

**The University of Cincinnati College of Medicine
PolyHeme Community Meeting Questions and Answers:**

**Millvale Community Meeting
January 13, 2004
Questions and Answers:**

- 1. How will polyheme effect sickle cell patients?**
Sickle cell patients will more than likely benefit from the administration of polyheme because it is an oxygen carrying product. A sickle cell patient is currently and will continue to be treated in the same way any other trauma patient would be.
- 2. It sounds as though this product will help but I am concerned that it has not been used in Cincinnati yet.**
Although the product has not been used in Cincinnati yet, it has already been used in 300 patients across the United States.
- 3. Aren't people being used as guinea pigs for this study?**
No. There are several entities that ensure that the research protocol (guidelines for the study) has been and continues to be reviewed on a regular basis. These groups include the US Food and Drug Administration (FDA) and the University of Cincinnati Institutional Review Board (IRB).

The University of Cincinnati has established three Institutional Review Boards (IRBs) to review all proposed research involving human subjects to ensure that the subjects' rights and welfare are adequately protected. IRBs are composed primarily of faculty members from disciplines in which research involving human subjects is integral to that discipline's work, as well as several members from the community whose primary interest is in non-scientific areas. The Board membership, policies, and procedures are governed by an Assurance agreement with the Federal government.
- 4. Some drugs have been given before that have side effects (example used was prednisone) and patient's are never made aware of the risks and side effects, How will we know what the side effects and problems are?**
There is a difference between prednisone, an approved drug and PolyHeme as an investigational product. As an investigational product, there is an extensive consent form that must (by federal law) be explained thoroughly to a patient or family member enrolled in or potentially being enrolled in a research study. The form has been written at the 6th grade reading level and ensures all risks are explained to the patient.
- 5. How will this (PolyHeme) effect kidney patients?**
This should not have any negative effects on kidney patients, beyond that which normal blood administration would. We believe that the benefit is probably greater than the risk.
- 6. Where will this be done, in the hospital or the ambulance?**
The product will be given first in the ambulance and then repeated in the hospital as needed for up to 6 units (doses) or 12 hours.

**Avondale Community Meeting
January 20, 2004**

Questions and Answers:

1. Please explain how someone can be enrolled in this study without providing informed consent?

The federal government, through the FDA allows for something known as "exception from informed consent" under certain circumstances. Under the "exception from informed consent", patients are enrolled in a clinical study without giving informed consent before being enrolled.

In order for "exception from informed consent" to be utilized, patients must be 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 must also have the potential for 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.

2. Who will be included in this 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. The study will be conducted throughout the city of Cincinnati.

3. Why is this not being trialed in the military?

Military personnel are not consistently in one geographic area so a clinical trial like this would be difficult to monitor and control. Additionally, when the PolyHeme trial was born, we were not at war and the number of patients would unlikely be supported by a military study.

4. Why were only 300 people given this product if it has been around for 10 years?

It is not that the product has been around for ten years, the sponsor (company who developed the product) has been working on the product and refining it for SAFE use in humans. Once the sponsor felt the product was safe to be trialed in humans, they went after and obtained approval to use the product in human trials.

5. **It is crazy to make people who do not want to participate in this study wear bracelets, make those that do want to participate wear them.**
It is unrealistic to think that we could get people who want to participate in the study to wear bracelets, rather it is easier to have those that are strongly opposed to the study to wear them.
6. **Is there a problem with administering this product to patient's with different blood types?**
No. Blood type is found on the outside of a red blood cell, what the product uses, is the hemoglobin, inside the blood cell, which is not effected by blood type. This product can be safely given to a person of any blood type.
7. **What else is in PolyHeme?**
PolyHeme is a human hemoglobin product in a saline (salt water-like) solution that has been pH balanced to be comparable to human body fluids.
8. **Is this study only being done in the 7 communities where the meeting is held or is it being done throughout the city?**
Throughout the city. The community meeting sites were identified in part by the City of Cincinnati Fire Department and have been identified because they are located in various areas of the city.
9. **What are the risks to taking PolyHeme?**
They are exactly the same ones as taking blood except for the fact that the viral load (amount of virus) in the solution is decreased by a billion times over blood. Also, because this is still new to human use, there is also the potential for unforeseen or not identifiable side effects.
10. **What if my son is enrolled in the study and I do not want him in the study?**
As a part of the exception from informed consent, we are responsible for trying to locate family members and gain consent to keep the patient enrolled in the study. As the mother (or an immediate relative) of the patient, you may withdraw your son from the study at any point in the study.
11. **How will PolyHeme effect Sickle cell patients?**
Sickle cell patients will more than likely benefit from the administration of polyheme because it is an oxygen carrying product. A sickle cell patient is currently and will continue to be treated in the same way any other trauma patient would be.
12. **How do I get more information on this study if I need it?**
Go to [www. Ucpolyheme.org](http://www.Ucpolyheme.org) or you may contact either the study coordinator, Will Krost, or the Prinicipal investigator, Dr. Donald Locasto at:

William Krost, EMT-P Study Coordinator Office: 558-5786 Pager: 343-1118 SC@polyhemeuc.org	Donald Locasto, MD Principle Investigator Office: 558-8299 Pager: 230-3790 PI@polyhemeuc.org
---	--

**Cincinnati City Council –Committee on Health -Meeting
January 21, 2004**

Questions and Answers:

Questions and Answers from the Health Committee meeting will be posted as soon as the official minutes from the meeting have been received. We estimate having this information available toward the beginning of February, 2004

**East End Community Meeting
January 22, 2004**

Questions and Answers:

- 1. What are the typical trauma patient's that you see at UC?**
The trauma service admits roughly 1600 patient's to the trauma service each year. The vast majority of these patient's are white males between 18 and 20 years of age, involved in motor vehicle collisions.
- 2. How do you effectively meet community consent requirements when so few people show up at the meetings?**
We do our best to get people to attend the meetings, we have taken out paid advertisements in 3 newspapers, done 4 television news interviews, a radio interview and several newspaper interviews. We have provided and continue to provide a number of forums for community members to voice their concerns, and have questions answered. In fact, we have been asked to come back to the Avondale community meeting for an additional questions and answers session.
- 3. How will you keep the community advised of the studies progress?**
We cannot disclose any patient specific information and can only disclose a limited amount of study information once the study is underway. This is a multi-center (many different locations) trial and we are only one location so our findings cannot be considered the only study findings. The (IRB) Institutional Review Board will be intimately involved and informed with all aspects of this study, they will make certain that there are not an unreasonable number of negative effects on patients involved in this study.
- 4. Have people been concerned that you are targeting the poor population?**
Yes. The reality is that the greatest majority of trauma victims seen at UC come from white males involved in motor vehicle collisions. The disbursement of trauma patients crosses all socioeconomic lines.
- 5. How many people will be trained to administer PolyHeme?**
There will be approximately 30 paramedics trained on the administration and use of PolyHeme. All ED nursing and trauma staff will also be trained on the administration of PolyHeme.
- 6. When will training be conducted?**
Training will be conducted upon completion of the community consent process (after all community meetings) and once IRB approval is granted.

7. When do you plan on starting the study?

We cannot tell for certain when the study will start, our hope is to start by the beginning of April, 2004. We are currently conducting informational meetings throughout the Cincinnati area and must report back to our Institutional Review Board (IRB) before moving forward with the study. Once the community consent process is complete and approval by our IRB is granted, the study will begin.

**Downtown Community Meeting
February 10, 2004**

Questions and Answers:

1. Is there a problem with administering this product to patient's with different blood types?

No. Blood type is found on the outside of a red blood cell, what the product uses, is the hemoglobin, inside the blood cell, which is not effected by blood type. This product can be safely given to a person of any blood type.

2. Would you take this product if you needed it and were given the opportunity?

Yes. I would take it and I would not hesitate to have it given to my family. I work in the City of Cincinnati so there is a chance I could be enrolled in this study and I would hope that if I needed the product it would be available.

3. Will all of the patient's that are enrolled in this study have to be transported to UH?

Yes. This is the current practice anyways, UH is the only level I Trauma Center in the region so as a result, all patient's (by Ohio law and current medical standards) would be required to go to UH whether they are enrolled in the study or not.

4. What are the risks to taking PolyHeme?

They are exactly the same ones as taking blood except for the fact that the viral load (amount of virus) in the solution is decreased by a billion times over blood. Also, because this is still new to human use, there is also the potential for unforeseen or not identifiable side effects.

**East Westwood Community Meeting
February 12, 2004**

Questions and Answers:

1. How will we be updated on the outcome of the study?

We cannot disclose any patient specific information and can only disclose a limited amount of study information once the study is underway. This is a multi-center (many different locations) trial and we are only one location so our findings cannot be considered the only study findings. The (IRB) Institutional Review Board and the FDA US Food and Drug Administration will be intimately involved and informed with all aspects of this study, they will

make certain that there are not an unreasonable number of negative effects on patients involved in this study.

2. 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.

3. What are the risks to taking PolyHeme?

They are exactly the same ones as taking blood except for the fact that the viral load (amount of virus) in the solution is decreased by a billion times over blood. Also, because this is still new to human use, there is also the potential for unforeseen or not identifiable side effects.

4. You mentioned that people have already received PolyHeme, what did the previous studies show?

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

5. For clarification, can you please explain who will be included in this 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. The study will be conducted throughout the city of Cincinnati.

**Avondale Community Meeting –
Additional Questions and Answers session
February 17, 2004**

Questions and Answers:

1. Why is this study only being done in the City of Cincinnati?

Since we were here last, we have expanded the study to include Colerain Township and the Western Joint Ambulance District, which includes Harrison, Cleves, Whitewater, Crosby Township, and Harrison Township.

2. What are the risks to taking PolyHeme?

They are exactly the same ones as taking blood except for the fact that the viral load (amount of virus) in the solution is decreased by a billion times over blood. Also, because this is still new to human use, there is also the potential for unforeseen or not identifiable side effects.

**Northside Community Meeting
February 23, 2004**

Questions and Answers:

1. Is there a problem with administering this product to patient's with different blood types?

No. Blood type is found on the outside of a red blood cell, what the product uses, is the hemoglobin, inside the blood cell, which is not effected by blood type. This product can be safely given to a person of any blood type.

2. What are the risks to taking PolyHeme?

They are exactly the same ones as taking blood except for the fact that the viral load (amount of virus) in the solution is decreased by a billion times over blood. Also, because this is still new to human use, there is also the potential for unforeseen or not identifiable side effects.

3. How will PolyHeme effect Sickle cell patients?

Sickle cell patients will more than likely benefit from the administration of polyheme because it is an oxygen carrying product. A sickle cell patient is currently and will continue to be treated in the same way any other trauma patient would be.

4. Is this study only being done in the City of Cincinnati?

No. The study is being conducted in over twenty sites across the US. In addition, the University of Cincinnati study has been expanded to include Colerain Township and the Western Joint Ambulance District, which includes Harrison, Cleves, Whitewater, Crosby Township, and Harrison Township.

5. How do I get more information on this study if I need it?

Go to www.Ucpolyheme.org or you may contact either the study coordinator, Will Krost, or the Principal investigator, Dr. Donald Locasto at:

William Krost, EMT-P Study Coordinator Office: 558-5786 Pager: 343-1118 SC@polyhemeuc.org	Donald Locasto, MD Principle Investigator Office: 558-8299 Pager: 230-3790 PI@polyhemeuc.org
---	--

Colerain Township Trustee's Meeting

February 24, 2004

Questions and Answers:

1. What are the risks to taking PolyHeme?

They are exactly the same ones as taking blood except for the fact that the viral load (amount of virus) in the solution is decreased by a billion times over blood. Also, because this is still new to human use, there is also the potential for unforeseen or not identifiable side effects.

2. Is there a problem with administering this product to patient's with different blood types?

No. Blood type is found on the outside of a red blood cell, what the product uses, is the hemoglobin, inside the blood cell, which is not effected by blood type. This product can be safely given to a person of any blood type.

3. Will all of the patient's that are enrolled in this study have to be transported to UH?

Yes. This is the current practice anyways, UH is the only level I Trauma Center in the region so as a result, all patient's (by Ohio law and current

medical standards) would be required to go to UH whether they are enrolled in the study or not.

4. Who will be included in this 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. The study will be conducted throughout the city of Cincinnati.

5. How will you keep the community know if the study is not going well or patients are not having good results from the administration of the PolyHeme?

We cannot disclose any patient specific information and can only disclose a limited amount of study information once the study is underway. This is a multi-center (many different locations) trial and we are only one location so our findings cannot be considered the only study findings. The (IRB) Institutional Review Board and the FDA US Food and Drug Administration will be intimately involved and informed with all aspects of this study, they will make certain that there are not an unreasonable number of negative effects on patients involved in this study.

**Western Joint Ambulance District (Harrison, Cleves, Whitewater, Crosby Township, and Harrison Township) Township Trustee's Meeting
March 4, 2004**

Questions and Answers:

1. What is the shelf Life of PolyHeme?

An excess of 12 months, the exact time beyond a year has not yet been established.

2. If a parent wants product given to the minor can it be given?

No. The FDA has currently only approved this study to be conducted on adults.

3. Do all patients have to go to UC?

Yes. This is the current practice anyways, UH is the only level I Trauma Center in the region so as a result, all patient's (by Ohio law and current medical standards) would be required to go to UH whether they are enrolled in the study or not.

4. Does it cost anything to get PolyHeme?

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.

5. Who determines what patient's will be enrolled in the study?

The paramedic on scene will make the determination whether to enroll a patient or not and will do so using strict guidelines outlined in the FDA approved PolyHeme protocol. Paramedics are accustomed to operating off of a written protocol system.

6. Seems to be a great product for organs, what about organ donors?

The sponsor has not had experience with organ donors so the efficacy (effectiveness) of the product in organ donors has not yet been established.

FUTURE MEETINGS

Future meeting locations, dates, and times, will be posted in the near future. Please check back or contact Will Krost. The Study Coordinator at:

William Krost, EMT-P
Study Coordinator
Office: 558-5786
Pager: 343-1118
SC@polyhemeuc.org