rooms may not be scheduled more than 12 times in a 12-month period.
10. Bookings must be made at least 48 hours in advance, and for groups of no fewer than five people. Meetings must begin during library hours and be completed no later than 45 minutes after closing hour. No meetings may be scheduled on a day the library is closed. If arrangements are made in advance, meetings may extend beyond the 45-minute limit for a fee of \$25.00 per hour.
11. Neither the name nor address of the SSPL may be used as the official address or headquarters of an organization. Publicity for events in the library should clearly identify the sponsoring organization. Telephone queries should be made to the sponsoring organization.

Amended December 8, 2003 by the SSPL Library Board



Saratoga Springs Public Library
49 Henry Street
Saratoga Springs, NY 12866-3224

Fax Cover Sheet

DATE: 9/7/05

TIME: 9:35 AM

TO: Susan Rouch

PHONE:
FAX: 262-6470

FROM: SUE PETTIT

PHONE: 518-584-7860 Ext. 264

FAX: 518-584-7866

RE:

CC:

Number of pages including cover sheet: 4

Message

Hi Susan,

Here is the paperwork that I spoke to you about on the phone. Please keep the Mtg. Rm. Policy for your own reference. Please fill out and fax back to me the Mtg. Rm. Request and User Registration forms. I will then sign and fax back your confirmation. If you have any other questions or you need to cancel your request, please give me a call at the above number. Thank you.

Sue



Community Consultation
Albany Medical Center Community Meeting
9/14/2005

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?

Age: 29 Ethnic background: Caucasian

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Albany Medical Center Community Meeting
9/14/2005

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?

great concept

Age: 56 Ethnic background: Caucasian

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Albany Medical Center Community Meeting
9/14/2005

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?

Age: 60 Ethnic background: W

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Albany Medical Center Community Meeting
9/14/2005

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?

Age: _____ Ethnic background: JUDGE ME BY THE
CONTENT OF MY CHARACTER
Gender: Male _____ Female _____

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Albany Medical Center Community Meeting
9/14/2005

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?

Age: 57 Ethnic background: white female

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Albany Medical Center Community Meeting
9/14/2005

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?

Age: 48 Ethnic background: _____

Gender: Male _____ Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

I have some ideas. Please feel free to call.

Juan Quintana RN

4589463 (H)

242-2000 (W)

Community Consultation
Albany Medical Center Community Meeting
9/14/2005

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

DK

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

DK

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

DK

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

Need more information

Age: 53

Ethnic background: white

Gender: Male

Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Albany Medical Center Community Meeting
9/14/2005

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?

Age: 26

Ethnic background: _____

Gender: Male _____ Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Albany Medical Center Community Meeting
9/14/2005

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?

excellent presentation

Age: 38

Ethnic background: W

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

I think that this is a wonderful
program.

Age: 41 Ethnic background: white

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 15 Ethnic background: African American
Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 74 Ethnic background: WHITE

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 78 Ethnic background: _____

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Let's get it in the
ON-LINE AEMT Protocols ASAP

Age: 42 Ethnic background: _____

Gender: Male Female _____

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 46 Ethnic background: INDIAN

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

NONE

Age: 52

Ethnic background: Caucasian

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 52 Ethnic background: _____

Gender: Male _____ Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

I FEEL, if a person's chance of
Survival is increased, ie) if person gets polyheme
person will live or if they don't get it person will
die, then person should get polyheme
regardless of study protocols.

Age: 44 Ethnic background: Caucasian

Gender: Male Female

Medical Technologist

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 64 Ethnic background: Irish American

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 56 Ethnic background: _____

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 55 Ethnic background: Irish American
Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 54 Ethnic background: Caucasian

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 27 Ethnic background: White

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 27 Ethnic background: Italian / English
Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 21 Ethnic background: Irish

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 29

Ethnic background: W

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 28

Ethnic background: Irish / English / Italian

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 31 Ethnic background: _____

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: 26 Ethnic background: German

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation
Empire State Plaza
9/15/2005 to 10/03/2005

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?

Age: _____

Ethnic background: _____

Asian / Chinese

Gender: Male _____

Female 24

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.



FEEDBACK FORM FOR PARTICIPANTS

Location and date of Community Consultation Select one COMPUTER ACCESS
INFORMATION

Ethnic Background Select One ASIAN Age 70yrs. Gender Male Female

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?

NONE SO FAR

Submit Reset



PolyHeme® Trauma Trial Information

AMC Home - Patient Care - Medical Education - Research - Site Directory



Polyheme® Trial

FEEDBACK FORM FOR PARTICIPANTS

Location and date of Community Consultation Select one computer-generated
information

Ethnic Background Select One ASIAN Age 70 Gender Male
Female

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?

Can Polyheme's potential risks be completely eliminated? I hope you can do something about these risks.

Submit Reset

Radio Disney

The Party People-climbing wall

Colonie Youth Center

Shaker Heritage Society

Wolf Rd Project

6

Community Consultation

9/18/2005

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?

Age: 50

Ethnic background: Caucasian

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation

9/18/2005

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?

Age: 51

Ethnic background: Caucasian

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation

9/18/2005

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?

Age: 37 yrs

Ethnic background: Caucasian

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation

9/18/2005

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?

Should use there are only positive people
to move forward, with us, help, since
the EMS team is unable to provide treatment
for some other than fluids.

Age: 52 Ethnic background: Caucasian

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation

9/18/2005

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?

Age:

47

Ethnic background:

Caucasian

Gender:

Male

Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation

9/18/2005

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?

I have a concern about the risk of ~~the~~ transmission of hepatitis and HIV viruses to my self

Age: 47 Ethnic background: White
Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation

9/18/2005

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?

Age:

56

Ethnic background:

Gender: Male

Female

Thank you for your participation today.

Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation

9/18/2005

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?

Age: 35

Ethnic background: White

Gender: Male

Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.

Community Consultation

9/18/2005

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?

 None

Age: 49 Ethnic background: White

Gender: Male Female

Thank you for your participation today.
Please call Susan Rauch at 518-262-2828 if you have any other questions.