

Community Consultation

9/18/2005

Please circle your answers

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

Yes No

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

Yes No

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

Yes No

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

Age: 51 Ethnic background: Cauc

Gender: Male _____ Female

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

Community Consultation

9/18/2005

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Yes No

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Yes No

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

Yes No

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

Age: 56 Ethnic background: white

Gender: Male Female

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

Community Consultation

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Yes No

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Yes No

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

Yes No

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

Age: 37 Ethnic background: white

Gender: Male Female

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Yes No

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

Yes No

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

Age: 46

Ethnic background: white

Gender: Male _____ Female

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Yes No

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

Yes No

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

Age: 48 Ethnic background: _____

Gender: Male _____ Female

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Yes

No

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Yes



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

Yes

No

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

Age: 22

Ethnic background: CANADIAN

Gender: Male Female

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Yes No

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

Yes No

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

Age: 42

Ethnic background: White

Gender: Male Female

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Yes No

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

Yes No

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

Present in high risk areas - bars, colleges,

Age: 49 Ethnic background: White

Gender: Male Female

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Yes No

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Yes No

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

great idea - and much needed

Age: 44 Ethnic background: white

Gender: Male _____ Female

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Yes No

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

Yes No

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

Are you going over to the local
rescue squads with this
program? & to (your companies
& EMT courses
(Parish audience)

Age: 53 Ethnic background: White

Gender: Male Female

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Yes

No

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

Yes

No

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

Age: 51

Ethnic background: Caucasian

Gender: Male _____ Female X

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Yes No

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

Yes No

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

Age: 36 Ethnic background: white

Gender: Male _____ Female X

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Yes No

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Yes No

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

Age: 50 Ethnic background: _____

Gender: Male _____ Female

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Yes No

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

Age: 46 Ethnic background: Caucasian

Gender: Male Female

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Yes

No

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

Yes

No

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

Age: 48

Ethnic background: Caucasian

Gender: Male Female

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Yes

No

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

Yes

No

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

Age: 37

Ethnic background: White

Gender: Male Female

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Yes No

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

Yes No

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

Age: 27

Ethnic background: white

Gender: Male

Female

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

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Yes

No

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

Yes

No

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

Yes

No

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

Age: 43

Ethnic background: Caucasian

Gender: Male

Female

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

Community Consultation

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Yes

No

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

Yes

No

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

Yes

No

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

want to know the outcome of the trial

Age: 57

Ethnic background: European American

Gender: Male

Female

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

Community Consultation

9/18/2005

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Yes

No

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

Yes

No

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

Yes

No

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

Age: 57

Ethnic background: CAUCASIAN

Gender: Male

Female

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

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Yes No

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

Yes No

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

Age: 47 Ethnic background: Caucasian

Gender: Male Female

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Yes No

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

Yes No

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

Age: 53 Ethnic background: White

Gender: Male Female

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Yes No

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Yes No

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

Age: 50 Ethnic background: ~~American~~ America
Gender: Male _____ Female

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Yes

No

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

Yes

No

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

Why not heard out to our patients at
our hospital

Age: 48

Ethnic background: white

Gender: Male

Female

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Yes

No

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

Yes

No

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

Age: 29

Ethnic background: white

Gender: Male Female

Thank you for your participation today.
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Community Consultation

9/18/2005

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Yes

No

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

Yes

No

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

Yes

No

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

Age: 40

Ethnic background: Asian

Gender: Male

Female

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Community Consultation

9/18/2005

Please circle your answers

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Yes

No

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

Yes

No

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

Yes

No

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

God bless on the study!
move forward!

Age: 39

Ethnic background: White/Caucasian

Gender: Male

Female

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Community Consultation

9/18/2005

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Yes

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

Yes

No

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

Yes

No

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

Age:

48

Ethnic background:

Irish American

Gender: Male

Female

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Yes No

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

Yes No

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

Age: _____

Ethnic background: _____

Non Hispanic

Gender: Male _____

Female

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Yes

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Yes

No

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

Yes

No

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

Would be beneficial to children
in field as well, hope to see
that done as soon as this is
proven effective

Age: 32

Ethnic background: caucasian

Gender: Male

Female

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Yes No

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Yes No

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

Age: 29 Ethnic background: Italian American

Gender: Male _____ Female

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Yes No

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Yes No

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

Age: 61 Ethnic background: Caucasian

Gender: Male Female

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Yes No

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Yes No

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

Age: 55 Ethnic background: Caucasian

Gender: Male Female

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Yes No

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

Age: 35 Ethnic background: Caucasian

Gender: Male Female

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Yes No

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

More research regarding Cardiovascular risk
factors.

Age: 31 Ethnic background: Caucasian

Gender: Male _____ Female

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Yes No

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

Age: 40 Ethnic background: Latvian ^{Caucasian} English, French, Dutch, Italian
Gender: Male Female German

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

Yes No

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

Yes No

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

Age: 51

Ethnic background: ~~White~~ White. Scotch/Irish

Gender: Male Female

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

Community Consultation

9/18/2005

Please circle your answers

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

Yes No

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

Yes No

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

Yes No

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

Age: 40 Ethnic background: white -

Gender: Male Female

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

Community Consultation

9/18/2005

Please circle your answers

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

Yes No

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

Yes No

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

Yes No

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

Age: 41 Ethnic background: CAUCASIAN

Gender: Male Female

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

Community Consultation

9/18/2005

Please circle your answers

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

Yes No

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

Yes No

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

Yes No

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

Age: 46 Ethnic background: white

Gender: Male _____ Female

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

Community Consultation

9/18/2005

Please circle your answers

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

Yes No

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

Yes No

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

Yes No

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

Age: 40

Ethnic background: Caucasian

Gender: Male Female

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



September 21, 2005

Schoharie Health Fair

Activity: Information Table and brochures

The study coordinator circulated throughout the event, talking to people about the study and handing out brochures. Handed out about 50 brochures, responses via website.

Community Consultation
Schoharie County Annual Health & Safety Fair
9/21/2005

Please circle your answers

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

Yes No

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

Yes No

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

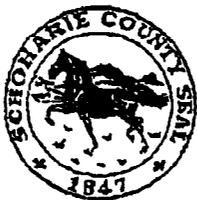
Yes No

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

Age: _____ Ethnic background: _____

Gender: Male _____ Female _____

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



Schoharie County Safety Committee

Glenn Packard, Chairman

PO Box 429-County Office Building

Schoharie, New York 12157

(518) 295-8347

glenpackard@co.schoharie.ny.us

Committee Officers

Chairman
Glenn Packard
Safety Department
Vice-Chair
Sara Davies-Griffin
Board of Supervisors
Secretary
Ruey Schell
Department of Social Services

Representing Members

Bruce Bywater
Department of Public Works
Larry Caza
County Clerk's Office
Department of Motor Vehicles
Records Management
Judy Cary
Emergency Management
Probation Department
Karl Cooper
Division of Buildings & Grounds
Veronica Diamond
Planning & Development Agency
Youth Bureau
C.J. Smith
Department of Public Health
William Dyer
Old Stone Fort
Nancy Getman
Department Head Association
Marlene Jorgensen
Mental Health Clinic
Susan Makely
Real Property
Treasurer's Office
Weights and Measures
Gretchen Randazzo
Central Data Processing
Board of Elections
Personnel & Civil Service Department
Charles Stanton
Fire Coordinator's Office
Amy Weitz
Office for the Aging
Public Transportation
Lisa Wright
CSEA Local #848

The Schoharie County Safety Committee would like to invite you to participate in our 1st Annual Schoharie County Health and Safety Fair. The Health and Safety Fair is scheduled for September 21st 2005 from 10:00 am thru 6:00 pm. The event is open to all County employees and County residents.

As a committee, we are dedicated to promoting health and safety awareness for employees, their families and County residents.

The Committee was established in 2000. Since the committee was established we have:

- Developed an Employee Safety & Health Handbook
- Instituted an Employee Safety Recognition Program
- Held a Safety Poster contest for children of Employees
- Received a grant for the past 3 years to provide training which was opened to County Employees, Town and Village Employees as well as other agencies i.e. ARC, Head Start, local school districts.
- Received the PERMA Safety Innovation Award this year.

We can provide tables and electricity for you at the Fair. Space may be limited so we would appreciate a response from you either way, no later than September 1st, 2005.

If you have any questions you may contact any of the following:

- Glenn Packard, Schoharie County Safety Officer – 295-8251
- Veronica Diamond, Safety Committee Member – 234-3751
- Marlene Jorgensen, Safety Committee Member – 295-8336
- Gretchen Randazzo, Safety Committee Member – 295-8465
- C.J. Smith, Safety Committee Member – 295-8474
- Amy Weitz, Safety Committee Member – 234-4219

We are looking forward to your participation and sharing of your expertise in Health and Safety for our employees and County Residents.

Sincerely,

Glen Packard
 County Safety Officer

Schoharie County 1st Annual Health & Safety Fair
September 21st 2005
10:00 am - 6:00 pm

Name of Participant: SUSAN RAUCH
 Number of Participants: 1
 Business Address: Albany Medical Center Pol. Div - MC-91
47 New Scotland Ave. Albany, N.Y. 12207
 Phone Number: 518-439-767-6608
 Email Address: 518-762-3661 Phone - 518-762-6608

Interested in participating and will need

- Table yes no
- Electric yes no
- Other Chair (I plan bring my own table chair if necessary)

Not interested at this time but please contact me again in the future
 Not interested. Please don't contact me again.

Please provide us a basic summary of your program/business and what information/handouts you will be providing at the fair.

Information & Survey for the polyhema trial
Amy,
We are in the process of a community
consultation (providing information to the community
at large and asking their opinion) about a planned

Please return this form in the self-addressed envelope no later than September 1st, 2005.
 We are looking forward to your participation.

Cont. -

Study at Albany Medical Center. This study is through
 Emergency Medicine / Trauma Surgery and involves
 the use of a blood substitute (oxygen carrier) for trauma
 patients. Please see that attached press release
 and Q&A material. I hope to be able to provide information
 answer question and obtain peoples opinions using
 a very short (attached) survey form.

8



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COMMUNITY CONSULTATION MEETING WEDNESDAY OCT. 5TH, 7PM, AMC HUYCK AUDITORIUM.

Dr. Rossati & Susan Rauch present to present material and answer questions. 9 people in the audience, including a group of 5 Jehovah's Witnesses.

Dr. Rossati presented information about the study and the qualities of PolyHeme, speaking from the podium and using power points.

Some points of interest from the presentation:

- Shock= lack of oxygen on the cellular level.
- (paraphrased)"Blood can cause all kinds of damage and complications and we should not use it if we don't need to.
- PolyHeme has none of the cellular structure of blood.
- 300 people have received PolyHeme. There are 5 published clinical trial studies already out there.
- PolyHeme has not been shown to cause organ damage.
- Dr. Rossati showed us the cooler to which the envelope that tells the first responders if the subject is to receive standard care or PolyHeme, is attached. If they are to receive PolyHeme that will also be in the cooler.
- What is informed consent? It is a discussion between patient and doctor about treatment or research participation. It gives the patient the information to say yes or no.
- Exceptions form informed consent is given when certain things hold: Life at risk, available treatment no satisfactory, pt. unable to give informed consent, risks are reasonable, there is an expectation of some benefit to the patient, research could not take place without this exception.
- Risks of PolyHeme: same risk profile as other products that came before it and as blood. In fact the risk profile seems lower for PolyHeme but the sponsors have decided to proceed as if it were the same – kind of a worst-case scenario approach.
- The benefits of PolyHeme are, among others, that it is compatible with all blood types, it is easily available in the field (blood is not available in the field b.c. it does not travel well and has to be typed before use).

Question and answer session: (questions and answers are paraphrased to capture the essence of what is being asked and how it is answered.)

Q1: Are the first responders the ones that make decisions about who gets chosen to be in the study?

A1: yes

Q2:is there a study available about the representation of different groups (women, blacks etc)?

A2: no

Q3: Are the first responders playing God?

A3: No – there is a protocol about who is eligible to be entered into the study – it is based on medical criteria – what kind of injury etc.. Trauma happens mostly to men so the sample will very likely have a greater number of males than females. This can be seen as a criticism of the study wince we might end up with results that are not conclusive when it comes to women. But

in another sense this is a benefit because this is the way it is out here in the real world – most trauma victims are men.

Q4: It might be of interest to those sitting here to know that the IRB that approved this study is not the local IRB. Could you please tell us about that?

A4: it is the western IRB – also approved the study in some of the other trauma centers that are participating, so it is familiar with the process. Albany Med uses the Western IRB for its larger studies – but it uses language and templates specific to AMC.

Q5: What does obviously pregnant mean? Is there a clause in the consent form that says that if a woman who is pregnant does get the PolyHeme there will be follow up through the birth and first month of child's life? There should be

A5: Susan Rauch thought that there was such a clause – person asking the question claimed that there was not.

Q6: Will the community have access to the approved consent form, once it is available?

A6: Yes.

Q7: What happens to PolyHeme in the body?

A7: the half life of the product is about 1 day. Some gets metabolized through the liver – but mostly it is RES metabolism that we don't know a whole lot about – like a lot of drugs.

Q8: Is the cooler cold at all times? How long can it stay cold?

A8: very long it is a high tech cooler (shows inside of cooler – all kinds of aluminum padding and fancy stuff). Dr. Rossati says that PolyHeme does not have to be kept cold but it does extend the life of the product to keep it cold.

Q9: What is the cost of PolyHeme? Is it more expensive than blood?

A9: In the beginning it will probably be fairly expensive and then go down in cost once it becomes widely available – this is the case with drugs in general. It will probably start out more expensive than blood. We don't have information about cost at this point so we are just guessing and inferring from prior experience with other new drugs and products.

Q10: When do you hope to be done with the study?

A10: Soon as possible – most optimistic forecast is spring of 06. It is more likely that it will take a year.

Q11: When will there be FDA approval? Not for a while, more studies are needed.

Q12: Will the product be fast tracked with the FDA?

A12: Not to my knowledge – although a good argument could be made that it should be.

Q13: What improvements have happened recently that have led to this product being reintroduced?

A13: Its not really being reintroduces – it has evolved to the point of being free from the problems it had earlier e.g levels of toxicity are no longer an issue.

Q14: Will minutes be made of this meeting?

Q14: No

Q15: You should check your protocol to see if you don't need to have minutes and make them available to the public.

Q16: When does the study start?

A16: The IRB wants to know about the community outreach – they need to see all our data on how we went about reaching and informing the community and if there is any disapproval. We will present all our data to them – the survey I gave you is part of that so please fill it out. After they asses our effort they will decide if we can go on with the trial.

Q17: Has there been feedback from other sites doing this study?

A17: Yes – it is overwhelmingly positive.

At this point Susan Rauch introduced information pamphlets about the study and made the point that they were available in large numbers if anyone needed to distribute them amongst their group/community. The Jehovah's Witness representatives took about 50.

Meeting lasted 1 hour.

Community Consultation
AMC Meeting
10/05/05

Please circle your answers

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

Yes No

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

Yes No

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

Yes No

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

Age: 48 Ethnic background: white-couple

Gender: Male Female

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

Community Consultation
AMC Meeting
10/05/05

Please circle your answers

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

Yes

No

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

Yes

No

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

Yes

No

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

Age: 57

Ethnic background: white

Gender: Male Female

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

Community Consultation
AMC Meeting
10/05/05

Please circle your answers

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

Yes No

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

Yes No

maybe

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

Yes No

maybe

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

- very informative - appreciated the doctor's simple explanations to those of us who are not trained in the medical field. This project may very well not only be a life saver for those in a trauma situation but also to those who would not accept a blood transfusion involving real blood cells or whole blood.

Age: 37

Ethnic background: Caucasian

Gender: Male Female

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

Community Consultation
AMC Meeting
10/05/05

Please circle your answers

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

Yes No

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

Yes No

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

Yes No

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

excellent presentation

Age: 70 Ethnic background: white

Gender: Male Female

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

Community Consultation
AMC Meeting
10/05/05

Please circle your answers

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

Yes No

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

Yes No

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

Yes No

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

Age: 56 Ethnic background: _____

Gender: Male Female _____

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

Community Consultation
AMC Meeting
10/05/05

Please circle your answers

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

Yes No

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

Yes No

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

Yes No

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

Age: 62 Ethnic background: Caucasian

Gender: Male Female

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

Community Consultation
AMC Meeting
10/05/05

Please circle your answers

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

Yes No

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

Yes No

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

Yes No

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

Age: 57

Ethnic background: Caucasian / Mohawk

Gender: Male Female

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

Community Consultation
AMC Meeting
10/05/05

Please circle your answers

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

Yes

No

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

Yes

No

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

Yes

No

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

1. Playing God in a way, how is this being handled in the study? Is everyone who is deemed appropriate medically for this study going to receive home care? If so, the other stipulations in study that requires certain race, age, gender subjects be studied;

Age: 48

Ethnic background: Caucasian

Gender: Male Female

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

Community Consultation
AMC Meeting
10/05/05

Please circle your answers

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

Yes No

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

Yes No

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

Yes No

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

Consent Form & helmet device
propose to follow up if absence of pregnant women.

Age: 70 f Ethnic background: CAUCASIAN

Gender: Male Female

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

Albany Medical Center

Website Summary as of October 6, 2005

Total number of responses: 118

	Approve	Decline	Undecided	%Approval
Survey Question 1	105	13	0	89%
Survey Question 2	110	8	0	94%
Survey Question 3	111	7	0	94.1%

Caucasian: 92 (77.9%)

African American: 9 (7.6%)

Asian: 11 (9.3%)

Hispanic: 1 (.84%)

Not Given: 5

Male: 40 (33.8%)

Female: 78 (66%)

Polyheme® Trial Reports

Survey Responses								
Date Entered	Ethnic Group	Gender	Age	Meeting Attended	Survey Question 1	Survey Question 2	Survey Question 3	Comments
09/09/05	Caucasian	F	53	None	Y	Y	Y	impressive product
09/12/05		M						
09/13/05	Caucasian	M	46	None	Y	Y	Y	no
09/13/05	Caucasian	F	67	None	Y	Y	Y	
09/13/05	Caucasian	F	51	None	Y	Y	Y	I really do not see the downside. I am happy to live in an area where there is a possibility that polyheme may be administered in an emergency.
09/13/05	Caucasian	F	51	None	Y	Y	Y	I really do not see the downside. I am happy to live in an area where there is a possibility that polyheme may be administered in an emergency.
09/13/05	Caucasian	F	46	None	Y	Y	Y	
09/13/05	Caucasian	F	55	Albany Medical Center 9/14/2005	Y	Y	Y	Exciting research study!
09/13/05	Caucasian	M	56		Y	Y	Y	Great idea.
09/13/05	Caucasian	F	53	None	Y	Y	Y	
09/13/05	Caucasian	F	51	None	Y	Y	Y	
09/14/05	African American	F	40	None	Y	Y	Y	
09/14/05	Asian	M	28	None	Y	Y	Y	questions about irreversible effects..This could lead to a breakthrough.
09/14/05	Asian	M	34	None	Y	Y	Y	
09/14/05	Caucasian	M	52	None	Y	Y	Y	
09/14/05	Caucasian	F	34	None	Y	Y	Y	
09/14/05	Caucasian	M	38	None	Y	Y	Y	good idea
09/14/05	Caucasian	F	57	None	Y	Y	Y	
09/14/05	Caucasian	F	50	None	Y	Y	Y	
09/14/05	Caucasian	F	55	None	Y	Y	Y	
09/14/05	Caucasian	F	54	None	Y	Y	Y	can you give it through a dialysis catheter?
09/14/05	Caucasian	F	33	None	Y	Y	Y	
09/14/05	Caucasian	F	45	None	Y	Y	Y	
09/15/05	Caucasian	M	55	None	Y	Y	Y	
09/15/05	African American	F	27	None	Y	Y	Y	
09/15/05	Caucasian	F	27	None	N	Y	Y	
09/15/05	Caucasian	M	49	None	Y	Y	Y	
09/15/05	Caucasian	F	49	None	Y	Y	Y	
09/15/05	Caucasian	M	21	None	Y	Y	Y	
09/15/05	Caucasian	F	27	None	Y	Y	Y	
09/15/05	African American	F	57	None	Y	Y	Y	
09/15/05	Caucasian	M	22	None	Y	Y	Y	
09/15/05	Caucasian	F	50	None	Y	Y	Y	
09/15/05	African American	F	43	None	Y	Y	Y	
09/15/05	Asian	M	7	None	Y	Y	Y	
09/15/05	Caucasian	F	32	None	Y	Y	Y	I read the brochure
09/15/05	Caucasian	F	47	None	Y	Y	Y	

09/15/05	Caucasian	M	53	None	Y	Y	Y	Why is it taken so long to come here?	
09/16/05	African American	F	48		Y	Y	Y		
09/16/05	Caucasian	M	48	None	Y	Y	Y		
09/16/05	Caucasian	F	39	None	Y	Y	Y		
09/16/05	Caucasian	F	29	None	Y	Y	Y		
09/16/05	Caucasian	M	43	None	Y	Y	Y		
09/16/05	Caucasian	M	31	None	Y	Y	Y		
09/16/05	Caucasian	F	48	None	Y	Y	Y		
09/16/05	Caucasian	F	39	None	Y	Y	Y		
09/16/05	Caucasian	M	42	None	Y	Y	Y		
09/16/05	Caucasian	F	25	None	Y	Y	Y		
09/16/05	Caucasian	M	28	None	Y	Y	Y		
09/16/05	Caucasian	M	71	None	Y	Y	Y		
09/16/05	African American	M	32	None	Y	Y	Y		
09/16/05	Caucasian	M	45	None	Y	Y	Y		
09/19/05	Caucasian	F	33	None	Y	Y	Y		
09/19/05	Caucasian	F	41	None	Y	Y	Y		sounds like a great alternative
09/19/05	Asian	F	39	None	Y	Y	Y		
09/19/05	Caucasian	F	28	None	Y	Y	Y		
09/19/05	Asian	F	30	None	Y	Y	Y		
09/19/05	Caucasian	F	46	None	Y	Y	Y		
09/19/05	Caucasian	F		None	Y	N	Y		
09/19/05	Asian	F	26	None	N	Y	Y		
09/20/05	Caucasian	F	37	None	Y	Y	Y		
09/20/05	Caucasian	F	54	None	Y	Y	Y	good luck	
09/20/05	African American	F	47	None	Y	Y	Y		
09/20/05	Hispanic	F	51	None	Y	Y	Y		
09/20/05	Caucasian	M	48		Y	Y	Y	religious affiliation refusal how identified? I support this study, even in light of the informed consent exception.	
09/20/05	Caucasian	M	39	None	Y	Y	Y		
09/20/05	Caucasian	M	38	None	Y	Y	Y		
09/21/05	Asian	M	23	None	Y	N	N	Sounds like a great blood product substitute.	
09/21/05	Asian	F	39	Albany Medical Center 9/14/2005	Y	Y	Y		I think this is a good product with relatively few side effects.
09/21/05	Asian	M	40	Albany Medical Center 9/14/2005	Y	Y	Y		
09/22/05	Caucasian	F	44	None	Y	Y	Y		
09/22/05	Caucasian	M	29	None	Y	Y	Y		
09/22/05	Caucasian	M	26	None	Y	Y	Y		
09/22/05	Caucasian	F	36	Albany Medical Center 9/14/2005	Y	Y	Y		
09/22/05	Caucasian	F	38	None	N	Y	Y	none	
09/22/05	African American	F	25	None	N	Y	Y	no	
09/22/05		M	57						
09/22/05		F	57		N	N	N		
09/22/05		F	57		N	N	N		
09/22/05		F	57		Y	Y	Y		

09/22/05	Caucasian	F	24	None	Y	Y	Y	
09/23/05	Caucasian	F	23	None	Y	Y	Y	
09/23/05	Caucasian	M-	21	None	Y	Y	Y	
09/23/05	Caucasian	M-	18	None	Y	Y	Y	
09/23/05	Caucasian	F	52	None	Y	Y	Y	NO
09/23/05	Caucasian	F	52	None	Y	Y	Y	NO
09/23/05	Caucasian	F	35	None	Y	Y	Y	
09/23/05	Caucasian	F	47	None	Y	Y	Y	Good Luck.
09/23/05	Caucasian	F	39	None	Y	Y	Y	I hope that this study shows that the use of PolyHeme decreases morbidity and mortality. I think it is a brilliant idea.
09/23/05	Caucasian	F	47	Albany Medical Center 9/14/2005	Y	Y	Y	
09/23/05	Caucasian	F	45	None	Y	Y	Y	
09/23/05	Caucasian	M-	25	None	Y	Y	Y	
09/23/05	Caucasian	M-	25	None	Y	Y	Y	Hopefully it works and increases our ability to help patients.
09/23/05	Asian	F	42	None	N	N	N	
09/23/05	Caucasian	F	36	None	Y	Y	Y	
09/23/05	Caucasian	F	27	None	N	Y	Y	
09/23/05	Caucasian	F	46	None	Y	Y	Y	
09/23/05	Caucasian	F	35	None	Y	Y	Y	
09/23/05	Caucasian	F	27	None	Y	Y	Y	
09/23/05	African American	M-	40	None	N	N	N	
09/23/05	Asian	F	36	None	N	Y	Y	
09/23/05	Caucasian	F	54	None	Y	Y	Y	
09/24/05	Caucasian	F	40	None	Y	Y	Y	
09/24/05	Caucasian	F	57	None	Y	Y	Y	I would be concerned that, after receiving numerous units of this product, that the blood testing (including blood typing) would be affected or possibly inaccurate.
09/24/05	Caucasian	F	43	None	Y	Y	Y	
09/25/05		M-	24	None	Y	Y	Y	
09/26/05	Caucasian	M-	45	None	Y	Y	Y	
09/26/05	Caucasian	F	53	None	Y	Y	Y	
09/27/05	Caucasian	F	24	None	Y	Y	Y	I would need to know more about the bad effects before a definite yes would be given
09/29/05	Caucasian	F	28	None	Y	Y	Y	
09/30/05	Caucasian	M-	54	Albany Medical Center 9/14/2005	Y	Y	Y	
10/04/05	Caucasian	M-	57	None	Y	Y	Y	Good luck!
10/04/05	Caucasian	F	33	None	N	N	N	
10/05/05	Caucasian	F	48	None	Y	Y	Y	This may provide a breakthrough in trauma care.
10/05/05	Caucasian	F	48	None	Y	Y	Y	
10/05/05	Caucasian	F	54	None	N	Y	Y	If this study were broadly made public so alot of people knew about it, I like the idea. But if someone didn't know about it, and it was used it seems wrong to me.
10/05/05	Caucasian	F	59	None	Y	Y	Y	
10/06/05	Caucasian	M-	36	None	Y	Y	Y	

10/06/05	Caucasian	M	48	None	N	N	N	Informed consent is a critical part of any experimental regimen and, regardless of the goals of the program, cannot be eliminated or minimized.
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Requesting Contact								
Date Entered	Ethnic Group	Gender	Age	Meeting Attended	How Contacted	Phone number	Email	Question

$\frac{1A}{Q1 - 11\% \text{ dis.} = 89\%.$
 $Q2 - 6\% = 94\%$
 $Q3 - 5.9\% = 94.1\%$

C.



Study Dedicated Phone Line - (518) 262-2828

Our dedicated phone line has been active since September 7, 2005.
However, we have received a total of **5 phone messages**, of which only 3 were relevant to the study.

- 1) A question as to whether this would be good for someone who receives frequent blood transfusions?
- 2) A request for bracelets from a Jehovah Witness (75 miles south of Albany).
A second call to confirm his address and number of requested bracelets.
- 3) Media group looking for a medical stories, group based in Florida
- 4) Gentlemen from a financial organization wanting to know if this was a private company.
- 5) A request for more information about the study.

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From: "Boardman, Caroline" <boardmac@union.edu>
To: "Susan Rauch" <RauchS@mail.amc.edu>
Date: Wed, Sep 14, 2005 1:06 PM
Subject: RE: AMC Polyheme Study

Hi Susan,
Sorry for the delay in my response. I have sent your info Carol Weiss, our Director of the Health Profession Program here at Union College. I don't think we can put your press release on our website, however, if our students participate, I can write a short article and include a link to your website, etc.

Thanks,
Caroline

Caroline Boardman
Communications Specialist
Office of Communications
Union College
Schenectady, NY 12308
boardmac@union.edu
<http://www.union.edu/News/>
phone: 518.388.6490 / 518.388.6131
fax: 518.388.6514

-----Original Message-----

From: Susan Rauch [mailto:RauchS@mail.amc.edu]
Sent: Monday, September 12, 2005 12:15 PM
To: Boardman, Caroline
Subject: AMC Polyheme Study

Caroline,

Albany Medical Center is one of several Level I trauma centers in the US considering participation in a clinical study to evaluate the life sustaining potential of an investigational product in the treatment of severely injured patients who are bleeding and in shock. A prerequisite for this approval is public disclosure and community consultation due to the inability to obtain prestudy consent.

The college age group is considered a target population for trauma and we want to be certain that they are included in the community consultation process.

I believe the best method would be through the local college's web/news pages. Our information/opinion line and web site are listed below and attached is the AMC press release.

Information Line: 262-2828
Web page: www.amc.edu/polyheme

Please let me know if any form of this would be possible and can I place information brochures in your student union?
Thank you again for your help!

Susan Rauch, RN
Study Coordinator
518-262-6608

Copies also sent to RTI and SUNY Albany - No response

From: Bob Kimmerle <bkimmerl@skidmore.edu>
To: "Susan Rauch" <RauchS@mail.amc.edu>
Date: Wed, Sep 14, 2005 9:05 AM
Subject: Re: AMC Polyheme Study

Susan: Thanks for sending along the Polyheme information. While this posting won't work on our top level pages, I will forward it to our Health Services office for possible inclusion on their site. I'll send it off to them this morning.

-Bob Kimmerle
On Sep 12, 2005, at 11:40 AM, Susan Rauch wrote:

> <09.07.05 PolyHemeRELEASE1.doc>

CC: Paul Dwyer <pdwyer@skidmore.edu>

From: "Eric J. Bryant" <bryaneri@hvcc.edu>
To: "Susan Rauch" <RauchS@mail.amc.edu>
Date: Mon, Sep 19, 2005 8:32 AM
Subject: RE: AMCPolyheme STudy

Susan,
We would be happy to help you spread the word about this study to students here at Hudson Valley Community College. I will forward your information to our internal web portal where students look for information from the college. Also, if you would like, feel free to send over some brochures that I can bring to our student affairs office.

Eric Bryant
Assistant Director of Communications and Marketing
Hudson Valley Community College
518-629-8072
bryaneri@hvcc.edu

-----Original Message-----

From: Susan Rauch [mailto:RauchS@mail.amc.edu]
Sent: Monday, September 12, 2005 12:34 PM
To: bryaneri@hvcc.edu
Subject: AMCPolyheme STudy

Dear Mr. Bryant,

Albany Medical Center is one of several Level I trauma centers in the US considering participation in a clinical study to evaluate the life sustaining potential of an investigational product in the treatment of severely injured patients who are bleeding and in shock. A prerequisite for this approval is public disclosure and community consultation due to the inability to obtain prestudy consent.

The college age group is considered a target population for trauma. We want to be certain that they are included in the community consultation process and that they are informed and have the opportunity to voice their opinion.

I believe the best method would be through the local college's web/news pages. Our information/opinion line and web site are listed below and attached is the AMC press release.

Information Line: 262-2828
Web page: www.amc.edu/polyheme

Please let me know if any form of this would be possible and can I place information brochures in your student union?

Thank you again for your help!

Susan Rauch, RN
Study Coordinator
518-262-6608
fax: 518-262-3661
rauchs@mail.amc.edu

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

Please circle your answers

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

Yes No

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

Yes No

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

Yes No

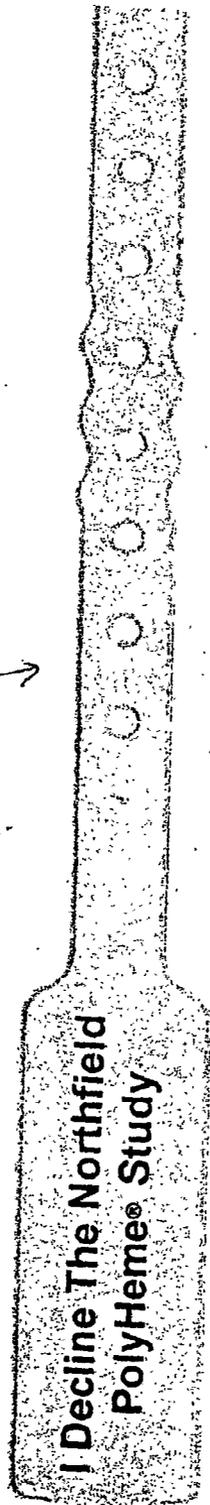
4. Do you have any comments or concerns you wish to share with the investigators?

Age: _____ Ethnic background: _____

Gender: Male _____ Female _____

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

Bracelets
will be
available →
for those
who wish to
have them.



QUESTIONS
&
ANSWERS
POLYHEME®
TRAUMA
TRIAL

← Small
Brochures
with
Questions
&
Answers
about
Polyheme



Albany
Medical
College



PolyHeme® Trauma Trial Information

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

Upcoming Events Employment Where to Find Us Telephone Directory



Albany Medical Center Home Page

Polyheme® Trial

QUESTIONS AND ANSWERS POLYHEME® TRAUMA TRIAL

Why is this study being conducted?

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

What is the title of this study?

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

What is PolyHeme®?

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

What is the design of this study?

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

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

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

What is hemorrhagic shock?

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

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

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

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

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

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

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

Who is eligible for the study?

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

Who will be excluded from the study?

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

How many patients will be enrolled in the study?

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

Has enrollment begun anywhere?

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

How will patient safety be assured in this trial?

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

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

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

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

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

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

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

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

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

What is an exception from informed consent?

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

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

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

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

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

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

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

Who grants such exceptions?

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

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

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

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

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

What are the potential benefits of PolyHeme®?

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

What are the potential risks of PolyHeme®?

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

How much will it cost patients to participate?

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

Will patients get paid to participate?

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

Who is the manufacturer of PolyHeme®?

Northfield Laboratories Inc., Evanston, IL. For more information, visit www.northfieldlabs.com
April 8, 2005

- [Click here for information about community meetings](#)
- [Click here for regulations permitting an exception from informed consent](#)
- [Click here for frequently asked questions about the study](#)
- [Click here to provide your opinion about the study](#)
- [Click here to contact the Study Coordinator](#)
- [Click here to go back to PolyHeme home page](#)

43 New Scotland Avenue
Albany, NY 12208

E-mail the AMC Webmaster



Webmaster@mail.amc.edu

See your health care provider for specific medical advice. AMC takes no responsibility for content provided at external link sites.

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14 Sample
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Jw

Sent to
10 local
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Meeting
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10/25/05



Albany Medical College
Department of Surgery
Section of Trauma, Critical Care, General & Laparoscopic Surgery

47 New Scotland Avenue, Mail Code 61GE, Albany, New York 12208-3479

(518) 262-5793

Fax: (518) 262-5560

Appointments: (518) 262-5623

David H. Kuchler, M.D., F.A.C.S.
Carl Rosati, M.D., F.R.C.S.C., F.A.C.S.
Hashim Hesham, M.D.
Joseph Pfeifer, M.D., F.A.C.F.A.S.

September 7, 2005

Rensselaer Congregation Kingdom Hall
Third Ave. Extension
Rensselaer, NY 12144

Dear Kingdom Hall,

The Albany Medical Center Hospital has been chosen to be one of several level one trauma centers to conduct a research study using PolyHeme[®], an investigational temporary oxygen-carrying red blood cell substitute, to evaluate its safety and efficacy in severely injured and bleeding patients. We feel it is important to inform you and other Kingdom Halls in the area of this research study because patients in this study will be randomized at the scene of injury to receive either PolyHeme (experimental treatment) or the standard of care (salt water and donated blood) without obtaining their informed consent to participate in the study. We take into strong consideration your beliefs and feel as though you should be informed about the study and how it works.

Most importantly, we want you to know that one of the exclusion criteria for the study is a known objection to blood transfusions. Therefore, this study will not enroll Jehovah's Witnesses, provided that the paramedics can identify you as such, because the investigators recognize that you cannot be randomly assigned to receive blood upon arrival to the hospital. In addition, we recognize that choosing to accept PolyHeme would be a matter of personal conscience since it is made from human hemoglobin, and in the event that you suffer a traumatic injury, you would most likely be physically and emotionally unable to make this decision. It is important that you identify yourself as a Jehovah's Witness (card, bracelet, etc.) so that, if you are injured, you are not accidentally enrolled into this study.

The purpose of this study is to evaluate the efficacy and safety of PolyHeme as a temporary oxygen-carrying red blood cell substitute in the prehospital setting where blood is not available and continuing for the 12-hour post-injury period in the hospital where blood will be used as the comparator.

April, 2005

In Albany, PolyHeme will be carried on medical evacuation flights and some ambulances and will begin to be infused in the prehospital setting to those patients randomized in accordance with the study plan.

As mentioned above, subjects can be enrolled into this research study without providing their informed consent. Regulations established by the Federal Government, (21 Code of Federal Regulations 50.24) specifies the conditions under which an exception from informed consent can be granted so that, in emergency situations, research can be carried out even when consent is not possible because of the nature and extent of the patients injuries.

If you would like to learn more about this study, or if you have any questions or concerns, please feel free to contact me or my study coordinator at anytime.

Sincerely,

A handwritten signature in black ink, appearing to read 'Carl Rosati', enclosed within a circular scribble.

Carl Rosati, MD
Director, Section of Trauma, Division of General Surgery
Albany Medical Center Hospital
518-262-2828
www.amc.edu/polyheme

April, 2005