

UNIVERSITY OF KANSAS  
Medical Center  
Kansas City, KS

October 11, 2005  
HSC #9723

COMMITTEE  
DISCUSSION OF

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RESULTS FROM THE  
COMMUNITY  
CONSULTATION

RECEIVED  
OCT 11 2005  
HSC-KUMC

THE UNIVERSITY  
OF KANSAS HOSPITAL  
**KUMED**

Trauma Services Administration

October 7, 2005

TO: Jerry Menikoff, JD, MD  
Chairman, Human Subjects Committee

RE: HSC 9723  
Protocol: RTBSE-11-(N)

We have conducted meetings with Public officials in Wyandotte, Johnson, Douglas and Leavenworth County. We have conducted Community meetings in Wyandotte, Johnson and Leavenworth County. We have presented at the Medical Societies in Wyandotte and Johnson County and a vote of approval was received to move forward. We have received approval from the EMS system in all Counties.

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We are asking for final approval for the above referenced protocol. We are asking for final approval in Wyandotte and Leavenworth Counties. On October 13 The Johnson County Commission will revisit the subject of Polyheme specific to the response received at the Johnson County Community Meeting. We are asking for final approval after this meeting. We would like final approval for Douglas County after the Community meeting on October 10.

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Sincerely,



Michael Moncure MD  
Principal Investigator

RECEIVED  
OCT 10 2005  
HSC-KUMC

## Polyheme Public Presentations

<b>Date</b>	<b>Purpose</b>	<b>Attendees</b>
August 1, 2005	News release	TV and radio representatives
August 3, 2005	General Information	Chair, JoCo Commissioners; EMS
August 17, 2005	General information	OP Mayor, municipal officials
August 22, 2005	General information	Steve Rose, Sun Publications
August 23, 2005	General information	Lenexa municipal officials
August 23, 2005	General information	Publisher, JoCo Sun
August 24, 2005	Solicit support	JoCo Medical Society
August 25, 2005	General information	40 members of WyCo Neighbor Assoc.
August 29, 2005	Solicit support	WyCo Medical Society
August 30, 2005	News release	Leavenworth Times
September 1, 2005	General information	Unified Govt: Mayor and council
September 15, 2005	General information	JoCo Board of Commissioners
September 21, 2005	Public forum - Wyco	2 citizens
September 22, 2005	Public forum - JoCo	2 citizens
September 26, 2005	General information	Leavenworth Co. commissioners
September 26, 2005	Public forum – Leaven.	4 citizens
October 3, 2005	News release	Lawrence Journal World
October 10, 2005	Public forum – Lawrence	2 citizens

### Summary of Questions/Comments at Community Meetings

Dr. Moncure and his research team presented the Polyheme study at each of the meetings listed. An HRPP representative attended each meeting. Presentations included the information approved by HSC regarding the study design, risk and potential benefits of Polyheme, FDA permission to conduct the study without prior informed consent, and the mechanism to opt-out. When the presentation was made to government officials or community leaders, their input was sought on how best to disseminate information to their citizens.

Questions from attendees included the following topics:

- Clarification on inclusion criteria, proposed start date and length of the study
- Clarification on randomization
- History and results of prior studies
- Clarification that study personnel will attempt to contact family members
- Shelf-life of Polyheme
- Clarification on standard care at the scene of the trauma

- Concern that study administration would not prolong "scene time" for the EMS
- Rationale for conducting the study only at KUMC
- Potential for use in the military
- Impact of Polyheme on a person's ability to remain a blood donor or organ donor
- Cost of Polyheme in the study and projected cost of Polyheme in the future
- Timetable for FDA approval
- Position of Jehovah's Witnesses

Strong support was expressed in each meeting with government officials or community leaders. Officials based their support most heavily on whether their EMS service favored the project and whether the medical society for the county was supportive. Government officials were helpful in offering guidance on reaching their constituents. Among the Wyandotte County and Johnson County commissions, one commissioner at each meeting raised the question of liability for the county if their EMS participated. KUMC personnel clarified that the study contract indemnifies the EMS. In Leavenworth County, one commissioner raised the question of liability for the county if only some but not all trauma victims received the potentially life-saving product.

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## **Media Releases and Contacts on the Polyheme Study**

### **Newspaper**

The research team has submitted copies of various newspaper articles about the Polyheme study. The HSC office is maintaining a copy of the articles. They include the following newspapers:

Kansas City Star  
Kansas City Kansan  
Lawrence Journal World (2 articles)  
Johnson County Sun (2 articles)  
The Rosedalian Newsletter  
Leavenworth Times (2 articles)  
The Chieftain, Bonner Springs

### **Television**

All major television stations discussed the study on August 1, 2005 following the media event that was held at the KCK fire station. The HSC office has a CD-Rom that contains all the television clips.

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### **Outreach contacts: phone calls and follow-up letters**

Jehovah's Witness congregations: Congregations at Indian Creek, Chelsea Heights, Coronado Hills, Indian Springs, Merriam, Overland Park, Roeland Park, Shawnee Mission, Overland Park Spanish and Indian Creek Spanish.

Archdiocese of Kansas City, Kansas, Public Affairs Office

El Centro: Ian Bautista and Susan Garrett (Spanish versions of Q&A and media release)

Church of the Resurrection

African American Newspapers: The Call and the Kansas City Globe

Hispanic newspaper Dos Mundos (Spanish versions of Q&A and media release)

State Representative Valdenia Winn

Reverend Jimmie Banks, President of the KCK Baptist Ministers Union

Rotary Clubs in Johnson, Wyandotte and Leavenworth Counties

Print Ads

Wyandotte County Ad

Kansas City Kansan/Wyandotte County Shopper-The ad ran 9/17

Bonner Springs Chieftan--Unable to get in paper, but ran meeting notice on web site all week and they get over 7,000 hits per day. It's on their front page to the right of the page, you click on the black box.

Kansas City Star Metro section announcement ran 9/17

Kansas City Star Wyandotte County tabloid-The ad ran 9/21

Johnson County Ad

Johnson County Sun-In 9/22 edition

Kansas City Star Johnson County tabloids-in 9/17 editions

Radio Ads

Spots ran on the following stations:

KPRS

KMJK

KPRT

KGGN

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**Submissions to the KUMC Polyheme Website: August 1 - October 5, 2005**

The Polyheme website offered the public opportunity to answer four questions. Nineteen persons submitted responses:

- |  |           |        |
|--|-----------|--------|
| 1. Do you understand what happens to patients in this study:             | Yes = 19  | No = 0 |
| 2. Would you support such a study?                                       | Yes = 14* | No = 5 |
| 3. If you were injured, would you want to be put in this type of study?  | Yes = 13  | No = 6 |
| 4. If a family member were injured, would you want him/her in the study? | Yes = 13  | No = 6 |

\*One person supported the study in theory, but not for herself or her family; her response was counted in the "Not support" tabulation below.

**Responses Supporting the Study**

Total = 13

Female	Male		
7	6		
Caucasian	Am. Indian	African Am.	Not specified
9	1	1	2
Under 25 yrs	25 - 45	45 - 65	Not specified
0	10	2	1

**Responses NOT Supporting the Study**

Total = 6

Female	Male		
4	2		
Caucasian	Am. Indian	African Am.	Not specified
2	0	2	2
Under 25 yrs	25 - 45	45 - 65	Not specified
1	4	0	1

**Thirty Persons Submitted Requests for a Total of 73 Opt-Out Bracelets**

Kansas City, KS	11	Eleven requests, totalling 36 bracelets
Tonganoxie, KS	1	
Topeka, KS	1	
Overland Park, KS	6	Six requests, totalling 13 bracelets
Olathe, KS	2	Two requests, totalling 3 bracelets
Ottawa, KS	1	
Roeland Park, KS	1	One request for 2 bracelets
KC MO	4	Four requests, totalling 9 bracelets
Independence, MO	1	
Lee's Summit, MO	1	
Richmond, MO	1	One request, totalling 5 bracelets

## Comments on Polyheme submitted via the KUMC Website

1. This is an ethical disgrace to the human race as well as an exploitation of a legal loophole. Nice to know that the difference between myself and a lab rat is now a bracelet. What exactly makes this product exempt from traditional voluntary studies? It seems as if Northfield is willing to violate humans while in a most vulnerable state in order to save a few dollars on voluntary clinical studies. This in itself definitely makes me question the ethics of this company. I am deeply disturbed by the actions of Northfield and Kansas University Medical Center as well as the other facilities willing to put their local community at risk. Lucky for me I happened to catch the brief local news reel on the subject. But what about the unsuspecting people, the people who missed the "meetings" and news briefs? I guess that's their own fault and they deserve any side effects or adverse complications of the product injected in them while unconscious. Needless to say I will never trust KU Med Center with my life.
2. I am a nurse and have worked trauma. I think this will be a great asset for trauma pts. I hope this study is a success!
3. I read the article re PolyHeme in the KC Star. I do believe the product will prove to be a benefit to society in the long run. Still, I choose to "opt out" of your program should the need for it come about. I am a regular whole blood donor and will not risk compromising my donations. The risk would be how it might affect future donations which, as I understand, you cannot guarantee over the next 15-20 years. My family is aware of my decision. I am requesting one of your blue bracelets to let emergency workers know of my decision also. I spend a great deal of time on the road between KC and Scranton (south of Topeka), an area included in your study.
4. Participation in any study should be voluntary. It is unethical to give a patient unproven treatment without giving the patient the chance to consider the risks. Those who would like to participate in this study should be allowed to "opt in" by wearing a bracelet not the other way around. The inability to say "no" should not be taken as a blanket "yes".
5. It is my understanding that because I am resident of Missouri I am ineligible for this study which is unfortunate. I drive to Kansas every day of the business week and I wish I had the opportunity to receive Polyheme should I be involved in a trauma. Thank you.
6. It seems odd to have to wear a permanent wrist band to opt out of the study. This reduces the number of people who really do not wish to participate from being able to decline, as very few would want to wear the wristbands. Perhaps you could also let family members at the scene say no to the study as well, in a sort of quick informed consent.
7. I find it very disturbing to use emergency patients in a clinical study. Since you already acknowledge it is likely consent cannot be given, the trial takes on a quality

that is dangerously close to human experiments against the will of the person. What is the standard you will use to determine consent was not possible? Is it only if the person is unconscious? What do you do if you know the blood substitute will save the person, but instead you use saline to keep up the scientific study? What do you call someone who dies in this manner? Killed? I think you should allow people to opt in to the blood substitute by wearing a microchip which you could carry without remembering. A wristband can be forgotten. What about children? Do they have the ability to consent or not. Are children likely to remove wristbands without thinking of the consequences. Beside, many children already wear bands for various causes. An opt out band might be socially unacceptable to children (peer pressure) and be "lost" often. What about the practice of providing the best care possible? How will the paramedic decide to use the polyheme? If I were a paramedic, I would be very uncomfortable knowing I was experimenting on seriously injured people. Can a paramedic opt out if their personal beliefs are challenged by this study? I really am not at all in favor of what you are doing to further your understanding of the blood substitute.

8. From what I've read, this product would be very beneficial if I ever need it. I would readily enter into this study.
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**LJWORLD.COM**  
LAWRENCE JOURNAL-WORLD

## Study tests artificial blood without patient consent

Friday, February 20, 2004

Chicago — Paramedics are testing an experimental blood substitute on severely injured patients without their consent in an unusual study under way or proposed at 20 hospitals around the country.

The study was launched last month in Denver and follows similar research that was halted in 1998, when more than 20 patients died after getting a different experimental blood substitute.

Supporters say the current product, PolyHeme, made by Northfield Laboratories of Evanston, Ill., is safer and could save many of the nearly 100,000 people who die of bleeding injuries each year nationwide.

"It could revolutionize how we take care of resuscitation in the United States and across the world," said lead investigator Dr. Ernest Moore, chief of trauma surgery at Denver Health Medical Center.

~~The research is part of a race to find what doctors call the holy grail of emergency medicine: a product that works like human blood to save victims of car crashes, shootings or other trauma but could be carried in ambulances and given to people of any blood type.~~

Patients will be randomly selected to receive PolyHeme intravenously or standard saline solution at the scene or en route to the hospital.

Because severely bleeding trauma patients often are unconscious or in shock, they are unable to give the consent required for experimental treatment. As a result, the researchers in this case are being allowed to bypass the consent rules under a 1996 federal exemption that applies to emergency, potentially lifesaving research.

The exemption requires the research to be publicized beforehand in communities where the study will be conducted, both to let people opt out if they are ever injured and to give the community a chance to express any objections. In effect, the community briefings are used to obtain consent.

The Food and Drug Administration has approved about 15 such no-consent studies since the exemption was added.

University of Pennsylvania bioethicist Dr. Jason Karlawish said there was nothing unethical about the concept.

Some patients' rights advocates disagreed, especially considering the deaths in the earlier study of emergency room patients given a Baxter Healthcare blood substitute.

The study "is another one along that slippery slope that's essentially demolishing your individual right not to become experimental subjects unless we give prior, voluntary, informed, comprehending consent," said Vera Sharav, president of the New York-based Alliance for Human Research Protection, a group concerned with the safety of the millions of Americans who participate in medical research each

year.

Baxter has said there was no proof its product caused the deaths; a spokeswoman said it had abandoned research into a blood substitute.

The centers where the PolyHeme study is under way or proposed include the University of Texas Medical School in Houston; Loyola University Medical Center in Maywood, Ill.; Mayo Clinic in Rochester, Minn.; and Regional Medical Center in Memphis, Tenn. Northfield Laboratories would not disclose the names of the other participating hospitals.

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The University of Kansas Medical Center  
Campus News

## **GENERAL INFORMATION**

### **The University of Kansas Hospital Seeks Community Input to Study Investigational Temporary Red Blood Cell Substitute in Trauma Patients. Landmark Clinical Study: Treatment to Begin at Scene of Injury**

Jul 30, 2005, 18:00

See: [KUMC PolyHeme® web site](#)

KANSAS CITY, Kan. – The University of Kansas Hospital is one of a select number of Level I 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, in treating critically injured and bleeding patients. Under the study protocol, treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during a 12-hour post injury period in the hospital.

During this study Polyheme® is compared to standard of care, saline (salt water) in the pre-hospital setting and blood in the hospital.

At the site of the injury, half of the subjects (like flipping a coin) receive Polyheme®, half receive standard care (saline). It is given by emergency medical personnel before reaching the hospital (may be up to 60 minutes).

Upon arrival to the emergency room, subjects receive Polyheme® or standard care (blood). Subjects that received Polyheme® at the emergency site continue to receive Polyheme® in the hospital instead of standard care (blood). PolyHeme® is given for up to 12 hours or 6 units of PolyHeme. Standard care (blood) will be given (if needed) after 12 hours or 6 units of PolyHeme®. Patients who originally receive the saline solution in the field will receive standard care (blood) upon arrival to the emergency room (standard of care).

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, when needed.

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

Because the patients eligible for this study are unlikely to be able to provide prospective informed consent due to the extent and nature of their injuries, the study will be conducted under federal regulations that allow for clinical research in emergency settings using an exception from the requirement for informed consent. These federal regulations require the hospital and KUMC to conduct community meetings to inform the public about plans for the study and solicit public comment prior to institutional approval. Public meetings are currently being scheduled, and hospital.

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

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

If someone in the community would like to be excluded from participating in this study, an "opt out" wristband

will be provided at no cost. If someone in the community is involved in a trauma and they are wearing the wristband they will not be placed in the study. Information regarding how to obtain the "opt out" wristband will be available on the KU websites: <http://www.kumc.edu/polyheme/> and [www.kumed.com](http://www.kumed.com) or by calling the study coordinator, Suzanne Porras, R.N. at 913-588-3005.

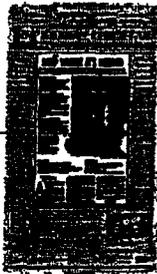
Members of the Jehovah's Witness faith will most likely want to opt out of this study. Opt out wristbands will be provided to all of the Jehovah's Witness community leaders in the Kansas City metro area.

If you have questions about the rights of research patients, please call the University of Kansas Medical Center Human Subjects Committee at (913) 588-1240.

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

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# HELP WHERE IT'S NEEDED

Kansas-side ambulance crews will use the blood substitute PolyHeme in tests of a product designed to aid trauma victims far from a hospital

By ALAN BAVLEY  
The Kansas City Star

**A**wreck survivor lies bleeding by the side of a country road. A wounded soldier hemorrhages on a battlefield.

Trauma victims like these need blood right away, but they must wait for rescue workers to take them to a hospital for a transfusion.

Now an alternative is headed to the Kansas City area for a tryout this fall: artificial blood that can be carried on ambulances and given to patients at an accident scene.

The experimental blood substitute PolyHeme can deliver oxygen to the body just as real blood does. It's made from human red blood cells unused at blood banks. And it has gone through years of testing in operating rooms and emergency rooms, where doctors credit it with saving lives.

Since early last year, PolyHeme has been

given to hundreds of U.S. trauma patients suffering life-threatening blood loss. Twenty-one trauma center hospitals are taking part in the study, including the medical centers of the University of California, San Diego; Loyola University in Illinois; and Duke University in North Carolina.

The University of Kansas Medical Center

plans to join them in October, stocking PolyHeme on ambulances in Wyandotte, Johnson, Leavenworth and Douglas counties. KU could expand the study later to include Franklin, Miami and Shawnee counties.

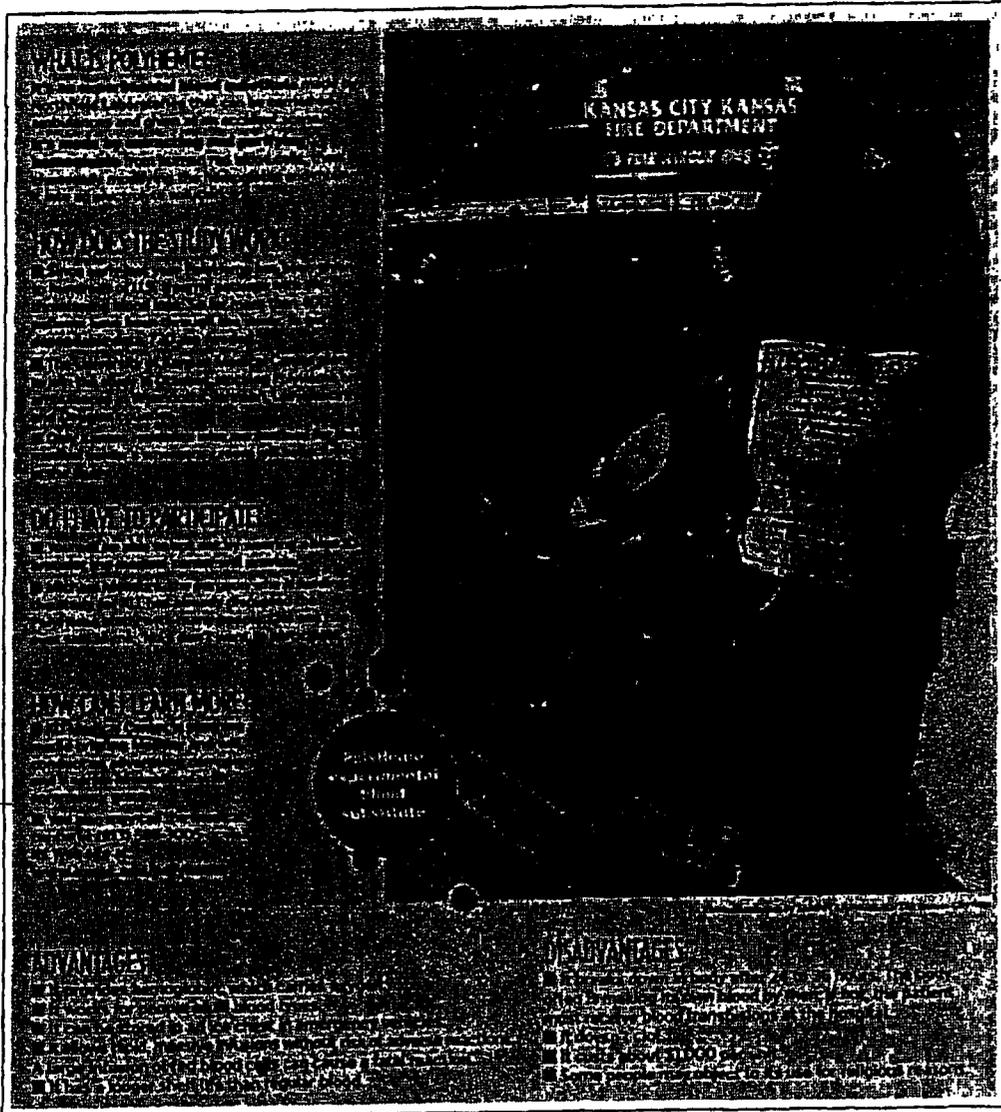
"This is an opportunity for our community to be on the cutting edge," said Michael Moncure, the surgeon in charge of KU's trauma services. "I think this is going to be the new standard of care by the time this study is over. It's going to revolutionize the way we treat patients."

Before the study can start here, KU faces a significant ethical issue that has caused con-

See BLOOM, A-6



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## BLOOD: Test of blood substitute to begin this fall

Continued from A-1

cern in some other cities: Because trauma patients are in no condition to make informed decisions about their treatment, rescue workers will be transfusing them with PolyHeme without their consent.

That's generally forbidden when researchers try something new on patients. But regulators allow it in rare life-threatening situations when the usual treatment is considered unsatisfactory and patients could directly benefit.

To satisfy these rules, KU will spread the word about the PolyHeme trial and meet with community groups to gauge whether there's significant opposition.

"This is huge," Moncure said. "We're asking the community to give us consent to perform this study. In good faith, we have to make sure this is at least as safe as the standard of care."

The current standard of care offers rescue workers few options for helping bleeding trauma victims. They can give intravenous fluids, such as saline solution, to maintain their patients' blood pressure until they reach the hospital. But only transfusions of red blood cells can prevent organ failure or death from lack of oxygen.

But carrying real blood on ambulances has never been practical. It must be stored under carefully controlled conditions. And it must be matched to patients' blood types.

Not PolyHeme.

Blood transfusions also are difficult in combat situations. In rural areas, hospitals many miles from a blood bank may not have adequate blood stocks on hand for an emergency. And even in big cities, blood banks may be hard-pressed during a disaster.

All this has made blood substitutes a kind of Holy Grail for emergency medicine researchers.

"Blood is a good product. I'd never say it isn't. But with the focus on the trauma, there are logistic limitations to using blood," said Steven Gould, a trauma surgeon and chief executive officer of Northfield Laboratories, the Evanston, Ill., company that makes PolyHeme.

If it wins approval from the Food and Drug Administration, Northfield expects to sell about 350,000 units a year in the United States. At

considerably more than the cost of red blood cells, the stakes are high.

### Years of research

Gould and his colleagues began their research shortly after the Vietnam War as part of a U.S. Army project. They wanted to develop a blood substitute that could be given in large quantities to wounded soldiers far from a field hospital.

Other scientists, working separately from Gould's group, also pursued blood substitutes. The search intensified in the 1980s as shortages and HIV contamination threatened the blood supply.

A number of blood substitutes have been developed, but many had serious safety problems. They

often ran into trouble because they relied on hemoglobin, the substance in red blood cells that holds oxygen and carries it to the body's tissues.

Hemoglobin is essential to life, but released from blood cells it can be very dangerous, said Jay Epstein, director of the FDA's office of blood research and review. Hemoglobin can harm heart muscle, cause inflammation, raise blood pressure and possibly damage the liver and pancreas, researchers have found.

"There's a reason why hemoglobin is kept within the red blood cells; free hemoglobin is quite toxic," Epstein said. "The question is, can you modify (hemoglobin molecules) so they don't have that effect?"

The inventors of PolyHeme think they've tamed hemoglobin by linking its molecules into larger molecules through a process called polymerization.

Human research on PolyHeme has been going on for about a decade. The studies started slowly by first giving a single unit to healthy volunteers to see if it was safe.

The next step was to give PolyHeme in the emergency room to trauma patients, starting with one unit, then two, three and finally up to six units. Patients who got PolyHeme did as well as those receiving red blood cells.

The most dramatic results came when trauma centers gave 171 bleeding patients as much as 20 units of PolyHeme — about twice an average person's total blood vol-

ume. Of the patients with the most

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"I think there are a number of people walking around Denver that I took care of who wouldn't have been alive without PolyHeme," said Jeff Johnson, a trauma surgeon at Denver Health.

One case that stood out was an 18-year-old man who attempted suicide with a hunting rifle.

"He basically blew out everything on the left side of his abdomen," Johnson said. "He was bleeding extraordinarily rapidly."

During his first 14 minutes at the hospital, the man received 10 units of PolyHeme. Researchers believe it was crucial to saving his life.

### Random selection

The ambulance study compares the benefits of PolyHeme with the standard treatment — saline solution — at an accident site.

When rescue workers encounter patients whose blood pressure is dangerously low from a loss of blood, they will select half at random to receive PolyHeme, and the rest will get saline solution.

Once they get to the hospital, patients receiving saline will get blood transfusions if they need them. PolyHeme patients will continue receiving the blood substitute for 12 hours before being switched to blood.

So far, more than 400 patients have been through the study. To get sufficient data, the study needs to enroll 720 people.

Most medical centers have launched the study without objections, although two Boston hospitals ultimately turned down PolyHeme for ethical reasons. And

some patient advocates have questioned the use of an experimental substance on unconscious patients.

"We should not have to fear that, as we are taken to the hospital by an emergency crew, we have been made into guinea pigs," said Vera Hassner Sharav, president of the New York-based Alliance for Human Research Protection.

"When a person doesn't have informed consent, people take chances with other peoples' lives."

PolyHeme should be tested only on consenting subjects such as patients who are hospitalized for elective surgery, Sharav said.

Not all medical ethicists agree.

Using an experimental treatment

on an emergency patient can be justified if there are no good alternatives, said MC Sullivan, former vice president of the Center for Practical Bioethics in Kansas City.

"The idea that you can have a large supply of a blood substitute on hand is a very exciting one," she said.

Because PolyHeme is in the final stage of testing, there is some assurance that it is safe, Sullivan said.

"But safeguards have to be in place. Suddenly we're turning a very vulnerable person in need of protection into an experimental subject.

"It should never become routine, even if we conclude it's absolutely the right thing to do."

To reach Alan Bawley, call (816) 234-4858 or send e-mail to [abawley@kcstar.com](mailto:abawley@kcstar.com).



Kansas City, Kan., firefighters recently heard Michael Moncure, a surgeon at the University of Kansas Medical Center, explain PolyHeme.

# TheKansasCityChannel.com

## KUMed To Test Synthetic Blood On Trauma Patients

### *PolyHeme Research To Begin In October*

POSTED: 4:04 pm CDT August 1, 2005  
UPDATED: 6:40 pm CDT August 1, 2005

**KANSAS CITY, Kan.** -- Doctors say a blood substitute in Kansas ambulances could help save lives, KMBC's Dan Weinbaum reported Monday.

The University of Kansas Medical Center has joined other level-one trauma hospitals across the country in testing the safety and effectiveness of PolyHeme. The synthetic blood will be used on trauma patients and its effects will be studied.

Medical officials said PolyHeme can deliver much-needed oxygen into the bloodstream. Researchers said the product is especially useful by paramedics because the synthetic blood is compatible with everyone.

The product is waiting on full approval from the Food and Drug Administration and is still in the research stage, officials said. PolyHeme has been used at other trauma hospitals for several years.

KUMed's Dr. Dennis Allin said about 10 percent of the hospital's trauma patients would be eligible to use PolyHeme. The patients will be chosen at random.

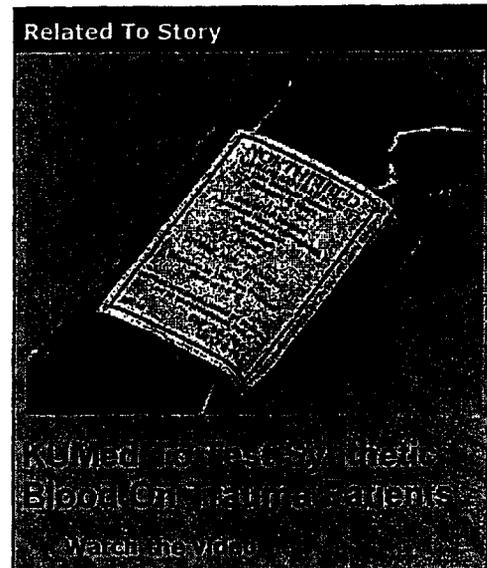
Federal regulations allow medical personnel to administer PolyHeme without consent, but Kansas researchers said patients can choose to be removed from the study.

KUMed is planning several public meetings in the upcoming months to explain the research. Paramedics will begin using PolyHeme in October.

### **Web Links:**

- [KUMed](#)
- [PolyHeme](#)

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**The University of  
Kansas Hospital**

**The University of Kansas  
Medical Center**

School of Medicine  
School of Nursing  
School of Allied Health

# News

Public Relations Media Line: 913-588-5246  
Fax: 913-588-1225

For Immediate Release  
August 1, 2005

Contact: Dennis McCulloch  
913-588-5246

## **The University of Kansas Hospital Seeks Community Input to Study Investigational Temporary Red Blood Cell Substitute in Trauma Patients Landmark Clinical Study: Treatment to Begin at Scene of Injury**

**KANSAS CITY, Kan.**— The University of Kansas Hospital is one of a select number of Level I 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, in treating critically injured and bleeding patients. Under the study protocol, treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during a 12-hour post injury period in the hospital.

During this study Polyheme® is compared to standard of care, saline (salt water) in the pre-hospital setting and blood in the hospital.

At the site of the injury, half of the subjects (like flipping a coin) receive Polyheme®, half receive standard care (saline). It is given by emergency medical personnel before reaching the hospital (may be up to 60 minutes).

Upon arrival to the emergency room, subjects receive Polyheme® or standard care (blood). Subjects that received Polyheme® at the emergency site continue to receive Polyheme® in the hospital instead of standard care (blood). PolyHeme® is given for up to 12 hours or 6 units of PolyHeme. Standard care (blood) will be given (if needed) after 12 hours or 6 units of PolyHeme®. Patients who originally receive the saline solution in the field will receive standard care (blood) upon arrival to the emergency room (standard of care).

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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, when needed.

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

Because the patients eligible for this study are unlikely to be able to provide prospective informed consent due to the extent and nature of their injuries, the study will be conducted under federal regulations that allow for clinical research in emergency settings using an exception from the requirement for informed consent. These federal regulations require the hospital and KUMC to conduct community meetings to inform the public about plans for the study and solicit public comment prior to institutional approval. Public meetings are currently being scheduled, and hospital.

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

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

If someone in the community would like to be excluded from participating in this study, an "opt out" wristband will be provided at no cost. If someone in the community is involved in a trauma and they are wearing the wristband they will not be placed in the study. Information regarding how to obtain the "opt out" wristband will be available on the KU websites: <http://www.kumc.edu/polyheme/> and [www.kumed.com](http://www.kumed.com) or by calling the study coordinator, Suzanne Porras, R.N. at 913-588-3005.

Members of the Jehovah's Witness faith will most likely want to opt out of this study. Opt out wristbands will be provided to all of the Jehovah's Witness community leaders in the Kansas City metro area.

If you have questions about the rights of research patients, please call the University of Kansas Medical Center Human Subjects Committee at (913) 588-1240.

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

###

The University of  
Kansas Hospital

The University of Kansas  
Medical Center  
School of Medicine  
School of Nursing  
School of Allied Health

# News

Public Relations Media Line: 913-588-5246  
Fax: 913-588-1225

For Immediate Release  
August 1, 2005

Contact: Dennis McCullochB  
913-588-5246

## **The University of Kansas Hospital and the Region's Only Nationally Accredited Level I Trauma Center**

KANSAS CITY, Kan.— Since 1980, The University of Kansas Hospital has been home to the regionally only nationally accredited Level I Trauma Center. The accreditation comes after an extensive review by the American College of Surgeons (ACS) and is the highest level any trauma program in the country can achieve.

The ACS Level 1 rating has been awarded to only 103 trauma programs in the country, and differs from the status designated by some individual states. It can take from one to two years and multiple on-site reviews by a team of ACS inspectors to achieve this status. Only after meeting hundreds of demanding criteria is a trauma program awarded this distinction. The University of Kansas Hospital trauma programs treats more than 1,300 patients per year.

Most emergency departments have a number of doctors on duty and others on call. But at the Level I Trauma Center at The University of Kansas Hospital, the trauma team includes board certified surgeons, emergency medicine physicians, nurses, anesthesiologists, blood bank, X-ray, laboratory and respiratory personnel and other highly trained specialists that can be assembled in minutes to start treatment the moment a patient arrives

Under the direction of Michael Moncure, MD, the trauma program will continue its participation in various research activities. Trauma program staff members will also continue to offer public education, injury prevention programs and other activities that are designed to make the community safer. As a teaching facility, The University of Kansas Hospital's trauma program will continue training medical students and residents how to treat injured patients.

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“Our community deserves the highest quality of care to be immediately available,” Moncure said. “KU Med’s trauma program has met the rigorous criteria set by the American College of Surgeons and is on the same level as the very best hospitals in the country.”

The University of Kansas Hospital is the region's premier academic medical center, providing a full range of care. The hospital was founded in 1906 and was removed from the University of Kansas system to be governed by an independent Authority Board in 1998. Since ~~then the hospital has seen record levels of patient volume, patient satisfaction and financial~~ stability. The hospital is affiliated with the University of Kansas Schools of Medicine, Nursing and Allied Health, and their various leading edge research projects.

The constantly growing facility contains more than 470 staffed beds and serves nearly 19,000 inpatients annually. Among The University of Kansas Hospital’s key clinical strengths are a comprehensive heart program, an inter-disciplinary cancer program and a leading neuroscience program. Construction is currently underway at the hospital on the 238,000-square-foot Center for Advanced Heart Care, which will house inpatient and outpatient heart care when it opens in 2006.

###

**The University of  
Kansas Hospital**

**The University of Kansas  
Medical Center**

School of Medicine  
School of Nursing  
School of Allied Health

# News

For Immediate Release  
August 1, 2005

Public Relations Media Line: 913-588-5246  
Fax: 913-588-1225

Contact: Dennis McCulloch  
913-588-5246

## **Questions and Answers PolyHeme® Trauma Trial**

KANSAS CITY, Kan.— Investigators for the PolyHeme® trial at The University of Kansas Hospital and The University of Kansas Medical Center have prepared this Question and Answer Guide to assist in the understanding of the project.

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

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

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

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

### **What is PolyHeme®?**

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

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

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

During this study Polyheme® is compared to standard of care, saline (salt water) in the pre-hospital setting and blood in the hospital.

~~At the site of the injury, half of the subjects (like flipping a coin) receive Polyheme®, half receive standard care (saline). It is given by emergency medical personnel before reaching the hospital (may be up to 60 minutes).~~

Upon arrival to the emergency room, subjects receive Polyheme® or standard care (blood). Subjects that received Polyheme® at the emergency site continue to receive Polyheme® in the hospital instead of standard care (blood). PolyHeme® is given for up to 12 hours or 6 units of PolyHeme. Standard care (blood) will be given (if needed) after 12 hours or 6 units of PolyHeme ®. Patients who originally receive the saline solution in the field will receive standard care (blood) upon arrival to the emergency room (standard of care).

**What is hemorrhagic shock?**

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

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

--more--

## Questions and Answers

Page 3

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

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

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

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

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

### **Who is eligible for the study?**

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

### **Who will be excluded from the study?**

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

--more--

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

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

**Has enrollment begun anywhere?**

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

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

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

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

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

--more--

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

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

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

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

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

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

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

Patients are enrolled (put) in a clinical study without giving informed consent before being enrolled.

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

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

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

- Patients are in a life-threatening situation that necessitates intervention
- Previous studies support the potential to provide a direct benefit to enrolled patients
- Risks associated with the use of the PolyHeme® are reasonable in relation to what is known about the patients' medical condition, the risks and benefits of standard therapy, and the risks and benefits of the proposed intervention

It is expected that patients will be unable to give informed consent because the extent of their injuries and the fact that they are in shock.

It is unlikely that there will be time to find and ask for consent from the patient's legally authorized representative (LAR) or to provide an opportunity for a family member to object to the patient's enrollment before beginning treatment.

**Who grants such exceptions?**

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

**What if someone doesn't want to participate in this study?**

*If someone in the community would like to be excluded from participating in this study, an "opt out" wristband will be provided at no cost. If someone in the community is involved in a trauma and they are wearing the wristband they will not be placed in the study. Information regarding how to obtain the "opt out" wristband will be available on the KU websites: [www.kumc.edu](http://www.kumc.edu) and [www.kumed.com](http://www.kumed.com) or by calling the study coordinator, Suzanne Porras, R.N. at 913-588-3005.*

**What if a patient wants to stop their participation in the study?**

Patients can withdraw from the study, without prejudice, at any time by notifying the investigator. If the patient is not competent to be making decisions about their participation, a family member does have the ability to request that the patient's participation be ended.

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

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

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

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

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

Rash  
Increased blood pressure  
Kidney or liver damage  
Transmission of hepatitis and HIV viruses  
Unforeseen happenings  
PolyHeme® may be less effective than blood

Some of these risks may lead to death.

Questions and Answers  
Page 8

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

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

**Will patients get paid to participate?**

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

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

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

# THE KANSAS CITY KANSAN

## News

### Blood substitute aims to save lives

By *BRANT STACY*

Kansan Staff Writer

A revolutionary blood substitute could soon give Kansans involved in a trauma-related injury a greater chance for survival.

The substitute, called PolyHeme, is a temporary oxygen-carrying red-blood cell substitute being produced by Northfield Laboratories in Evanston, Ill. The substitute is made from human blood cells and will soon be used by the University of Kansas Medical Center for a clinical research study on trauma victims as early as October.

During a press conference Monday at Fire station No. 1, 96th Street and State Avenue, Dr. Dennis Allin, director of emergency operations for the hospital and medical center, said the KU Med was chosen for the study because it is a Level I Trauma Center. He said the medical center's research using PolyHeme will combined with that of 17 other Trauma I Centers already testing the substitute across the United States.

"The aim of the study is to enroll 720 trauma patients nationwide," Allin said. "We haven't put a target number on how many we will enroll at the med center, but we feel in terms of traumatic resuscitation this (PolyHeme) could be a good answer to help seriously hurt patients."

PolyHeme, which costs 1,000 per unit, is universal to all blood types, reduces the risk of viral transmission and has a shelf life of 12 months. It will be used starting at the scene of an injury and upon arrival to the emergency room, Allin said. At the scene of the injury, the study will instruct emergency medical personnel to give half the subjects PolyHeme and the other half standard care, which is saline up to a 60-minute period. Upon arrival to the emergency room, patients who received PolyHeme at the scene will continue and those receiving saline will

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receive blood, both for up to 12 hours and six units each, if needed. Allin said the study, which is non-paid and only for Kansas residents, will require their consent.

"Under federal regulations, Kansans 18 and over will only be able to participate," Allin said. "If the person is unable to consent their identification will be checked. Also, women who are visually pregnant and those with head injuries will not be included in the study."

Suzanne Porras, RN and study coordinator for trauma and burn care, said identification will most likely be their driver's license or license plate. She also said the Med Center is currently planning public information meetings about PolyHeme where residents can find out more about the substitute. At these meetings if a resident should decide not to participate, they can obtain a bracelet stating they decline the Northfield PolyHeme study.

"We hope the study will prove that PolyHeme is very helpful in saving lives," Porras said. "But, not everyone will want to participate. Those wanting to be excluded can be provided with a bracelet at no cost at one of the public meetings currently being scheduled."

Porras said those unwilling to take part in the study should wear their bracelet all the times.

"We don't want to convince someone this is the right thing," Porras said. "We can only answer questions and make sure the study proves this (PolyHeme) is a good thing."

Dr. Michael Moncure, a surgeon overseeing KU's trauma services, stated in a press release Monday that he and the Med Center were excited about this trial. He referenced to the Centers for Disease Control's National Center for Injury Prevention and Control, stating trauma-related injuries are a leading cause of death among Americans under 45 years old and that almost one in five of those patients die from their injuries.

"If we can begin to treat these patients very early with an oxygen-carrying solution and keep their hemoglobin levels up, we may see more survivors," Moncure said.

Porras said she has consulted with other Trauma I Centers, such as Duke and Loyla University in Illinois, that have been conducting the study for at least a year,

and said none of those facilities trauma patients have experienced any severe reactions.

Once the study is complete, Porras said the results will go to the FDA. If PolyHeme shows it's making a difference and saving lives, the FDA will go forth, she said.

"It takes awhile," Porras said. "Hopefully PolyHeme will be the next thing to save lives. It could be the wave of the future."

For information about the study, upcoming meetings or to acquire an exclusion wristband, call study coordinator, Suzanne Porras, R.N. at (913) 588-3005 or go to [www.kumed.com](http://www.kumed.com).

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## Artificial Blood

The University of Kansas Medical Center will join a national study this fall to determine the usefulness of an experimental blood.

- > The blood, called PolyHeme, carries oxygen to the body, just like real blood.
- > Initially, the blood will be used by ambulance crews in Wyandotte, Johnson, Leavenworth and Douglas counties. It's designed to be used for people who need blood immediately, such as accident victims.
- > Twenty-one other trauma center hospitals are taking part in the study. Doctors in operating and emergency rooms have used PolyHeme for years and say it has saved lives.
- > Researchers will meet with community groups to explain the study. Some people question whether using an experimental treatment on accident victims unable to give their consent is ethical.

### Find this article at:

<http://www.wibw.com/home/headlines/1755412.html>

Check the box to include the list of links referenced in the article.

# THE KANSAS CITY KANSAN

Tuesday,  
August 2, 2005

The Daily Newspaper for Kansas City, Kansas & Wyandotte County

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## Blood substitute aims to save lives

By BRANT STACY

Kansan Staff Writer

A revolutionary blood substitute could soon give Kansans involved in a trauma-related injury a greater chance for survival.

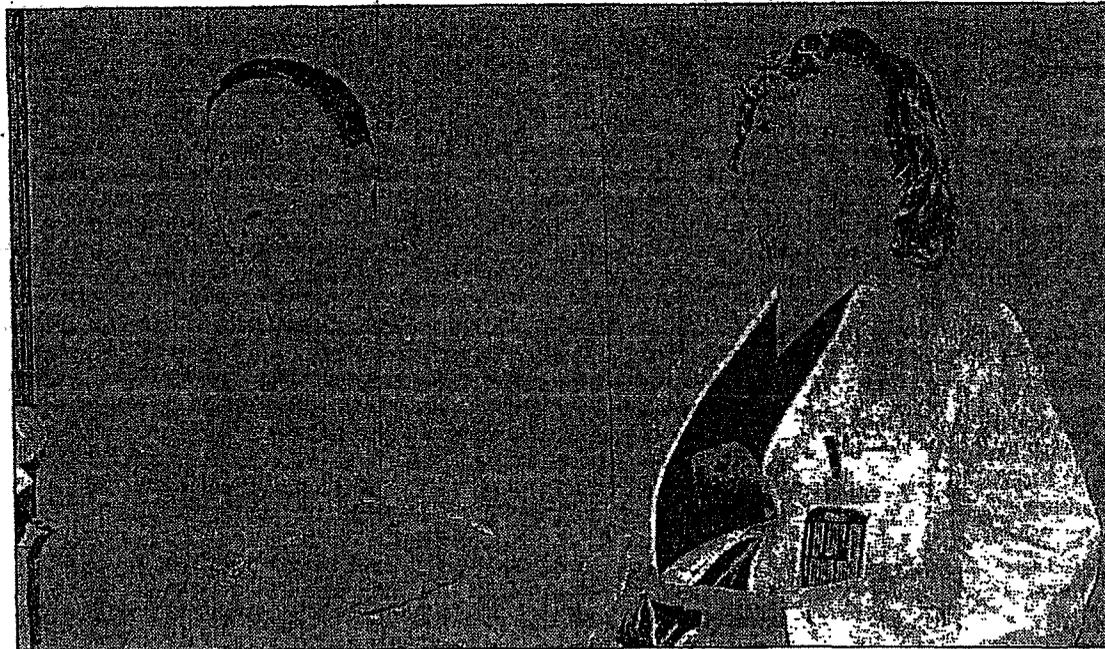
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"The aim of the study is to enroll 720 trauma patients nationwide," Allin said. "We haven't put a target number on how many we will enroll at the med center, but we feel in terms of traumatic resuscitation this (PolyHeme) could be a good answer to help seriously hurt patients."

PolyHeme, which costs 1,000 per unit, is universal to all blood types, reduces the risk of viral transmission and has a shelf life of 12 months. It will be used starting at the scene of an injury and upon arrival to the emergency room, Allin said. At the scene of the injury, the study will instruct emergency medical personnel to give half the



BRANT STACY/The Kansan

**Dr. Dennis Allin, director of emergency operations for the University of Kansas hospital and medical center, and Suzanne Porras, RN and study coordinator for trauma and burn care at KU Med, speak to media Monday morning about an upcoming study the medical center will carrying out regarding the usage of PolyHeme on trauma patients.**

Please see BLOOD/Page 6

## Blood

Continued from PAGE 1

subjects PolyHeme and the other half standard care, which is saline up to a 60-minute period. Upon arrival to the emergency room, patients who received PolyHeme at the scene will continue and those receiving saline will receive blood, both for up to 12 hours and six units each, if needed. Allin said the study, which is non-paid and only for Kansas residents, will require patient's consent.

"Under federal regulations, Kansans 18 and over will only be able to participate," Allin said. "If the person is unable to consent their identification will be checked. Also, women who are visually pregnant and those with head injuries will not be included in the study."

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Once the study is complete, Porras said the results will go to the Federal Drug Administration. If PolyHeme shows it's making a difference and saving lives, the FDA will go forth, she said.

"It takes awhile," Porras said. "Hopefully PolyHeme will be the next thing to save lives. It could be the wave of the future."

For information about the study, upcoming meetings or to acquire an exclusion wristband, call study coordinator, Suzanne Porras, R.N. at (913) 588-3005 or go to [www.kumed.com](http://www.kumed.com).

# PolyHeme

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## Program

**Sunday, July 31, 2005**

**4 WDAF - Kansas City**

## Text/Summary

5:00 PM 4 at Five  
Time/Length: 00:40:22 / 00:34

Fox 4 Health. KU Med

> The University of KS Med Center will join a national study this fall on the use of experimental blood PolyHeme. GR; PolyHeme study and counties where blood will be used

9:00 PM Primetime  
Time/Length: 00:07:07 / 00:20

Artificial blood.. KU Med

This fall the University of KS Medical Center will begin participation in a study on artificial blood, PolyHeme. The blood will be distributed to emergency workers in several KS counties. GR; Artificial blood study.

10:00 PM 4 at Ten  
Time/Length: 00:05:16 / 00:26

Fake blood. KU Med

to  
using

A national study could help paramedics treat people in accident. The Univ Of KS Medical Center will start seeing if artificial blood called Polyheme, can help ambulance crews. The blood carries oxygen to the body. Ambulance crews in Wyandotte, Johnson, Douglas and Leavenworth counties will start using the blood in the fall.

**5 KCTV - Kansas City**

9:30 AM Sunday Morning  
Time/Length: 00:34:25 / 00:20  
it

Fake blood.. KU Med

KU Medical Center will give KCMO ambulance crews fake blood to administer to patients who need it immediately. GR; Fake blood.

10:30 AM Sunday Morning  
Time/Length: 00:34:40 / 00:24  
KS

Fake blood. KU Med

Kansas City area ambulance crews will start carrying fake, experimental blood this fall. The Univ of Medical Center is joining a national study of the experimental blood, Polyheme. It will be used on accidents and others who need blood immediately. GR; Experimental blood, Wyandotte, Johnson, Leavenworth and Douglas Co crews will start using the product.

**9 KMBC - Kansas City**

7:00 AM Sunday Morning  
Time/Length: 00:33:50 / 00:25  
emergencies.

Artificial Blood. KU Med

KCMO area paramedics and ambulance crews will use artificial blood to treat patients in

The KU Med Center is participating in a national study of the experimental blood.

8:00 AM Sunday Morning  
Time/Length: 00:03:05 / 00:25

Blood.. KU Med

KU Medical Center plans to give artificial blood to ambulance crews in KCMO for victims who need it right away.

5:00 PM 9 News at Five  
Time/Length: 00:29:58 / 02:10  
call

TZ; Blood substitute.. KU Med

Some ambulances in the Kansas City metro area are going to start carrying a new blood substitute

PolyHeme  
synthetic

Polyheme. V; KCK fire dept and paramedics on scene of a crash. I; Chris Alexander, KCK EMS supervisor, says it allows them to give something to the patient that will carry oxygen. GR;

information. KU Medical Center, along with ambulance services are part of a study to test the

blood. V; KU Medical Center. The testing will start this fall in Wyandotte, Douglas, Johnson, Leavenworth counties. Dan Weinbaum reporting.

10:00 PM 9 News at Ten  
Time/Length: 00:13:51 / 01:54  
over

Health Watch. Dan Weinbaum. KU Med

ambulance  
something

TZ: Paramedics currently use straight saline to keep blood pressure up but that may be changing

to a blood substitute. V: KCK Police, ambulance, and fire truck on accident scene, inside an

I: Chris Alexander, KCK - EMS Supervisor, says that it gives them ability to give the patient

that will carry oxygen before the patient gets to the hospital. GR: PolyHeme information. PolyHeme carries oxygen, and acts like human hemoglobin. Currently KU Med services and ambulance

services

says

are part of a test program. V: KU Med center sign. Alexander says that it is better than real blood because it does not have to match the blood type, is portable and it has a shelf life of a year. He

that if it can increase chances to survive then it is an ideal thing. The test area for PolyHeme should expand this fall.

41 KSHB - Kansas City

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Program  
**Sunday, July 31, 2005**  
**41 KSHB - Kansas City**

Text/Summary

10:00 PM 41 News at Ten  
Time/Length: 00:05:25 / 00:23  
ambulances.

Fake blood. KU Med  
The Univ of KS Medical Center is taking part in a national study to use fake blood in some

blood  
using

The fake blood, called Polyheme works like real blood by carrying oxygen to the body. GR; Fake study information. Crews from Wyandotte, Johnson, Leavenworth and Douglas counties will start the blood this fall.

**Monday, August 01, 2005**  
**4 WDAF - Kansas City**

5:00 AM Daybreak  
Time/Length: 00:04:02 / 01:16

Artificial blood KU Med  
It is much the same as real blood, Starting in the fall the University of KS Med Ctr will take part in a national study. The City argues is it unethical 21 trauma centers are also taking part. V; Blood.

5:00 AM Daybreak  
Time/Length: 00:31:55 / 01:25

Artificial blood KU Med  
The University of KS Med Ctr will take part in a study starting this fall Repeat

5:00 AM Daybreak  
Time/Length: 00:48:33 / 00:53

Top Stories KU Med  
> 435 sniper.  
> Artificial blood at KU Med  
> Community responds

6:00 AM Sunrise  
Time/Length: 00:03:21 / 01:08

TZ; Artificial Blood KU Med  
Starting this fall, area ambulance agencies will carry artificial blood to emergencies. This is part of a national study involving KU Med. The artificial blood, PolyHeme, works the same as real blood. V; blood bank footage? Crews in Wyandotte, Johnson, Douglas and Leavenworth Counties will receive

the  
consent.

blood first. Critics argue that it is unethical to experiment on patients who aren't able to give Twenty one centers across the nation are also participating in the study. KU Med is planning on holding a press conference today. Kathy Quinn reporting.

6:00 AM Sunrise  
Time/Length: 00:32:14 / 01:14

TZ; Artificial Blood KU Med  
Area paramedics will start using artificial blood called PolyHeme this fall. This is part of a national study KU Med is participating in. A press conference will be held later today so KU Med can explain the study. V; blood bank footage? Wyandotte, Johnson, Leavenworth and Douglas Counties will

receive

the blood first. Kathy Quinn reporting. Repeat.

7:00 AM Morning Show  
Time/Length: 00:03:27 / 01:20

Artificial blood KU Med  
The University of KS will be studying it. V; Med Ctr.

7:00 AM Morning Show  
Time/Length: 00:34:16 / 01:04

Artificial blood KU Med  
The University of KS Med Ctr will be studying it. Repeat

7:00 AM Morning Show  
Time/Length: 00:48:01 / 00:43

Top Stories KU Med  
> Sniper  
> Artificial blood at KU Med  
> Community responds

8:00 AM Morning Show  
Time/Length: 00:08:40 / 01:50

TZ; Artificial blood. KU Med  
Starting this fall area ambulance agencies will start carrying artificial blood. This is part of a national study involving KU Med using artificial blood called Polyheme. It works the same as real blood and saves lives according to some doctors. Crews in Wyandotte, Johnson, Leavenworth and Douglas county will be the first in the metro to receive the artificial blood. V; polyheme blood and doctors in operating room. KU Med will hold a press conference this morning to explain the study. Kathy Quinn reporting.

8:00 AM Morning Show  
Time/Length: 00:32:14 / 01:06

Artificial blood. KU Med  
Starting this fall some ambulances will use the artificial blood called Polyheme. They are Johnson, Wyandotte, Leavenworth and Douglas Counties. KU Med is taking part in a study on artificial blood

that

people  
years.

works like real blood and pumps oxygen into the body. Some say that this is unethical to use of  
that cant give their consent. There are also doctors who say they have used the artificial blood for

KU Med also plans to hold a press conference this morning. Kathy Quinn reporting.  
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Program  
**Monday, August 01, 2005**  
4 WDAF - Kansas City

Text/Summary

12:00 PM Midday  
Time/Length: 00:28:42 / 02:16  
artificial  
blood.  
V;

Artificial blood. KU Med  
KU Med held a news conference at the fire station at 96th & State Ave to discuss plans to put blood called Polyheme on local ambulances. They are taking part in a medical trial. V; polyheme I; Dr. Dennis Allin, KU Med says that trauma related injuries take the most lives for people under 45. KCK ambulance. Toby Cook reporting.

5:00 PM 4 at Five  
Time/Length: 00:15:28 / 02:14  
PolyHeme,  
Polyheme.

Fox 4 Health. Meryl Lin McKean. KU Med  
> Some trauma patients in KS will soon no longer receive saline IV but instead will receive a blood substitute. V; Bag of blood substitute with Northland Laboratories sticker. University of KS Medical Center will be participating in a study using PolyHeme. I: Suzanne Porris, registered nurse, says getting a unit of PolyHeme will be like getting two units of saline; says hemoglobin is in the PolyHeme. V; accident scene with MAST, KCMO Police. Some controversy over the use of because trauma patients are not able to give their consent.  
> Red Cross is asking for blood donations because donations fall in the summer. V; Donors.  
> Cigarette smoke may increase risk of metabolic syndrome in teens. V; teens smoking.  
> GR; Healthy Habits Tip: Food intolerance  
> Teases for 9 pm; Chronic heartburn or reflux.

6:00 PM 4 at Six  
Time/Length: 00:12:28 / 00:40  
part

Artificial Blood. KU Med  
An artificial blood substitute is being tested at KU Med and other trauma centers throughout KS as of a statewide study. V; bag of the artificial blood. The substitute, called Polyheme, acts just like real blood. The blood substitute is approved for accident victims who need blood right away. I; Suzanne Perris, study coordinator, says Polyheme is like getting not only like getting 2 liters of saline, but also extra hemoglobin, vital in keeping organs from failing. Polyheme is universally compatible and has a shelf life of more than a year.

10:00 PM 4 at Ten  
Time/Length: 00:08:26 / 00:23

Synthetic Blood Trial KU Med  
KU Med is part of a new study this fall with the new synthetic blood PolyHeme. KU Med says that the new product works just like blood by carrying oxygen. PolyHeme works with all blood types. V: Bag of PolyHeme

5 KCTV - Kansas City

12:00 PM 5 at Noon  
Time/Length: 00:01:28 / 01:45  
saline.  
children  
bracelet

Blood Substitute. KU Med  
KU Med is beginning a study that will give an artificial blood called Polyheme to patients requiring blood transfusions. V; fake blood, press conference Patients in Kansas will be randomly selected to receive this artificial blood, and their condition will be compared to those who receive blood and I; Suzanna Porras, KU Med, says getting a unit of polyheme is like getting two liters of saline, and hemoglobin. V; ambulance. Only patients being transported to KU Med are eligible, excluding and severe head trauma patients. Those who do not want to participate in the study must wear a at all times indicating so. Amy Anderson reporting.

5:00 PM 5 at Five  
Time/Length: 00:03:58 / 01:14  
and  
money

Moat death.  
Jennifer Hill was found on Friday in a moat of the Isle of Capri Casino. She died over the weekend now her family is planning her funeral. She was to start paying restitution of 1,837.50 for stealing while working as a public health specialist for KCMO. V; City Hall. She was currently working at KU Med Center in the offices of Cultural enrichment and diversity. Liana Joyce reporting.

6:00 PM 5 at Six  
Time/Length: 00:15:11 / 02:40

TZ; Blood substitute trial.

KU Med

Clinical trial will soon be underway at KU Med in KCK for blood substitute. Anyone entering hospital will be part of study for blood substitute unless wearing a bracelet stating you decline to be part of

the

study. V; Bracelet declining Northfield PolyHeme Study; bag of IV saline fluid; bag of PolyHeme. I; Dennis Allin, KU Med Dir of Emergency Medicine, says it's a temporary oxygen-carrying red blood cell substitute; study will compare survival rates of patients with and without PolyHeme. V; Press conference at KU Med. PolyHeme could be used to save lives in serious trauma situations. V;

Inside

KCK Fire Dept ambulance. I; Suzanne Porras, KU Med, says it could be something that is the way of  
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hospitals

the future. V; KU Medical Center building and signs. Study is nationwide with select level 1

participating. I; Unidentified blonde male in white t-shirt with black sunglasses says he will wear bracelet; doesn't know enough about it. I; Unidentified female with highlighted brown hair wearing black sleeveless shirt and dark sunglasses says she would have to research to decide on risks. GR; PolyHeme Hotline info; patients who are not eligible list. Amy Anderson reporting from KCK outside

Program  
Text/Summary

**Monday, August 01, 2005**

5 KCTV - Kansas City

KU Med.

10:00 PM 5 at Ten

Time/Length: 00:12:04 / 00:50

TZ; Fake Blood Controversy KU Med

KU Med is taking part in a major clinical trial using fake blood in emergency situations. V; outside of KU Med. I; Dennis Allin, KU Med Dir. Of Emergency Medicine, says the PolyHeme is temporary

blood

substitute. The study will start in the fall. If residents do not want to be part of the trial, they need to wear a bracelet at all times indicating so. V; Blue bracelets for those who do not want to be part of

the

trial. GR; Blood Substitute, information, Polyheme Hotline

9 KMBC - Kansas City

5:00 AM First News

Time/Length: 00:48:02 / 00:35

Artificial Blood For Patients. KU Med

Paramedics will be carrying PolyHeme. KU Med Center is now working with Ambulance services to distribute the artificial blood called PolyHeme. It is the part of blood that carries oxygen through the body. Doctor's sat in an emergency it will help Our. The test study of PolyHeme will begin this fall in Johnson County, Leavenworth and Douglas County.

5:00 PM 9 News at Five

Time/Length: 00:00:34 / 02:18

Synthetic blood KU Med

A blood substitute called PolyHeme is being studied by KU Med Center as an alternative in KS ambulances. V; KCK Fire Dept. truck, car accident scene, bag of IV saline. KU Med has joined over Level 1 trauma centers in the country in testing the safety and effectiveness of PolyHeme. I; Dr.

Dennis

Allin, KU Med Director of Emergency Medicine, says saline can help restore volume, but does

nothing

to restore ability to deliver oxygen. V; bag of PolyHeme, label reads Poly SFH-P Injection,

Polymerized

Human Hemoglobin (Pyridoxylated) 10 g/dl, Northfield Laboratories, new drug limited by federal law

to

investigational use. PolyHeme can deliver oxygen into the bloodstream. I; Suzanne Porras, RN,

KU

Med Study Coordinator, says its compatible with everybody, because it's not a blood product, is the hemoglobin which gives oxygen to organs. V; KU Med building and sign. It is still waiting on full

FDA

approval but regulations say that medical personnel can give it to you without your consent. I;

Suzanne

Porras says if someone chooses not to receive it, they'll just remove them from the study. You can

opt

out by wearing a wristband for the next 6 to 7 months. V; Dan Weinbaum indicates the bracelet. According to Dr. Allin, about 10% of KU's trauma patients, less than 200, are eligible to use

PolyHeme

in the study. I; Dr. Allin, says it's exciting that we're offering anything other than if someone's in

shock,

other than just manage the airway, turn on the lights and drive faster. Patients are chosen at

random.

KU Med is planning several public meetings over the next several months. PolyHeme will be in use starting in October. Dan Weinbaum reporting.

6:00 PM 9 News at Six

Time/Length: 00:10:10 / 00:45

TZ: Blood substitute. KU Med

KU Medical Center will provide a blood substitute to ambulance crews for trauma victims. V; Fake blood. I; Male in yellow shirt, excited this blood substitute is offered.

10:00 PM 9 News at Ten  
Time/Length: 00:08:55 / 00:50  
trauma

Blood study. KU Med  
KU Medical Center will provide a blood substitute for emergency workers for use on patients at  
scenes. V; Blood substitute. I; Dr Dennis Allin, U of KS hospital emergency center, says he's glad  
blood is being offered to patients.

**41 KSHB - Kansas City**

5:00 AM NBC 41 Today  
Time/Length: 00:54:40 / 00:22

Fake blood study KU Med  
The University of KS Med Ctr will be testing it. GR; Jayhawk

5:00 PM 41 News at Five  
Time/Length: 00:08:10 / 02:15

TZ; Fake Blood. KU Med  
Beginning in Oct if you are in need of emergency care and are being taken to KU Med by ambulance  
you will receive artificial blood. Paramedics will begin using PolyHeme, or fake blood, V; Northfield  
Laboratory label on PolyHeme. I; Suzanne Porras, University of KS Hospital, describes what the  
PolyHeme does. KU will begin a study of the blood substitute that gives oxygen to patients, which

the

standard saline solution given to trauma patients does not give. I; Dennis Allen, Medical Director,

KCK

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Program  
Text/Summary

**Monday, August 01, 2005**

the

41 KSHB - Kansas City

Fire Dept, says this gives them the opportunity to give resuscitation fluid wise; says there has been debate in medicine about whether giving a patient saline solution is a good thing when they are in shock. V; Lactated Ringer's Injection USP saline solution; KCK ambulance. Porras says the product

will hopefully save people's lives. If one wants to opt out of the study and the use of the PolyHeme

patient must be wearing a white bracelet with indicated. V; bracelet, available on KU website. Public hearings will be held in a couple weeks to provide more info. Jade Hernandez reporting.

6:00 PM 41 News at Six  
Time/Length: 00:02:17 / 01:38

on a

KU

field

thinks,

You

Fake blood. KU Med

Starting in Oct, if you are not wearing a bracelet and you live in KS and an ambulance picks you up

trauma case, it is highly likely the paramedics will administer you fake blood, called Polyheme. V;

Medical Center. The Univ of KS Hospital will be running a trauma trial on the blood substitute. V; bags of Polyheme, KCK fire and rescue, KCK police on an accident scene. I; Dennis Allen, Med Dir KCK Fire dept, says there has been a debate in medicine over whether giving a lot of saline in the

is actually a bad thing. I; Suzanne Porras, Univ of KS RN, says it depends on how fast the FDA

if this shows it's making a difference, they can decide how long it will take to get it in the market.

can opt out of the program by picking up a wristband on the KU Medical Center website. Jade Hernandez reporting live.

10:00 PM 41 News at Ten  
Time/Length: 00:06:25 / 00:41

to

Fake Blood KU Med

KU Med Center will start using fake blood, PolyHeme, in the fall. V; outside of KU Med Center, bags of PolyHeme. I; Suzanne Porras, University of KS, says people do not need to be typed or crossed

use the blood. V; ID bracelets for those not wishing to be part of the study.

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**LJWORLD.COM**  
LAWRENCE JOURNAL-WORLD

## **Synthetic blood treatment may soon be available**

Thursday, August 4, 2005

Critically injured trauma patients in Douglas County may soon be eligible for a new type of treatment — synthetic blood.

Officials with Lawrence-Douglas County Fire & Medical are meeting to decide whether to pursue allowing the use of PolyHeme, a blood-like substitute that has been promising in saving lives during early clinical trials.

The Kansas University Medical Center is launching a new trial and is seeking area counties to participate.

“We haven’t yet decided whether we’ll be participating or not,” said Mark Bradford, deputy chief of Lawrence-Douglas County Fire & Medical.

Several area counties — including Wyandotte, Johnson and Leavenworth — have shown interest in the trial, KU officials said. Franklin and Miami counties also might participate.

Currently, EMTs at an accident site are only allowed to give trauma patients who are severely bleeding a saline solution, which can’t carry oxygen to the body. Blood transfusions are impractical in the field, in part, because of difficulty matching blood types and the availability of blood.

PolyHeme, which is manufactured by Northfield Laboratories in Evanston, Ill., can be given instead. The fluid allows for oxygen transport in severely wounded patients, increasing their chances for survival.

“I think it’s going to make a big difference from the standpoint of being able to administer something that’s safe,” said Michael Moncure, the KU doctor who is overseeing the study. “We don’t have to worry about a reaction or patients that don’t want blood transfusions.”

The Food and Drug Administration generally requires individuals to consent before subjecting them to clinical trials.

But since trauma patients generally can’t give that consent, the FDA has allowed a rare exception. Instead, KU will seek community support for the project in the counties pursuing participation in the trial, including meetings with EMS personnel, government leaders and the public.

Opt-out bracelets will be given to anyone who wouldn’t want to be treated with PolyHeme.

In counties that do give support for the trial, responding personnel will give PolyHeme to half the major trauma patients they treat, with the rest receiving the usual saline solution.

The study results will be combined with results from about 20 other hospitals across the country. The FDA is expected to decide in six months to a year whether to approve use of PolyHeme beyond the

trials, Moncure said.

In Douglas County, only patients headed to the University of Kansas Hospital would be eligible to receive PolyHeme. Those include those transported by ground ambulance and air ambulance.

Patients headed to Lawrence Memorial Hospital wouldn't be eligible, Moncure said. He said the project wouldn't lead to a loss of patients at LMH.

If Lawrence-Douglas County Fire & Medical personnel decide to pursue the trial, KU would conduct community meetings in the next six to eight weeks to inform the public.

Moncure said he hoped Douglas County gave the project the green light.

"I think it's a tremendous opportunity," he said. "It's probably one of the most exciting studies around the country, particularly in trauma."

# KU Hospital tests resuscitative fluid

**ELAINE BESSIER**

STAFF WRITER

The University of Kansas Hospital is among 21 Level I trauma centers nationally, and the only one in Kansas, participating in a clinical trial of PolyHeme to treat critically injured and bleeding patients.

PolyHeme is a temporary, oxygen-carrying, red blood cell substitute.

The University of Kansas Hospital and Medical Center on Monday announced a month-long campaign to inform the public about the study. Public meetings are scheduled for October.

KU Hospital patients come from Johnson, Douglas, Wyandotte and Leavenworth counties.

The Food and Drug Administration study will involve 720 patients nationwide, said the

study coordinator at KU, Suzanne Porras, RN, Shawnee.

"It is an exciting opportunity for us and for the people — very cutting edge. It will make a big difference for saving lives in the future," Porras said.

The local study is estimated to take six months, said Dr. Dennis Allen, medical director for the Kansas City, Kan., Fire Department and one of the co-investigators. The study began at the national level more than a year ago and so far has 400 participants.

"Many traumas involve shock, massive blood loss and the lack of ability to deliver oxygen," Allen said. "The only thing available is an infusion of saline, or salt water, which restores blood volume but does nothing to restore oxygen. Before, the only thing we had to offer was 'Turn on the lights and drive faster.'"

PolyHeme is an immediately available, oxygen-carrying resuscitative fluid. The fluid is universally compatible with all blood types and requires no matching.

Trauma-related injuries are a leading cause of death among Americans under 45 years old, affecting more than 2 million persons per year. Nearly one in five trauma victims dies.

Survival rates for patients using PolyHeme will be compared to those getting saline in the pre-hospital setting and blood at the hospital. Hospital blood is not necessarily free of side effects.

"PolyHeme has a component that carries blood. It is not a blood product so there is no chance of carrying AIDS," Allen said. "It has a shelf life of a year and is kept in a cooler with ice packs. So far, there have been no reactions or outcomes that have

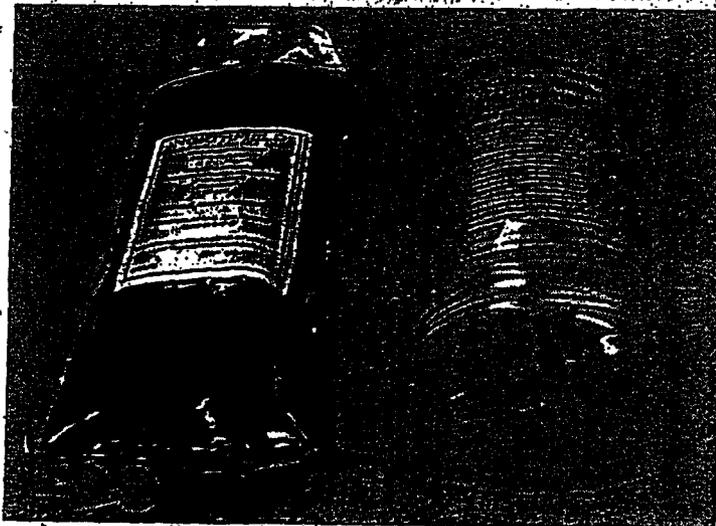
made them stop the trials."

For test purposes, half of the subjects will receive PolyHeme and half will get standard care.

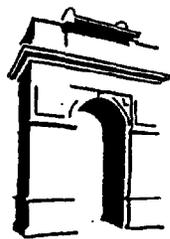
PolyHeme is given for up to 12 hours or six units. Standard care will follow, if needed.

PolyHeme has been rapidly infused in clinical trials in sufficiently large quantities to be considered well tolerated, according to research.

Northfield Laboratories Inc., Evanston, Ill., makes PolyHeme and is paying for the study. The FDA will decide whether the product can be marketed.



POLYHEME appears burgundy; the saline solution is clear.



# The Rosedalian

## ROSEDALE DEVELOPMENT ASSOCIATION NEWSLETTER

### Moving forward with new housing in Rosedale

Dignitaries from a variety of community, governmental, and private institutions attended the Mission Cliffs housing development groundbreaking ceremony on Aug. 24. The Mission Cliffs development, along with the nearby Rainbow Park development, will bring 120 new single-family homes and townhomes to the bluffs west of the University of Kansas Medical Center and the 39th St. district (near the intersection of Lake Ave. and Minnie St. in Kansas City, Kan.).

Eleven homes have already been completed in the area as part of the Rainbow Park development. The Mission Cliffs development is the next phase of the project. Both housing developments, which aim to provide middle and lower-income residents an opportunity for homeownership in the urban core, represent the fruition of many years of hard work by many people and organizations, including: RDA; City Vision Ministries; the Unified Government of Kansas City, Kan./Wyandotte County; Brotherhood Bank; Fannie Mae; and the U.S. Department of Housing and Urban



JOEL COEHLING PHOTO

Shown during the groundbreaking ceremony are (from left to right) John Harvey, Executive Director of City Vision Ministries; Wendy Wilson, Executive Director of RDA; U.S. Sen. Pat Roberts; Mayor Joe Reardon; and Commissioner John Mendez.

Development (HUD).

For more information, visit [www.cityvisionministries.org/mission.html](http://www.cityvisionministries.org/mission.html) or contact City Vision Ministries: (913) 371-5200. ☐

### U.G. Commissioners approve Rosedale Master Plan

The Unified Government Board of Commissioners unanimously approved the Rosedale Master Plan during its meeting on Aug. 25.

The Plan is the product of a thorough process of community dialogue and partnership. Neighborhood leaders, business owners, representatives from local agencies, schools, churches, and the University of Kansas Medical Center, and other com-

Now that the Commissioners have approved the Plan, it will serve as a roadmap for future development in Rosedale. It does not change current zoning or existing structures. Rather, it is a concrete guide to ensure that future development coincides with community wants and needs.

To view the proposed future use map under the Plan or for more information,

### Construction update

Thanks to recent heavy rains, many construction and infrastructure projects have been delayed around the city. Here is an update on several projects affecting Rosedale:

1. Repairs to I-35 from about 7th St. to Mission Rd./Southwest Blvd. will be complete in early October. The Mission Rd. viaduct over Turkey Creek is scheduled to be finished by Thanksgiving. However, drivers can expect to have access to southbound Mission Rd. from Southwest Blvd. by the third week in September.

2. The repaving of Southwest Blvd. (from the Mission Rd. overpass to Rainbow Ext. —this takes the work further east than originally planned) and of Mission Rd. (from 43rd Ave. to the Turkey Creek viaduct) will happen in early to mid-September.

Source: Unified Government City Engineer

### Upcoming Events

September 5

Labor Day (RDA office closed).

September 7, 14, 21, 28

Rosedale Youth Academy. 1401 Southwest Blvd. 1-6 p.m.

September 20

RDA Board meeting. 1401 Southwest Blvd. 5:30-8:30 p.m.

September 21

Rosedale Leadership Council. 1401 Southwest Blvd. 5:30-6:30 p.m.

September 25

Dedication of renovated building for Rainbow Mennonite Church/Sharing Community in Rosedale. 1444 Southwest Blvd. 1:30 p.m.

September 30

Free concert at the Landon Center on Aging. Featuring *Andean Express*. 3599 Rainbow Blvd. 6-8 p.m.

October 1

Christmas in October (minor home repair program for Rosedale residents).

October 9

*The Hindu and the Cowboy* (play about University of Kansas Medical Center. Battenfield Auditorium (corner of Rainbow

## KU Med asks for community input on study

The University of Kansas Hospital and the University of Kansas Medical Center are soliciting comments and responses from the broader community in regard to a proposed clinical research study to evaluate the safety and effectiveness of PolyHeme, an oxygen-carrying blood substitute, in treating critically injured and bleeding patients. The hospital and medical center want the community to be informed about the study and to provide feedback about any concerns.

Under the study protocol, treatment would begin before arrival at the hospital, either at the scene of the injury or in the air/ground ambulance, and continue for 12 hours. Since blood is not presently carried in air/ground ambulances, the use of PolyHeme in these settings could address an unmet medical need for an oxygen-carrying solution where blood is currently not available. Polyheme has not yet been proven to be effective and may have unknown risks – hence the need for the proposed study.

The hospital and medical center are required to obtain community input before proceeding with this study. To learn more and to submit a feedback form, visit [www.kumc.edu/polyheme](http://www.kumc.edu/polyheme). For more information, contact the study coordinator, Suzanne Porras, R.N.: (913) 588-3005. ☐

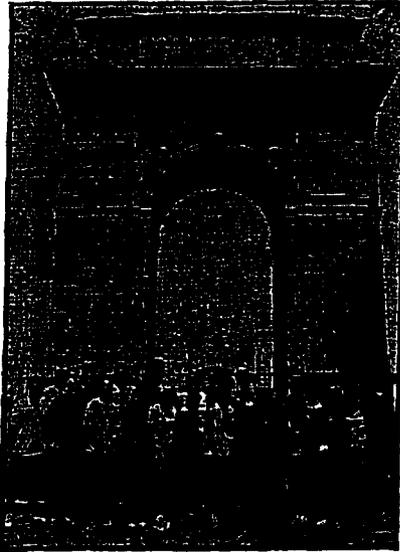
Reprinted with permission of Univ. of Kansas Hospital and Univ. of Kansas Medical Center.

## Dagwood's owner Dennis "Denny" Morlan passes away

Dennis Eugene Morlan, 62, co-proprietor of Rosedale's famous Dagwood's Café (1117 Southwest Blvd.), died Aug. 3, 2005, at his home. Funeral services were held on Aug. 6 at Maple Hill Funeral Home and the burial was at Creighton Cemetery. Known as "Denny" to many of his family and friends, Dennis was a lifelong Kansas City resident with many Rosedale connections. Denny and his wife, Ruby, owned Dagwood's for the past 11 years. Many of his closest friends were customers and other business owners on Southwest Blvd. He was a founding member of the Rosedale Rowdies, a lawnmower racing organization. To view a tribute to Denny from his family, visit [www.dagwoods.com/Denny.htm](http://www.dagwoods.com/Denny.htm). Rosedale will truly miss this native son. RDA wishes to express its condolences

## RDA volunteers go full force in August

Thank you to almost 70 volunteers who made major improvements throughout Rosedale last month. In total, 281 volunteer hours were invested in projects involving youth, senior citizens and community spaces.



KARLY JANDRA PHOTOS



Two groups helped spruce up the grounds at the Rosedale Memorial Arch in early August, including 20 students each from the KU Med Center and Blue Springs South High School.

## The Hindu and the Cowboy comes to Rosedale

RDA encourages members of the Rosedale community and others in the Kansas City metropolitan area to attend a public performance of *The Hindu and the Cowboy* on Sunday, Oct. 9, 3-5 p.m., at the University of Kansas Medical Center's Battenfield Auditorium (corner of Olathé Blvd. and Rainbow Blvd. in Kansas City, Kan.). Following the performance, there will be a facilitated discussion on community issues raised by the play.

The play's content is drawn from real-life stories of Kansas City residents

and explores themes of diversity and cross-cultural relationships. The stories – which convey tragedy, healing, humor and reconciliation – were collected through personal interviews and storytelling circles. People of all ages and from many religious traditions were involved in the project.

The performance on Oct. 9 is sponsored by the KU Med Center, the Rosedale Ministerial Alliance, and other community partners. We hope to see you at this important event in our local community. ☐

## Membership application

Annual business dues: \$100 ☐ Annual household dues: \$15

Name of business or name of household

Address

City

State

ZIP code

Contact person

Day phone

Evening phone

Fax

Please mail application, along with check made payable to:

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THE JOHNSON COUNTY



Home -> News -> News -> Top Stories

Friday 5 August 2005

NEWS SEARCH  
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## Top Stories

### KU Hospital tests resuscitative fluid

Elaine Bessler, Staff Writer

August 04, 2005

Email to a friend  Voice your opinion

The University of Kansas Hospital is among 21 Level I trauma centers nationally, and the only one in Kansas, participating in a ground-breaking clinical trial.

The trial will evaluate the safety and effectiveness of PolyHeme in treating critically injured and bleeding patients. PolyHeme is a temporary, oxygen-carrying, red blood cell substitute.

The University of Kansas Hospital and Medical Center on Monday announced a month-long campaign to inform the public about the study. Public meetings are scheduled for October.

Patients come to KU Hospital from Johnson, Douglas, Wyandotte and Leavenworth counties.

The Food and Drug Administration study will involve 720 patients nationwide, said the study coordinator at KU, Suzanne Porras, RN, Shawnee.

"It is an exciting opportunity for us and for the people - very cutting edge. It will make a big difference for saving lives in the future," Porras said.

The local study is estimated to take six months, said Dr. Dennis Allen, medical director for the Kansas City, Kan., Fire Department and one of the co-investigators. The study began at the national level more than a year ago and so far has 400 participants.

"Many traumas involve shock, massive blood loss and the lack of ability to deliver oxygen," Allen said. "The only thing available is an infusion of saline, or salt water, which restores blood volume but does nothing to restore oxygen."

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Before, the only thing we had to offer was "Turn on the lights and drive faster."

PolyHeme is an immediately available, oxygen-carrying resuscitative fluid. The fluid is universally compatible with all blood types and requires no matching.

Trauma-related injuries are a leading cause of death among Americans under 45 years old, affecting more than 2 million persons per year. Nearly one in five trauma victims dies.

During the study, survival rates for patients using PolyHeme will be compared to those getting saline in the pre-hospital setting and blood at the hospital. Blood at the hospital is not necessarily free of side effects.

"PolyHeme has a component that carries blood. It is not a blood product so there is no chance of carrying AIDS," Allen said. "It has a shelf life of a year and is kept in a cooler with ice packs. So far, there have been no reactions or outcomes that have made them stop the trials."

For test purposes, half of the subjects will receive PolyHeme and half will get standard care.

PolyHeme is given for up to 12 hours or six units. Standard care will be given, if needed, afterward.

Manufactured by Northfield Laboratories Inc. of Evanston, Ill., PolyHeme has been rapidly infused in clinical trials in sufficiently large quantities to be considered well tolerated, according to research.

Northfield is paying for the study. The FDA will decide whether the product can be marketed.

©The Johnson County Sun 2005

Email to a friend  Voice your opinion  ↑ Top

*Send us your community news, events, letters to the editor and other suggestions. Now, you can submit birth, wedding and engagement announcements online too!*

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THE UNIVERSITY  
OF KANSAS HOSPITAL  
KUMED

Trauma Services Administration

August 5, 2006

The Honorable Sam Brownback  
United States Senate  
303 Hart Senate Office Bldg  
Washington DC 20510

Dear Senator Brownback:

I am writing to inform you about a very important clinical study that may be conducted at the University of Kansas Hospital.

The University of Kansas Hospital is one of a select number of Level I trauma centers in the U.S. being asked to participate in a groundbreaking national clinical study to evaluate the life-sustaining potential of PolyHeme®, an investigational temporary oxygen-carrying red blood substitute, in treating critically injured and bleeding patients. Under the study protocol, which has been cleared for initiation by the U.S. Food and Drug Administration (FDA), treatment will begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during the initial 12 hour post-injury period in the hospital. The study will compare the survival rate of patients receiving PolyHeme to that of patients who receive the current standard of care, which is saline (salt water) solution followed, in the hospital, by donated blood, when needed.

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).

Clinical trials at the University of Kansas Hospital are overseen by the local Institutional Review Board (IRB). The IRB is an independent body composed of medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of patients enrolled in clinical trials. The traditional IRB approval of a clinical trial includes a requirement that informed consent be obtained from patients before enrollment can occur. Under the current regulations, the IRB responsible for the review, approval and continuing monitoring of a clinical trial may give approval for patient enrollment in trials in emergency situations without requiring informed consent provided specific criteria are met. The patients must be in a life-threatening situation, and the experimental therapy being evaluated must offer patients the potential for direct clinical benefit in the form of increased survival.

# THE UNIVERSITY OF KANSAS HOSPITAL

**KUMED**

Trauma Services Administration

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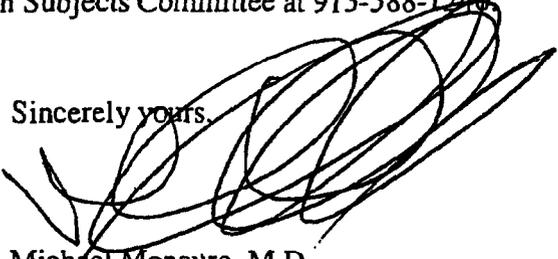
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Please feel free to contact me directly should you wish to discuss this study and the implications for our community. I can be reached at 913-588-7230.

If you have questions about the rights of research patients, please call the University of Kansas Medical Center Human Subjects Committee at 913-588-1240.

Sincerely yours,



Michael Moncreure, M.D.  
Principal Investigator

THE UNIVERSITY  
OF KANSAS HOSPITAL  
KUMED

Trauma Services Administration

August 5, 2006

The Honorable Dennis Moore  
U.S. House of Representatives  
1727 Longworth House Office Bldg  
Washington DC 20515

Dear Congressman Moore:

I am writing to inform you about a very important clinical study that may be conducted at the University of Kansas Hospital.

The University of Kansas Hospital is one of a select number of Level I trauma centers in the U.S. being asked to participate in a groundbreaking national clinical study to evaluate the life-sustaining potential of PolyHeme®, an investigational temporary oxygen-carrying red blood substitute, in treating critically injured and bleeding patients.

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Trauma Services Administration

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Please feel free to contact me directly should you wish to discuss this study and the implications for our community. I can be reached at 913-588-7230.

If you have questions about the rights of research patients, please call the University of Kansas Medical Center Human Subjects Committee at 913-588-4240.

Sincerely yours,



Michael Moncure, M.D.  
Principal Investigator

THE UNIVERSITY  
OF KANSAS HOSPITAL  
KUMED

Trauma Services Administration

August 5, 2006

The Honorable Jerry Moran  
U.S. House of Representatives  
2443 Rayburn House Office Bldg  
Washington DC 20515

Dear Congressman Moran:

I am writing to inform you about a very important clinical study that may be conducted at the University of Kansas Hospital.

The University of Kansas Hospital is one of a select number of Level I trauma centers in the U.S. being asked to participate in a groundbreaking national clinical study to evaluate the life-sustaining potential of PolyHeme®, an investigational temporary oxygen-carrying red blood substitute, in treating critically injured and bleeding patients. Under the study protocol, which has been cleared for initiation by the U.S. Food and Drug Administration (FDA), treatment will begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during the initial 12 hour post-injury period in the hospital. The study will compare the survival rate of patients receiving PolyHeme to that of patients who receive the current standard of care, which is saline (salt water) solution followed, in the hospital, by donated blood, when needed.

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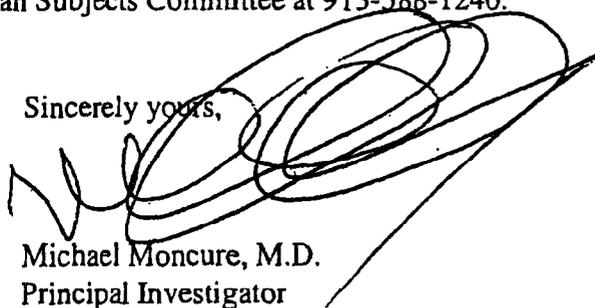
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If you have questions about the rights of research patients, please call the University of Kansas Medical Center Human Subjects Committee at 913-588-1240.

Sincerely yours,



Michael Moncure, M.D.  
Principal Investigator

August 5, 2006

The Honorable Pat Roberts  
United States Senate  
109 Hart Senate Office Bldg  
Washington DC 20510

Dear Senator Roberts:

I am writing to inform you about a very important clinical study that may be conducted at the University of Kansas Hospital.

The University of Kansas Hospital is one of a select number of Level I trauma centers in the U.S. being asked to participate in a groundbreaking national clinical study to evaluate the life-sustaining potential of PolyHeme®, an investigational temporary oxygen-carrying red blood substitute, in treating critically injured and bleeding patients. Under the study protocol, which has been cleared for initiation by the U.S. Food and Drug Administration (FDA), treatment will begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during the initial 12 hour post-injury period in the hospital. The study will compare the survival rate of patients receiving PolyHeme to that of patients who receive the current standard of care, which is saline (salt water) solution followed, in the hospital, by donated blood, when needed.

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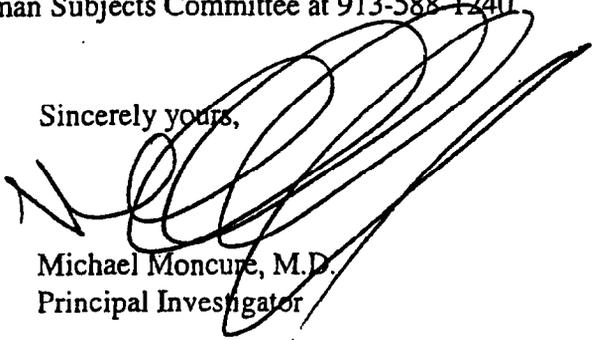
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If you have questions about the rights of research patients, please call the University of Kansas Medical Center Human Subjects Committee at 913-588-1240.

Sincerely yours,



Michael Moncure, M.D.  
Principal Investigator

THE UNIVERSITY  
OF KANSAS HOSPITAL  
**KUMED**

Trauma Services Administration

August 5, 2006

The Honorable Jim Ryun  
U.S. House of Representatives  
1110 Longworth House Office Bldg  
Washington DC 20515

Dear Congressman Ryun:

I am writing to inform you about a very important clinical study that may be conducted at the University of Kansas Hospital.

The University of Kansas Hospital is one of a select number of *Level I* trauma centers in the U.S. being asked to participate in a groundbreaking national clinical study to evaluate the life-sustaining potential of PolyHeme®, an investigational temporary oxygen-carrying red blood substitute, in treating critically injured and bleeding patients.

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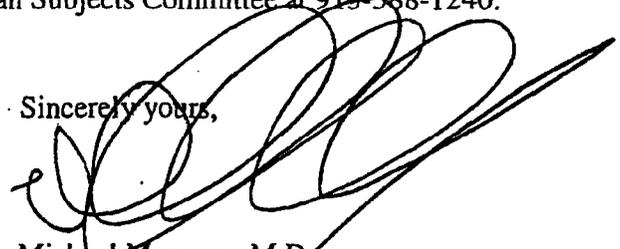
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Sincerely yours,



Michael Moncure, M.D.  
Principal Investigator

THE UNIVERSITY  
OF KANSAS HOSPITAL  
**KUMED**

Trauma Services Administration

August 5, 2006

The Honorable Todd Tiahrt  
U.S. House of Representatives  
2441 Rayburn House Office Bldg  
Washington DC 20515

Dear Congressman Tiahrt:

I am writing to inform you about a very important clinical study that may be conducted at the University of Kansas Hospital.

The University of Kansas Hospital is one of a select number of Level I trauma centers in the U.S. being asked to participate in a groundbreaking national clinical study to evaluate the life-sustaining potential of PolyHeme®, an investigational temporary oxygen-carrying red blood substitute, in treating critically injured and bleeding patients. Under the study protocol, which has been cleared for initiation by the U.S. Food and Drug Administration (FDA), treatment will begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during the initial 12 hour post-injury period in the hospital. The study will compare the survival rate of patients receiving PolyHeme to that of patients who receive the current standard of care, which is saline (salt water) solution followed, in the hospital, by donated blood, when needed.

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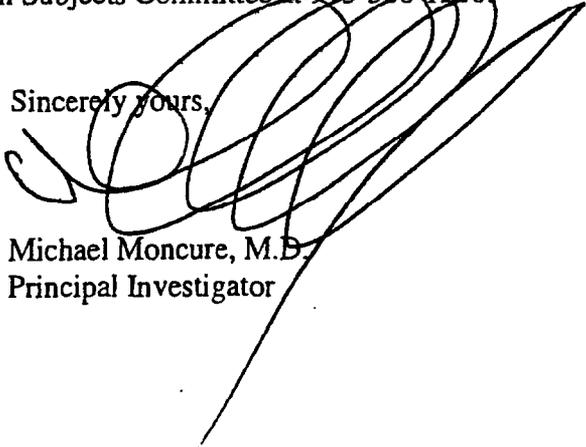
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Sincerely yours,



Michael Moncure, M.D.  
Principal Investigator

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THE JOHNSON COUNTY

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Friday 12 August, 2005

NEWS SEARCH

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### Top Stories

## Med-Act may join in study

August 11, 2005

Email to a friend  Voice your opinion

Johnson County Med-Act may participate in the University of Kansas Hospital's study of PolyHeme, a temporary, oxygen-carrying, red-blood-cell substitute to treat critically injured and bleeding patients.

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KU discussed the study with Med-Act several months ago. Med-Act's medical advisory committee will consider whether the ambulance service should participate, said Ted McFarland, chief of Med-Act.

KU is one of a few Level 1 trauma centers nationwide chosen to participate in the national clinical trial to evaluate PolyHeme.

"If the committee does want us to participate, they will be drafting protocols to define how we participate," McFarland said. "Issues involved in the decision include whether or not the research is going to be relevant to our group. The University of Kansas Hospital is not our primary destination; Overland Park Regional Medical Center is. KU would be just a subset of our trauma patients, most of which go to Overland Park Regional Medical Center."

The project is in the early stages. KU is trying to find out whether there is community support for the study, McFarland said.

"It is not a typical study because it involves a product that is blood derived. It also involves issues such as the fact that it is given without consent. Another

issue (for Med-Act) is the number of patients this might involve with us and whether or not these numbers justify our participation."

Treatment for patients would begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during a 12-hour post injury period in the hospital. KU could begin the study in October.

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## Blood substitute could save patients' lives

By *CONNIE PARISH, Times Staff Writer*

Trauma-related injuries, such as serious car accidents, are the leading cause of death for people under 45.

That's why University of Kansas physician Michael Moncure is excited about the potential for a product that is the subject of a research trial sponsored by the KU Med Center and the University of Kansas Hospital.

A blood substitute, known as PolyHeme, will be the topic of the trial, which could eventually lead to approval by the Federal Drug Administration. It is produced by Northfield Laboratories Inc. Moncure, the chief investigator for the trial, said it's produced from "old banked blood that's getting ready to be thrown out."

The blood is washed down and sterilized to such a degree that the "cellular envelope" is completely removed, Moncure said. That's an advantage for several reasons.

First, it requires no cross-matching, and therefore is compatible with all blood types. Patients, who initially receive this at the accident scene, have no transfusion or immune reactions. Previous studies have revealed no infections and patients also appear less likely to have dysfunction of organs such as the liver or kidneys.

Now, the standard of care for patients with what is known as the level one, or most serious, trauma, is a saline solution, administered at the scene and in the ambulance on the way to a trauma center, Moncure said.

The hemoglobin, he said, "is the building block; it's the hemoglobin that carries the oxygen, and that oxygen is what sets this apart from the normal saline."

In PolyHeme, he said, "the molecule is polymerized and made into a long chain able to carry the same amount of oxygen that a normal unit of blood would be able to carry."

The PolyHeme units, which have a shelf life of about a year, would be kept on ambulances, such as those operated by Leavenworth County Emergency Medical Service.

The patient would continue to receive PolyHeme until he's had six units, or 12 hours have elapsed, Moncure said. The study coordinator, registered nurse Suzanne Porras, said one hope is that patients receiving the blood substitute would spend less time in intensive care and/or need less ventilation or dialysis. The result could be fewer deaths resulting from the traumas, Moncure said.

The KU site is one of 21 trauma centers across the nation picked for the study, Moncure said. It is one of three certified level one trauma centers in Kansas and the only one in the Kansas City area.

But nothing about the proposed trial has been easy or fast. Helen Blackwell, director of the human research protection program, represents an ethics review board that looks carefully at the procedures.

Because the trial would not require informed consent, the FDA sets stringent requirements, she said.

Informed consent likely wouldn't be possible if a victim is in shock at the scene of a serious accident. And if the person was "somewhat lucid, it wouldn't be appropriate to delay treatment" to obtain that consent, she said.

Because of that status, the team working toward the trial must go through numerous steps. One of the most important is informing the public that it's planned and getting community input, Blackwell said.

The proposed area for the study includes Leavenworth County as well as Johnson, Wyandotte and Douglas counties, all of which might have patients going to the KU trauma center.

The proposed subjects for the trial would have to meet certain criteria. First, the victim would have to suffer a level one trauma, which is life threatening. Most level one traumas treated at the Kansas City, Kan., hospital involve vehicle accidents. The figure is about 60 percent, Moncure said, noting they do treat some gunshot wounds as well.

The patient also would have to have dangerously low blood pressure, Moncure said. In addition, the KU trial involves only patients from Kansas.

Once a patient fits all those criteria, the pick would be random, Blackwell said. The EMS personnel would pick an envelope coded randomly and there would be an equal chance for PolyHeme and saline treatment.

Though informed consent isn't required, the staff must try every half-hour to find a family member who could give consent, Moncure said.

Porras said there is a way for those who object to being part of the trial to opt out. She demonstrated blue bracelets a person could wear that say "I Decline the Northfield PolyHeme Study."

A person would have to be wearing the bracelet at the time of an accident, Porras said, because there wouldn't be time to go through wallets or pockets to find it.

The hope is to be able to start the trial by mid-October, with the idea it could last from 12 to 18 months. The number of subjects the KU trial has targeted is 20, which would contribute to the nationwide enrollment of 720 patients.

Before the trial starts, however, large community meetings will be planned, so the public can provide input, Blackwell said. One for Leavenworth County will likely be scheduled in Leavenworth, with meetings also set for the other three counties.

Information is also available by accessing the Web site, [www.kumc.edu/polyheme/](http://www.kumc.edu/polyheme/) and [www.kumed.com](http://www.kumed.com) or by calling Porras, the study coordinator, at (913) 588-3005.



# News Release

Unified Government Public Relations  
701 N. 7<sup>th</sup> Street, Room 620  
Kansas City, Kansas 66101

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FOR IMMEDIATE RELEASE

September 2, 2005

## **KCK Fire EMS Part of National Study**

### **KU Hospital and KCK Ambulance Service Conducting Trials on PolyHeme Blood Substitute**

The University of Kansas Hospital and the KCK Fire Department Emergency Medical Service are participating in a field trial of PolyHeme, a blood substitute product for use in seriously injured trauma patients.

The oxygen carrying fluid is undergoing field trials nationally prior to securing Food and Drug Administration approval. The experiences of KCK EMS personnel are considered vital to that approval process. Field trials are set to start in Kansas City, Kansas in September and continue for six to eight months.

The University of Kansas Hospital is one of a select number of Level I trauma centers in the US chosen to take part in the ground breaking study. PolyHeme is a universally compatible, immediately available, oxygen carrying resuscitative fluid designed for use in urgent blood loss when blood is not quickly available.

If someone in the community who would be served by the KCK Fire Department EMS wants to be excluded from taking part in the study, an "opt out" wristband is available from the University of Kansas Hospital. Members of the Jehovah's Witness faith will most likely want to opt out of the PolyHeme study. Opt out wristbands are being provided to all Jehovah's Witness community leaders in the metro area.

For more information about PolyHeme, or how to obtain an "opt out" wristband, go to [www.kumc.edu/polyheme](http://www.kumc.edu/polyheme) or [www.kumed.com](http://www.kumed.com) for more information. Citizens can also call the study coordinator, Suzanne Poras, at 913-588-3005.

### **PUBLIC MEETING ON POLYHEME**

A public meeting for Wyandotte County residents about the PolyHeme study is being held on Wednesday, September 21 at 7pm at the University of Kansas Medical Center Campus, at the corner of Rainbow and Olathe Boulevards in the Battenfeld Auditorium.

**QUESTIONS AND ANSWERS  
POLYHEME® TRAUMA TRIAL  
THE UNIVERSITY OF KANSAS HOSPITAL  
THE UNIVERSITY OF KANSAS MEDICAL CENTER**

**Why is this study being conducted?**

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

**What is the title of this study?**

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

**What is PolyHeme®?**

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

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

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

*During this study Polyheme® is compared to standard of care, saline (salt water) in the pre-hospital setting and blood in the hospital.*

*At the site of the injury, half of the subjects (like flipping a coin) receive Polyheme®, half receive standard care (saline). It is given by emergency medical personnel before reaching the hospital (may be up to 60 minutes).*

*Upon arrival to the emergency room, subjects receive Polyheme® or standard care (blood). Subjects that received Polyheme® at the emergency site continue to receive Polyheme® in the hospital instead of standard care (blood). PolyHeme® is given for up to 12 hours or 6 units of PolyHeme. Standard care (blood) will be given (if needed) after 12 hours or 6 units of PolyHeme ®. Patients who originally receive the saline solution in the field will receive standard care (blood) upon arrival to the emergency room (standard of care).*

**What is hemorrhagic shock?**

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

*Shock is a life-threatening condition that might include:*

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

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

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

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

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

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

**Who is eligible for the study?**

*Patients who have lost a large amount of blood and are in shock*

*Patients who are at least 18 years old*

*Patients who have sustained severe injuries*

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**Who will be excluded from the study?**

*Women who are obviously pregnant*

*Patients with severe brain injuries*

*Patients who require CPR to maintain their heartbeat*

*Patients with "unsurvivable" injuries*

*Patients who are known to object to blood transfusions*

*Patients who are known to refuse resuscitation*

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

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

**Has enrollment begun anywhere?**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Patients are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions.*

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

- *Patients are in a life-threatening situation that necessitates intervention*
- *Previous studies support the potential to provide a direct benefit to enrolled patients*
- *Risks associated with the use of the PolyHeme® are reasonable in relation to what is known about the patients' medical condition, the risks and benefits of standard therapy, and the risks and benefits of the proposed intervention*

*It is expected that patients will be unable to give informed consent because the extent of their injuries and the fact that they are in shock.*

*It is unlikely that there will be time to find and ask for consent from the patient's legally authorized representative (LAR) or to provide an opportunity for a family member to object to the patient's enrollment before beginning treatment.*

**Who grants such exceptions?**

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

**What if someone doesn't want to participate in this study?**

*If someone in the community would like to be excluded from participating in this study, an "opt out" wristband will be provided at no cost. If someone in the community is involved in a trauma and they are wearing the wristband they will not be placed in the study. Information regarding how to obtain the "opt out" wristband will be available on the KU websites: [www.kumc.edu](http://www.kumc.edu) and [www.kumed.com](http://www.kumed.com) or by calling the study coordinator, Suzanne Porras, R.N. at 913-588-4022.*

**What if a patient wants to stop their participation in the study?**

*Patients can withdraw from the study, without prejudice, at any time by notifying the investigator. If the patient is not competent to be making decisions about their participation, a family member does have the ability to request that the patient's participation be ended.*

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

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

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

*PolyHeme® may increase the likelihood of survival after traumatic injury*

*The need for blood transfusion might be reduced*

*Patients might avoid a reduction in the function of internal organs that sometimes follows blood transfusion*

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

*Rash*

*Increased blood pressure*

*Kidney or liver damage*

*Transmission of hepatitis and HIV viruses  
Unforeseen happenings  
PolyHeme® may be less effective than blood*

*Some of these risks may lead to death.*

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

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

**Will patients get paid to participate?**

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

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

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

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## New take on emergency care

**T**he University of Kansas Hospital in Kansas City, Kan., is known for seeking out innovative advances in treating and healing those in need of medical care. That approach is the underlying purpose of a current project to determine whether area residents approve use of a new blood-related alternative to salt water for severely injured and bleeding patients.

The alternative is PolyHeme, described by hospital officials as a temporary oxygen-carrying red blood cell substitute made from human blood.

The hospital and the KU Medical Center would be partners in a clinical trial of the product here. Currently they are sampling community sentiment on whether to participate in the national study.

KU is one of 17 or so Level I trauma centers in the nation invited to take part. KU has the only nationally accredited Level I center in the metropolitan area.

The goal of the experiment here would be part of an effort by Northfield Laboratories, Inc., Evanston, Ill., which developed PolyHeme, to obtain approval of the Food and Drug Administration for its general use.

A public meeting on the proposed trial will be at 7 p.m. next Thursday in the General Education Building at Johnson County Community College. Forms will be available for those who want to express their views on the undertaking.

PolyHeme is produced, according to Northfield and KU officials, this way: Hemoglobin is extracted from human red blood cells and filtered to remove impurities. The hemoglobin is then chemically modified to create what scientists call a "polymerized" form of hemoglobin. The modified product is combined with chemicals present in human bodies to form PolyHeme.

The polymerization process is used, officials said, to "eliminate the undesirable effects historically associated with hemoglobin-based blood substitutes..." Those include increased blood pressure and kidney or liver damage. In some cases the body-threatening substitutes were created from nonhuman blood.

The main focus of the clinical trial here would be use of PolyHeme at the scene of medical emergencies in which the KU Hospital is the destination for subsequent treatment. The geographical area would be northeast Johnson County, which is served by Johnson County Med-Act.

On a random basis, half of the patients would receive PolyHeme and half standard care, which is the saline solution. After reaching the emergency room the patients would receive more PolyHeme or blood.

Ted McFarlane, chief of emergency medical services in Johnson County, estimated that, based on the criteria of the program, one or two patients a year would receive the new product.

McFarlane said, as he understands the product, the trial cases in other places have had a satisfactory outcome.

PolyHeme, officials said, is compatible with all blood types and thus does not require cross-matching.

Northfield contends the use of PolyHeme in massive blood loss is superior to salt water because its product carries oxygen to vital organs and may restore sufficient circulating levels of hemoglobin to improve the potential for survival. Saline solutions do not carry oxygen.

Anyone who would not want to participate in the trial could obtain an "opt out" wristband from KU. Information is available at [www.kumcd.com](http://www.kumcd.com) or [www.kumc.edu/polyheme/](http://www.kumc.edu/polyheme/). The telephone number is 586-1246.

An Independent Data Monitoring Committee, with a membership of medical and statistical experts, was designated to check the results. The committee, according to information distributed by KU, reviewed safety data on mortality and serious adverse effects from the study of the first 50, 120 and 250 patients in other places. After following their progress for 30 days the committee recommended the study proceed.

Research on a product with the characteristics of PolyHeme was conducted by the U.S. Army after the Vietnam War. The military was seeking a product that could be used in massive quantities on the battlefield. Early development was unsatisfactory because of impurities. The filtration process for PolyHeme is intended to avoid such problems.

WY THE KANSAS CITY STAR.  
Wednesday, September 21, 2005

Don't Miss Your Chance to Learn More  
and Express Your Views About a Research Study  
Proposed for Wyandotte County

7 p.m., Wednesday, September 21, 2005

Battenfeld Auditorium  
Southwest Corner of Rainbow and Olathe Boulevards  
The University of Kansas Medical Center, Campus  
(Parking: Olathe Boulevard Garage)

The University of Kansas Hospital, in partnership with The University of Kansas Medical Center, is one of a select number of U.S. trauma centers being asked to participate in a national clinical research study to evaluate the safety and effectiveness of PolyHeme®, an oxygen-carrying blood substitute, in treating critically injured and bleeding patients.

Because 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. These federal regulations require the hospital and KUMC to conduct community meetings to inform the public about plans for the study and solicit public comment prior to institutional approval.

For more information, go to [www.kumc.edu/polyheme/](http://www.kumc.edu/polyheme/) or [www.kumc.com](http://www.kumc.com). Or call study coordinator, Suzanne Porras, RN, at 913-588-3005.

If you have questions about the rights of research patients, please call the University of Kansas Medical Center Human Subjects Committee at 913-588-1240.

## Briefing Sheet for Study Session

To: Board of County Commissioners  
Michael Press, County Manager  
From: Ted McFarlane, Chief, Med-Act  
Date: September 15, 2005

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**Issue:** KU Medical Center is asking the Commission to endorse a research study involving people in Johnson County who experience significant physical trauma and are treated in the pre-hospital setting by Med-Act.

**Background:** Med-Act provides pre-hospital medical care to victims of accidents who suffer a traumatic injury. The Johnson County Medical Society has approved treatment guidelines (protocols) for Med-Act which provide for the transport of these victims to the closest trauma center. There are 2 trauma centers that routinely receive Med-Act patients, the Overland Park Regional Medical Center and the KU Medical Center. The destination hospital is determined based on the shortest travel time from the scene of the accident. In the recent 1-year period we transported 360 patients to OPRMC and 75 patients to the KUMC. ~~Most of the severely injured patients suffer from shock. The~~ pre-hospital treatment of these patients usually involves the administration of saline IV solutions to increase the volume of the circulatory system. Once in the hospital, if there has been significant blood loss, the patient would receive blood. KUMC is participating in a study of a new product called PolyHeme. PolyHeme is a temporary blood substitute made from human blood. It retains the oxygen carrying capacity of blood but without the other properties of blood. The study involves administering PolyHeme in the pre-hospital setting by EMS personnel. Typically, patients must consent to participate in a medical research project. In the case of PolyHeme the patient will be in no condition to consent or refuse so the FDA has insisted that the research facility obtain community consent.

**Analysis:** KUMC has asked Med-Act to participate in the study. The Johnson County Medical Society EMS Committee has met concerning this request and recommends that Med-Act participate in the study. Dr. Richard Rosenthal, Chairman of the Committee and the Med-Act Medical Director, will attend the study session to answer the Commission questions. The logistics of Med-Act's participation in the study are reasonable. We would utilize our 3 most northern ambulances because they are the most likely to transport to KUMC. The Polyheme will be provided to us at no cost by KUMC. Northfield Laboratories, the PolyHeme manufacturer, will provide all training for our staff, reimburse us for training costs, and provide the refrigerated PolyHeme storage containers. Northfield has also agreed to indemnify all study participants. The addition of PolyHeme to the standard of care for trauma patients has the potential to greatly improve patient outcomes for those patients who fall into the inclusion group.

**Alternative:** Choose to not participate in the study and continue providing care in accordance with the current standard of care.

**Legal Review:** It will be necessary for legal to review the program before action is taken.

**Funding:** No additional county funding is required.

**Budget Approval:** Scott A. Neufeld, Budget Director (by ch)

**Recommendation:** Staff recommends that the Commission consider all community input and seriously consider authorizing Med-Act and Johnson County citizens to participate in the study.

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FOR APPROVAL ONLY/DRAFT ONE

**Don't Miss Your Chance to Learn More  
and Express Your Views About  
a Research Study Proposed  
for Wyandotte County**

**7 pm Wednesday**

**September 21, 2005**

**Battenfeld Auditorium**

**Southwest corner (Rainbow and Olathe Blvds.) of the  
University of Kansas Medical Center campus  
Park in Olathe Boulevard Garage**

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The University of Kansas Hospital (and partner The University of Kansas Medical Center) is one of a select number of trauma centers in the U.S. being asked to participate in a national clinical research study to evaluate the safety and effectiveness of PolyHeme®, an oxygen-carrying blood substitute, in treating critically injured and bleeding patients.

Because the patients eligible for this study are unable to provide informed consent due to the extent and nature of their injuries, the study will be conducted under federal regulations that allow subjects to be placed in a research study without giving informed consent. These federal regulations require the hospital and university to conduct community meetings to inform the public about plans for the study and solicit public comment.

For more information, go to [www.kumc.edu/polyheme/](http://www.kumc.edu/polyheme/) or [www.kumed.com](http://www.kumed.com). Or call study coordinator, Suzanne Porras, R.N. at 913-588-3005.

If you have questions about the rights of research patients, please call the University of Kansas Medical Center Human Subjects Committee at (913) 588-1240.

**THE UNIVERSITY  
OF KANSAS HOSPITAL**  
**KUMED**

**The University of  
Kansas Hospital**

**The University of Kansas  
Medical Center**

School of Medicine  
School of Nursing  
School of Allied Health

# News

Public Relations Media Line: 913-588-5246  
Fax: 913-588-1225

For Immediate Release  
For Approval Only/Draft One

Contact: Bob Hallinan  
913-588-5246

## **Wyandotte County Public Meeting Set to Discuss Study of a Temporary Red Blood Cell Substitute**

KANSAS CITY, Kan.— The University of Kansas Hospital and the University of Kansas Medical Center have set a meeting for members of the general public to discuss the proposed clinical trial for PolyHeme, a synthetic blood product designed for use in trauma patients.

The meeting will be 7:00 p.m. Wednesday, September 21, 2005 at Battenfeld Auditorium on the southwest corner (Rainbow and Olathe Blvds.) of the University of Kansas Medical Center campus.

Attendees will hear a brief overview of the proposed clinical trial and then have a chance to ask questions. Attendees will be asked to fill out a form expressing their views on the project.

The University of Kansas Hospital (and partner the University of Kansas Medical Center) is one of a select number of Level I 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, in treating critically injured and bleeding patients. Under the study protocol, treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during a 12-hour post injury period in the hospital.

During this study Polyheme® is compared to standard of care, saline (salt water) in the pre-hospital setting and blood in the hospital.

--more--

PolyHeme ®  
Page 2

At the site of the injury, half of the subjects (like flipping a coin) receive Polyheme®, half receive standard care (saline). It is given by emergency medical personnel before reaching the hospital (may be up to 60 minutes).

Upon arrival to the emergency room, subjects receive Polyheme® or standard care (blood). Subjects that received Polyheme® at the emergency site continue to receive Polyheme® in the hospital instead of standard care (blood). PolyHeme® is given for up to 12 hours or 6 units of PolyHeme. Standard care (blood) will be given (if needed) after 12 hours or 6 units of PolyHeme ®. Patients who originally receive the saline solution in the field will receive standard care (blood) upon arrival to the emergency room.

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. These federal regulations require the hospital and KUMC to conduct community meetings to inform the public about plans for the study and solicit public comment prior to institutional approval.

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

--more--

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

If someone in the community would like to be excluded from participating in this study, an "opt out" wristband will be provided at no cost. If someone in the community is involved in a trauma and they are wearing the wristband they will not be placed in the study. Information regarding how to obtain the "opt out" wristband will be available on the KU websites: <http://www.kumc.edu/polyheme/> and [www.kumed.com](http://www.kumed.com) or by calling the study coordinator, Suzanne Porras, R.N. at 913-588-3005.

If you have questions about the rights of research patients, please call the University of Kansas Medical Center Human Subjects Committee at (913) 588-1240.

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

###

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Breaking news

## UG unveils plan for \$300 million waterpark

Thursday, September 15, 2005

## Jury acquits embattled deputy

Thursday, September 15, 2005

## DUI charge against Linwood mayor dismissed

Thursday, September 15, 2005

## Voters approve school bond issue

Thursday, September 15, 2005

For months the Bonner Springs-Edwardsville School District's bond issue committee has been asking patrons to "Vote Yes for Kids."

Although voter turnout during Tuesday's special election was paltry, district residents answered that call.



Kevin Anderson/staff  
Principal Jerry Abbott inspects the turf playing surface at Shawnee Mission South High School. With the bond issue passing, a similar turf will be installed at BSMS.

## Trial to begin for couple accused of attempt on mayor's family

Thursday, September 15, 2005

As next week's trial date approaches, Edwardsville Mayor Stephanie Eickhoff said she is apprehensive about sharing a courtroom with the two individuals police and prosecutors say tried to kill her family.

## How safe is our city?

Thursday, September 15, 2005

Looking at images of devastation along the Gulf Coast brought grief, sadness and a full range of emotions from people across the country. From the emotions came generous offers of support from around the country.

Sports (more...)

## Opinion: What a great league (Sep. 15)

Week 1 of the 2005 National Football League season is in the books, and as I sit here wondering whether my beloved Denver Broncos will ever be able to bounce back from the 34-10 beatdown they suffered in south

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# News

Public Relations Media Line: 913-588-5246

Fax: 913-588-1225

For Immediate Release  
For Approval Only/Draft One

Contact: Bob Hallinan  
913-588-5246

## **Wyandotte County Public Meeting Set to Discuss Synthetic Blood Clinical Trial**

KANSAS CITY, Kan.— The University of Kansas Hospital and the University of Kansas Medical Center have set a meeting for members of the general public to discuss the proposed clinical trial for PolyHeme, a synthetic blood product designed for use in trauma patients.

The meeting will be 7:00 p.m. Wednesday, September 21, 2005 at Battenfeld Auditorium on the southwest corner (Rainbow and Olathe Blvds.) of the University of Kansas Medical Center campus.

Participants will hear a brief overview of the proposed clinical trial and then have a chance to ask question of the leaders of this research project. Meeting participants will be asked to fill out a form expressing their views on the project.

The University of Kansas Hospital (and partner the University of Kansas Medical Center) is one of a select number of Level I 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, in treating critically injured and bleeding patients. Under the study protocol, treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during a 12-hour post injury period in the hospital.

During this study Polyheme® is compared to standard of care, saline (salt water) in the pre-hospital setting and blood in the hospital.

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At the site of the injury, half of the subjects (like flipping a coin) receive Polyheme®, half receive standard care (saline). It is given by emergency medical personnel before reaching the hospital (may be up to 60 minutes).

Upon arrival to the emergency room, subjects receive Polyheme® or standard care (blood). Subjects that received Polyheme® at the emergency site continue to receive Polyheme® in the hospital instead of standard care (blood). PolyHeme® is given for up to 12 hours or 6 units of PolyHeme. Standard care (blood) will be given (if needed) after 12 hours or 6 units of ~~PolyHeme®. Patients who originally receive the saline solution in the field will receive standard~~ care (blood) upon arrival to the emergency room (standard of care).

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. These federal regulations require the hospital and KUMC to conduct community meetings to inform the public about plans for the study and solicit public comment prior to institutional approval.

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

--more--

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If someone in the community would like to be excluded from participating in this study, an "opt out" wristband will be provided at no cost. If someone in the community is involved in a trauma and they are wearing the wristband they will not be placed in the study. Information regarding how to obtain the "opt out" wristband will be available on the KU websites: <http://www.kumc.edu/polyheme/> and [www.kumed.com](http://www.kumed.com) or by calling the study coordinator, Suzanne Porras, R.N. at 913-588-3005.

If you have questions about the rights of research patients, please call the University of Kansas Medical Center Human Subjects Committee at (913) 588-1240.

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

###

FOR APPROVAL ONLY/DRAFT ONE

**Don't Miss Your Chance to Learn More  
and Express Your Views About  
a Ground Breaking Clinical Trial  
Proposed for Wyandotte County**

**7 pm Wednesday**

**September 21, 2005**

**Battenfeld Auditorium**

**Southwest corner (Rainbow and Olathe Blvds.) of the  
University of Kansas Medical Center campus  
Park in Olathe Boulevard Garage**

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The University of Kansas Hospital (and partner The University of Kansas Medical Center) is one of a select number of trauma centers in the U.S. being asked to participate in a national clinical research study to evaluate the safety and effectiveness of PolyHeme®, an oxygen-carrying blood substitute, in treating critically injured and bleeding patients.

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. These federal regulations require the hospital and KUMC to conduct community meetings to inform the public about plans for the study and solicit public comment prior to institutional approval.

For more information, go to [www.kumc.edu/polyheme/](http://www.kumc.edu/polyheme/) or [www.kumed.com](http://www.kumed.com). Or call study coordinator, Suzanne Porras, R.N. at 913-588-3005.

If you have questions about the rights of research patients, please call the University of Kansas Medical Center Human Subjects Committee at (913) 588-1240.

**THE UNIVERSITY  
OF KANSAS HOSPITAL**  
**KUMED**

## New take on emergency care

September 15, 2005

Email to a friend  Voice your opinion

The University of Kansas Hospital in Kansas City, Kan., is known for seeking out innovative advances in treating and healing those in need of medical care. That approach is the underlying purpose of a current project to determine whether area residents approve use of a new blood-related alternative to salt water for severely injured and bleeding patients.

Advertisement

The alternative is PolyHeme, described by hospital officials as a temporary oxygen-carrying red blood cell substitute made from human blood.

The hospital and the KU Medical Center would be partners in a clinical trial of the product here. Currently they are sampling community sentiment on whether to participate in the national study.

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KU is one of 17 or so Level I trauma centers in the nation invited to take part. KU has the only nationally accredited Level I center in the metropolitan area.

The goal of the experiment here would be part of an effort by Northfield Laboratories, Inc., Evanston, Ill., which developed PolyHeme, to obtain approval of the Food and Drug Administration for its general use.

A public meeting on the proposed trial will be at 7 p.m. next Thursday in the General Education Building at Johnson County Community College. Forms will be available for those who want to express their views on the undertaking.

PolyHeme is produced, according to Northfield and KU officials, this way: Hemoglobin is extracted from human red blood cells and filtered to remove impurities. The hemoglobin is then chemically modified to create what scientists call a "polymerized" form of hemoglobin. The modified product is combined with other chemicals present in human bodies to form PolyHeme.

The polymerization process is used, officials said, to "eliminate the undesirable effects historically associated with hemoglobin-based blood substitutes ..." Those include increased blood pressure and kidney or liver damage. In some cases the body-threatening substitutes were created from nonhuman blood.

The main focus of the clinical trial here would be use of PolyHeme at the scene of medical emergencies in which the KU Hospital is the destination for subsequent treatment. The geographical area would be northeast Johnson County, which is served by Johnson County Med-Act.

On a random basis, half of patients would receive PolyHeme and half standard care, which is the saline solution. After reaching the emergency room the patients would receive more PolyHeme or blood.

Ted McFarlane, chief of emergency medical services in Johnson County, estimated that, based on the criteria of the program, one or two patients a year would receive the new product.

McFarlane said, as he understands the product, the trial cases in other places have had a satisfactory outcome.

PolyHeme, officials said, is compatible with all blood types and thus does not require cross-matching.

Northfield contends the use of PolyHeme in massive blood loss is superior to salt water because its product carries oxygen to vital organs and may restore sufficient circulating levels of hemoglobin to improve the potential for survival. Saline solutions do not carry oxygen.

Anyone who would not want to participate in the trial could obtain an "opt out" wristband from KU. Information is available at [www.kumed.com](http://www.kumed.com) or [www.kumc.edu/polyheme/](http://www.kumc.edu/polyheme/). The telephone number is 588-1240.

An Independent Data Monitoring Committee, with a membership of medical and statistical experts, was designated to check the results. The committee, according to information distributed by KU, reviewed safety data on mortality and serious adverse effects from the study after the first 60, 120 and 250 patients in other places were involved. After following their progress for 30 days the committee recommended the study proceed.

Research on a product with the characteristics of PolyHeme was conducted by the U.S. Army after the Vietnam War. The military was seeking a product that could be used in massive quantities on the battlefield. Early development was unsatisfactory because of impurities. The filtration process for PolyHeme is intended to avoid such problems.

Any experiment has its risks and should be weighed carefully. That is why county officials and the public should make an effort to study this proposal.

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# THE LEAVENWORTH TIMES

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## Local trauma patients may take part in research trial

By JOHN  
RICHMEIER  
Times Staff  
Writer

After presenting information about a blood substitute before the county commission, officials involved in a study at an area hospital seemed pleased.



(Times photo/John Richmeier) Dr. Michael Moncure, left, reviews a PolyHeme study with county commissioners Monday at the Leavenworth County Courthouse. Included in the audience were officials from Leavenworth County EMS and Leavenworth city government.

"We didn't hear any negative comments today," said Dennis McCulloch, director of public and government relations for the University of Kansas Hospital.

The hospital and the University of Kansas Medical Center are partnering for a research trial of PolyHeme, which is described as a temporary oxygen-carrying red-blood-cell substitute made from human blood.

They're looking for community approval to include Leavenworth County in the study.

If this happens, some trauma patients may begin receiving PolyHeme from Leavenworth County EMS.

The treatment would continue at the University of Kansas Hospital.

Dr. Michael Moncure, the hospital's principal investigator for the trial, went over PolyHeme and the study for the county commissioners.

In the audience were officials from Leavenworth County EMS, the county health department and the Leavenworth city government.

At the end of the meeting, County Commission Chairman Clyde Graeber said he wanted to run the matter by the county counselor.

Graeber said he wanted to determine if the county would be opened up to any liability if patient A receives PolyHeme and patient B doesn't as part of the study.

Leavenworth Mayor Lisa Weakley suggested a presentation about the study be made during a meeting of the city commission, which would be televised on local cable. McCulloch said someone could be available for a presentation.

Officials from the University of Kansas Hospital and KU Medical Center also held a meeting on the study for the public Monday evening in Leavenworth.

During the meeting with county commissioners, Moncure said one of the important things to know about the study is that it will be conducted with an exception to an informed consent.

This means emergency medical workers will not have to obtain permission to start giving PolyHeme to a trauma patient.

There are means for somebody to opt out of the study in advance.

McCulloch explained at the county commission meeting that patients meeting the criteria for the study probably aren't going to be in any shape to go through and sign and initial a multi-page consent form.

As Moncure explained, the current standard of care for trauma patients at the scene is salt water. They don't receive blood until arriving at the hospital.

Salt water doesn't carry oxygen. And without oxygen organs stop functioning, Moncure said.

Not all trauma patients may meet the criteria needed for participation in the study.

And not all patients meeting the criteria will receive PolyHeme.

Moncure said half will receive salt water as part of a control group.

He described the procedure for determining which patients receive PolyHeme and which ones don't as being like a coin toss.

People eligible for the study will include those who have lost a large amount of blood and are in shock, are at least 18 years old and have suffered severe injuries.

People who will be excluded include those who are obviously pregnant, have severe brain injuries, require CPR to maintain their heartbeat, have "unsurvivable" injuries, object to blood transfusions and are known to refuse resuscitation.

Moncure said only the patients who are transported directly to the University of Kansas Hospital, either by helicopter or ground ambulance, would be included in the study.

Those who are first taken to a hospital such as Saint John or Cushing would not be included.

McCulloch said only Kansas counties in the area are being included in the study.

In fact, if emergency medical personnel believe a patient is from Missouri, he or she will be excluded from the study.

Moncure said PolyHeme, which is produced by Northfield Laboratories, Evanston, Ill., is made from blood from blood banks that is about to be thrown out.

"This is currently being used in Iraq and other theaters as well," Moncure said of PolyHeme.

The trial at the University of Kansas Hospital will be part of a nationwide study involving 720 patients.

If the University of Kansas Hospital gets 20 people for its study, Moncure said he would be happy.

He said the hospital could start its trial as early as October.

County Commissioner Dean Oroke first raised the issue of liability. He asked how it would be explained to a family of three injured people why they all didn't receive the same treatment.

Graeber later said he couldn't speak for residents in the city of Leavenworth only county residents who live outside of city limits.

McCulloch said if the county ambulances are authorized to participate, the hospital will probably go forward with the study in the county.

At the end of the meeting, he said if officials are overwhelmed with negative comments, they may not be comfortable with going forward with the study in the community.

County Commissioner Don Navinsky asked Interim EMS Director Jamie Miller if he thought the program was a positive or negative.

Miller said he thought it was very positive. He said EMS has been looking for an oxygen-delivery device.

"Hopefully this is the new horizon for EMS," he said.

Health Department Director Sylvia Burns said she also sees it as being very positive.

People who want to opt out of the study can obtain a wristband to indicate they don't want to be included.

Information on how to obtain wristbands is available on Web sites for the hospital and KU Medical Center: [www.kumed.com](http://www.kumed.com) and [www.kumc.edu](http://www.kumc.edu).

One also can call study coordinator Suzanne Porras at (913) 588-3005.

### **Board plans special retreat**

The Lansing School Board will start developing a new strategic plan for the district during a special retreat from 8 a.m. to noon Saturday at Sallie Zoll School.

### **Local trauma patients may take part in research trial**

After presenting information about a blood substitute before the county commission, officials involved in a study at an area hospital seemed pleased.

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**Don't Miss Your Chance to Learn More  
and Express Your Views About a Research Study  
Proposed for Leavenworth County**

**7 p.m., Monday, September 26, 2005**

**Riverfront Convention & Community Center  
Riverview Room  
123 Esplanade, Leavenworth, Kansas**

The University of Kansas Hospital, in partnership with The University of Kansas Medical Center, is one of a select number of U.S. trauma centers being asked to participate in a national clinical research study to evaluate the safety and effectiveness of PolyHeme®, an oxygen-carrying blood substitute, in treating critically injured and bleeding patients.

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If you have questions about the rights of research patients, please call the University of Kansas Medical Center Human Subjects Committee at 913-588-1240.

[washingtonpost.com](http://washingtonpost.com)

## Kansas Counties to Test Synthetic Blood

The Associated Press  
Tuesday, October 4, 2005; 7:41 PM

LAWRENCE, Kan. -- Four Kansas counties are part of a national study that will test a new synthetic blood on critically injured trauma victims.

University of Kansas Medical Center researchers are participating in the Food and Drug Administration trial with patients traveling by ambulance to the hospital from Douglas, Johnson, Wyandotte and Leavenworth counties.

Emergency medical technicians are currently only allowed to give severely bleeding accident patients a saline solution, which can't carry oxygen to the body. The substitute, PolyHeme, carries oxygen to the body like real blood and doctors say it can dramatically increase trauma victims' chances for survival.

"There are not many times we who are involved in trauma do something that is truly landmark, that changes entirely what we do," said Dr. Michael Moncure, the University of Kansas physician overseeing the study, which is being undertaken in 21 hospitals nationwide.

Half of participating patients will be given PolyHeme, the other half the traditional saline solution.

The FDA has allowed a rare exception for this trial to waive consent before subjecting patients to clinical trials because trauma victims generally can't give consent. Individuals not wanting to participate can wear a blue opt-out bracelet.

While some critics say using an experimental treatment on accident victims unable to give their consent is unethical, Mark Bradford, deputy chief of Lawrence-Douglas County Fire and Medical, said little opposition has developed.

Still, University of Kansas researchers plan to host a public meeting in the next week to gain additional support for the project.

Information from: Lawrence Journal-World, <http://www.ljworld.com>

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## Four Kansas Counties to Test Synthetic Blood

Oct 4, 2005, 02:04 PM

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Information from: Lawrence Journal-World, <http://www.ljworld.com>

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## **Douglas County wants to test synthetic blood**

Tuesday, October 4, 2005

Synthetic blood may be on its way to ambulances serving Douglas County.

Officials with Lawrence-Douglas County Fire & Medical have approved their participation in a clinical trial that would use the product to treat critically injured trauma victims.

Researchers with the Kansas University Medical Center, who are spearheading the trial, plan to host a public meeting in the next week to gain support for the project, which scientists said could dramatically increase trauma victims' chances for survival.

"There are not many times we who are involved in trauma do something that is truly landmark, that changes entirely what we do," said Dr. Michael Moncure, the KU physician who is overseeing the study.

KU is one of 21 study sites across the country involved with the Food and Drug Administration trial of PolyHeme, a blood substitute manufactured by Northfield Laboratories in Evanston, Ill.

So far, three other counties — Johnson, Wyandotte and Leavenworth — have signed on to use PolyHeme through the KU portion of the study.

Currently, emergency medical technicians at an accident site are only allowed to give trauma patients who are bleeding severely a saline solution, which can't carry oxygen to the body. Blood transfusions are impractical in the field, in part because of difficulty matching blood types and the availability of blood.

PolyHeme allows for oxygen transport in severely wounded patients, increasing their chances for survival.

In the trial, half of patients in the field would be given PolyHeme, while the other would continue receiving the saline solution.

The trial would affect only patients being transported to the University of Kansas Hospital. Patients receiving PolyHeme at the scene and in an ambulance would continue to receive it for up to 12 hours after treatment begins.

The FDA generally requires individuals to consent before subjecting them to clinical trials. But since trauma patients generally can't give that consent, the FDA has allowed a rare exception for this trial.

Instead of individual consent, KU will seek community support for the project in the counties involved. That will mean meetings with emergency personnel, government leaders and the public.

Individuals not wanting to participate can wear a blue opt-out bracelet.

Mark Bradford, deputy chief of Lawrence-Douglas County Fire & Medical, said county medical