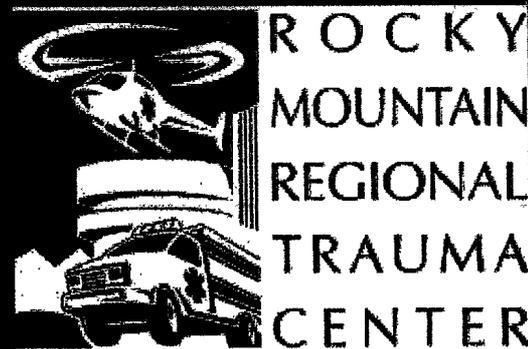




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DENVER HEALTH

Level One Care for ALL

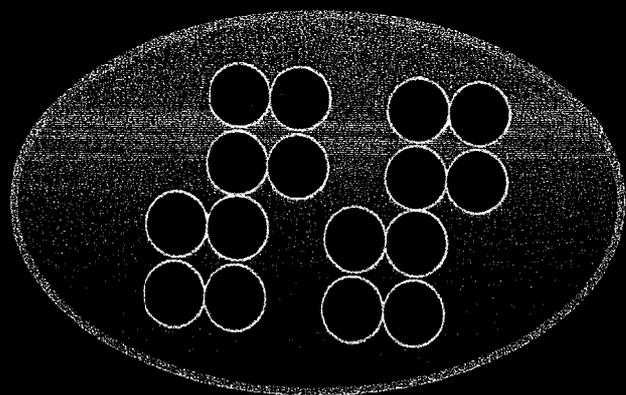
Denver Health PolyHeme Research Team

- **Jeffrey Johnson, M.D., Co-Investigator**
- **Jeffrey Long, R.R.T., Clinical Trials Coordinator**
- **Chris Colwell, M.D., Medical Director Paramedic Division**
- **Jim Manson, NREMT-P Clinical Coord., Paramedic School**
- **Dee Martinez, Director, Marketing Communications**

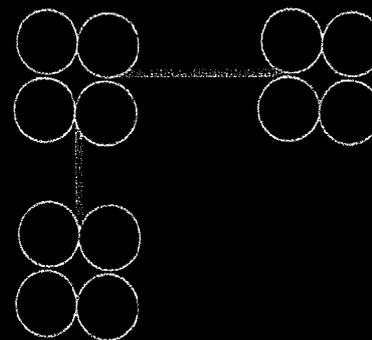
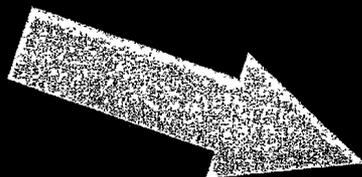
Study Purpose

To evaluate the life saving potential of a blood substitute ... when given to severely injured patients who have suffered major blood loss ...

What is a "Blood Substitute"



Red Blood Cell Substitute



Hemoglobin Based Oxygen Carrier

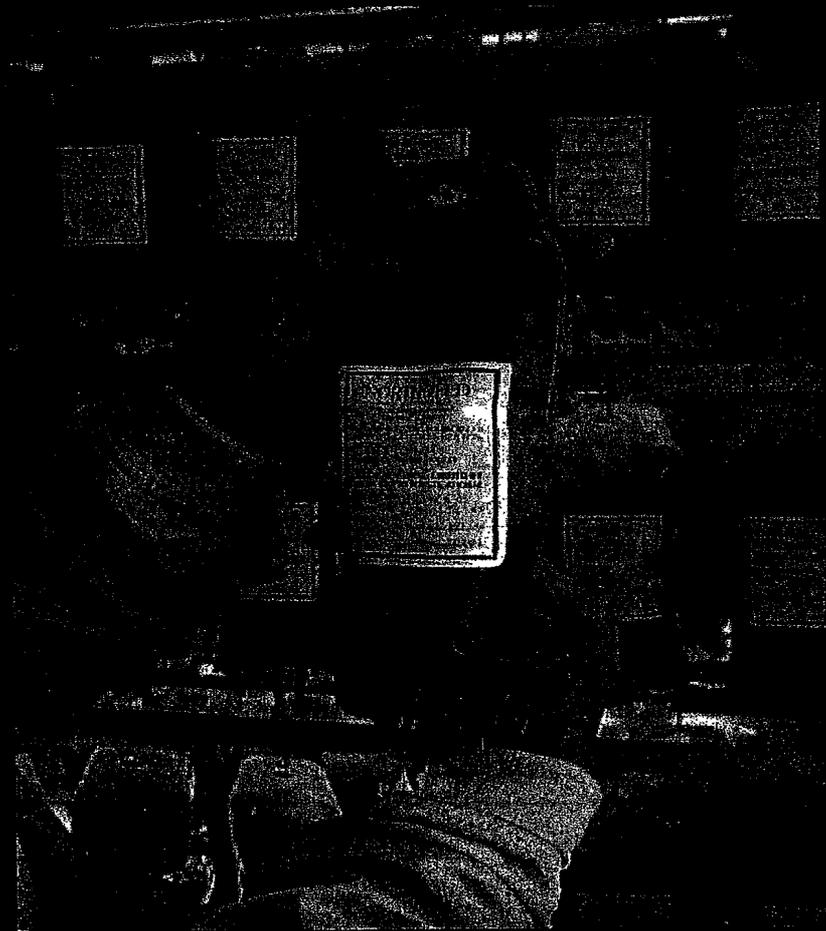
What is PolyHeme[®]?

*A blood substitute
... that carries
oxygen as
efficiently as stored
blood, using
hemoglobin ...
derived from
outdated human
blood.*



What are the advantages of PolyHeme[®]?

- **Compatible with all blood types; therefore it is immediately available**
- **Can be given using a standard I.V. in the arm**



Why Use PolyHeme[®]?

*To treat blood loss
when stored blood is not available*

*Blood is not available
in the ambulance*



Why a Civilian Ambulance Trial?

- **The Center for Disease Control (CDC) lists trauma as the leading cause of death among Americans from 1 - 44 years of age**
- **More than 150,000 trauma patients die each year in the United States**
- **Many of these patients die because the "standard of care" cannot reverse the damaging effects of hemorrhagic shock**

What is the Standard of Care at the Scene and in the Ambulance?

Sterile Salt Water (Saline)



Limitation: Salt water does not carry oxygen

Without oxygen ... internal organs do not function properly ... and severely injured patients may die

A Decade of PolyHeme[®] Experience

**171 trauma patients at Denver Health have
shown that PolyHeme[®]**

- **Carries as much oxygen as blood
(1 unit of PolyHeme[®] = 1 unit of blood)**
- **Reduces need for stored blood**
- Has replaced up to two times a person's
entire blood volume (2 x 10 units = 20 units)
with no organ damage

How will this Study be Done?

Severely injured trauma patients will be assigned to either one of two groups by chance

50%

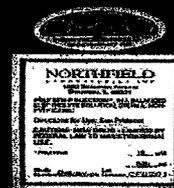
50%

Control

Receive salt water

Test

Receive PolyHeme[®]



How will this Study be Evaluated?

50%

50%

Receives Salt Water

Receives PolyHeme

Primary Endpoint

Increased Survival at 30 days

Secondary Endpoints

Reduce use of stored blood

Reduce multiple organ failure

Reduce adverse events

Who Would Be Included in this study?

- **At least 18 years old**
- Sustained severe injuries
- **Lost a large amount of blood**
-

What is Hemorrhagic Shock?

Hemorrhagic: Massive blood loss

Shock: Dangerously low blood pressure

Internal organs don't receive enough oxygen

May cause death

What is the Primary Purpose of this Presentation?

**Application has been made to the
Colorado Multiple Institutional Review Board
to approve an**

Exception from Informed Consent Requirements

for this clinical trial.

Informed Consent

Traditionally required for all research studies that compare two treatments (standard vs. test)

Patients are informed of the potential risks and benefits associated with treatments

Patients choose whether to participate in the study

Exception from Informed Consent

Patients are enrolled in a research study without requiring their informed consent

How can that occur?

A federal regulation (21 CFR 50.24), created in 1996, allows certain studies that meet the following criteria to use this exception

- Patients lives must be at risk
 - Participation in the research could provide a direct benefit to the patient
- Patients are unable provide informed consent
 - The research could not practicably be carried out without an exception from informed consent
- Potential risks of new treatment are reasonable
 - Available treatments are not satisfactory

Potential Benefits of PolyHeme[®]

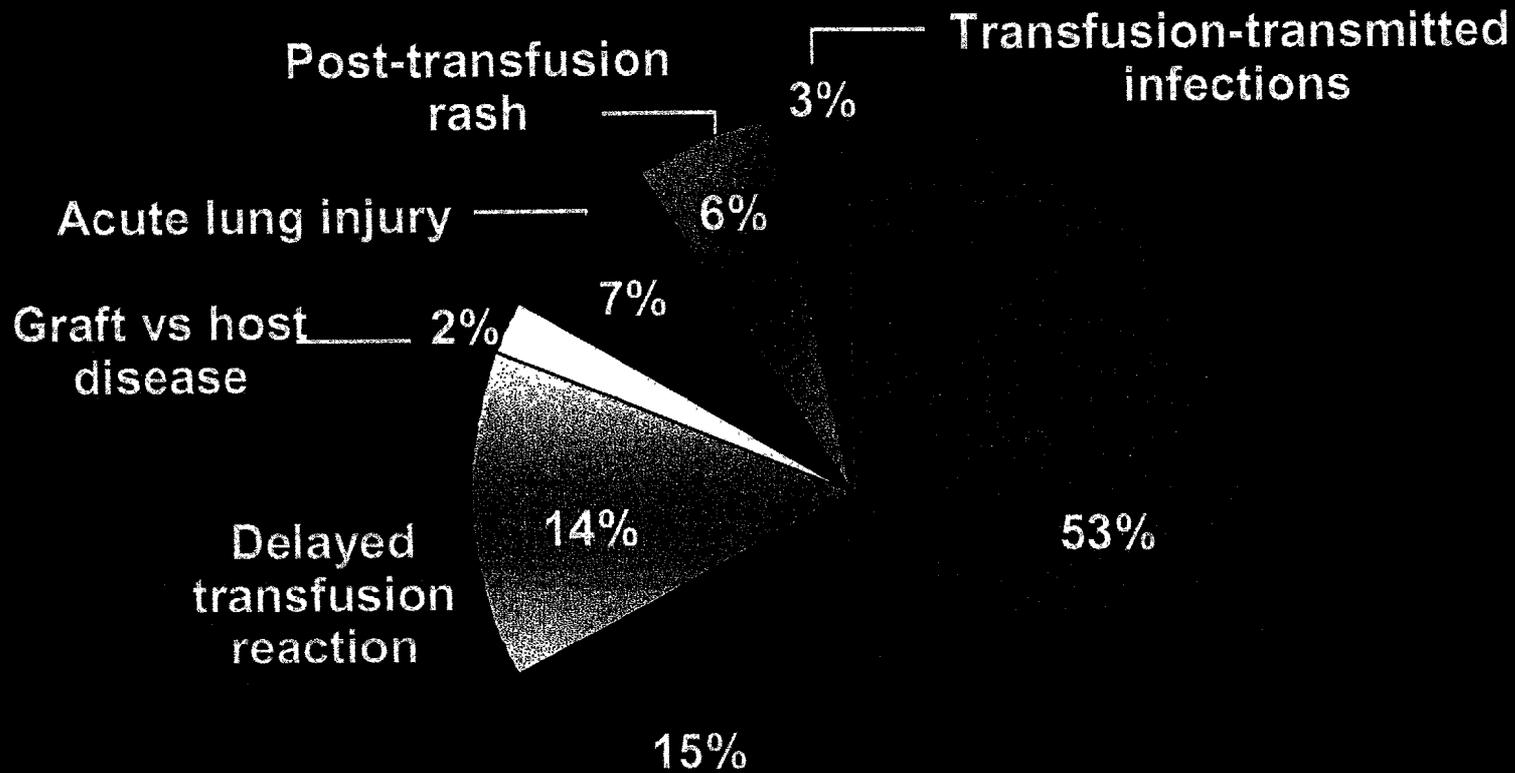
Increase the likelihood of survival because:

- Immediately available
- Carries oxygen to vital organs
- Reduces the need for stored blood

Potential Risks of PolyHeme[®]

- **Rash**
- **Increased blood pressure**
- **Kidney or liver damage**
- **Viral infection (HIV, hepatitis, etc.)**
-

Serious Hazards of Transfusion



Data Safety Monitoring Board

**After 60, 120, 240, etc., patients enrolled
... an independent DSMB will
completely evaluate ALL patients from
both the standard and test groups for
unexpected outcomes.**

Right of Refusal

Subjects who wish to not be included in this clinical trial ... may indicate their preference not to participate by means of a “Medic Alert” bracelet or a signed note kept with their identification.

*For Further Information or to
offer opinion, please contact:*

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www.denverhealth.org

then click on “Physician Research”

(www.denverhealth.org/

TraumaCenter/Polyheme.aspx)

or

www.northfieldlabs.com



Questions
or
Comments?

