# Inova to join blood substitute study - PolyHeme said to potentially fill role of regular blood

*By RAHKIA NANCE*
*Examiner Staff Writer*

The Inova Regional Trauma Center at Fairfax Hospital has been selected to take part in a national study of a blood substitute that could "revolutionize the care of trauma patients," the center's chief of trauma and surgical critical care services said Monday.

PolyHeme, as the blood substitute is called, "can potentially fill the role of regular blood," said Samir Fakhry, who is also a clinical investigator of the study.

"This is a very promising study with potentially very important implications," Fakhry said. "The need for this has been around for a very long time, at least 25 to 30 years. Technology did not allow us to prepare a safe and effective product."

PolyHeme, made up of blood donated but never used, is compatible with all blood types. It cuts down on blood matching time, which can take up to an hour, Fakhry said.

The hemoglobin is taken out of donated blood to make PolyHeme and when given to a trauma patient, it allows oxygen to flow through the body.

Trauma patients now are given a saline solution en route to the hospital, "a temporary maneuver that buys time but doesn't substitute adequately for blood," Fakhry said, adding 20 percent of patients suffering hemorrhagic shock die.

Unlike human blood, PolyHeme would be readily available in an ambulance. Its shelf life is a year when refrigerated, nearly nine times longer than human blood, which cannot be used after 42 days.

Northfield Laboratories located outside of Chicago, the developers of PolyHeme, selected the center to participate because of Fairfax County's population density and the center's number of trauma patients, Fakhry said.

"We see a lot of car accidents," Fakhry said. "We have a large volume of trauma patients.

Inova is one of two dozen trauma centers nationwide that have been selected to participate in the study, said Christopher P. Michetti, a clinical investigator and trauma surgeon. The hospital needs approval from county residents to proceed with the study, which is exempt from the Food and Drug Administration's informed consent requirements.

If approved, doctors anticipate the study to begin as early as late spring, Michetti said.

"We need 720 participants across the board in order to detect a difference," Michetti said, adding it's difficult to estimate when the study would end.

Using PolyHeme would also resolve a growing problem- a lack of blood donors. The majority of Americans do not donate blood, Fakhry said, adding PolyHeme could be used during natural or man-made disasters or for military units.

"The demand goes up and the number of donors has gone down," said Tracy Laubach, an American Red Cross spokeswoman. "When you look at your base of eligible donors, it certainly is a little more challenging than it was a while back."

In addition to more stringent donor regulations, Laubach said, most people aren't aware of the need for donors.

"There's a mentality out there that people have that says, 'Other people take care of it.'"

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# Health Officials Debate Use Of Fake Blood

Written by Jennifer Ryan
Last Updated: 3/8/2005 10:52:03 AM

Often in the most critical medical emergencies what a patient needs the most, is not available.
But now, Fairfax County is trying to launch a project to put "fake" blood on its rescue helicopters.

Right now, there is no blood on these helicopters, causing many trauma patients to die before they ever get to the hospital. Real blood has too short a shelf life, but now, Fairfax wants to start using an experimental blood substitute to give the most critical patients a better chance at survival.

When seconds count 20% of trauma victims die because they lose too much blood. But by this Spring, Inova Fairfax Hospital hopes it's involvement in a national research study, will allow flight paramedics to keep patients alive with a new a blood substitute.

The announcement was made Monday, with the hope Fairfax residents will support the study which means they could get the fake blood if their lives are on the line.

The product is called PolyHeme, a synthetic blood substitute derived from real donated blood. Its long shelf life and availability could make it helpful in other situations too.

"[In cases] where there is a national disaster, terrorism, [or] in the military [this fake blood would] be beneficial tremendously," Dr. Samir Kakhry said.

PolyHeme is designed to carry oxygen to the body--which it does quite effectively, but unlike the real thing, what it doesn't have is platelets, which help with blood clotting or white blood cells, which fight infection.

Because of this Dr. Matthew Coleman says, "It's not a blood substitute...still need blood."

Dr. Coleman, who works with Inova Blood Services, worries that donations could fall off if people mistakenly think Polyheme could replace the real thing. Blood donors, however, say they will keep giving and welcome any idea even an experiment if it saves lives.

So far 300 test patients in America have received the product which poses a few minor side effects, but in a life or death situation it has saved lives.

Before Polyheme can be used in Fairfax, the public has to agree. Notices and public hearings are being scheduled.

The FDA requires these notices, because trauma patients are in no position to decline a transfusion.

And bracelets are being offered for people who want to opt-out of the study. In the event you're in a life threatening situation, the

bracelet is your voice.

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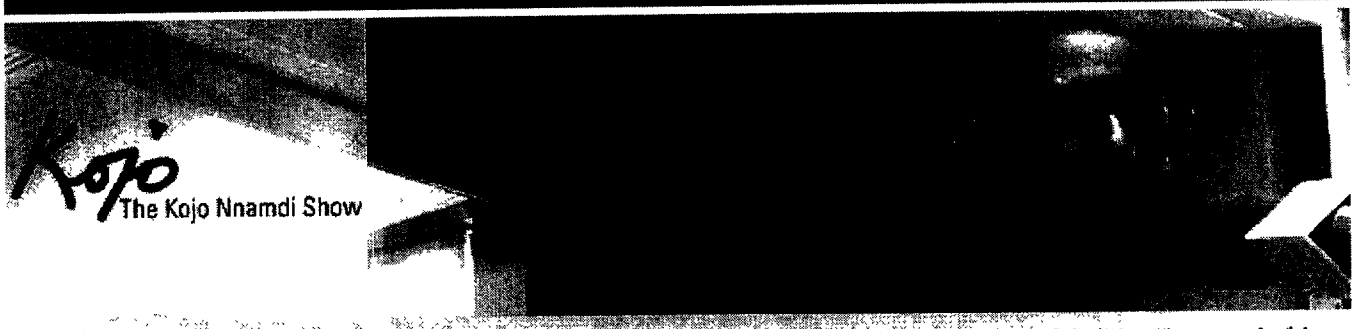




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WAMU Schedule Help

Week of March 7, 2005

Monday

12:06 - Trauma and Memory

13:06 - Juvenile Executions

13:32 - Danny Boyle

Tuesday

12:06 - Web Browsers

13:06 - Haiti

13:32 - Kaizen: Feng Shui for the Brain

Wednesday

12:06 - Aging Out of Foster Care

13:06 - Mercury

13:32 - Thailand

Thursday

12:06 - Blood Transfusions and Synthetic Blood

13:06 - Open Phones

Friday

12.00 - DC Politics Hour with Kojo and Jonetta

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## 12:06 Blood Transfusions and Synthetic Blood

By this Spring, a Fairfax County hospital hopes to launch a project to put a "fake" blood substitute called Polyheme in emergency vehicles. The new substance holds promise for reducing the number of extreme trauma victims who die in transit to the hospital. But the terms of the trial have alarmed some medical ethicists. We look at the challenges of blood transfusions and the promises of synthetic alternatives.

### Guests

**Dr. Gerald Sandler**, Professor of Medicine and Pathology; Director, Transfusion Medicine at Georgetown University Hospital

**Leonard Glantz**, Professor of Health Law; Associate Dean for Academic Affairs at Boston University's School of Public Health

**Dr. Christopher Michetti**, Trauma surgeon; Polyheme trial sub-investigator at Inova Fairfax Hospital

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## 13:06 Open Phones

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# THE KOJO NNAMDI SHOW

## BLOOD TRANSFUSIONS AND SYNTHETIC BLOOD

**PANEL:**

**LEONARD GLANTZ,**
**PROFESSOR OF HEALTH LAW, ASSOCIATE DEAN FOR ACADEMIC AFFAIRS AT BOSTON UNIVERSITY'S SCHOOL OF PUBLIC HEALTH**

**DR. CHRISTOPHER MICHETTI,**
**TRAUMA SURGEON; POLYHEME TRIAL SUB-INVESTIGATOR AT INOVA FAIRFAX HOSPITAL**

**DR. GERALD SANDLER,**
**PROFESSOR OF MEDICINE AND PATHOLOGY; DIRECTOR, TRANSFUSION MEDICINE AT GEORGETOWN UNIVERSITY HOSPITAL**

**THURSDAY, MARCH 10TH, 2005**

*Transcript by:*
*Federal News Service*
*Washington, D.C.*

(Music break.)

NARRATOR: From WAMU, at American University in Washington. Welcome to the Kojo Nnamdi Show.

(Music break.)

KOJO NNAMDI: Twenty percent of trauma victims die because they lose too much blood, in part, because emergency workers are unable to conduct blood transfusions in the field. Emergency vehicles cannot stock blood donations, and by the time victims make it to the hospital, many cannot be saved. But this could be about to change. An innovative and promising synthetic blood called Polyheme is currently in medical trials in over 20 hospitals around the country. Unlike saline solutions currently used, Polyheme functions similar to blood, maintaining victim blood pressure and carrying oxygen throughout the body.

This spring, Inova Fairfax Hospital could become the first area hospital using Polyheme on some of its trauma patients. However, the trial has alarmed some medical ethicists. Thanks to an unusual loophole in the strict rules of medical ethics, the trial will be conducted without informed consent, with roughly half of the trauma victims transported by emergency helicopters receiving the unproven technology.

Joining us to discuss the science of blood transfusions and the promises and problems with the new synthetic technology is Dr. Gerald Sandler. He is professor of medicine and pathology and director of transfusion medicine at Georgetown University Hospital. Dr. Sandler, thank you very much for joining us.

GERALD SANDLER: Good afternoon.

MR. NNAMDI: How do you feel about this concept of having a new unproven technology used on you? That's what we're asking our audience. You can call us at 1-800-433-8850. Have you had a blood transfusion, and what are your fears? The number again, 1-800-433-8850. You can also send email to kojo@wamu.org.

Dr. Sandler, in a trauma system, how and why are blood transfusions used?

DR. SANDLER: Well, they're used because people lose sufficient blood, so there's really not enough liquid in the pipes, so to speak, to take the red cells that have the oxygen and pump them through to the brain, to the heart, to the kidneys, and the other organs. That's why saltwater is very effective, because it adds liquid and allows the heart

to pump the residual red cells. When you have a massive hemorrhage – you just have a major blood loss – the amount of liquid in the system isn't enough to pump the red cells. So you can use saltwater because you don't bleed out. You don't empty your entire circulation. You lose a certain amount and fill it back up with saltwater is the standard approach.

MR. NNAMDI: That's the strength of saline. What are its disadvantages?

DR. SANDLER: Well, the disadvantage of saline is that if the person can't be transported from the site where you start the saltwater, and the tear, the wound, remains open, and it's pouring the fluid into an open system, and you're going to essentially wash it out and lose the capacity of red cells to deliver oxygen.

MR. NNAMDI: Well, some of our listeners might be saying right now, you mean, emergency vehicles do not carry supplies of blood? Why is this?

DR. SANDLER: Blood is a very special material that has efficacy and can be lifesaving under certain conditions, but other under – certain other conditions, it could make things worse. First, you have to store it. It's like food, it's a biological – it has to be kept under strict conditions, and in an emergency where perhaps there's someone on the highway, and you start out to do resuscitation, and you do a variety of things, you may not notice that an hour and a half has passed by in very hot conditions and you are actually giving blood, thinking you're going to be doing good, and that blood has been spoiled. So, there's the risk of spoilage and of course, O negative blood, which is what you'd have to use because it matches most people, can't be provided to all the ambulances and all the helicopters in emergency situations for preparedness. It has to be rotated.

And lastly, even though we talk about universal donor blood, we say, well, if you are group O negative blood, you can use it. That's not without a risk. People who've had a previous blood transfusion or who have been pregnant previously may have built up resistance to certain blood types, and while for the first time in your life a blood transfusion could be universal donor O negative, you don't know when someone's sprawled out on the highway whether that person has had 50 previous blood transfusions and really requires very special blood. You need a laboratory. So you just can't have red blood cells sitting in an ambulance ready to go, for all cases.

MR. NNAMDI: So we can understand why that would make a synthetic blood desirable. What does Polyheme do? How does it work?

DR. SANDLER: Well, of course the real question is, does it work? I mean, that's what the trial is. The trial is, does it work.

MR. NNAMDI: True.

DR. SANDLER: So, we're talking about the promise of what Polyheme might do, rather than what it has been established to do.

MR. NNAMDI: Correct.

DR. SANDLER: Polyheme – let me first begin by saying what it is. It's the insides of red corpuscles, basically, put into a liquid solution that without the corpuscle membrane around it doesn't have any blood type on it. So it's a true, universal oxygen carrier. It's the three hemoglobin inside red cells that has been taken out without the membrane. Then it's been hooked up with other hemoglobin molecules to make it big enough to stay in the circulation. If we just took the insides of red cells and put them in a solution they would last minutes before they would pass out in the urine. To prevent that from happening you have to make the hemoglobin big. That's the synthetic part of starting with natural hemoglobin, making it about four times larger than it would be, and that way you can have a product that will stay in the circulation maybe as long as a day.

Now, it's an oxygen carrier. It will pick up oxygen in the lungs, it will deliver it to organs, and that's been established. And it has been changed, though, from the way that mother nature designed it to work. And that's what the real question is. In all higher forms of animal life -- humans and others – mother nature found it desirable to put hemoglobin inside a capsule so that it can deliver oxygen and pick up carbon dioxide, by the way, on the way out. But it doesn't have a chemical effect, because it's not itself in direct contact with all the tissues.

One of the big surprises that came about when – and we call these oxygen carriers hemoglobin-based oxygen carriers, so when the first hemoglobin-based oxygen carriers were tried in animals and in humans, we learned for the first time that hemoglobin is active. It has effects on blood pressure and other situations when taken out of the red cell. So we've got some good things that it does. It picks up oxygen and lets it out. And it has some other effects that have to be studied.

MR. NNAMDI: We are talking with Dr. Gerald Sandler. He is professor of medicine and pathology and director of transfusion medicine at Georgetown University Hospital. We're discussing blood transfusions and synthetic blood, particularly Polyheme, a synthetic blood that is being tried at some 20 hospitals or more around the country and may soon be in use at Inova Fairfax Hospital.

Dr. Sandler, where does the blood used in Polyheme come from?

DR. SANDLER: At the moment, it comes from outdated blood. There's something less than 1 percent of the 14 million units of red cells that are collected in the United States that go beyond the 42 days when they can be used. And that small amount of blood is sufficient for Northfield Laboratories, the manufacturer of Polyheme, to make arrangements to receive it and to process it, manufacture it into this product. Now, should this product become approved for clinical use by the Food and Drug

Administration, it's quite possible that that source of outdated blood would be inadequate, and in that circumstance then, there would be a need to have persons donate fresh red cells to be processed into the product Polyheme.

MR. NNAMDI: You can join this conversation at 800-433-8850. How do you feel about the idea of a synthetic blood transfusion? Would you like to be involved in that kind of trial? Would that cause you to be pretty nervous? Call us, 800-433-8850, or send email to kojo@wamu.org.

DR. SANDLER: Kojo, can I jump in and talk a little bit about the words that you've been using, blood substitute and synthetic blood substitute?

MR. NNAMDI: Please do.

DR. SANDLER: Because if you look at this national trial, the way it's going to work is to compare conventional saltwater as the resuscitating solution – as a solution given to the person in shock on the street – versus Polyheme, to see if it works better. So if you think about it very precisely, we're talking about a saltwater substitute. We're talking about, does Polyheme in this national experiment work as well as, or better than, saltwater? If, legitimately, we wanted to call this a study of blood substitute, then the helicopters and the ambulances would have blood on them for the study for half the people, and they'd have Polyheme on it for the other half. And then they would compare Polyheme with blood, and the result would be technically a blood substitute. But if we're comparing how this works against saltwater, then let's, if we can, recognize that there is a –

MR. NNAMDI: We are talking about a saltwater substitute.

DR. SANDLER: We're talking – yeah. And others are hyping, promoting, or being overly enthusiastic before any efficacy has been shown that it even works better than saltwater. So we're in a question mode. We're not in a mode where we're discussing the results.

MR. NNAMDI: How about calling it synthetic blood? Is that an appropriate way to describe it?

DR. SANDLER: Well, it's nature's own hemoglobin. Nature made the hemoglobin, and Polyheme was kind of hooked up to make it a bigger hemoglobin. I guess if it gets licensed the terms of the licensing are going to define whether it is really substituting for blood or whether it's simply a better saltwater solution.

MR. NNAMDI: Some people are still uneasy about blood transfusions; some for religious reasons, others because of a fear of contracting disease. What are the current bloodless alternatives to transfusions?

DR. SANDLER: Well, let me begin by talking about the fear if I can –

MR. NNAMDI: Please.

DR. SANDLER: – because I think that's very important.

As I got up this morning, I listened to news, and former President Clinton is going in for what is described as a very rare complication of open-heart surgery. In fact, it's so rare that the particular complication that President Clinton has to have addressed occurs in one in 1,000 people who have had open-heart surgery.

MR. NNAMDI: And we all know is it has something to do with his lungs.

DR. SANDLER: Right. And the risk there is one in 1,000: very rare. Now we talk about fear of blood, the risk of getting an infection from HIV is not one in 1,000, not one in 10,000, not one in 100,000, not one in a million. One in two million. The risk of hepatitis C? One in two million. Hepatitis B? About one in a million. So, when we talk about the fear of getting blood, we are absolutely off the scale of what your anesthesiologist and your surgeon will be talking about, if you need blood as a lifegiving or a lifesaving treatment for conventional medical problems.

MR. NNAMDI: In other words, you're likely to be safer getting blood than you are getting into your car and driving in traffic. (Laughs.)

DR. SANDLER: Well, that's certainly a statistic that's been well established.

MR. NNAMDI: We're going to take a short break. When we come back, we'll continue our conversation on blood transfusions and Polyheme with Dr. Gerald Sandler, professor of medicine and pathology and director of transfusion medicine at Georgetown University Hospital. We will also be joined by Leonard Glantz, who is a professor of health law and associate dean for academic affairs at Boston University School of Public Health, and you'll soon find out why.

I'm Kojo Nnamdi.

(Music break.)

(Commercial break.)

MR. NNAMDI: Welcome back to our conversation on blood transfusions and Polyheme, which is currently being tried as a substitute for saline even though it is being, in some ways, advertised or described as synthetic blood. We're talking with Dr. Gerald Sandler of Georgetown University Hospital. He is director of transfusion medicine and a professor of medicine and pathology.

I wanted to go to the telephone and talk with John in Falls Church, Virginia. John, you're on the air, go ahead please.

Q: Hello. I had a couple of questions. One is, do you think there will be an effect on the donor crunch? I mean, Inova is always putting up the emergency donor needed sign by their blood bank. And will the use of the (respiratory ?) blood expander ease that crunch?

MR. NNAMDI: Well, John, I suspect that most of us would think logically that it would. I think you'll be surprised at the answer you'll get from Dr. Sandler.

DR. SANDLER: If the promise of this is realized, and it really works, it will have just the opposite effect on the blood supply. First, to manufacture Polyheme, there will be a need for more donors to go to Northfield Laboratories and donate fresh blood. There won't be enough outdated blood to meet the need.

But more importantly the good news would be, if this works, that persons with massive trauma, massive injuries who in the past have died and would be dying, they'll be saved. And they'll come into the hospital with massive injuries, and the – to manage this, first, the Polyheme that was given will have to be replaced with blood. It's not going to last more than a day or so. So all of the Polyheme clear red solution in the circulation will pass out, and that will have to be replaced with blood. And of course, the category of person, a massively injured person, who in the year 2004 and 2005 would have died on the street or on the way into the hospital, that person is going to be a 30, 40, 50 unit of red blood cell user to save his life. And that's a good goal, but having this material, if it works, will increase the need for blood, not decrease it.

MR. NNAMDI: John, thank you very much for your call.

Q: Well, actually, the other question was, the – you said it was a – synthetic in that the hemoglobin was bound – several of them were bound together with something else, I presume?

DR. SANDLER: To each other. In other words, if a person has his own red cells break up, if – we call that hemolysis. If the red cells –

Q: Right.

DR. SANDLER: – for some medical reason break up, then the four molecules of hemoglobin aren't sufficiently tightly held together to keep them from passing through the kidney and being filtered into the urine. Polyheme binds the small molecules more firmly, so that they have a longer circulation than natural hemoglobin.

MR. NNAMDI: And John, thank you very much for your call.

You too can call us, 800-433-8850, or send email to kojo@wamu.org. We got an email from Brody (sp) in Washington DC, who writes, "let me start by saying that I'm a certified EMT, that's emergency medical technician, and have worked under medic – under emergency conditions on an ambulance. Normal saline solution will always have a place in emergency medicine. But in cases of extreme trauma, its capacity for maintaining oxygen saturation in tissue, in cases of extreme trauma, its capacity for maintaining oxygen saturation and tissue." I'm not sure how that sentence was supposed to end. However, Brody carries on, "if I were on laying on a highway, facing the possibility of bleeding out, I want the attending emergency workers to have every tool possible. I absolutely support the trial of Polyheme."

I say that by way of introducing to you, Leonard Glantz. He joins us by telephone from Boston. He is a professor of health law and associate dean for academic affairs at the Boston University School of Public Health.

Leonard Glantz, thank you very much for joining us.

LEONARD GLANTZ: Well, thank you for inviting me.

MR. NNAMDI: You just heard what Brody had to say, "I absolutely support the trial of Polyheme." Well, Boston University considered participating in the aforementioned trial, but opted out citing ethical flaws. What were your main concerns?

MR. GLANTZ: Well, so far, there has not been a discussion of the entire protocol. That the protocol – there are really two parts of the protocol. One has to do with providing Polyheme for people who are in the ambulance. The difficulty becomes when people come to the emergency room, and under the protocol that people will remain on Polyheme, they either get six units or to stay on it for 12 hours. So although it is, in fact, a saltwater substitute protocol while in the ambulance, it is actually a blood substitute protocol when in the emergency room. And that to withhold blood, which as Dr. Sandler said is a very safe and very effective means of treating hemorrhaging – to withhold blood without the consent of the individual and having them be a research subject when there is blood available in the emergency room is unethical.

MR. NNAMDI: Well, it is my understanding that many of the hospitals who are participating in the trial have said they will only be using Polyheme, for instance, when it comes to Inova, in helicopters, and won't be using it in the emergency room. Does the fact that it is a part of the protocol imply that that means that use in emergency rooms is permitted and therefore will take place?

MR. GLANTZ: Well, if you look at the frequently asked questions for the study on the Inova website, it points out that Polyheme will continue during the 12-hour post-injury period in the hospital, and that's the part that was of concern to our committee. If it were just used as a saline substitute in the emergency room – in the ambulance, there

isn't much of an ethical problem. The ethical problem arises in that post-12 hour period where blood is available and being withheld without the consent of the individual.

MR. NNAMDI: So the informed consent issue is your issue here. The parameters of the trial allow for people to opt out, declining treatment with Polyheme. Why was that insufficient for you?

MR. GLANTZ: I'm not sure which people you're talking about who can opt out.

MR. NNAMDI: People in –

MR. GLANTZ: I mean, the people in the emergency room are by definition not capable of consenting.

MR. NNAMDI: Is that necessarily true? You may be in the emergency room and conscious enough to –

MR. GLANTZ: Well, there's not an issue if a person is conscious –

MR. NNAMDI: Right.

MR. GLANTZ: – what's making the Polyheme study controversial is that it's being done under an exception to the informed consent requirement, which is permitted by the FDA in only limited circumstances. And again, if we look at the Polyheme website or we look at the Inova website, it's the exception for informed consent under 21CFR 50.24. That's what makes it controversial is that there are people who will not be able to consent, who will be having blood withheld.

MR. NNAMDI: It is my understanding that the opting out factor has to do with, it's really a kind of – people have to know in advance and have to be wearing a blue bracelet in order to indicate – (laughter) – that they don't want Polyheme, which is something that you won't expect in an emergency situation.

MR. GLANTZ: Yeah, I think that the idea – that informed consent requires an affirmative affirmation, an affirmative affirmation that one is willing to undergo a particular procedure. That opting out is not something which is generally done or even permissible in biomedical research. The idea that everybody in the area of the hospital needs to wear blue bracelet in order not to be a research subject really runs contrary to our notion of consent – of active consent.

MR. NNAMDI: Mark in Washington, DC, has a question about informed consent. Mark, you're on the air, go ahead please.

Q: Yeah, I just I see the obvious benefits of the research and applying it to patients, but I also have a problem with the informed consent. It seems kind of like a

primary invasion of a person's body to be taking without consent, and I don't know a way around it, but that's my comment.

MR. GLANTZ: Well, I think that if I could suggest it, that one way around it is that, again, I don't think that – I think that it is suitable to waive consent in the ambulance where this – where a person is in a life-threatening condition, and there literally is no substitute.

On the other hand, if one wants to do – use Polyheme as a blood substitute, one has to get the consent from people who are – will foreseeably (ph) need blood, such as people undergoing serious cardiac operations or some orthopedic operations or some other operations of that sort.

MR. NNAMDI: Mark, thank you very much for your call.

Q: Thank you.

MR. NNAMDI: And, Dr. Sandler, care to comment on anything we've been discussing?

DR. SANDLER: Well, I think that Dr. Glantz is the expert in the biomedical issues, and I would defer to him, but I will make this comment on the subject. The manufacturer of the product has selected an extreme example of blood utilization, so extreme for the investigation that, as pointed out, persons are not going to be conscious or in a state of mind where they can participate in an informed consent. If this product really works – if it is, in fact, going to be able to do what it says it can do, then perhaps the study design should have been 25 percent lower in the extreme nature, so that people who were pretty sick, but not unconscious, needing massive surgery, back surgery, for example, always requires blood pretty much, or maybe hip replacement or some other massive blood surgeries where this product would be used that might provide an opportunity for evaluating its efficacy and its safety in a population of persons who are highly motivated, yet capable of rational informed consent.

MR. NNAMDI: Leonard Glantz, is it realistic to think that someone would opt in for something like a heart surgery, or how would you structure it so that it would still work in that situation?

MR. GLANTZ: Well, what I would say – the way I would answer that – I just want to say that I think Dr. Sandler really hit the nail on the head about competent people – using competent people, but if we are convinced that competent people would not agree to this, then we certainly should not be giving it to incompetent people. That would be the standard; that if we think that the community would perceive this as so risky or so untenable that as a general matter people would not do it, that it becomes particularly unethical to do it on folks who cannot voice their own concern.

MR. NNAMDI: Well, in that case, if you adhered so stringently to the rules of informed consent, some would argue that research on materials like Polyheme would never happen because it would be too slow and too cost prohibitive.

MR. GLANTZ: Well, one is that it can happen in the ambulance and that the requirement for this sort of research is that the human subject is in a life-threatening situation and available treatments are unproven or unsatisfactory. And that's certainly true in the ambulance circumstance. It's just not true in the emergency room circumstance.

The question is, why does it matter whether it works in the emergency room? Because there is blood available. The real researchable question is, does it help people when they are in an ambulance when there is nothing available? And if you limit the study to that, I think that there will be valuable information that can be derived.

MR. NNAMDI: Okay, allow me to go back to the telephones and go to Peter in Columbia, Maryland. Peter, you're on the air, go ahead please.

Q: Hi, I'm calling because I lived in England about 10 years ago and because of that the Red Cross and other people won't take my blood because they're afraid I might be infected with mad cow disease. And I wondered if the manufacturing process for Polyheme would make it possible for me to be a blood donor for that?

MR. NNAMDI: Dr. Sandler?

DR. SANDLER: Obviously the answer to your question is a matter of regulation and determination that will be made by the Food and Drug Administration. My personal opinion is that there's no way that the manufacturers of Polyheme can ensure that prions, that's the – it's not a bacteria, it's not a virus, it's something called a prion, that is the infective agent of variant Creutzfeldt-Jakob disease or the human variant of mad cow disease, that type of an agent is extremely unlikely to be able to be studied and getting a definite answer.

So if we follow current guidelines you would be excluded as a donor for source material for any blood product. That does not in any way mean that you are infected. It just means that our society has made a determination to take the broadest kinds of precautionary principles so that we don't get behind the eight ball with a potential infection. But don't interpret my comments as implying that you are at high risk.

Q: Oh, I don't think –

DR. SANDLER: Interpret them as we're doing our very, very maximum to protect our patients.

Q: Okay.

MR. NNAMDI: Peter, thank you for your call.

Q: Thank you.

MR. NNAMDI: You, too, can call us to join this discussion on blood transfusions and Polyheme; the alternative to saline. According to Dr. Sandler, it's really a saltwater substitute rather than a blood substitute. However, Leonard Glantz claims that if it is used in the emergency room, it would, in fact, become a blood substitute. Leonard Glantz is professor of health law and associate dean for academic affairs at Boston University School of Public Health which has declined to take place in the trial for Polyheme. In our studio is Dr. Gerald Sandler, professor of medicine and pathology and director of transfusion medicine at Georgetown University Hospital.

Here is Robert in Burke, Virginia. Robert, you're – Robert, you're on the air, go ahead please.

Q: Hi. Yes, good afternoon.

MR. NNAMDI: Good afternoon.

Q: I have a question for your guests. I also think that's a very worthwhile study under emergency situations in a helicopter or an ambulance. My question is, since you're trying to find out the efficacy of this versus the saline solution, are there things we know about it as far as side effects go? Do we know that it's not going to cause an embolism? Do we know that it's not going to increase your susceptibility to a stroke before we start this program?

MR. NNAMDI: I guess that's what we're trying to find out. What do we know, Dr. Sandler?

DR. SANDLER: The good news is that 300 people have received this material in relatively small doses in much less extreme circumstances than the current trial and for the things that were looked for, nothing was found that was of considerable adversity.

Now, when you look at 300 people you certainly don't talk about the complications that occur with a frequency of one in 1,000, one in 2,000, one in 5,000, or a higher number. So we don't really, really know about the uncommon risks that are going to occur with this. That's what the study – the study is called a research study of safety and efficacy. And that's 50/50.

MR. NNAMDI: But the study is now in phase three. What were phases one and two all about?

DR. SANDLER: They established safety at a certain level. But one thing we've learned, and I'm going to throw Vioxx out just as a topic, we've learned that even –

MR. NNAMDI: A lot of people are throwing it out as a medication, but go ahead. (Laughter.)

DR. SANDLER: Even when we take a medication that has passed phase one, phase two, phase three studies, and is in post-marketing evaluations and surveillance, even then, we start to learn about them. This is a totally, completely new category of biological agent that would be given to people who are very sick. I mean, they are very, very sick. So we – I don't think we're going to find out, even in this study, enough to be able to say, well, of course this is safe.

MR. NNAMDI: Well, you are welcome to join the conversation with your opinion or question. You can call us at 800-433-8850 as we discuss blood transfusions and the trial of the – of Polyheme, which is a substitute either for saline or in some situations for blood. Again, the number 800-433-8850. Have you had a blood transfusion? What was your experience? Or you can send us email to kojo@wamu.org.

We're going to take a short break. When we come back we'll talk with Dr. Christopher Michetti. He is at Inova Fairfax Hospital, involved in that trial. I'm Kojo Nnamdi.

(Music break.)

(Commercial break.)

Welcome back to our conversation about Polyheme, sometimes called synthetic blood, and blood transfusions. Again, you're invited to join the conversation at 800-433-8850 or send email to kojo@wamu.org.

We're talking by phone with Leonard Glantz, professor of health law and associate dean for academic affairs at Boston University School of Public Health. Dr. Gerald Sandler is professor of medicine and pathology and director of transfusion medicine at Georgetown University Hospital. Joining us now by telephone is Dr. Christopher Michetti. He joins us by phone from Fairfax. He is a trauma surgeon and a Polyheme trial sub-investigator at Inova Fairfax Hospital.

Dr. Michetti, thank you for joining us.

CHRISTOPHER MICHETTI: Thank you, Kojo.

MR. NNAMDI: We've heard about the national Polyheme trial, can you give us the parameters of the Inova trial as proposed?

DR. MICHETTI: The Inova trial is part of the national study. This is being run in the same fashion at every institution that's participating across the country. So we really are running the trial as described, starting with the use of Polyheme in the field. In Fairfax, we're using it on helicopters rather than ambulances, because most of the patients that will qualify in Fairfax County would arrive at the trauma center by helicopter. And then we would continue the trial the same way in the hospital.

MR. NNAMDI: Where along the trial continuum is Inova right now? What are the odds of someone getting this treatment in the near future?

DR. MICHETTI: We're not started yet, but we're in the process of what we call the community consultation, where we are going out to the community of Fairfax, describing the study, asking for feedback, and welcoming anyone's feedback or opinion on whether or not we should proceed with the study. After we do that, we have to go back to our review board with that information and see if we get approval to actually start the study by about summertime.

MR. NNAMDI: What are the chances of a (Fairfaxian ?) citizen being enrolled in this study? They have to wait until that review process is completed?

DR. MICHETTI: We would have to have approval by the final review process. Then once we start the study, the chance of any one individual actually being enrolled would be very, very low. Even though we get over 3,000 trauma patients a year at Fairfax – that's our trauma population – the chance of being one of those patients is already low, then being someone that's so severely injured that you're bleeding to death or in hemorrhagic shock, that would be much lower. So we anticipate that over the course of a year, anywhere from 10 to 25 patients would end up being enrolled.

MR. NNAMDI: What does Inova Hospital get out of participating in this study besides possibly saving some lives, which is always important, of course?

DR. MICHETTI: Well, that's it. We get the pleasure of participating in rigorous scientific research that has the potential to improve healthcare and save lives. You know, there hasn't really been an advance in the treatment of hemorrhagic shock in about four decades, since around the time of the Vietnam War. And this has the potential to be an advance.

MR. NNAMDI: How about the ethical issue of informed consent? We understand that the protocol indicates that you can administer Polyheme for as much as – for up to 12 hours, which would imply to most of us that that means you can use it in the emergency room. So far you say you're limiting it to helicopters. What's to stop you or any of the other trial participants from expanding it at will?

DR. MICHETTI: Let me just clarify that. We are using it both in the field, meaning in the helicopter and in the hospital, up to 12 hours after the injury. So the study

is designed to administer in the field, because there's a need for an oxygen-carrying solution as opposed to saline as was described by Dr. Sandler. It's going to be continued in the hospital for 12 hours, up to six units of Polyheme, because we want to see if this is better than our current standard of care.

And here's where I think we differ a little bit in what's been described before. Although our standard of care now, saline plus blood transfusion is good, up to 20 percent mortality rate, or death rate, doesn't seem quite adequate. The previous studies in trauma patients have shown that trauma patients who receive up to six units of blood have a much higher risk of organ failure, and organ failure leads to death. So that's one of the main benefits that has been shown in the previous Polyheme studies, decreasing the incidence of organ failure, and we hope to see the same with this study.

MR. NNAMDI: The first community consultations started March 7th is my understanding. Where can people get information on participating and what feedback have you gotten thus far?

DR. MICHETTI: Well, people are certainly to – welcome to go to the website at www.inova.org. And –

MR. NNAMDI: And you can find a link to that website if you come to wamu.org.

DR. MICHETTI: Correct. And, we also are having a community forum here at Fairfax Hospital on March 15th and March 22nd at 7:00 PM in the physician's conference center, and anyone from the public is welcome to come and attend to learn about the study and give us feedback.

MR. NNAMDI: Leonard Glantz, can you talk about the concept of community consultation of which we've just heard Dr. Michetti describe in lieu of informed consent?

MR. GLANTZ: Well, it's not the community consultation that is in lieu of informed consent. There's no such thing as community consent. I think that the point is to just not have these things be done in secret and to have the community have some input. I don't – I think that makes a very good – it's a very good practice. It's not a substitute for consent, however.

MR. NNAMDI: Allow me to go to the telephones. Here is Howard, in Emmetsburg, Maryland. Howard, you're on the air, go ahead please.

Q: Yes, my question is, are all blood products going to be excluded at the time that the patient arrives into the emergency room such as platelets, SFP, other things that are blood products that the patient actually also requires?

MR. NNAMDI: Dr. Michetti?

DR. MICHETTI: Well, no. Other kinds of blood products would not be excluded. If the patient needed platelets or clotting factors, they would continue to receive them. But again, this is different that was described before. Patients will not need the Polyheme to be replaced by blood. In the previous studies in trauma patients and other patients, use of Polyheme has been shown to reduce the need of blood transfusion. So although the Polyheme will go out of someone's system within about a day, that patient may need a regular blood transfusion. But if this study works out like the other studies have, they would need less blood than if they did not receive the Polyheme.

MR. NNAMDI: Okay, Howard, thank you very much for your call.

Q: Thank you.

MR. NNAMDI: We got an email from Michael, who I should say in the interest of full disclosure, is Michael Slocum, who is special counsel for Inova. He said, "As noted, it's important to know that the study is only to test Polyheme against saline solution in trauma patients on the way to the hospital. If the patient can consent, the study provides for such consent to be obtained. If there's a family member who can consent, that family member is to be queried. The only time that no consent will be obtained is when the patient is unable to communicate because the patient is badly injured and in need of immediate treatment, and there is no one else available to give or withhold consent."

Is that correct according to your understanding, Dr. Michetti?

DR. MICHETTI: Yes, that's correct. We anticipate that by definition patients in hemorrhagic shock have low blood flow and low blood pressure and decreased blood flow to their brain. So they are – most often have an altered mental status or are unconscious. When they arrive to the hospital, we have an extensive process whereby we will try to contact the legally authorized representative for that patient and continue that process until every option is worn out to then describe the study to that person, and see if they would like their loved one to continue to participate or not. We will make every effort to have the patient participate in that process when they are awake enough to do so.

MR. GLANTZ: Can I just say that that's not the controversy. The controversy –

MR. NNAMDI: This is Leonard Glantz.

MR. GLANTZ: Yes, Leonard Glantz, sorry. The controversy is for the group who can't consent, and that it's assumed that that will be many, many, many of them; that they can't consent, and that relatives won't be able to be contacted right away because this is all happening in an emergency.

So where there was patient consent or even next-of-kin consent, that takes care of much of the ethical problem. It's the remaining group in which there is no consent who

are not getting blood, which Dr. Michetti described himself as good therapy. Who are not getting blood that raises the ethical question.

MR. NNAMDI: We got an email from Michael in Washington that I'm sure you'll be interested in responding to, Dr. Sandler. Michael writes, "If this will increase the need for blood donors to enable the production of the synthetic substitute, will the same restrictions be applied as to regular blood donations? I am a healthy gay man who is outright prohibited from donating blood regardless of my health status or HIV test results. Will this same restriction apply to donating blood for the production of Polyheme?"

DR. SANDLER: The answer to the question of course is that these products are regulated by the federal government and the Food and Drug Administration establishes the regulations. At the present time, we have biological products that go through manufacturing, such as immune serum globulin, antihemophilic factor, and the requirements are the same, practically speaking, as for whole blood.

I have no reason to anticipate that a different category of manufactured product is going to have a different set of regulations. Short answer is, I think it's going to all be the same, but it's not up to my opinion.

MR. NNAMDI: How about the pasteurization process that Polyheme is capable of?

DR. SANDLER: The pasteurization process, or we call it viral inactivation, whatever the words are, are used for antihemophilic factor and immune serum globulin and other noncellular, that is to say, products that don't have red cells that can be cooked. They can be pasteurized. And the same rules apply. The persons who donate for those products have the same federal regulations apply to their qualifications, and it would be surprising to me if the government decided to have different categories.

MR. NNAMDI: Dr. Sandler, why don't conventional blood banks pay for blood?

DR. SANDLER: There are many reasons, one of which Dr. Glantz may want to comment, which is the ethical one. But the – historically, when you test blood from persons who are paid, and you test blood from persons who aren't paid, you find that not everyone tells the truth if telling the truth is going to deprive them of the $50 or $100 or so that they're going to get for doing this. There's a certain inducement and what really, really makes blood safe is a true history. Taking for example, the biggest concern is HIV and hepatitis C, our tests today totally, completely detect persons who have been infected for a month or longer. The issue of residual infections which is very, very small, relates to people who have just become infected within the last few days or weeks, and who have so few virus particles in their blood that when you take out a few drops to test, you just don't get a virus in the drops you're testing. So telling the truth is the key to blood safety, not testing.

MR. NNAMDI: Leonard Glantz, care to weigh in on that?

MR. GLANTZ: No, I think that the safety issue is the primary issue. There is some question about paying people for their body parts, generally. And that when you pay for blood, you certainly focus on the poorer members of society, and there's a question of exploitation. But I think that Dr. Sandler's point that the blood supply becomes less safe when you pay for it is really the key point.

MR. NNAMDI: Allow me to go back to the telephones. Here we go to Jean Marie 9sp) in Alexandria, Virginia. Jean Marie, you're on the air, go ahead please.

Q: Hi, thank you very much. I understood that hemoglobin outside of the red blood cell was poisonous in the body, and how is this product getting around that?

MR. NNAMDI: Dr. Sandler?

DR. SANDLER: It used to be thought years ago – many years ago, that if you gave a unit of, for example, group A blood to a group O person, and very often that would be a fatal transfusion from a mismatch, that the cause of the death was, as you said, the poisonous effect of the free hemoglobin. And that concept evolved from looking at the tissues and seeing that red color, that hemoglobin in the kidneys and in the other organs. It turns out that when you look under the microscope very, very carefully, you find out that the fact is really the mismatch of the blood types and in the small vessels, you actually see clots. And the blood vessels get stopped up with blood clotting. The hemoglobin by itself turns out not to be poisonous. It used to be thought it was highly toxic, but in fact it's not.

MR. NNAMDI: Jean Marie, thank you very much for your call.

Q: Thank you.

DR. MICHETTI: Kojo, if I may respond also to that question –

MR. NNAMDI: Is this Dr. Michetti?

DR. MICHETTI: Yes, this is Dr. Michetti. Free hemoglobin indeed may be dangerous, but this product Polyheme, the "poly" means there are several hemoglobin molecules joined together that when done in that fashion don't have the same effect as free hemoglobin. They used to see complications such as renal failure, hypertension, from the free hemoglobin which are not really seen when the product is made in this fashion.

MR. NNAMDI: And we're just about out of time. Dr. Michetti, thank you for joining us.

DR. MICHETTI: Thank you.

MR. NNAMDI: Christopher Michetti is a trauma surgeon and Polyheme trial sub-investigator at Inova Fairfax Hospital.

Leonard Glantz, thank you for joining us.

MR. GLANTZ: Well, thank you very much, I enjoyed it.

MR. NNAMDI: Leonard Glantz is a professor of health law and associate dean for academic affairs at Boston University School of Public Health.

And Dr. Gerald Sandler, thank you for joining us.

DR. SANDLER: Thank you, Kojo.

MR. NNAMDI: Dr. Sandler is a professor of medicine and pathology and director of transfusion medicine at Georgetown University Hospital.

I'm Kojo Nnamdi.

(Music break.)

Friday at noon, Anthony Williams talks trash about DC's potential mayoral candidates. Does this mean the mayor is planning to run for a third time? Find out on the DC Politics Hour with Kojo and Jonetta, Friday at noon on WAMU 88.5 FM.

(Music break.)

(Commercial break.)

(END)

# Inova to join blood substitute study - PolyHeme said to potentially fill role of regular blood

*By RAHKIA NANCE*
*Examiner Staff Writer*
March 8, 2005

The Inova Regional Trauma Center at Fairfax Hospital has been selected to take part in a national study of a blood substitute that could "revolutionize the care of trauma patients," the center's chief of trauma and surgical critical care services said Monday.

PolyHeme, as the blood substitute is called, "can potentially fill the role of regular blood," said Samir Fakhry, who is also a clinical investigator of the study.

"This is a very promising study with potentially very important implications," Fakhry said. "The need for this has been around for a very long time, at least 25 to 30 years. Technology did not allow us to prepare a safe and effective product."

PolyHeme, made up of blood donated but never used, is compatible with all blood types. It cuts down on blood matching time, which can take up to an hour, Fakhry said.

The hemoglobin is taken out of donated blood to make PolyHeme and when given to a trauma patient, it allows oxygen to flow through the body.

Trauma patients now are given a saline solution en route to the hospital, "a temporary maneuver that buys time but doesn't substitute adequately for blood," Fakhry said, adding 20 percent of patients suffering hemorrhagic shock die.

Unlike human blood, PolyHeme would be readily available in an ambulance. Its shelf life is a year when refrigerated, nearly nine times longer than human blood, which cannot be used after 42 days.

Northfield Laboratories located outside of Chicago, the developers of PolyHeme, selected the center to participate because of Fairfax County's population density and the center's number of trauma patients, Fakhry said.

"We see a lot of car accidents," Fakhry said. "We have a large volume of trauma patients.

Inova is one of two dozen trauma centers nationwide that have been selected to participate in the study, said Christopher P. Michetti, a clinical investigator and trauma surgeon. The hospital needs approval from county residents to proceed with the study, which is exempt from the Food and Drug Administration's informed consent requirements.

If approved, doctors anticipate the study to begin as early as late spring, Michetti said.

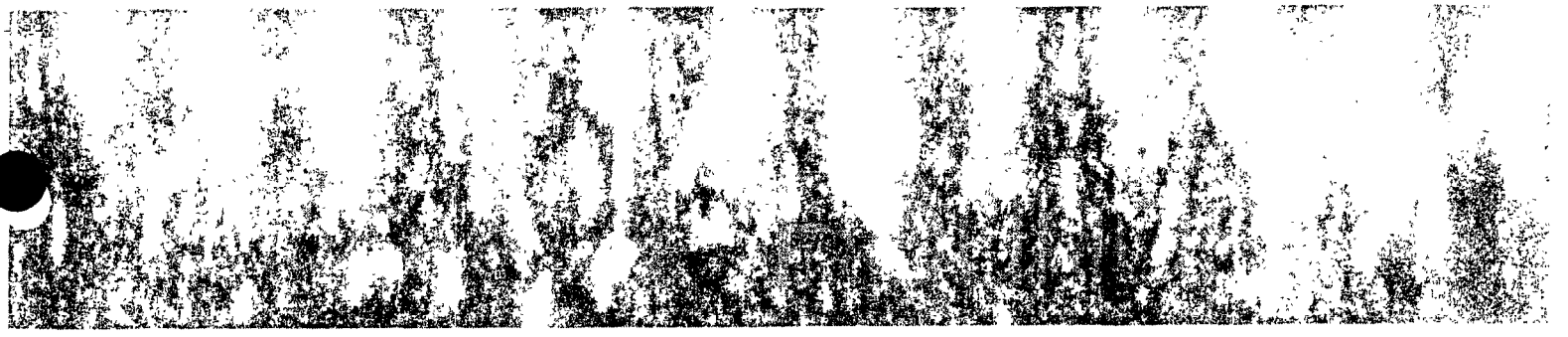
"We need 720 participants across the board in order to detect a difference," Michetti said, adding it's difficult to estimate when the study would end.

Using PolyHeme would also resolve a growing problem- a lack of blood donors. The majority of Americans do not donate blood, Fakhry said, adding PolyHeme could be used during natural or man-made disasters or for military units.

"The demand goes up and the number of donors has gone down," said Tracy Laubach, an American Red Cross spokeswoman. "When you look at your base of eligible donors, it certainly is a little more challenging than it was a while back."

In addition to more stringent donor regulations, Laubach said, most people aren't aware of the need for donors. "There's a mentality out there that people have that says, 'Other people take care of it.'"

*rnance@dcexaminer.com*



# March 14, 2005

## Community Meetings for Clinical Trial Scheduled

Inova Fairfax Hospital will participate in a national clinical research study of PolyHeme®, an investigational oxygen-carrying blood substitute for trauma use. To comply with federal regulations, which permit this trial to be conducted without obtaining the informed consent of the patients enrolled, we will hold community meetings on Monday, March 14, and Tuesday, March 22 both beginning at 7 p.m. in the Physician's Conference Center. To learn more about this study, visit www inova.org and look for the PolyHeme Trial under either Inova News or Health Information. In addition, please review the PolyHeme trial information on Inova's Web site and fill out the Feedback Form. It is a very brief one-page form that requires only yes or no responses.

## Guidelines for Atrium Use

To meet Fairfax County fire regulations and keep the Atrium looking its best for everybody, the following guidelines have been established:

- Reservations required! Anyone wishing to use the Atrium must do so through the Community Relations office. Call **703-776-2260.**
- Deposit required! All private vendors must provide a $350 deposit, which will be returned if the conditions below are met.
- Obey the Fire Marshall! Table size, number and set-up must meet Fairfax County Fire Marshall specifications – no exceptions.
- Serving food? If so, an Environmental Services staff member and security officer are required at a charge of approximately $15.50 per hour.
- Moving stuff around? Benches, plants and tables are to be moved by Environmental Services staff only.
- Clean up your mess! Break down boxes, pick up trash, remove food and leave the Atrium as you found it.

## New Smoking Policy

Coming soon to Inova Fairfax Hospital/Inova Fairfax Hospital for Children/Inova Heart and Vascular Institute...a new smoking policy. We need your help, so watch for details!

## Campus Corner – Making Life Easier

Coming March 21 to a corner near you... dry cleaning and laundry drop off, movie tickets, film drop off. Located on the basement level between the cafeteria and gray elevator. Open 6 a.m. – 8 p.m.

## Magnet Poster Contest

Nurses Week 2005 (May 6 – 12) will feature a Magnet poster contest! Submit an entry individually or with your department. The theme is "Be the Best...Be Magnet" and posters should reflect how you or your department strive to meet that goal. *Deadline for entries is Monday, May 2.* All posters will be displayed in the Physicians Conference Center during Nurses Week and judged following the Nurse of the Year Ceremony on May 11. This contest is open to all Inova Fairfax Hospital, Inova Fairfax Hospital for Children and Inova Heart and Vascular Institute employees. You don't have to be a nurse to enter! For contest rules and an entry form, contact Kathy Chappell at 703-208-6630.

## Annual Nursing Recognition Program

Celebrate your nursing colleagues by nominating them for recognition in one of the following categories: Excellence in Clinical Practice, Leadership in Clinical Practice, Preceptor, Educator, Mentor, Visionary, Community Responsibility, Exemplary Courage, Commitment to Nursing Practice or Outstanding New Graduate. Applications are due by Monday, April 18 and the awards will be presented during Nurses Week (May 6-12). For more information or an application form, contact Kathy Chappell at 703-208-6630.

## Nursing Stars Program

Make your nurse a star and support continuing education programs for nurses at Inova. The more nursing stars you name, the more you'll help *all* Inova nurses expand their knowledge and skills. Be sure your nurses receive their stars in time for Nurses Week. Prices are $50 per star, $200 for 5 nurses, $400 for 10 nurses or $1,000 for an entire patient care unit. Pay by check, credit card or payroll deduction. For more information and instructions on how to name your Nursing Stars, call **703-204-3325** or visit www.inova.org.

INOVA FAIRFAX HOSPITAL

INOVA HEART AND VASCULAR INSTITUTE
*Inova Fairfax Hospital*

INOVA FAIRFAX HOSPITAL FOR CHILDREN

## Nursing Exploration Summer Camp

Attention parents of middle school students! Looking for something interesting and rewarding for your child this summer? Inova's popular Nursing Exploration Summer Camp introduces boys and girls in sixth, seventh and eighth grade to the world of nursing and nursing careers. Three week-long sessions are offered this summer: **July 11-15, July 18-22** and **July 25-29.** More information is available on InovaNet. Registration deadline is April 30, so if your child is interested, call Ashley Elzein, **703-205-2196** or Ellen Swartwout, **703-205-2207** to register today!

## Inova Nurses Create Northern Virginia NBNA Chapter

We did it! At our first meeting in Feb. we had enough participation and interest to create a Northern Virginia Chapter of the National Black Nurses Association. This chapter will provide a great forum for African American nurses to make a difference on health care issues. If you are interested in being a founding member of the Northern Virginia Chapter, attend the next meeting on Thurs., March 17 at the Inova Alexandria Hospital Auditorium, from 6- 8 p.m. RSVP to Jayne James at **703-776-3652** or Pat Lane at **703-205-2141** by March 15.

## Oppose Medicaid Cuts

As Congress prepares its 2006 budget, major reductions in Medicaid spending are under consideration. Medicaid is such a major funder of children's health care that it affects children's hospitals ability to serve *all* children, not just children of low income families. Please join the National Association of Children's Hospitals and Related Institutions (NACHRI) and Inova Fairfax Hospital for Children in opposing this budget cut by contacting your members of Congress by March 15. Go to http://capwiz.com/nach for more information and to locate your representatives.

## Great Escapes Benefits the OB/GYN Clinic and SANE Program

The Assistance League® of Northern Virginia cordially invites you to its spring benefit, "Great Escapes," Sunday, April 10, 5-7 p.m., at Dante Ristorante in Great Falls. Enjoy a wine tasting presented by *The Wine Seller*, a silent auction and Northern Italian cuisine. Tickets are $75 per person ($40 tax deductible). To make reservations or for more information, call Mary Ann Bridges at **703-860-0412** or Carol Tether at **703-914-2882**. The Assistance League of Northern Virginia is an all-volunteer, non-profit organization that provides philanthropic services to the OB/GYN Clinic and SANE Program at Inova Fairfax Hospital through Operation Ba[illegible]

## Diabetes Alert Day

Diabetes Alert Day, Tuesday, March 22, is a national, one-day call to action to raise awareness about diabetes, its seriousness and its prevalence. You may have diabetes and not know it. To find out, take a short quiz to learn your potential risk by logging on to www.diabetes.org.

Diabetes Alert Day is also the launch date for the Inova Diabetes Center's new pre-diabetes class, in collaboration with Inova HealthSource. According to the American Diabetes Association, 41 million people in the U.S. have pre-diabetes, a condition where blood sugars are higher than normal, but not high enough to be considered full-fledged diabetes. If you have been told that you have pre-diabetes, take action to learn how to delay or prevent type 2 diabetes. The two-session class costs $35, and Inova employees receive a 75 percent discount! Pre-registration is required. For information on class dates or to register, call Inova HealthSource at **703-204-3366**.

## HSFCU Annual Meeting

The Healthcare Systems Federal Credit Union will hold its annual meeting on Wed., March 30, at 5:30 p.m., in the Physicians Conference Center at Inova Fairfax Hospital. This year's speaker is from the Credit Union National Association and will discuss "Identity Theft." A light buffet begins at 5 p.m. Door prizes, some including cash, will be announced throughout the meeting and members must be present to win. Free parking will be available in the Blue Garage.

## DC Avon Walk for Breast Cancer

The Inova Sports Medicine Program has formed a partnership with the DC Avon Walk for Breast Cancer to provide workshops for walkers, as well as volunteer medical crew members. The walk will take place April 30 – May 1 in Washington, DC. Both clinical and non-clinical volunteers are needed. Walk, volunteer or both! *Hurry – the deadline for medical crew volunteers is Tuesday, March 15.* Contact Annemarie Francis at **703-569-7335**.

## *Monday Rounds* Deadline

If you have information for the next *Monday Rounds*, send it to Kim Perry in the hospital's Marketing Communications Office or fax it to **703-776-2649**. The next deadline is Monday, March 21.

*Monday Rounds* is published biweekly by Inova's Marketing Communications Department and is for and about employees of Inova Fairfax Hospital, Inova Fairfax Hospital for Children and Inova Heart and Vascular Institute

Doug Cropper, *administrator*
Kim Perry, *managing editor*

Inova Health System is a not-for-profit health care system based in Northern Virginia that consists of hospitals and other health services including emergency and urgent care centers, home care, nursing homes, mental health and blood donor services, and wellness classes. Governed by a voluntary board of community members, Inova's mission is to provide quality care and improve the health of the diverse communities we serve.

www.inova.org

New Blood Substitute Introduced
Inova Regional Trauma Center prepares to participate in national study on PolyHeme.
By Brynn Grimley
March 16, 2005
In an attempt to potentially save the lives of people with trauma-related injuries and assist with increasing donated blood shortages, an oxygen-carrying blood substitute, PolyHeme, has been introduced to trauma centers nationwide for research purposes.

At the local level, Inova Regional Trauma Center at the Inova Fairfax Hospital has been asked to participate in the third phase of the study.
"It really can be revolutionary for trauma-injury treatment," said Dr. Christopher Michetti, trauma surgeon at Inova Regional Trauma Center. "The current trauma care we have is very good, but it's been unmodified for decades," he said.

DEVELOPED MORE than 10-years ago by Northfield Laboratories, Inc., the original concept for a blood substitute came following the Vietnam War.

Because massive quantities of blood cannot be administered to trauma victims on the battlefield, according to Northfield Laboratories, the objective was to develop something that could be infused rapidly in large quantities at makeshift settings before victims could be evacuated to hospitals for better care.

The scenario is the same for non-military trauma victims. Today, trauma-related injuries are a leading cause of death in Americans under 45 years of age, according to the Centers for Disease Control and Prevention (CDC).

"Up to 20-percent of people in hemorrhagic shock die from trauma," said Michetti, explaining 200 of the center's estimated 3,500 trauma-related injuries patients last year would have met the criteria for the blood substitute.

Michetti said the national study is meant to evaluate the life-saving potential of PolyHeme when given to severely injured and bleeding patients in hemorrhagic shock, starting at the scene of the injury.
He defined hemorrhagic shock as "a massive loss of blood causing a life threatening condition including dangerously low blood pressure and a lack of oxygen to internal organs that could lead to death."

Under the study's criteria, the potential use of PolyHeme would be to use it on site, as opposed to

What is PolyHeme?
Potential Risks of PolyHeme

* A blood substitute that carries oxygen.
* It is made from human blood.
* It is compatible with all blood types.
* It is immediately available.
* It reduces the risk of viral disease.
* One unit of PolyHeme is equal to one unit of blood.
* PolyHeme was developed to treat blood loss when blood is not available (i.e., in an ambulance, in a medical helicopter, in a military setting.)

Potential Risks of PolyHeme:
* Rash
* Increased blood pressure
* Kidney or liver damage
* Viral infection (HIV, hepatitis, etc.)
* Unforeseen happenings

current trauma response practices where patients are given saline solution until they are brought to a hospital and are able to receive blood.
"We can give patients O-negative, which is universal," said Michetti, adding it takes up to an hour to match donated blood with patients.

"Emergency response vehicles can't carry blood because it has to be refrigerated and stored in a particular way," he said. Because PolyHeme does not require the same storage as real blood, has a shelf life of up to 12 months and is universal, Michetti said medical helicopters and ambulances would be able to carry it to all trauma accidents.

Made from human blood, PolyHeme is "compatible with all blood types and can reduce the use of donated blood in the first 12-hours after injury," according to Northfield Laboratories.
The use of PolyHeme, if approved, would benefit trauma victims because it reduces the possibility of oxygen deprivation not only to internal organs but also the brain.

"There have been five studies so far, but this is the largest study using an oxygen carrier like this," said Michetti about the national study.

THROUGH THE STUDY, 720 patients will be reviewed at 20 to 25 different Level One trauma centers across the country.

To make the sample random, emergency personnel will not know until they are on site and open an envelop, what treatment the patient will receive — the current saline treatment or PolyHeme transfusion.

Treatment will begin at the scene of injury, continue in the ambulance during transport to the hospital and for 12 hours post injury in the hospital, according to Northfield Laboratories' study criteria.

Michetti explained that because trauma patients are not capable of making a sound decision due to blood loss, among other factors, those included in the study will generally not be able to give consent.

Because of this, the trial will be conducted under federal regulations that allow clinical research in emergency settings to be used with an exception from the requirement for informed consent, which the Food and Drug Administration (FDA) has authorized.

"It wouldn't be done this way if the product didn't have the ability to save the lives of people who could die from trauma otherwise," said Michetti.

Currently, Michetti said about 15 centers are already participating in the study across the country.

"If we get positive feedback from the community [about PolyHeme] we will hopefully start the study this spring or summer," he said. Before Inova Regional Trauma Center can begin

participation in the study, the doctors are required to conduct community forums on PolyHeme to better educate residents and answer any questions.

Michetti said he did not attend the first meeting, so could not say what the primary concerns were, although he added preliminary feedback has been positive.

"At Inova Fairfax Hospital, it's a teaching and research institution," he said about colleague response to the study. "People here use an analytical and skeptical thought process for any study."

As the third phase of the research study, Northfield Laboratories states that "PolyHeme has been studied in more than 300 individuals and five different clinical trials."

IN ADDITION, it has been extensively studied in hospitalized trauma patients and "kept trauma patients alive when they have lost all of their own blood," according to Northfield Laboratories. Michetti said if approved the study will follow strict criteria for participation including assisting people at the risk of dying who have sustained severe injuries, lost a large amount of blood and are in shock and who are at least 18 years old.

The study will not include patients who are pregnant, who have severe head injuries or brain injuries, who have "unsurvivable" injuries, who require CPR, patients with known objections to blood transfusions and who have known orders to "do not resuscitate."

Michetti said although if approved PolyHeme could change the way trauma centers operate, they first have to wait and see what the study returns.

"The study is to see if [PolyHeme] is at least as safe as the current treatment, or if in some cases it could be better," he said. "If it's just as good then it will be used in certain applications where you can't use blood."

In addition, he said if results are successful, the use of PolyHeme could benefit other areas of traumatic medicine.

"We're in a perpetual blood shortage," he said. "So anything we can do to take the pressure off of that is good."

New Blood Substitute Intoduced
Inova Regional Trauma Center prepares to participate in national study on PolyHeme.
By Brynn Grimley
March 16, 2005

In an attempt to potentially save the lives of people with trauma-related injuries and assist with increasing donated blood shortages, an oxygen-carrying blood substitute, PolyHeme, has been introduced to trauma centers nationwide for research purposes.
At the local level, Inova Regional Trauma Center at the Inova Fairfax Hospital has been asked to participate in the third phase of the study.
"It really can be revolutionary for trauma-injury treatment," said Dr. Christopher Michetti, trauma surgeon at Inova Regional Trauma Center.
"The current trauma care we have is very good, but it's been unmodified for decades," he said.

What is PolyHeme?/
Potential Risks of
PolyHeme

Printable Version

DEVELOPED MORE than 10-years ago by Northfield Laboratories, Inc., the original concept for a blood substitute came following the Vietnam War.
Because massive quantities of blood cannot be administered to trauma victims on the battlefield, according to Northfield Laboratories, the objective was to develop something that could be infused rapidly in large quantities at makeshift settings before victims could be evacuated to hospitals for better care.
The scenario is the same for non-military trauma victims.
Today, trauma-related injuries are a leading cause of death in Americans under 45 years of age, according to the Centers for Disease Control and Prevention (CDC).
"Up to 20-percent of people in hemorrhagic shock die from trauma," said Michetti, explaining 200 of the center's estimated 3,500 trauma-related injuries patients last year would have met the criteria for the blood substitute.
Michetti said the national study is meant to evaluate the life-saving potential of PolyHeme when given to severely injured and bleeding patients in hemorrhagic shock, starting at the scene of the injury.
He defined hemorrhagic shock as "a massive loss of blood causing a life threatening condition including dangerously low blood pressure and a lack of oxygen to internal organs that could lead to death."
Under the study's criteria, the potential use of PolyHeme would be to use it on site, as opposed to current trauma response practices where patients are given saline solution until they are brought to a hospital and are able to receive blood.
"We can give patients O-negative, which is universal," said Michetti, adding it takes up to an hour to match donated blood with patients.
"Emergency response vehicles can't carry blood because it has to be refrigerated and stored in a particular way," he said. Because PolyHeme does not require the same storage as real blood, has a shelf life of up to 12 months and is universal, Michetti said medical helicopters and ambulances would be able to carry it to all trauma accidents.
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Because of this, the trial will be conducted under federal regulations that allow clinical research in emergency settings to be used with an exception from the requirement for informed consent, which the Food and Drug Administration (FDA) has authorized.
"It wouldn't be done this way if the product didn't have the ability to save the lives of people who could die from trauma otherwise," said Michetti.
Currently, Michetti said about 15 centers are already participating in the study across the country.
"If we get positive feedback from the community [about PolyHeme] we will hopefully start the study this spring or summer," he said. Before Inova Regional Trauma Center can begin participation in the study, the doctors are required to conduct community forums on PolyHeme to better educate residents and answer any questions.
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"We're in a perpetual blood shortage," he said. "So anything we can do to take the pressure off of that is good."

IN DEPTH: HEALTH CARE
From the March 25, 2005 print edition

# Inova using blood substitute as part of national study

Neil Adler
Washington Business Journal
Staff Reporter

If the sight of blood -- or anything that looks like blood- -- grosses you out, this study isn't for you.
The trauma center at Inova Fairfax Hospital has been named one of about two-dozen health care sites nationwide participating in a pivotal Phase III study to evaluate the safety and effectiveness of a blood substitute for severely injured and bleeding patients who are in shock.
Each trauma center will accommodate at least 30 participants, according to the substitute's manufacturer, Northfield Laboratories.
Treatment with the blood substitute, called PolyHeme, would begin before a patient arrives at the hospital and continue through a 12-hour, post-injury period in the hospital.
Inova is holding community forums this month to discuss the study in detail.
PolyHeme (www.northfieldlabs.com/polyheme.html) is a chemically modified substance that restores lost blood volume and can be rapidly and massively infused into patients.
Northfield is developing PolyHeme to treat urgent, large-volume blood loss in trauma and surgical settings.
*E-mail: Nadler@bizjournals.com Phone: 703/816-0332*

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Inova Fairfax Hospital

Research News

# COMMUNITY MEETINGS FOR CLINICAL TRIAL SCHEDULED

Inova Fairfax Hospital has been chosen to participate in a national clinical research study of PolyHeme®, an investigational oxygen-carrying blood substitute for trauma use. To comply with federal regulations, which permit this trial to be conducted without obtaining the informed consent of the patients enrolled, Inova Fairfax Hospital will hold three community meetings on **Monday, March 7th, Tuesday, March 15th, and Tuesday, March 22nd** all beginning at 7 p.m. in the Physician's Conference Center.

To learn more about this study, visit **www.inova.org** and look for the PolyHeme Trial under either Inova News or Health Information.

Distribution data
- flyers
- emails
- press releases

For Immediate Release
March 2, 2005

Kathleen Thomas, 703-776-2811
Beth Visioli, 703-504-3438

# INOVA REGIONAL TRAUMA CENTER AT INOVA FAIRFAX HOSPITAL TO HOLD NEWS CONFERENCE REGARDING ITS PARTICIPATION IN NATIONAL STUDY OF POLYHEME

## Blood Substitute Will Be Used To Treat Some Severely Injured Trauma Patients Who Are In Shock

Falls Church, VA – Trauma-related injuries are a leading cause of death in Americans under 45 years of age, striking more than two million people a year. Nearly one in five trauma victims in hemorrhagic shock dies as a result of his or her injuries.

Inova Regional Trauma Center at Inova Fairfax Hospital will soon begin participating in a national research study to evaluate an investigational blood substitute in severely injured and bleeding patients who are in shock. In this study, PolyHeme® will be compared to the usual care. Study treatment would begin before arrival at the hospital, either at the scene of injury or in transport, and continue through a 12-hour post-injury period in the hospital. Only people over 18 years of age who meet specific study criteria will be eligible for inclusion.

| | |
|---|---|
| **WHAT:** | News conference to discuss details of PolyHeme study |
| **WHEN:** | Monday, March 7<br>10:30 a.m. |
| **WHERE:** | Inova Regional Trauma Center at Inova Fairfax Hospital<br>3300 Gallows Road – Physicians Conference Center (lower level)<br>Falls Church, VA |
| **WHO:** | Samir Fakhry, MD, chief, Trauma and Critical Care Services,<br>Inova Regional Trauma Center at Inova Fairfax Hospital |

Inova Regional Trauma Center at Inova Fairfax Hospital will hold several community meetings to hear details of the national research study.

This research is being conducted in accordance with federal regulations permitting an exception from informed consent requirements under 21 CFR 50.24. Samir Fakhry, MD, chief, Trauma and Critical Care Services, Inova Regional Trauma Center at Inova Fairfax Hospital, will explain these regulations and the study protocol, as well as the potential risks and benefits associated with participation.

Media may park in the Blue Parking Garage located across from the Physicians Conference Center.

*Inova Health System is a not-for-profit health care system based in Northern Virginia that consists of hospitals and other health services including emergency and urgent care centers, home care, nursing homes, mental health and blood donor services, and wellness classes. Governed by a voluntary board of community members, Inova's mission is to provide quality care and improve the health of the diverse communities we serve.*

# # #

From: Arletta VanBreda
To: lisa.collins@inova.com
Date: 4/5/2005 12:48:35 PM
Subject: Fwd: Inova in the new...

for tomorrow

Arletta van Breda, R.N., MSN, CCRC
Clinical Research Manager
703-504-3071 office
703-764-7310 ID# 73527 pager
703-504-3944 fax
arletta.vanbreda@inova.com

>>> Kathleen Thomas 3/28/2005 2:41:06 PM >>>
There are two items about Inova in the news today.

Be sure to watch WTTG-TV Channel 5 tonight during the 5 p.m. newscast for a story about Cole's Closet, a local organization that has donated thousands of toys to Inova Fairfax Hospital for Children. Today after delivering a truck load of toys, the organization also made a $10,000 contribution to the Inova Fairfax Hospital for Children Foundation to name a pediatric room in memory of Cole Tomczyk.

There is an article in this week's Washington Business Journal about the PolyHeme study that will be conducted at the Inova Regional Trauma Center at Inova Fairfax Hospital. PolyHeme is a blood substitute that will be used to treat trauma patients suffering from hemorrhagic shock.
The article is attached.

Kathleen Thomas
Media Relations Manager
Inova Health System
703-776-2811
kathleen.thomas@inova.com

NEWS RELEASE - COMMUNITY MEETING

**FOR IMMEDIATE RELEASE**
**CONTACT: NAME: Samir Fakhry, M.D. via Arletta van Breda, RN**
**PHONE 703 504 3071**
**EMAIL : arletta.vanbreda@inova.com**

INOVA FAIRFAX HOSPITAL INVITES THE PUBLIC TO ATTEND A COMMUNITY MEETING TO DISCUSS THE RESEARCH STUDY OF AN INVESTIGATIONAL BLOOD SUBSTITUTE IN TRAUMA PATIENTS TO BE CONDUCTED IN OUR COMMUNITY

Falls Church, VA-MONTH, DATE, YEAR –Trauma-related injuries are a leading cause of death in Americans under 45 years old, affecting more than 2 million persons annually. Nearly one in five trauma victims in hemorrhagic shock dies as a result of his/her injuries.

INOVA FAIRFAX HOSPITAL invites the public to attend community meetings at which members of its Trauma Service will explain the details of a national research study to evaluate an investigational blood substitute in severely injured and bleeding patients who are in shock. In this study, PolyHeme will be compared to the usual care. Study treatment would begin before arrival at the hospital, either at the scene of injury or in the ambulance, and continue through a 12-hour post injury period in the hospital. Only persons over 18 years of age who meet specific study criteria will be eligible for inclusion.

This research study is being conducted in accordance with federal regulations permitting an exception from informed consent requirements under 21 CFR 50.24. Samir Fakhry, M.D., will explain these regulations and the study protocol and the potential risks and benefits associated with participation. He will be available to answer questions. Your comments and concerns will be solicited and addressed.

The forum will take place on: March 7
March 15
March 22
In the Physician's Conference Center on the Inova Fairfax Campus at 7PM.
Please review our web page at www.inova.org and look for the PolyHeme Trial under either Inova News or Health Information for more information.

Members of the media are invited to cover this event.

# Co... Re... ch Request

**om:** Lisa Collins
**:** Switzer, Gary
**Date:** 3/2/2005 3:14:31 PM
**Subject:** Research Request
**CC:** Arletta Van Breda; Fakhry, Samir; Jean Donovan; Michetti, Christopher

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Hi Gary,

I left a flyer earlier today with your personnel in Safety & Security. I'm requesting that you allow us to post one flyer in each shuttle for the next month. I have additional flyers for this purpose because they need to be on special paper.

To give you some background on this request, we are working with Trauma Services to bring up a new study ....the Polyhemo trial. One of our major requirements from the governing Western IRB is that we notify the public and staff on as grand a scale as possible so they are educated, informed and have the opportunity to learn about the study before it starts. The reason for this is that the patients that will eventually be enrolled in this study will not be able to give consent prior to receiving a blood substitute product because they will be very critically injured. To that end, we are using many media means to make the public and staff aware of this trial and posting flyers in and around the hospital campus is one of those tools.

If you have any questions, please call me. I look forward to hearing from you regarding the use of your shuttles for about 1 month. Thank you.

Lisa J. Collins
Database Analyst
00 Gallows Road
lls Church, VA 22042
ork # 703-776-6574
Pager # 703-660-2299