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Docket Number 95S-0158
Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr. rm. 1-23
Rockville, MD 20857

RE: Investigational New Drug Application #6859

Dear Sir/Madam:

In accordance with 21 CFR §312.54 we are enclosing copies of information concerning research involving an exception to informed consent. This includes information that has been publicly disclosed by the IRBs at Akron General Medical Center, Akron, OH, University Medical Center, Las Vegas, NV, and Temple University Hospital, Philadelphia, PA. Additional information from Lehigh Valley Hospital, Allegheny General Hospital, and Hershey Medical Center is also included.

Akron General Medical Center

The public disclosure/community consultation information from Akron General Medical Center includes: an outline of a presentation by the Principal Investigator to the members of the Board of Directors of Akron's Victims Assistance Program (Attachment 1) and the summary notes from this board meeting (Attachment 2); a copy of the Akron General Medical Center's Web Page with information describing the clinical study (Attachment 3); a news release announcing the start of the study posted on the hospital's Web site (Attachment 4); an article that appeared in the September 1997 edition of *Physicians IN GENERAL*, a newsletter for the Medical Staff of Akron General Medical Center (Attachment 5); an article that appeared in the Summer/Fall 1997 edition of *Developments*, an Akron General publication, which is distributed to physicians and staff (Attachment 6); an article that appeared in the October-November-December 1997

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edition of *Voice*, a hospital newsletter (Attachment 7); an article that was published in a local newspaper, *Akron Beacon Journal*, on September 23, 1997 (Attachment 8); and a copy of an advertisement announcing the study that appeared in the following local newspapers on the following dates (Attachment 9):

Akron Beacon Journal June 19, 24, 1997; September 18, 23, 1997; November 20, 25, 1997
West Side Leader June 19, 26, 1997; September 11, 18, 1997; November 20, 27, 1997
The Green Leader June 19, 26, 1997; September 11, 18, 1997; November 20, 27, 1997
Tallmadge Express June 22, 29, 1997; September 14, 28, 1997; November 23, 1997, December 7, 1997
Cuyahoga Falls News Press June 22, 29, 1997; September 14, 28, 1997; November 23, 1997, December 7, 1997
Hudson Hub Times June 22, 29, 1997; September 14, 28, 1997; November 23, 1997, December 7, 1997
Stow Sentry June 22, 29, 1997; September 14, 28, 1997; November 23, 1997, December 7, 1997
The Suburbanite June 23, 30, 1997; September 18, 25, 1997; November 20, 27, 1997
The Reporter June 24, 1997; September 16, 30, 1997; November 25, 1997; December 9, 1997

In addition, information about the clinical study was released to local radio stations (WAKR, WONE, WQMX, WNIR, WKDD) (Attachment 10), signs of notification of the study were posted in the Emergency Department waiting room (sign not included), and a review of the protocol was made to all departments, to inform Akron General physicians and staff of the study.

In summary, based on the information received from the clinical site, the investigator and IRB of Akron General Medical Center achieved community consultation by presenting study information to members of the Board of Directors of Akron's Victims Assistance Program (Attachment 1 and 2), posting study information on the hospital's Web Page that included a request for comments via either e-mail or telephone (Attachment 3 and 4), publishing an advertisement that appeared in various local newspapers, also soliciting comments and offering a phone number with a dedicated voice mailbox for responses (Attachment 9), placing articles and announcements of the study in various hospital publications (Attachment 5, 6, and 7), and by posting notifications of the study in the waiting room of the Emergency Room.

University Medical Center

The public disclosure/community consultation information from the University Medical Center includes a Public Notice for the study and notice for the Public Hearing that was published in local Las Vegas newspapers, *Las Vegas Review Journal*, and *Las Vegas Sun* on September 26, 27, and 28, 1997, (Attachment 11) and *El Mundo* on September 27, 1997 (Attachment 12), a flyer announcing the Public Hearing that was posted in the required areas around the city as defined by the Notice Provisions of Nevada's Open Meeting Law (Attachment 13), a flyer announcing the Grand Rounds, presented by Dr. Edward P. Sloan, national physician investigator for DCLHb, that was distributed through the University system and posted in the Government Center, the Oncenter, City Halls, and Health Districts (Attachment 14), minutes from an Administrative Meeting on June 4, 1997, which included discussion of the study (Attachment 15), a press release (Attachment 16) and the list of where it was sent (Attachment 17), a copy of a letter that was sent to the area Jehovah's Witnesses Congregations announcing the Public Hearing (Attachment 18) and a list of the congregations to which the letter was sent (Attachment 19). Included with the letters to the various congregations was a copy of the Public Notice (Attachment 11) and the flyer announcing the Public Hearing (Attachment 13). Also included in this submission is a copy of a letter that was sent to STOP D.U.I. (MADD) announcing the Public Hearing (Attachment 20). A copy of the Public Notice (Attachment 11) and the flyer announcing the Grand Rounds (Attachment 14) were included with the letter.

In summary, based on information received from the clinical site, the investigator and IRB of University Medical Center achieved community consultation by publishing in both English and Spanish, a Public Notice advertising the Public Hearing to discuss the study in local newspapers (Attachment 11), and also distributing flyers advertising the Public Hearing (Attachment 13) and Grand Rounds (Attachment 14). Additionally, both the Public Notice and the flyer advertising the Public Hearing solicited communication from the public and offered a phone number for questions and comments.

Temple University Hospital

The public disclosure/community consultation information from Temple University Hospital includes an advertisement that was published in the December issue of *Temple Neighbors*, a community newsletter from Temple University Health Sciences Center (Attachment 21), and also in two local newspapers, *Girard Home News* on October 23, 1997 (Attachment 22), and *Philadelphia New Observer* on October 22, 1997 (Attachment 23).

Also included in this submission is a summary of six community meetings that were held to provide the public with an opportunity to ask questions regarding the study (Attachment 24), and the handout that was distributed to attendees of the meeting (Attachment 25).

In summary, based on information received from the clinical site, the investigator and IRB at Temple University Hospital achieved community consultation by publishing advertisements in community newsletters (Attachment 21) and local newspapers (Attachments 22 and 23), and by holding various community meetings (Attachments 24 and 25).

Sites Previously Submitted - Additional Information

This submission also contains additional Public Disclosure/Community Consultation information from sites previously submitted. This information is as follows: for Lehigh Valley Hospital in Allentown, PA, an article published in the March/April 1997 edition of a hospital newsletter, *Healthy You* (Attachment 26) and an article published October 6, 1997 in a local newspaper, *The Morning Call* (Attachment 27); for Allegheny General Hospital, in Pittsburgh, PA, a flyer that was posted in the fall of 1997 in municipal buildings, libraries, and churches (Attachment 28), and transcripts of local news broadcasts that aired December 1996 (Attachment 29) and July 1997 (Attachment 30); for Hershey Medical Center in Hershey, PA, an article that appeared in a hospital publication, *Penn State Medicine Quarterly Magazine* (Attachment 31); and for Albert Einstein Medical Center in Philadelphia, PA, an article that was published in a local newspaper on September 3, 1997, *Philadelphia New Observer* (Attachment 32).

The submission has been organized as follows:

Akron General Medical Center

- Attachment 1: Outline of presentation to Board Members of Akron's Victims Assistance Program, June 9, 1997
- Attachment 2: Summary notes from June 3, 1997 presentation to Board Members of Akron's Victims Assistance Program
- Attachment 3: Akron General Medical Center's Web Page (www.agmc.org)
- Attachment 4: September 15, 1997 news release posted on Akron General Medical Center's Web Page
- Attachment 5: September 1997 article in *Physicians IN GENERAL*
- Attachment 6: Summer/Fall 1997 article in *Developments*
- Attachment 7: October-November-December 1997 article in *Voice*
- Attachment 8: September 23, 1997 article in *Akron Beacon Journal*
- Attachment 9: Advertisement published in several local newspapers
- Attachment 10: Study information released to local radio stations

University Medical Center

- Attachment 11: Public Notice and notice for Public Hearing published in local newspapers, September 26, 27, 28, 1997
- Attachment 12: Public Notice and notice for Public Hearing published in local Spanish, newspaper on September 27, 1997
- Attachment 13: Flyer announcing Public Hearing
- Attachment 14: Flyer announcing Grand Rounds
- Attachment 15: Minutes from Administrative Meeting, June 4, 1997
- Attachment 16: September, 1997 press release
- Attachment 17: List of addresses where press release was sent
- Attachment 18: Letter sent to area Jehovah's Witnesses Congregations
- Attachment 19: List of Jehovah's Witnesses congregations where letter was sent
- Attachment 20: Letter sent to STOP D.U.I. (MADD)

Temple University Hospital

- Attachment 21: December advertisement in *Temple Neighbors*
- Attachment 22: October 23, 1997 article in *Girard Home News*
- Attachment 23: October 22, 1997 article in *Philadelphia New Observer*
- Attachment 24: Summary of six community meetings
- Attachment 25: Handout distributed to attendees of meetings

Lehigh Valley Hospital

- Attachment 26: Article from March/April 1997 edition of hospital newsletter, *Healthy You*
- Attachment 27: October 6, 1997 article in local newspaper, *The Morning Call*

Allegheny General Hospital

- Attachment 28: Flyer that was posted in municipule buildings, libraries, and churches
- Attachment 29: Transcript of December 1996 local news broadcast
- Attachment 30: Transcript of July 1997 local news broadcast

Hershey Medical Center

- Attachment 31: Article from hospital publication, *Penn State Medicine Quarterly Magazine*

Albert Einstein Medical Center

- Attachment 32: September 3, 1997 article published in local newspaper, *Philadelphia New Observer*

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This IND (BBIND #6859) is cross-referenced to Baxter's original BBIND #4426 and subsequent amendments.

In accordance with 21 CFR §312.54, this information is also being submitted to the IND file.

If there are any questions concerning this submission, please contact me at (847)270-5313.

Sincerely,



Maulik Nanavaty, Ph.D.
Director Regulatory Affairs
Blood Substitutes Program



Appendix 1

Outline of Presentation to Victims Assistance Program Board of Directors

Background

Previous Law: In order to be enrolled in a research study, the patient, (or their legal guardian) must give "informed consent" BEFORE receiving ANY study drug or experimental treatment.

The Problem: Patients that are critically ill or injured are unable to give consent to any form of treatment thereby eliminating any possibility of performing life saving research on this group of patients.

New Law

In October, 1996, the federal government published new regulations allowing research to be conducted with a "waiver of informed consent" for a very narrow spectrum of research studies in which it was otherwise impossible to obtain the patients' consent.

A key requirement of this waiver process is a "Community Consultation" period followed by a "Public Notification" process. This presentation represents one facet of the Community Consultation process developed by the emergency medicine research division at Akron General Medical Center.

Goal

Our goal is to solicit your input after we have described our proposed study. Your comments will be summarized and forwarded to the Institutional Review Board at AGMC (which has the final authority to allow this study to begin) and to Baxter Healthcare, Inc., the developer of this product.

About the Study

Akron General Medical Center is one of about 40 hospitals participating in a research study (Phase 3 trial) of a new investigational human-derived blood substitute in trauma patients with severe shock.

The purpose of this study is to determine if this therapy can prevent the harmful effects of blood loss due to severe injury more effectively than the current treatments that are available.

Justification

Previous animal studies and limited studies in humans not in shock have shown the solution to decrease the need for repeated blood transfusions.

This research is sponsored by Baxter Healthcare, Inc., and has been approved by the Institutional Review Board (IRB) at AGMC.

Additionally, this clinical trial will be supervised by the FDA as well as an independent safety committee to help safeguard the patients entered into this study.

The Study

Twenty to thirty critically ill patients at our institution, who are in shock will receive either the hemoglobin substitute solution, or regular treatment for this condition. A total of 850 patients will be entered into the study at different sites throughout the United States. Patients who may be entered into the study include men and women greater than 18 years of age in severe shock.

Patients not in severe shock; children, known Jehovah's Witnesses or those patients who have previously expressed a desire to not receive blood products would not be entered into the study.

All patients will receive all standard treatments, including blood if needed. Possible side effects of receiving the hemoglobin substitute that MAY possibly occur include: high blood pressure, yellowing of the skin, stomach, back and muscle pain, nausea and vomiting.

The maximum amount of study solution any single person would receive would be one liter or about 2 pints.

Expected Benefits

If the study drug works as predicted, a 25% decrease in mortality is expected in those patients receiving the study solution.

Attachment 2

FURNACE STREET MISSION, INC.
BOARD MEETING
JUNE 3, 1997

Meeting was opened with prayer by Bob Denton at 5:02 p.m.

MINUTES OF PREVIOUS MEETING: Marvin Shapiro made a motion to accept them as mailed with a second by Carol Dezso. It was carried by the Board.

FINANCIAL REPORT: Treasurer, Tim Malloy, said there was nothing out of the ordinary in expenses. We are 3% under plan. Key Trust Investments for the Mission are \$83,300.00. Tim Malloy moved we accept the financial statement for March/April. It was seconded by Sandy Selby and carried by the Board.

DIRECTOR'S REPORT: Bob Denton told of a time change for our daily broadcasts to 1 p.m. He also shared that May Denton had been awarded an honor by the Akron Area Realtors - Women for all she has done and continues to do in this community. She was pleased and of course Bob was very proud of her. She also got \$500.00 from the group for the Mission.

No new business so the FSM Board meeting adjourned.

VICTIM ASSISTANCE PROGRAM, INC.
BOARD MEETING
JUNE 3, 1997

MINUTES OF PREVIOUS MEETING: Marvin Shapiro moved to accept the Minutes as received. There was a second by Alberta Hensley and carried by the Board.

FINANCIAL REPORT: Tim Malloy stated that on the grant side we received \$3,000 from B. F. Goodrich - we are lagging year to date on grants. Local and Public contracts are behind but we have received \$75,000 from County. We are behind on paper work to get those funds but we have corrected that and Bob added we expect about \$11,000.00. Thru April - 3% under plan but that should correct itself on May's. We may end up over budget on Personnel and bookkeeper is checking that. The three trusts/investments for VAP as of May 31st - \$684,427. Tim Malloy made a motion to accept the Financial report as presented with a second by Marvin Shapiro and carried by the Board.

PRESENTATION BY JIM DOUGHERTY: He brought a new policy concerning health care and trauma patients in the emergency rooms. He discussed fully the issue and took questions from the Board and answered each one. He also wrote down the questions asked so he can present it to his board. Jim is in charge of research at AGMC. They plan to look at patients who are in severe trauma. These patients would not be able to make or understand what a doctor says which is where the "waiver of informed consent" comes in. This type thing has never been done before. It would enable them to use a human-derived blood substitute. He explained the study *completely*.

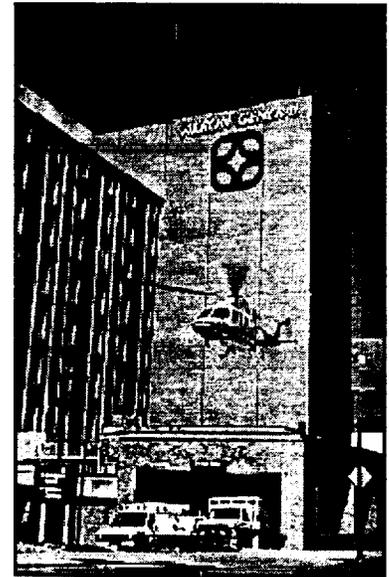
Akron General Studies New Treatment for Patients with Severe Blood Loss

[Click here for more information](#)

Department of Emergency Medicine

Akron General Medical Center

- An Overview
 - EMS Medical Control
 - Renovations and Innovations
- Regional Trauma Care
 - Patient Care
 - Education and Prevention Programs
 - Disaster Planning
- Emergency Medicine Residency Program
 - About the Program
 - Paramedic Education Program
- Emergency Medicine Research
 - Research Direction
 - Publications
 - SuperGroup



An Overview

- 47,651 patients (130/day) were evaluated and treated in Akron General's Emergency Department (ED) in 1995.
- To meet patients' needs, the Emergency Department staff includes 15 board-certified emergency physicians, 18 resident physicians and a physician assistant. Registered nurses, technicians, registration clerks, unit clerks, medical transcriptionists and paramedics complete the ED staff.
- Specialists from other medical subspecialties, social workers and pastoral care personnel are available to provide consultation for Emergency Department patients.
- The Emergency Department contains 26 beds. Most are designed to provide optimal care for patients with cardiac disease or traumatic injuries.
- Special multidisciplinary teams are activated in response to trauma, heart attack and stroke. Members of these teams work together to provide the most up-to-date care available without delay.
- All 15 Emergency Department attending physicians are faculty members who hold clinical teaching appointments at the Northeastern Ohio Universities College of Medicine (NEOUCOM).



Emergency Medical Services Medical Control

- Akron General's Emergency Department is the "Command Center" for Akron Fire EMS. Emergency physicians and paramedics provide 24-hour coverage of the "Radio Room," and are ready to provide support and guidance for EMTs in the field.

- Seven Akron General physicians serve as medical advisors to seven different EMS squads throughout the county, providing ongoing medical direction and continuing medical education.

Renovations and Innovations

Currently under way is a multi-phase expansion of the Emergency Department. Patient bed capacity will be increased from 26 to 31.

The ED has recently integrated a computer-based patient management system, designed to provide an efficient method of directing resources and care to the patient. This new software also provides computer-generated patient discharge instructions, specific to each patient.

Regional Trauma Care

- One of the most valued and life-sustaining services Akron General provides to the area is major trauma care, and we are firmly committed to establishing ourselves as a regional center for excellence in the care of critically injured adults.
- Trauma patient treatment requires that many resources be available at all times. Akron General supports adequate staffing for operating rooms, diagnostic services and rehabilitation services, and recruits high-quality trauma specialists so that medical and surgical needs of a patient are met.
- Akron General educates all health care professionals, from prehospital to rehabilitation settings, regarding the delivery of high-quality trauma care.
- In 1996, 855 major trauma patients were admitted to Akron General, and 74 major trauma patients were transported from area hospitals.
- As a regional primary and tertiary care provider, Akron General provides a continuum of care, from admission into the Emergency Department throughout the period of recovery. Services available include hyperbaric oxygen treatment, referral to Wound Center and Limb Reconstruction Center programs, inpatient and outpatient rehabilitation services, and continued care through our Northeast Ohio Sports Medicine Institute and Health & Wellness Center.



Education and Prevention Programs

- In addition to ensuring quality care and providing continuity, the trauma service is dedicated to providing both professional and community education programs.
- Professional Education Courses:
Trauma Nurse Core Courses (TNCC) are provided three times a year, and are offered to nurses who practice in Northeast Ohio.
 In cooperation with area hospitals, Akron General offers *Advanced Trauma Life Support Courses* twice a year.
Akron/Canton Trauma Conferences are offered on a quarterly basis to provide a multidisciplinary perspective on trauma education. This conference is open to all prehospital care providers, nurses and physicians.
- Public Awareness and Prevention Programs
 Akron General is working with *Summit County Safe Kids Coalition* to provide children and adults with the opportunity to purchase discounted bike helmets. Participation in the annual *State of Ohio Injury Prevention Poster Contest* offers trauma service personnel the unique opportunity to educate school age children regarding important safety issues. During Trauma Awareness Month (May), the trauma coordinator presents *10 Tips To Save Your Life* on local radio stations.
Halloween Safety and *ENCARE* programs (*Emergency Nurses Cancel Alcohol-Related Emergencies*) are offered to area school students.

Disaster Planning

- Akron General is involved in regional disaster planning with the Emergency Management Agency for Summit County. Under this plan, Akron General acts as a coordinating and receiving hospital in the event of a disaster. Numerous disaster drills are conducted every year, including internal drills and others that simulate airport and mass casualty disasters which may occur within the

drills and others that simulate airport and mass casualty disasters which may occur within the community.

- Akron General is the regional hazardous materials hospital in Summit County, prepared for decontamination and treatment of hazardous materials exposures. Our hospital participates in the annual Summit County Hazardous Materials Drill.

Emergency Medicine Residency Program

- Akron General offers a fully accredited residency training program, meeting the special Residency Review Committee requirements for Emergency Medicine. Established in 1973, our program was the first community hospital-based residency training program in the country.
- Six resident physicians are selected each year to enter the three-year program.
- Advantages of the community-based, medical school-affiliated program include: excellent faculty-to-student ratio; pediatric emergency medicine experience at Children's Hospital Medical Center of Akron; elective programs which include EMS administration, poison control, toxicology and aeromedical experience; and a full month of administrative exposure offered during a resident's third year.

[Akron General's Emergency Medicine Residency Program -- A Comprehensive Look](#)
[Sample Rotation Schedule for Emergency Medicine](#)
[Akron General Medical Education Page](#)

Paramedic Education Program

Akron General's paramedic training program was initiated in 1977 as a commitment to the community in providing prehospital care to citizens within Summit County and adjoining areas. Since 1977, the program has graduated more than 800 paramedics, most of whom are still practicing within the Summit County area.

Our program is accredited by the Ohio Department of Public Safety and the Commission on Accreditation of Allied Health Education Programs (CAAHEP) of the American Medical Association. The Paramedic Education Program is one of only four in Ohio that meet the rigid CAAHEP quality standards for excellence in paramedic education.

The program is offered once a year, beginning in September. Applicants must meet several entrance requirements, including EMT-A certification status in Ohio.

The Paramedic Education Program currently offers a 10-month course to prepare students in meeting entry level EMT-paramedic criteria. For more information on the program, or to obtain an application, call (330) 384-6655.



Emergency Medicine Research

The Department of Emergency Medicine supports the emergency medicine residency training program. One goal of our training program is to ensure that resident physicians have been exposed to scholarly research and are familiar with the basic concepts that comprise the research process. Akron General Emergency Medicine residents and faculty have designed and implemented numerous research projects in the past, and continue to produce and publish quality research today.

Research Directions

Emergency medicine allows physicians to study a variety of topics. At Akron General, residents have investigated such topics as: the use of ultrasound in diagnosis of the Emergency Department patient; pain management and choice of analgesics; cardiac pacing in hypothermia; and patient satisfaction with discharge instructions. Other physicians have examined relationships between pharmaceutical representatives and Emergency Medicine residency programs, medical researchers and the media, and the transfer of nursing home patients to the Emergency Department.

Akron General has worked closely with Akron Fire EMS, Fairlawn Fire EMS and Cuyahoga Falls EMS squads in the study of hazardous materials and worker safety, as well as in the use of asthma medications in a prehospital setting and for the treatment of cardiac arrest. Public awareness and satisfaction with Akron EMS services, the use of medications to treat seizures while en route to the hospital and sensitivity training for EMTs regarding older patients, have also been studied with enthusiastic cooperation of local EMS squads.

Publications

Recent peer-review publications from the Department of Emergency Medicine at Akron General include:

Scott D, Schelble D; White LJ: An important question in the evaluation of sexual assault victims. *Academic Emergency Medicine*. 1996; In press.

Dixon R, Lombino D; Dougherty JM; White LJ et al: Transcutaneous pacing in a hypothermic dog model. *Annals of Emergency Medicine*. 1996; In press.

Fleisher F; White LJ; McMullen MJ: The geriatric obstacle course: Recognizing stereotypes and misconceptions among out-of-hospital care providers. *Journal of Emergency Medicine*. 1996; 14:439-444.

White LJ, Felton CW; Jones JS: Informed consent for medical research. *Academic Emergency Medicine*. 1996; 3:745-750.

Jones JS, White L, Faflik R: Structure and practice of institutional review boards in the United States. *Academic Emergency Medicine*. 1996; 3:804-809.

Menze, R, McMullen MJ, White LJ: Core temperature monitoring of firefighters during hazardous materials training sessions. *Prehospital and Disaster Medicine*. 1996; 11:108-111.

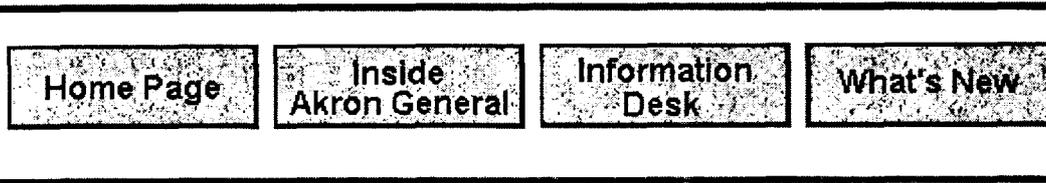
Jones J, Holstege C, Riekse R, White LJ, Bergquist T: Metered-dose inhalers: Do emergency health care providers know what to teach? *Annals Emergency Medicine*. 1995; 26:308-311.

Schmidt H, Belleza J, White LJ, Dougherty JM, Lammers R: Adverse effects with administration of phenytoin: infusion pump vs. manual infusion. *Academic Emergency Medicine*. 1995; 2:758-759.

SuperGroup



- Emergency medicine researchers at Akron General initiated the formation of SuperGroup -- a group of individuals from Summit County and surrounding areas interested in Emergency Medical Services (EMS) research. The objective of SuperGroup is to promote quality EMS research in Summit County.
- Representation on SuperGroup includes individuals from Akron Fire Department EMS, Fairlawn Fire EMS, Cuyahoga Falls Fire Department EMS, Akron General Medical Center, Summa Health System and Children's Hospital Medical Center of Akron.



**** Click here to see previous Akron General news releases ****

Akron General is area's only Trauma Center

Akron General Medical Center has been verified as a Trauma Center by the American College of Surgeons Committee on Trauma, making it the only Trauma Center between Cleveland and Columbus. The hospital's Trauma Center status means it provides definitive trauma care regardless of the severity of the injury.

Traumatic injury is the number-one health problem in the U.S. and accounts for more than 5,300 deaths in Ohio annually. National research shows that 20 to 45 percent of trauma deaths can be prevented if the patients are cared for in an appropriate trauma facility. Last year alone, Akron General cared for nearly 1,000 seriously injured patients.

"Achieving Trauma Center status provides Akron and surrounding communities with a great opportunity to minimize injuries and receive optimal care close to home," said Farid Muakkassa, MD, Director of Trauma at Akron General.

The year-long verification process included a rigorous and meticulous review of all aspects of trauma care including emergency department, anesthesia, surgery, surgical intensive care unit and rehabilitation.

Akron General clinical capabilities include cardiac and thoracic surgery, orthopedic surgery, neurosurgery and nuclear and neurodiagnostic services. The 24-hour, on-site availability of Akron General's specialized trauma team meets the complex needs of the trauma patient.

Akron General's commitment to trauma care and injury prevention are expanding through participation in national research studies, including the first study involving a blood derivative that may benefit seriously injured patients receiving emergency treatment for injuries resulting in severe blood loss.

Adult trauma patients can be transferred to Akron General by calling toll-free (888) 215-3894. A trauma surgeon and helipad for transport are available 24 hours a day.

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Akron General Studies New Treatment for Patients with Severe Blood Loss

Akron General Medical Center is one of 35 hospitals nationwide studying a blood derivative that may benefit seriously injured patients receiving emergency treatment for injuries resulting in severe blood loss.

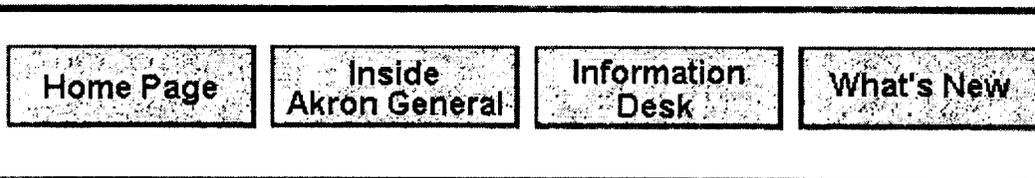
Akron General agrees with the sponsors of this study that this treatment should be available to all patients, even without a signed consent form, who face a life-threatening situation for which standard therapy is not effective.

The Food and Drug Administrations (FDA) requires new drugs to be proven effective with volunteer patients before formal approval. The FDA has ruled that under strict guidelines, a patient whose life is in danger and who has no one to give consent, may be given promising experimental treatment. Patients or families will be informed as soon as possible.

Akron General agrees with the sponsors of this study that injury victims with severe blood loss justify a waiver of consent. The hospital is required by the FDA to inform the public and receive public comment before offering this treatment which should lower loss of life in emergency situations. Possible side effects include elevated blood pressure, nausea or jaundice.



Most physicians at Akron General are independent practitioners.



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What's New

**** [Click here to see previous Akron General news releases](#) ****

EMERGENCY DEPARTMENT STUDIES NEW TREATMENT

FOR IMMEDIATE RELEASE

Date: September 15, 1997

Contact: Mary Adams -or- Mary Brackle
Communications Department
330-384-6376

Akron General is one of 35 hospitals nationwide participating in a study involving a blood derivative that may benefit seriously injured patients receiving emergency treatment for injuries resulting in severe blood loss. The FDA has granted permission to reinstate Emergency Department research involving seriously injured patients. A patient whose life is in danger and who has no one to give consent may be given promising experimental treatment if family members are informed of the treatment as soon as possible.

"Patients who have experienced a critical injury often suffer from shock due to excessive blood loss," states Jim Dougherty, MD, Principal Investigator of the study and an Emergency physician at Akron General. "During shock, the body is unable to deliver enough blood and oxygen to all of the vital organs and tissues. Death may occur as a result."

The current treatment involves the rapid infusion of large volumes of liquids and blood transfusion to replace the loss. Dr. Dougherty explains, "The purpose of this study is to find out how well this new blood derivative works in treating patients with extreme blood loss and shock. It may give us the potential to save more lives." Possible side effects of this treatment include elevated blood pressure, nausea or jaundice.

The blood derivative, Diaspirin Cross-Linked Hemoglobin (DCLHb), is a purified human hemoglobin solution. Hemoglobin is the protein in red blood cells that carries oxygen. The product is prepared from units of human red blood cells from donors which have been tested for certain infectious diseases. "DCLHb can be given immediately to patients of any blood type and it does not need to be cross-matched. It can be easily stored in our Emergency Department and is available as soon as the patient arrives," states Dr. Dougherty. "It may give us the potential to conserve blood products until a blood transfusion is needed." DCLHb carries oxygen and may improve oxygen delivery to vital organs and may reverse the destructive effects of shock increasing survival rates of severely injured patients. Approximately 150,000 people die each year due to critical trauma injuries.

The clinical trial will be monitored by the Akron General's Institutional Research Review Board and an independent safety committee.

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physicians

IN GENERAL

September 1997

STRECK NAMED SR. VP MEDICAL AFFAIRS

This month Richard J. Streck, MD, MBA, assumed his duties as Senior Vice President for Medical Affairs, serving as administrative liaison in all clinical, financial and planning issues related to medical staff.

Dr. Streck is a graduate of the University of Miami School of Medicine and the recipient of an MBA from Xavier University. Following his residency in internal medicine at Good Samaritan Hospital in Cincinnati, Streck has held various appointments at that teaching institution and has been Chairman of the Department of Medicine and Director of the Internal Medicine Residency Program for the last five years. He is a practicing general internist and on the faculty of the University of Cincinnati School of Medicine.

A reception to meet Dr. Streck and his wife, Joan, will be held in September.

MEDICAL STAFF ADDITIONS

Akron General welcomes the following new medical staff members:

- Dr. Angela J. DeJulius and Dr. Kian H. Bhe, Family Practice.
- Dr. Thomas M. File, Jr., Dr. Amy S. Indorf and Dr. David A. Watkins, Infectious Disease.
- Dr. Kristine E. Kokeny, Radiation Oncology.
- Dr. Vinayak T. Mehta, Pathology and Clinical Labs.
- Dr. Pankil J. Vora, Dr. Verdena L. Lee, Dr. David A. Miller and Dr. Patricia A. Mullen, General Medicine.
- Dr. Richard E. May, Nephrology.
- Dr. Frances S. Ballo, Dermatology.
- Dr. Felix A. Okah and Dr. Elizabeth M. Specht, Newborn Service.
- Dr. Marcia L. Williams, Ob Gyn.
- Dr. Brian J. Donelan, Cardiology.
- Dr. Manzoor Quadir, Gastroenterology.
- Dr. Bradley K. Weiner, Orthopaedic Surgery.

NATIONAL STUDY CAN SAVE LIVES

Akron General is one of 35 hospitals nationwide studying diaspirin cross-linked hemoglobin, a blood derivative, that may benefit seriously injured patients receiving emergency treatment for trauma resulting in severe blood loss and shock.

In order to receive FDA approval, this treatment is available to all patients, even without a signed consent form, facing a life-threatening situation for which standard therapy is not effective. Patients or families will be informed as soon as possible.

The study is being conducted by the Emergency Medicine Research Office, under the direction of Dr. James Dougherty. Call 384-6963 with comments.

LEVEL II TRAUMA CENTER STATUS

The American College of Surgeons recently verified Akron General as the area's only Level II Trauma Center, providing definitive trauma care regardless of the severity of injury. Trauma research activities are being expanded.

BUSY TIME FOR MED ED

Mark your calendars for **Orthopedics in Primary Care** on Sept. 19 and 20 at Health & Wellness Center and Firestone Country Club. Call 996-2663. **Sixth Annual Medical Symposium on Women's Health** covering incontinence and chronic pelvic pain, on Oct. 24 at Health & Wellness Center. Call 384-6014. **New Horizons in Wound Care Management** on Oct. 29 at Health & Wellness Center. Call 376-HEAL. **Functional Approach to Primary Care in Sports Medicine** on Dec. 5 and 6. Call 665-8200.



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AKRON GENERAL

Developments

*Back from brain
surgery? Yes, twice!*

*Emergency Department
renovation reduces
your wait*

Summer / Fall 1997

Heart attack?

Early warning signs could save your life

Larry, a 56-year-old construction worker, had spent a regular day on the job—from 8 a.m. to 4 p.m. at the latest construction site. He had a normal lunch and dinner, but when evening came, he felt nauseated. Then chest pains and cold sweats began to occur on and off. Larry feared that he was having a heart attack, but dreaded going to the emergency room.

"What if it's just something I ate? Who wants to waste all that time waiting in an ER?"

Thoughts raced through his mind, but when the symptoms got worse, he called 911. And today he's very glad he did. Here's what happened:

12:08 a.m. Akron General's Emergency Department (ED) received the call from a local emergency medical squad: "We have a 56-year-old white male with a suspected heart attack. Experiencing severe chest pain, jaw pain and shortness of breath. BP is 156 over 100 and heart rate is 130 beats per minute. We're six minutes away from Akron General."

12:09 a.m. One of 15 monitored beds in the ED was immediately reserved for Larry.

12:14 a.m. The ambulance arrived at the hospital and Larry was taken directly to the reserved bed, bypassing ambulatory triage. His EKG was taken, blood was drawn, portable chest X-rays were taken and he was evaluated by an ED physician.

12:26 a.m. The doctor diagnosed a heart attack and began to consider the treatment options. He evaluated Larry as a potential candidate for thrombolytic therapy (clot-busting medication).

12:32 a.m. The physician decided Larry's symptoms, EKG and medical history were within the criteria for administering thrombolytic therapy.

12:33 a.m. The area's only reperfusion team (for administering thrombolytic therapy) made up of an ED physician, registered nurse and senior technician, along with a Coronary Care physician and registered nurse, was paged to the Emergency Department.

Emergency Department Director of Nursing/Patient Services, Kris Kipp, RN, explains that the most critically ill patients are cared for first in the ED because rapid response can save lives.

Emergency Department studies new treatment

For the first time in over two years, the FDA has granted permission to reinstate Emergency Department research involving seriously injured patients. Akron General is one of 35 hospitals nationwide participating in this first study involving a blood derivative that may benefit seriously injured patients receiving emergency treatment for injuries resulting in severe blood loss.

THE STUDY

"Patients who have experienced a critical injury often suffer from shock due to excessive blood loss," states Jim Dougherty, MD, Principal Investigator of the study and an Emergency physician at Akron General. "Shock means the body is unable to deliver enough blood and oxygen to all of the vital organs and tissues. Death may occur as a result."

The current treatment involves the rapid infusion of large volumes of liquids and blood transfusion to replace the loss. Dr. Dougherty explains, "The purpose of this study is to find out how well this new blood derivative works in treating patients with extreme blood loss and shock. It gives us the potential to save more lives."

12:36 a.m. Reperfusion team was assembled in ED and specific protocols for thrombolytic therapy were initiated.

12:56 a.m. Thrombolytic therapy was administered and Larry was stable enough to move to the Coronary Care Unit under the care of the same Coronary Care physician and nurse who participated in the reperfusion team.

Larry's experience in Akron General's Emergency Department lasted 42 minutes. Thanks to his early recognition of symptoms and calling 911, along with fast action by the entire emergency medical team, Larry is alive today.

Akron General's Chief of Cardiology George I. Litman, MD, states that, "Fifty percent of people with heart attack symptoms wait too long to seek medical care. Treatment can significantly limit or prevent heart damage if begun within four hours of the onset of a heart attack."

"Akron General's Heart Center, including state-of-the-art catheterization labs and surgery suites, is available to respond to emergencies 24 hours a day, 365 days a year."

IS IT HEARTBURN? OR HEART ATTACK?

Learn these early signs of a heart attack—they could save your life:

- Pain, from mild to severe, can come and go in the upper chest, mid-chest, neck, jaw, inside arms, upper abdomen or between the shoulder blades.
- Difficulty breathing
- Cold sweat
- Palpitations (fluttering or pounding of the heart)
- Dizziness
- Nausea/Indigestion
- Weakness

Encourage anyone with one or more of these symptoms to call 911 or go to the nearest hospital emergency department.

For more information on recognizing heart attack symptoms, call the Heart Center at (330)38-HEART (384-3278) for a free brochure.

Is it
Heartburn?
Or a Heart
Attack?

Learn These
Early Signs
of a Heart
Attack

Learn These
Early Signs
of a Heart
Attack

DCLHB — WHAT IS IT?
Diaspirin Cross-Linked Hemoglobin (DCLHb) is a purified human hemoglobin solution. Hemoglobin is the protein in red blood cells that carries



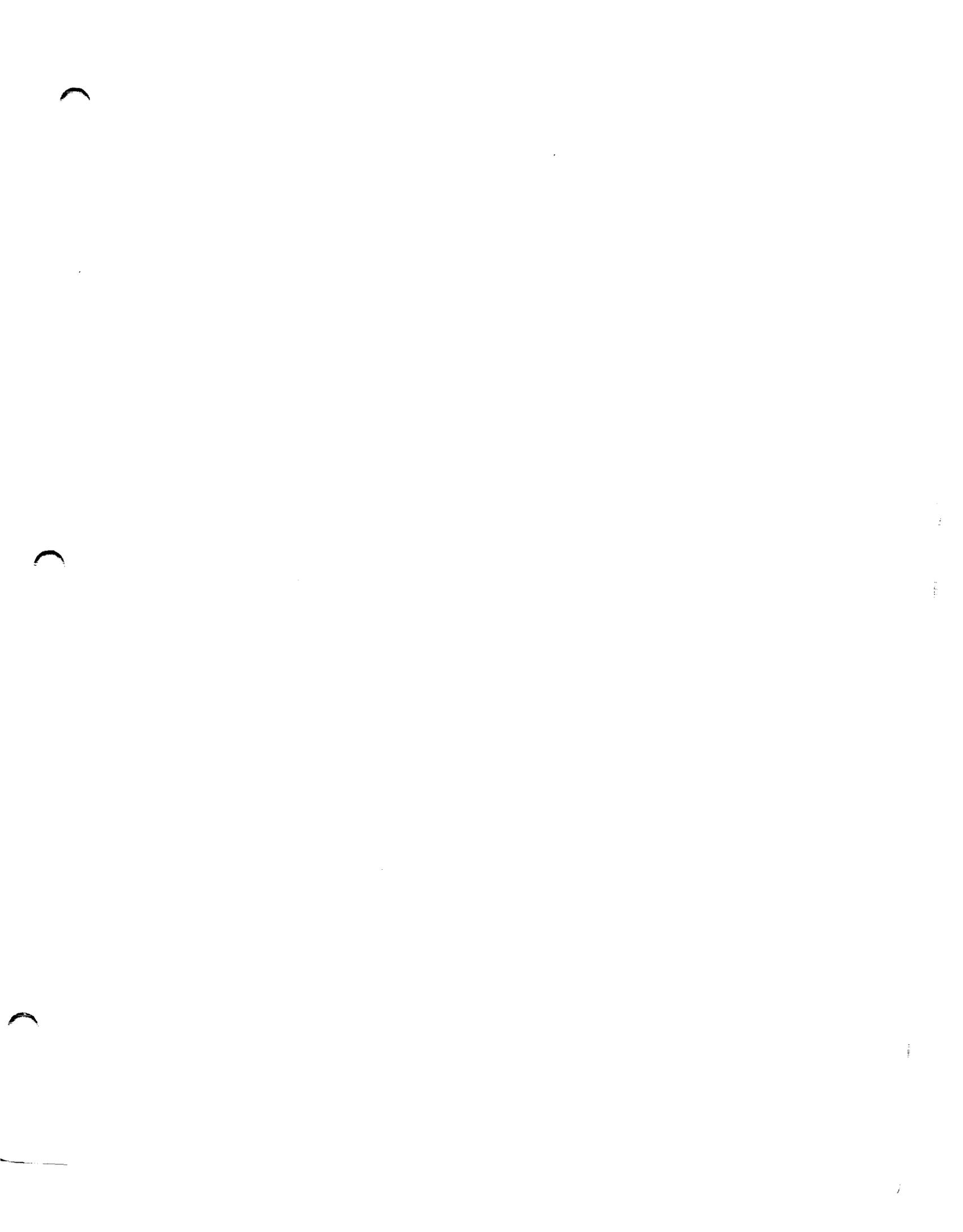
oxygen. The product is prepared from units of human red blood cells from donors which have been tested for infectious diseases.

"DCLHb can be given immediately to patients of any blood type and it does not need to be cross-matched. It can be easily stored in our Emergency Department and is available as soon

as the patient arrives," states Dr. Dougherty. "It also gives us the potential to conserve blood products until a blood transfusion is needed."

DCLHb carries oxygen and may improve oxygen delivery to vital organs and may reverse the destructive effects of shock increasing survival rates of severely injured patients. Approximately 150,000 people die each year due to critical trauma injuries.

The clinical trial will be monitored by the Akron General's Institutional Research Review Board, the FDA and an independent safety committee.



VOICE

October • November • December 1997

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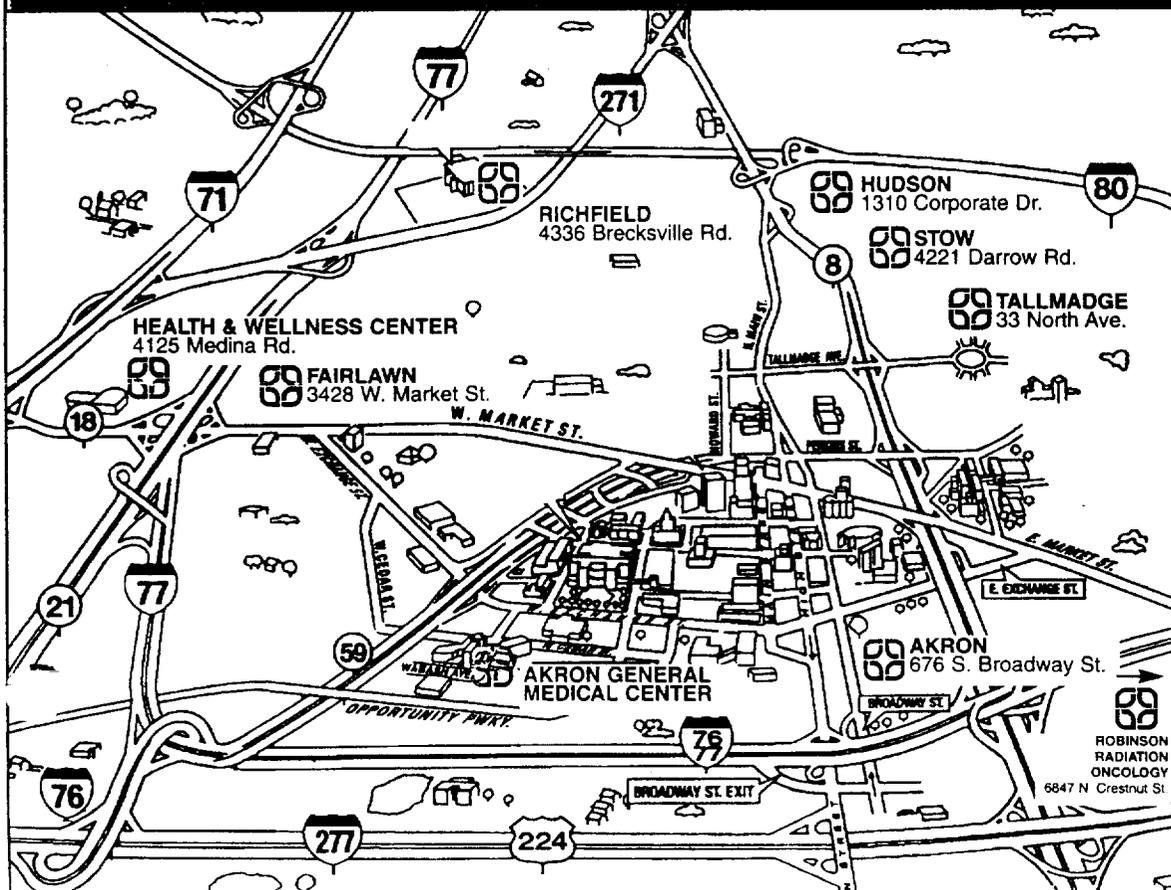
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Akron General Health System— Working together to care for our community

Akron General Community Health Centers



Akron General Health System—our newly named network of Akron General Medical Center, Network Health Ventures, Inc., Network Health Group and Akron General Development Foundation—is more than buildings, equipment and technology. It's dedicated employees, physicians and volunteers who provide quality health care, preventive care and indigent care in Akron, Richfield, Fairlawn, Hudson, Stow, Tallmadge, Green and many other locations.

■ Thanks to the generous response by Akron General employees, volunteers, retirees and physicians last year, we donated a record \$57,000 to United Way. Help us meet this year's goal by returning your pledge card for the 1997 United Way campaign. Your contribution of \$4 a week could provide three home health visits to the elderly; \$2 a week could help an adult with learning disabilities; \$1 a week could help a developmentally disabled preschooler or two families with emergency food, clothing or utility payments. Cash prizes of \$250, \$500 and \$1,000 will be raffled. Thank you for supporting the United Way.

Briefs

■ The 1997 Employee Annual Appeal will support the expansion of our Emergency Department. Employees have been asked to raise \$60,000 toward the project's \$750,000 goal—and we're almost there! Those contributing \$1 a pay will receive a first aid kit. If you haven't returned your pledge card, please return it today, or call 384-6888 for a card.

■ Akron General won the blood drive challenge against Akron City Hospital—232 units vs. 152 units. These units have the potential of helping 1,536 people. Thanks to all who donated. The next AGMC blood mobile is on Oct. 15 from 7 a.m. to 6 p.m. and Oct. 16 from 11 a.m. to 5 p.m. in the Eva P. Craig Auditorium. Refreshments and an appreciation gift will be offered. Please give.

■ Akron General's Cancer and Women's Centers and Main Street Muffins are teaming up again for Muffins for Mammograms—Oct. 7 & 9—to distribute healthful muffins along with breast health information. All proceeds help provide mammograms for area women without insurance. For an order

We're Tops

AGMC makes the news with these top achievements

Trauma alert

Akron General has been verified as an Adult Level II Trauma Center by the American College of Surgeons Committee on Trauma—making it the only Trauma Center between Cleveland and Columbus. Our Trauma Center status means we provide definitive trauma care regardless of the severity of the injury.

The year-long verification process included a rigorous and meticulous review of all aspects of trauma care including Emergency Department, anesthesia, surgery, Surgical Intensive Care Unit, rehabilitation and clinical capabilities. The 24-hour, on-site availability of our specialized trauma team

meets the complex needs of the trauma patient.

ED studies new treatment

Akron General is one of 35 hospitals nationwide participating in the first study involving Diaspirin Cross-Linked Hemoglobin (DCLHb), a blood derivative, that may benefit seriously injured patients receiving emergency treatment for injuries resulting in severe blood loss. The current treatment involves the rapid infusion of large volumes of liquids and blood transfusion to replace the loss.

"The purpose of this study is to find out how well this new blood derivative works in treating patients

with extreme blood loss and shock. It gives the potential to save more lives," says Jim Dougherty, MD, Emergency physician and principal investigator of the study. "DCLHb can be given immediately to patients of any blood type and it does not need to be cross-matched. It can be easily stored in our Emergency Department and is available as soon as the patient arrives."



The Women's Board of Akron General Presents

An elegant and memorable evening is planned featuring a silent auction of signature items and the music of the Jack Schantz Quartet

- 7:00 p.m. Cocktails, Hors d'oeuvres, Silent Auction
- 7:30 p.m. Buffet Extraordinaire, Entertainment & Dancing
- 9:45 p.m. Grande Dessert

Tickets: Bronze—\$75 per person, Silver—\$150 or Gold—\$200

Saturday, November 8, 1997
Health & Wellness Center

Call Volunteer Services at **384-6351** for invitation information.



SAVE

• Akron hospital offers 24-hour trauma team

Continued from Page A1

tem," according to a fact sheet published by the Ohio Chapter of the American College of Surgeons Committee on Trauma.

With Akron General's trauma center, verified Aug. 12, patients won't have to be flown via helicopter to Cleveland or Columbus for specialized care, and emergency workers will be able to make a faster choice about where to go.

"It's very difficult to pick between two hospitals when they're equal distance," said Sally Jo Zupan of the Ohio Chapter of the American College of Surgeons Committee on Trauma, which certifies the centers. "But when one hospital has been certified by an outside body for specializing in trauma cases, it makes it much, much easier for patients, EMS workers and others to know what the better choice would be."

Emergency workers, for example, immediately took 14-year-old David Browning to Akron General's trauma center on Aug. 20 after he was run over by a car and dragged more than 400 feet.

Browning had bruises everywhere, a fractured skull, pelvis and left elbow, and severe abrasions to his left knee (he needed skin grafts). But by the time he arrived, a team of 20 people was waiting, including a neurosurgeon, an orthopedic surgeon and technicians to conduct a CT scan.

"They did an excellent job," said Kathleen Haines, his legal guardian. "They really did - and that's part of the reason why he's doing so well now." Browning, of Akron, was released 10 days after the accident.

That's not to say other emergency departments are deficient - it's estimated that almost 90 percent of emergency cases can be handled just fine by hospitals that do not have trauma centers.

Summa Health System, for example, has the busiest emergency departments in the Akron area, said Amanda Balika, its spokeswoman. "We see over 90,000 patients a year through our two emergency rooms and we expect that number to remain steady."

But for the remaining 10 percent of the cases, not getting to a trauma center within the first hour after the accident can mean death or a slower recovery. What occurs during that "golden hour" is considered the best indicator of survival.

"If you've got a bee sting, I think just about any ER can handle that just fine," said Dr. Ste-



ROBIN WITEK/Beacon Journal

Akron General Medical Center trauma team members work to stabilize a patient who was injured in an industrial fall. Trauma injury is the No. 1 cause of death for U.S. children and young adults.

phen Loeb, professor and chairman of the graduate program of hospital management and policy at Ohio State University's College of Medicine and School of Public Health. "But when it comes to a life-or-death situation, I think it's pretty clear you want a trauma center."

Being a trauma center means the hospital has created a special 24-hour, on-site trauma team. It means heart, bone, lung and brain surgeons are always available and lab technicians are always present to run tests faster and operating rooms can always be cleared.

It took Akron General, which sees annually about 1,000 trauma patients, years to build the program.

"It means Akron General has made a commitment of resources, personnel and equipment to provide the best care, if heaven forbid, someone needs it," said Daniel T. Schelble, chairman of the hospital's department of emergency medicine.

The new standing also helps the hospital attract more national studies of cutting-edge medicine.

For example, Akron General will become one of 35 hospitals to

use an experimental blood product, called Diaspirin Cross-Linked Hemoglobin. The purified blood product, which the hospital will receive on Oct. 1, can be used without taking the time to type an accident victim's blood, which can take up to a half-hour.

The blood product also has the advantage of being extremely efficient in transporting oxygen to organs - raising the chances of survival and a good recovery, according to Dr. Jim Dougherty, an emergency physician at Akron General and the local principal investigator.

"This trial is definitely one of the advantages (of being verified as a trauma center)," he said.

Having a trauma center can also be good business. It makes the facility more attractive to insurers and employers who, in turn, like to tout the fact they have a trauma center within their net-

works.

"If hospitals are trying to sell the fact they offer a comprehensive range of services, having a trauma center certainly fits into that agenda," Loeb said.

Typically, emergency rooms don't make money - their cost is spread out over the entire financial structure of the hospital. But they are still the gateway for most hospital admissions. That means the more visits to the trauma center, the higher probability the hospital will get more in-patient admissions - which translates, perhaps, to more money.

But for a Wayne County accident victim, the value might be his or her life. Instead of being transported to a trauma center in Cleveland, "it would be a matter of minutes to Akron," said Rachel White, a trauma case manager at Akron General.

AKRON BEACON JOURNAL

September 23, 1987

Serving the community for 159 years

Survival tactics

Akron General Medical Center's new trauma center provides special care, immediate attention and a staff with nerves of steel



ED SUBA JR./Beacon Journal

Surgical attendant Kelly Brown (left) and emergency department registered nurse Jim Porebzk transport a patient from the trauma center to the operating room at Akron General Medical Center.

Helping patients within first hour is a vital concern

BY DIANE LORE
Beacon Journal medical writer

The beeper sounds.
"OK, we've got a trauma."

Lisa Love cuts off the conversation and heads to Akron General Medical Center's emergency department.

Almost a dozen people are waiting when the patient arrives. Love, the hospital's trauma coordinator, stands at the side while surgeons, residents, nurses, a respiratory therapist and X-ray technicians swarm the 80-year-old woman involved in a car wreck.

Akron General's new trauma center is in high gear. The chaos of an emergency room remains, but underneath the frenzied pace is a deliberate effort to make sure the right people are there at the right time to save someone's life.

Within minutes, the trauma team is dealing with a slow heart rhythm, fractured ribs, a fractured wrist and a damaged spleen. Antibiotics are being administered. X-rays - taken while the doctors and nurses work - are slapped up on a light wall.



ED SUBA JR./Beacon Journal

Dr. Rodney Lutz takes a closer look at a patient in Akron General Medical Center's trauma room. It is the only official trauma center between Cleveland and Columbus.

"When it comes to a life-or-death situation, I think it's pretty clear you want a trauma center."

DR. STEPHEN LOEBS

professor and chairman of the graduate program of hospital management and policy at Ohio State University's College of Medicine and School of Public Health

Yet, within 45 minutes of the beeper's call, the room is deserted. The patient is stable and has been shipped to an operating room. Nothing remains of the team except a few discarded gloves and one bloody bandage.

This is the pulse of the only official trauma center between Columbus and Cleveland, where victims of car accidents, gunshot wounds, stabbings, falls or burns have a better chance at survival, health care experts say.

Trauma is the No. 1 cause of death for children and adults under 38 years old. Each year, more than 5,300 Ohioans die because of traumatic injuries.

"Each year in Ohio, 400 to 1,200 innocent people die unnecessarily due to delays in treatment, transfer to a hospital with adequate trauma resources, and lack of a trauma sys-

See SAVE, Page A1



Akron General Studies New Treatment for Patients with Severe Blood Loss

Akron General Medical Center is one of 35 hospitals nationwide studying a potentially life saving blood derivative (Diaspirin Cross-Linked Hemoglobin DCLHb) for trauma patients with critical injuries resulting in severe blood loss. The purpose of the study is to evaluate the effectiveness of DCLHb in treating or preventing the harmful effects of blood loss and shock caused by severe trauma. This study has been authorized by the Food and Drug Administration (FDA) and the Akron General Medical Center Institutional Review Board (IRB). The IRB is a committee which reviews research studies to ensure that they are well designed with safeguards for patients.

Patients, due to the nature of their condition and the critical need for immediate treatment, may not be able to give their consent for participation in the study. Akron General is in compliance with the FDA Informed Consent Exception Regulations which are designed to protect the rights of critically ill and injured patients who may not be able to provide informed consent. Under these regulations, physicians may administer promising new therapy when available treatments have proven ineffective or unsatisfactory, and when there is evidence that the product may benefit the patient.

Any individual who does not want to participate in this trial may elect to carry a notice, provided by Akron General. To obtain your notice, call 330/384-6963. Persons with known objection to the use of blood, blood products or this product (DCLHb) will not be entered into the study. A patient may withdraw from the study at any time without influencing his/her medical care. Patients who decide not to participate or are not eligible to enroll in the study will continue to receive the best possible medical care critically injured trauma patients currently receive at Akron General's Trauma Center.

If you have questions about the study or if you wish to decline study participation, contact the Emergency Medicine Research Office, Akron General Medical Center, 400 Wabash Ave., Akron, OH, 44307 or call 330/384-6963.

 **AKRON GENERAL**

Most physicians at Akron General are independent practitioners.

Akron General Studies New Treatment for Patients with Severe Blood Loss

Akron General Medical Center is one of 35 hospitals nationwide studying a blood derivative that may benefit seriously injured patients receiving emergency treatment for injuries resulting in severe blood loss.

Akron General agrees with the sponsors of this study that this treatment should be available to all patients, even without a signed consent form, who face a life-threatening situation for which standard therapy is not effective.

The Food and Drug Administration (FDA) requires new drugs to be proven effective with volunteer patients before formal approval. The FDA has ruled that under strict guidelines, a patient whose life is in danger and who has no one to give consent, may be given promising experimental treatment. Patients or families will be informed as soon as possible.

Akron General agrees with the sponsors of this study that injury victims with severe blood loss justify a waiver of consent. The hospital is required by the FDA to inform the public and receive public comment before offering this treatment which should lower loss of life in emergency situations. Possible side effects include elevated blood pressure, nausea or jaundice.

Please send your comments to Emergency Medicine Research Office, Akron General Medical Center, 400 Wabash Avenue, Akron, Ohio 44307 or call (330) 384-6963 by July 1, 1997.



Most physicians at Akron General are independent practitioners.

Akron General Studies New Treatment for Patients with Severe Blood Loss

Akron General Medical Center is one of 35 hospitals nationwide studying a blood derivative that may benefit seriously injured patients receiving emergency treatment for injuries resulting in severe blood loss and shock. This treatment will be available to a select group of patients who meet the study's criteria.

The Food and Drug Administration (FDA) requires new drugs to be proven effective with volunteer patients before formal approval. The FDA has ruled that under strict guidelines, a patient whose life is in danger and who has no one to give consent, may be given promising experimental treatment. Patients or families will be informed as soon as possible.

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Most physicians at Akron General are independent practitioners.

Baxter Healthcare Corporation
Model Information for Use in Community Consultation and Public Disclosure

“The Efficacy Trial of Diaspirin Cross-linked Hemoglobin (DCLHb™) in the Treatment of Severe Traumatic Hemorrhagic Shock”

The information in this document is provided in accordance with the U.S. Food and Drug Administration (FDA) regulation, effective November 1, 1996: “Exception from informed consent requirements for emergency research” (21 CFR 50.24). This information is provided to aid in informing the public about the nature of this trauma study, including the risks and potential benefits to patients.

Overview

Trauma is an important public health problem in today's society. The effect of severe trauma is immediate and catastrophic with approximately 150,000 people dying each year due to trauma injuries. Many others suffer from prolonged illness. Advancements in trauma care are necessary in order to make more likely the survival and complete recovery of people suffering from severe traumatic injuries.

Study Introduction

Patients who have experienced a severe traumatic injury often suffer from shock due to excessive blood loss. Shock means the body is unable to deliver enough blood and oxygen to all of the vital organs and tissues. When this happens, vital organs may no longer be able to function correctly and death may occur as a result. This shock cannot always be cured by medical treatments now available. The current medical treatment often involves the rapid infusion of large volumes of different liquids such as saline (salt water) and the transfusion of blood, to replace the fluid and blood loss. Immediate surgery is often needed to repair the injuries.

Patients eligible for this study are suffering from a catastrophic traumatic event and are often not able to give consent due to their medical condition. Because the onset of traumatic injury is unpredictable, a legally authorized representative is usually not available to provide consent for the patient and contacting a family member is often not possible. An exception from consent will be utilized when obtaining prospective informed consent from the patient or their legally authorized representative is not feasible, due to the critically short time in which the patient must be treated and DCLHb infused.

DCLHb Background

Diaspirin Cross-Linked Hemoglobin (DCLHb) is a purified human hemoglobin solution. Hemoglobin is the protein in red blood cells that carries oxygen. The product is prepared from units of human red blood cells from volunteer donors which have been

tested and found negative for the viruses that cause hepatitis and AIDS. Also, the DCLHb is heated and filtered during the manufacturing process. These processes add extra steps to make the solution safe from viruses.

DCLHb can be given immediately to a patient of any blood type. It does not need to be cross-matched which must be done before giving blood. It can be easily stored in the emergency department of the hospital so that it is available as soon as a patient arrives. DCLHb carries oxygen and may improve oxygen delivery to the organs that need oxygen the most. The delivery of oxygen to vital organs may reverse the destructive effects of shock, and may allow for increased survival and complete recovery of more patients who are severely injured.

Informed Consent Background

The FDA, in cooperation with the National Institute of Health (NIH), issued regulations that will allow for certain emergency research to be conducted with an exception from informed consent in response to growing concerns that the former rules were making it impossible to carry out emergency care research at a time when the need for such research is increasingly recognized. These new regulations allow for a study to be conducted with an exception or waiver from the requirement for obtaining written informed consent only in those rare circumstances when the patient cannot provide consent and the nature of the patient's medical condition requires immediate treatment.

Informed consent is the process which allows a patient to decide, after understanding the risks and benefits of the research, whether or not he or she wants to voluntarily participate. An exception to this consent requirement is a serious matter and in response, the FDA and NIH have developed these regulations requiring additional protections for the patients eligible for these research protocols. The Institutional Review Board (IRB) at a center participating in a study utilizing the exception to informed consent is responsible for ensuring the protection of the patients. The additional protections include 1) consulting with the communities from which patients will be drawn 2) public disclosure of the study and its risks and expected benefits prior to starting the study 3) public disclosure of information after the study is completed to inform the community and researchers of the results of the study 4) establishing an independent data monitoring committee to exercise oversight of the study and 5) if consent from the patient is not feasible and a legally authorized representative is not available, providing an opportunity, if feasible, for a family member to consider the patient's participation in the study.

The development of these regulations allow for the advancement of vital emergency research with careful attention to the protection of the rights and welfare of the patients who are enrolled in the experimental protocol. The FDA and NIH expect that the studies conducted under these rules will allow patients in certain life-threatening situations, who are unable to give informed consent because of their condition, the

chance to receive potentially lifesaving treatments. They also expect that these studies will increase the knowledge and improve the treatments currently used in emergency medical situations that have poor patient outcomes, despite optimal care.

DCLHb Preclinical Information

In the last 10 years more than 100 major preclinical studies have been performed with DCLHb. Over 50 different academic and contract laboratories in North America, Europe, and Australia have participated in preclinical research to investigate the pharmacology, physiology, safety, and efficacy of DCLHb. DCLHb has been studied in animal models of hemorrhagic shock, sepsis, stroke, myocardial infarction, balloon angioplasty (PTCA), burn injury, and trauma. These include studies looking closely at the safety of DCLHb and have shown that DCLHb may be safely infused into humans.

The knowledge gained from preclinical studies has led to the design of clinical trials that will determine the ability of DCLHb to safely and effectively treat human illness and injury. All of the preclinical studies performed to date have been approved by the review committees of the participating universities.

DCLHb Clinical Information

In the over 700 patients who have participated in DCLHb studies to date, more than 350 have received DCLHb. The clinical studies have involved 26 hospitals or universities in the U.S. and 8 other countries. During the 5 years of human clinical work, 12 studies have been completed and 4 are currently underway. DCLHb is or has been studied in many different clinical settings, including hemorrhagic shock, trauma, stroke, kidney dialysis, overwhelming infection, critical ICU illness, acute anemia, and peri-operative use, including orthopedic, cardiac, abdominal aortic repair, and other major surgeries. All human trials include close monitoring for patient safety and all studies were reviewed by the appropriate regulatory agencies and the Institutional Review Boards (IRBs) or Ethics Committees (ECs) of the participating centers.

Allergic, renal, pulmonary, cardiac, neurologic, or infectious complications have not been consistently seen with DCLHb use. Some laboratory tests have been noted to change with DCLHb use, including proteins and enzymes that could indicate damage to organs such as the pancreas and liver, or to muscles. In patients who have received doses of DCLHb greater than 500 mL, blood amylase (an enzyme of the pancreas, a digestive organ) and jaundice (yellow coloring of the skin) have been seen. The jaundice starts soon after DCLHb infusion and usually lasts approximately three days without the occurrence of any medical problems. Inflammation of the pancreas, or pancreatitis, has been seen in four patients (two reported as serious and related to DCLHb) who received DCLHb and two patients who did not receive DCLHb in these studies.

The initial clinical trial of DCLHb in shock and trauma patients studied the infusion of

saline (salt water) or DCLHb in 139 patients (71 of the patients, 51%, received DCLHb) with mild to severe shock. The trial was divided into three dose levels, 50 mLs, 100 mLs, and 200 mLs. Each dose level included approximately 40 patients (approximately half received saline and the other half received DCLHb). In this trial, the number of patients who died and the rate of side effects was not greater in patients who received DCLHb.

DCLHb has been extensively studied in heart surgery patients and is currently being studied in selected orthopedic surgery and abdominal aortic repair patients to test DCLHb's safety and effectiveness in preventing blood transfusions. DCLHb is also going to be tested in a prehospital trial of hemorrhagic shock in trauma patients in Europe.

The purpose of this research study is to find out how well this new hemoglobin solution works in treating or preventing the harmful effects from the blood loss and shock that occur with severe traumatic injury. The harmful effects of shock can include prolonged illness or death. This research study will include only severely injured trauma patients whose death rate may be as high as 40% despite receiving the best medical treatment available. In this study, all of the patients who participate will receive all of the currently available therapies known to save lives following injury. Those patients who are given DCLHb will receive it as additional therapy to the best standard therapies available. DCLHb will be studied to see if using it prevents death and prolonged illness in patients who receive it. The standard treatment for severe trauma includes giving large volumes of fluids and transfusion of blood through a vein. Surgery is often necessary to stop the bleeding and repair the injuries. These standard therapies will be made available to all of the patients treated in this research protocol, including those that receive the DCLHb. The new treatment is to begin giving 500 mLs (1 pint) to 1000 mLs (2 pints) of DCLHb within sixty minutes of arriving at the hospital. This is in addition to any standard treatment required, including surgery.

If this study shows a clear benefit and little or no harm to patients, this investigational solution may be cleared by the U.S. Food and Drug Administration (FDA) for use in patients who suffer from shock as a result of severe injury.

Study Design

In this trial, the patients will be randomly (like a flip of the coin) assigned to receive either the DCLHb or an equal amount of saline (a salt solution currently used as a treatment for shock). The order of assignment will be determined prior to any patients being entered into the study so that neither the patients nor the patients' doctors can choose which solution is given.

Saline is used during the emergency treatment for shock patients to help replace the blood loss due to the injury. The patients who receive saline in this study will be the control group. These patients will not receive DCLHb. All patients will receive the best

known current therapy for shock. The outcome (survival and illness) of patients who receive saline will be compared to the patients who receive the DCLHb to see if the addition of DCLHb to the current therapy improves survival and decreases illness.

This study will take place at approximately 35 trauma centers across the United States, each of which will treat 20-30 patients in the protocol. Approximately 850 patients will participate in the study. Participation in this protocol will not interfere with the timely delivery of any of the lifesaving therapies currently available for treating severe traumatic shock including the immediate infusion of resuscitation fluids and blood, as well as emergency surgery if needed.

Primary Clinical Benefit Measurement

- This study is designed to determine whether or not there is a decrease in 28 day mortality in patients treated with DCLHb compared to those in the control group (not receiving DCLHb).

Secondary Clinical Benefit Measurement

- This study is designed to determine whether or not there is a decrease in serious illness due to the harmful effects from the blood loss in patients treated with DCLHb compared to those in the control group (not receiving DCLHb).
- This study is also designed to determine whether or not there is a decrease in 24 hour lactate levels in patients treated with DCLHb compared to those in the control group (not receiving DCLHb). Lactate is a byproduct of shock caused by a lack of oxygen being delivered to tissues and cells.
- This study is designed to determine whether or not there is a decrease in 48 hour mortality in patients treated with DCLHb compared to those in the control group (not receiving DCLHb).

Patient Population

The patients entered into this study will be a very small number of the total trauma patients who are treated in trauma centers across the U.S. Most will have been treated by emergency medical personnel prior to getting to the hospital and many will still be in shock despite the emergency care outside of the hospital. Patients will participate in the study only after meeting strict entry criteria. These criteria are designed so that only the most severely injured patients who have serious shock and lack of blood flow due to bleeding will participate in the study. These patients are at the greatest risk of death. Patients may be males or females who are believed to be at least 18 years old. Patients with severe head injuries or whose heart has stopped in the hospital will not be entered into the study.

The DCLHb or the control solution (saline) will be given to the patient no later than 30 minutes after meeting these strict criteria and within 60 minutes of arrival at the emergency department.

Study Procedures

All standard therapies and procedures normally used to treat patients with severe shock will be provided. These standard therapies include the immediate infusion of resuscitation fluids and blood, as well as emergency surgery if needed. In addition to standard therapy, patients will initially receive either 500 mL (1 pint) of DCLHb or saline. The solution will be given through a vein, similar to the way in which blood is provided to these shock patients.

After the first infusion of DCLHb or saline, the doctor will evaluate the patient's condition and decide if additional infusions of fluid are needed. Up to two additional 250 mL (½ pint each) of DCLHb or saline can be given within 60 minutes after the start of the first infusion in order to stabilize the patient's shock condition. Strict guidelines will be used to decide whether the infusion should be stopped at any time in order to maximize the patient's safety.

During the study, the doctor will collect information from the patient through physical examinations and laboratory tests including urine specimens, blood withdrawn from a vein, and blood withdrawn from an artery. These procedures are not significantly different from the usual tests done to evaluate and treat a patient in this severely ill condition. Each blood sample drawn will be 5 to 15 cc in volume (between a teaspoon and a tablespoon sized sample).

The healthcare team will also evaluate the patient's vital signs (systolic and diastolic blood pressure, heart rate, respiratory rate and effort) often during the first 48 hours of the study. The patient will also have blood collected and vital signs evaluated at days 4, 7, 10, 14, 21 and 28 after infusion. The patient's participation in the study lasts for a total of 28 days.

Informed Consent for this Study

The consent procedures followed in the protocol will follow the Federal Regulations set forth in 21 CFR 50.24 "Exception from informed consent requirements for emergency research". The IRB from the hospital giving this presentation has reviewed this study and has made sure that all of the rules are met and that they will be followed as the study goes on. The IRB has found the following:

- The shock from blood loss suffered by patients eligible for this study are in is life-threatening and the current treatments are limited and need to be improved.
- The patients eligible for this study are not able to give informed consent because they are in a severe shock state.
- Informed consent is not feasible before starting treatment with DCLHb because DCLHb must be given as soon as possible within minutes of the onset of the severe shock, in order to increase the patient's chance of surviving.

- The patients eligible for this study cannot be identified before they are entered into the study because no one knows who will get hurt and end up in shock.

- The study is in the best interest of all severely injured trauma patients because their life-threatening injuries require immediate treatment and DCLHb may improve their treatment.

- Enough studies have been done with DCLHb to suggest that it may help trauma patients.

- The risks in giving DCLHb are reasonable given the condition of the trauma patients that is, the chance of DCLHb helping severely ill shock patients is much greater than the chance DCLHb will further harm them.

- This study could not reasonably take place without an exception to informed consent.

- An attempt will be made to contact a legally authorized representative for each patient within the window of time before the patient needs to be entered into the study, if feasible.

- An informed consent document is available for obtaining consent from the patient or their legally authorized representative, if feasible.

- If the patient or their legally authorized representative is not available, an attempt will be made to contact a family member of the patient's within the window of time before the patient needs to be entered into the study, if feasible.

- Information is available to provide to a family member of the patient and the family member will be able to refuse to allow the patient to be included in the study.

- If consent is not feasible during the therapeutic window, the patient, their legally authorized representative, or their family member will be notified of the study, as soon as feasible, and may refuse to continue participation in the study for any reason, at any time without any penalty. The patient's medical care will not be affected by their decision, nor will they lose any benefits they might otherwise receive.

Safety Monitoring

An independent Data Monitoring Committee (members not affiliated with Baxter Healthcare or the conduct of the study) will be established in accordance with the Federal Regulations. Ongoing safety monitoring will be independently performed by this committee during the enrollment of study patients. If major safety concerns arise,

the study can be changed so that patient safety can be maximized.

Potential Risks

As with most medical treatments, it is possible that DLCHb could cause reactions or discomforts that were seen in previously completed animal and/or human studies with various hemoglobin solutions. Possible reactions that may occur from infusion with DCLHb are:

- stomach pain (gas, bloating), stomach cramps, constipation, nausea or vomiting shortly after infusions
- back pain or muscle aches
- temporary general weakness or discomfort, headache
- a red discoloration of urine caused by hemoglobin (the protein found in red blood cells that carries oxygen)
- temporary elevation (rise) of certain laboratory test results; for example: proteins and enzymes that could indicate damage to organs such as the pancreas or liver, or to muscles
- temporary inability to do certain laboratory tests accurately
- temporary rise in blood pressure requiring treatment
- temporary jaundice-like condition (yellow skin)
- abnormal kidney function
- temporary increase in the time it takes for blood to clot
- small areas of damage in heart muscle, liver, or kidneys (only seen in some laboratory animals)
- allergic reactions such as chills, elevated temperature, or skin rash

DCLHb has been studied in over 350 patients, thus far, including patients with conditions other than severe traumatic shock, including patients undergoing various surgical procedures including cardiac surgery, orthopedic surgery and abdominal aortic repair, patients on renal dialysis and patients suffering acute ischemic stroke. However, there may be risks relative to the use of this product that cannot be anticipated from such prior human use and the use of DLCHb could cause reactions (side effects) that are currently unknown.

Also, patients with severe trauma are currently being treated with a number of therapies including surgical and drug therapies. These currently used treatments carry substantial risks in and of themselves, including death and permanent injury.

Because DCLHb is an investigational solution and the effects in pregnancy have not been determined, risks to an unborn baby are unknown at this time. DCLHb will not be given to patients who are known to be pregnant.

The risks associated with drawing blood include pain, bruising, lightheadedness, and occasionally, infection. These risks are usually small. Some blood drawing will be done through already-existing catheters (tubes) left in the blood vein or artery. This greatly reduces the painful part of repeated blood drawing. Insertion of a catheter (tube) into a blood vein or artery will only be done if needed as part of the usual care of the patient. This practice is typical for patients who are critically injured.

Benefits

Patients who receive DCLHb may have an increased chance of survival or of avoiding serious prolonged illness. However, there is no guarantee that this solution may benefit those who receive it. The potential benefits to all of the study participants include extensive medical testing and examination. Another important potential benefit is that the information gained from this study could help patients who need this type of medical care in the future.

Additional Costs

Special laboratory studies will be done on the blood samples, at the expense of the researchers and at no extra cost to the patient. There will be no additional cost to the patient for participating in the research protocol beyond the costs of the standard medical care required to treat the patient's condition.

Alternative (Other) Treatments

It is important to note that all patients who participate in this study will receive the best known current therapy for traumatic hemorrhagic shock, including the immediate infusion of resuscitation fluids and blood and emergency surgery, if needed. In other words, being a patient in this study will not hinder the delivery of any of the lifesaving therapies that are currently used in patients with severe shock.

The alternative to participating in this study, is to receive the standard medical care that critically injured trauma patients currently receive in the emergency setting.

Additional Information

Besides the risks and side effects described, additional risks that are not currently known may arise. If additional side effects are discovered, the sponsor (Baxter Healthcare) will notify each doctor participating in the study. The doctor will be responsible for sharing this information with his/her patients.

Voluntary Continued Participation and Withdrawal

If consent from the patient or their legally authorized representative is feasible, the decision to participate will be voluntary. If informed consent is not feasible, an attempt will be made to inform a family member. The family member's decision to include the patient in the study will be voluntary. Even if the decision is made for the patient to take part in the study, the patient may be withdrawn from the study at any time. The patient's medical care will not be affected by this decision, nor will the patient lose any

benefits he or she might otherwise receive.

In addition, if consent is not feasible during the time in which DCLHb must be given, the patient, their legally authorized representative, or their family member will be notified of the study, as soon as feasible. Any of these parties may refuse to the continued participation of the patient in the study for any reason, at any time without any penalty. The patient's medical care will not be affected by their decision, nor will they lose any benefits they might otherwise receive. If a patient decides to withdraw from the study, all data collected from that patient will be used up to the time he or she withdrew. This information is necessary in determining the safety and efficacy of the product and is mandated by the FDA. Any patient who decides to withdraw, or declines to continue participation in the study, will be asked to consent to a 28 day follow-up contact which may be made by phone. Once a patient has declined to participate further in the study, no other contact will be made with the patient unless a safety issue arises that requires further contact. Information that is part of public record may be used.

A patient's doctor may withdraw them from a study at any time without their consent if they believe that withdrawal is in the patient's best interest. The study sponsor or the FDA may also cancel this study at anytime.

Confidentiality

A patient's participation in this study will remain confidential. To make sure the information from this study is accurate, the study sponsor (Baxter Healthcare), their representatives (ClinTrials Research or other auditors), the Institutional Review Board, the FDA, and other governmental agencies, may inspect the records concerning a patient's participation in this study. Information gathered from this study may be submitted to governmental or regulatory agencies in other countries where the study drug may be considered for approval. No patients will be identified by name as a result of any audit or in any publication of information from this study.

Compensation for Research-Related Injury

Patients will not be compensated for their participation in the study. Any patients physically injured as a direct result of participation in this study will be provided the medical care needed to help them recover, at no cost to them, by the sponsor. No compensation other than free medical care will be provided.

Contact for Further Information

For any questions regarding this study, or patient's rights, please contact the doctor responsible for the study at this clinical site.

After its publication, an EIS was available for public review and comment. The EIS was prepared that the comments on the EIS after its publication, the was also made available to the public and agency review and comment. The General Services Administration believes that there are no outstanding issues to be resolved with respect to the proposed project. Copies of the full text of the Record of Decision (ROD) can be obtained from Mr. John Garvey, Portfolio Management (997), Buildings Service, 650 Golden Gate Avenue, San Francisco, California 94102, (415) 523-3400.

9/22/97
Notice for
1. Kaiima
21 Administrator (9A)
September 28, 1997
Las Vegas Review-Journal

Rainbow Boulevard, Las Vegas, Nevada 89102 and H. H. Ivey & Associates Consulting Engineers, 4811 West Cherronne Avenue, North Las Vegas, Nevada 89008. Envelopes containing bids must be clearly marked on the outside "BID FOR: MAIN FACILITY DIRECT DIGITAL CONTROL SYSTEM, CLARK COUNTY HEALTH DISTRICT", must bear the name of the bidder and be delivered in a sealed envelope to:

Clerk County Health District
c/o David Rowles, Director,
Administrative Services
Administration Division
425 Shadow Lane
Las Vegas, NV 89108

on or before 3:30 P.M., OCTOBER 14, 1997. Bids will then be opened and publicly read aloud in the Administrative Conference Room of the Health District, 425 Shadow Lane.

John Davis, Director
Purchasing Department
PUB: September 28, 1997
Las Vegas Review-Journal

**NOTICE
REQUEST FOR PROPOSALS -
PHARMACY SERVICES**

Southern Nevada Adult Mental Health Services, State of Nevada, will be accepting proposals from qualified pharmacy service providers to provide pharmacist and pharmacy technician coverage to handle staff's vacation, sick leave, emergencies and regularly scheduled days off. Providers desiring to submit a proposal may pick up a "Request for Proposal" at the reception desk at 1616 W. Charleston Blvd., Las Vegas, NV or request by phone, 482-8076. Proposals will be accepted until 5:00 P.M., 10/10/97. The State reserves the right to reject any or all proposals.

PUB: Sept. 24, 27, 28, Oct. 3, 4, 1997
Las Vegas Review-Journal

The Owner reserves the right to accept or reject any or all offers and to waive irregularity in the bidding and accept the bid which is determined by the Owner to be in his own best interest.

Dates of publication for this advertisement: Sunday, September 21, 1997 and Sunday, September 28, 1997, by order of the Board of Trustees of the Clark County School District
PUB: September 21, 28, 1997
Las Vegas Review-Journal

NOTICE IS HEREBY GIVEN that Section 2 of Nevada will be held OCTOBER 1, 1997 at 9:00 a.m. at 3971 South Pecos. Bids over \$1,000.00 will be considered. Cash only. For one black mare & one gray gelding. For board bid by Lori Kloss. This is final notice.

PUB: September 21, 28, 1997
Las Vegas Review-Journal

Community College of Southern Nevada is interested in purchasing and will accept sealed bids to the date and time indicated.

ATERING SERVICES
RFP #112
September 14, 1997 - 3:30 P.M.

It will be opened in the Purchasing Department, Physical Plant Administrative Services Building, City College of Southern Nevada, 250 East Cheyenne Avenue, Las Vegas, Nevada. For information, please contact: Purchasing Department
TOLLAND,
Director of Purchasing
702) 451-4320
September 28, 1997
Las Vegas Review-Journal

ADVERTISMENT FOR BIDS

Sealed bids will be received at the Clark County School District, REHAB AND MODERNIZATION SERVICES OFFICE, 4828 S. PEARL ST., LAS VEGAS, NV 89121, until 3:00 PM, OCTOBER 9, 1997, and then opened and read aloud publicly at the CONTRACTS AND CONSTRUCTION MANAGEMENT CONFERENCE ROOM for the furnishing of all labor, materials to perform the work in conjunction with:

**NEW GYM FLOOR
WILLIAM ORR MIDDLE SCHOOL**

One complete set of Bid Documents may be obtained at no charge, after September 26, 1997, between the hours of 8:30 am to Noon and 1:00 pm to 4:00 pm, for the REHAB AND MODERNIZATION SERVICES OFFICE, 4828 S. PEARL ST., LAS VEGAS, NEVADA 89121. ADDITIONAL SETS CAN BE OBTAINED WITH COMPANY CHECK OR MONEY ORDER FOR A NON-REFUNDABLE FEE OF \$15.00. Plans may be reviewed locally at the office of the Owner, Sierra Construction Notebook, and P.W. Dodge Plan Rooms. Bidders will be required to provide a Security Deposit in the form of a Bid Bond, issued by a Surety Company, licensed to do business in the State of Nevada, and acceptable to the Owner, or certified check of a sum of no less than five percent (5%) of the bid price.

Bids must be submitted on the Bid Forms provided in the Bid Documents and shall be irrevocable for a period of sixty (60) days after Bid Closing.

The Owner reserves the right to accept or reject any or all offers and to waive irregularity in the bidding and accept the bid which is determined by the Owner to be in his own best interest.

By order of the Board of Trustees of the Clark County School District
PUB: September 24, 28, 1997
Las Vegas Review-Journal

ADVERTISMENT FOR BIDS

Sealed bids will be received at the Clark County School District, Construction Management Dept., 4828 S. Pearl St., Las Vegas, NV 89121, until 3:00 PM, MONDAY, OCTOBER 26, 1997, and then opened and read aloud publicly for the furnishing of all labor, materials, and performing all work in conjunction with the construction of:

Virgin Valley Elementary School
Modernization
CCSD Project No. 9885

The Project consists of interior demolition work, partially renovating existing toilets, classrooms, teacher's lounge and workroom, offices, auditorium and stage, health center, kitchen and canteen, and library. (Replacement with new facilities: Headband room and new health center rest room.) This includes all electrical, mechanical, plumbing, and carpentry.

PUBLIC NOTICE

**UMC EVALUATION
NEW TREATMENT FOR
SEVERE BLOOD LOSS**

University Medical Center of Southern Nevada (UMC) has been asked to evaluate a new treatment for seriously injured patients admitted to its Trauma Center with severe loss of blood. Baxter Healthcare Corp. has developed a patented product which has potential as a blood substitute during the emergency treatment and recovery period. The blood substitute is derived from human red blood cells and is heated and filtered to make it safe from viruses. Typical side effects seen in other studies include temporary increases in blood pressure, yellowing of the skin and reddening of the urine.

University Medical Center would like to make this available to those for whom there may or may not have someone to sign a consent form while they face a life-threatening situation for which standard therapy offers little hope.

NOTICE TO ALL INTERESTED PARTIES

SALE OF 8312 VIBRANT DRIVE, LAS VEGAS

NOTICE IS HEREBY GIVEN that on September 29, 1997, the United States District Court, Central District of California, in a pending action known as Securities and Exchange Commission v. Financial Services, Inc., et al., Civil No. 94-4228-RAP (Ex), authorized the Receiver for Financial Services, Inc. ("CFS") to sell a property located at 8312 Vibrant Drive, Las Vegas, Nevada for \$154,000 pursuant to an agreement entered into with an interested buyer.

The sale is subject to the Court's confirmation. A hearing for the Court's confirmation of the sale on or 28 U.S.C. ss 2007 is currently scheduled for October 20, 1997, at 9:30 a.m. in Courtroom 1 of the United States District Court, Central District of California, located at 255 East Temple Street, Los Angeles, California.

Any other party interested in purchasing this property by overbid must appear at the Court's confirmation hearing on October 20, 1997 with a cashier's check in the amount of at least \$10,000.

NOTICE TO ALL INTERESTED PARTIES

USE RE-ROOF

NUMBER: 97-8-12
SCHEDULED: September 28, 1997
CLOSING DATE: October 13, 1997
3:00 P.M. MST

Bids will be received by the Clark County Purchasing Department, P.O. Box 7000, Kingman, Nevada 89402-7000 until the opening of bids stated above. The bids

ADVERTISMENT FOR BIDS

Sealed bids will be received at the Clark County School District, Construction Management Dept., 4828 S. Pearl St., Las Vegas, NV 89121, until 3:00 PM, MONDAY, OCTOBER 26, 1997, and then opened and read aloud publicly for the furnishing of all labor, materials, and performing all work in conjunction with the construction of:

Virginia Valley Elementary School
Modernization
CCSD Project No. 9885

The Project consists of interior demolition work, partially renovating existing toilets, classrooms, teacher's lounge and workroom, offices, auditorium and stage, health center, kitchen and canteen, and library. (Replacement with new facilities: Headband room and new health center rest room.) This includes all electrical, mechanical, plumbing, and carpentry.

The U.S. Food and Drug Administration (FDA) required new drugs and therapies to be proven effective with volunteer human patients before approval for marketing. The FDA has recently ruled that, under strict circumstances, unconscious patients whose life is in danger and for whom there is no alternative with a good chance of success. Patients or their families will be notified of the unique opportunity of their inclusion in the research study.

UMC believes that injury victims with severe loss of blood meet all of these conditions where a waiver of consent could be justified. The FDA requires UMC to inform the public and receive public input before a decision is made to allow this treatment.

To communicate with UMC on this subject, please contact us at:
Trauma Services
University Medical Center
1800 W. Charleston Blvd
Las Vegas, NV 89102
(702) 383-3729

A public hearing will be held on:
DATE: October 3, 1997
TIME: 9:00 AM
LOCATION: 2840 W. Charleston Boulevard, 6th Floor - Rooms E&F
Las Vegas, Nevada 89102

PUB: September 26, 27, 28, 1997
Las Vegas Review-Journal & Sun

*Las Vegas
Review-Journal
and Sun
Sept. 26, 27, 28, 1997*

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Why Walk?

Una carrera para atletas élite en Nevada

Juan In A Million 5K

A Brian de Almeida, Kevin y Melissa se dieron cita en la escuela vespertina de la carrera dedicada a la memoria de John Bailey, oficial asesinado durante un saqueo bancario en Las Vegas.

Resultados cortesía de Jan Callanan TRI-A-RUN



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La corredora americana Joseph Alder no pudo repetir



EL ORIGINAL
GOOD TIME
Photography & Festival

FOTOS PARA
 • INMIGRACION
 • PASAPORTES
 • FUTBOL SOCCER
 • CARTILLA
 • BODA Y QUINCEAÑOS

RECIBA UN ROLLO GRATIS
 CON CADA REVELADO EN NUESTRO FOTO-LAB

REVELADO DE ROLLO EN UNA HORA!

574 No. Eastern

382-5378

UMC ANUNCIA NUEVO TRATAMIENTO

Se le ha anunciado al University Medical Center of Southern Nevada (UMC) que existe un nuevo tratamiento para pacientes seriamente lesionados que son admitidos a su Centro de Trauma con pérdida severa de sangre. Baxter Healthcare Corp. ha desarrollado un producto de plasma que tiene la potencialidad de ser un sustituto para la sangre durante el periodo de emergencia y de recuperación. Este sustituto de la sangre es un derivado de células humanas y es coagulable y filtrado para hacerlo seguro contra los virus. Los efectos tóxicos laterales que se han visto en otros estudios incluyen aumentos temporales en la presión de la sangre, amarillamiento de la piel y ensordecimiento de la orina.

Al University Medical Center le gustaría hacer disponible este tratamiento para aquellos pacientes para los que pueda o no pueda haber alguna que firme de consentimiento para recibir este tratamiento, mientras encaran una situación en que se pone en peligro su vida, y para quienes la terapia normal ofrece poca esperanza.

El U.S. Food and Drug Administration (FDA) requiere que nuevas drogas y terapias prueben que sean efectivas con pacientes humanos voluntarios antes de ser aprobadas para su uso. La FDA recientemente ha determinado, que bajo circunstancias específicas, pacientes inconscientes cuya vida está en peligro y por quienes no hay ningún consentimiento disponible se les puede dar tratamientos experimentales si no existen otras alternativas con esperanzas de recuperación. Los pacientes o sus familias serán notificados a la primera oportunidad de su inclusión en esos estudios de investigación.

UMC cree que una víctima lesionada con severa pérdida de sangre satisfizo estas condiciones, en las que la excepción de una autorización es justificada. El FDA requiere que el UMC informe al público y reciba una opinión pública antes que se tome la decisión de permitir este tratamiento.

Para comunicarse con el UMC sobre este asunto, por favor comuníquese con nosotros a:

Trauma Services
 University Medical Center
 1840 W. Charleston Blvd.
 Las Vegas, NV 89102
 (702) 363-3739

Una audiencia pública será sostenida en:
 FECHA: Octubre 3, 1997
 TIEMPO: 5:00 pm.
 DONDE: 2640 W. Charleston Boulevard
 6th Floor - Romas E y F
 Las Vegas, Nevada 89102.

UN PUEBLO SIN CINE ES UN PUEBLO TRISTE

SE BUSCAN PROMOTORES
 Necesitamos promotores para funciones nocturnas. Personalidad sobresaliente, excelentes ingresos, interesados llamar al **434-4477**

Attachment 13

BOARD OF TRUSTEES

Erin Kenny, Chair
Mary J. Kincaid, Vice Chair
Yvonne Atkinson Gates
Lorraine T. Hunt
Lance M. Malone
Myrna Williams
Bruce L. Woodbury



*Care How Much We Know
Know How Much We Care.*

PUBLIC NOTICE

NOTICE IS HEREBY GIVEN that a public hearing will be held by the Trauma Service of University Medical Center of Southern Nevada for the purpose of providing opportunity for public comment regarding the use of Diaspirin-Cross-Linked Hemoglobin (DCLHb™) in the treatment of patients with severe, hemorrhagic shock.

Friday, October 3, 1997 - 5:00 pm
2040 W. Charleston Boulevard
6th Floor, Rooms E & F
Las Vegas, Nevada 89102

THIS MEETING HAS BEEN PROPERLY NOTICED AND POSTED IN THE FOLLOWING LOCATION:

1. CLARK COUNTY GOVERNMENT CENTER, 500 SOUTH GRAND CENTRAL PARKWAY, LAS VEGAS, NEVADA
2. UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA, 1800 WEST CHARLESTON BOULEVARD, LAS VEGAS, NEVADA
3. NORTH LAS VEGAS CITY HALL, 2200 CIVIC CENTER DRIVE, NORTH LAS VEGAS, NEVADA
4. DISTRICT HEALTH DEPARTMENT, 1600 PINTO LANE, LAS VEGAS, NEVADA

CITIZENS WHO WISH TO PROVIDE TESTIMONY OR COMMENT PLEASE STEP TO THE PODIUM, CLEARLY STATE YOUR NAME AND ADDRESS -- PLEASE SPELL YOUR NAME FOR THE RECORD AND LIMIT YOUR COMMENTS TO NO MORE THAN THREE MINUTES.

UNIVERSITY MEDICAL CENTER

1800 W. Charleston Blvd. • Las Vegas, Nevada 89102 • (702) 383-2000

An Equal Opportunity (including the Handicapped) - Affirmative Action Employer



UNIVERSITY OF NEVADA SCHOOL OF MEDICINE

Department of Surgery

EDWARD P. SLOAN, M.D., M.P.H., FACEP,
Associate Professor
Dept. of Emergency Medicine
University of Illinois
College of Medicine - Chicago

SPEAKING ON

OXYGEN CARRYING SOLUTIONS IN THE TREATMENT OF HEMORRHAGIC SHOCK

THURSDAY, SEPTEMBER 18, 1997

AT 5:00 P.M.

AUDITORIUM, SIXTH FLOOR

2040 WEST CHARLESTON BOULEVARD

FOR: General surgeons, emergency room doctors, internists, family practitioners, pediatricians, intensivists, and surgery specialists

The University of Nevada School of Medicine is accredited by the Nevada State Medical Association to sponsor Continuing Medical Education for physicians. The University of Nevada designates this continuing medical education activity for 1 credit hour in Category 1 of the Physicians Recognition Award of the American Medical Association.

**Department of Surgery
University of Nevada School of Medicine
(702) 671-2339**

UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA
MEETING MINUTES

ATTENDANCE: John Fildes, MD - Chief, Dept. Of Trauma & Principal Investigator
 Connie Clemons-Brown, RN - Clin. Mgr, Trauma & Study Coordinator
 Jacqueline Taylor - Chief Administrative Officer
 Stanton Carroll, M.D. - Medical Director, Administration
 Dale Pugh - Assistant Administrator, Public Relations/Marketing
 Kim Voss - Director, Performance Improvement/Utilization Management
 Joan Ryan - Director, Medical Staff Services
 Martin Heiny - Director, Risk Management/Safety
 Kathleen Kline - IRB Coordinator

MEETING: DCLHB™ Informational Meeting
 Administrative Staff
DATE: June 4, 1997
TIME: 3:00 pm - 4:00 pm
LOCATION: Trauma Service Office-Suite 507

TOPIC	DISCUSSIONS	CONCLUSION/ACTION	FOLLOW-UP
INTRODUCTION AND OVERVIEW	Dr. John Fildes began the meeting by welcoming all in attendance and providing an overview of the "Efficacy Trial of <i>Diaspirin Cross-Linked Hemoglobin (DCLHB™)</i> in the Treatment of Severe, Traumatic Hemorrhagic Shock" recently approved by the UMC Institutional Review Board. The overview included an overhead projection presentation of the information distributed to the members prior to the meeting and a discussion regarding the history of blood substitute products. (See attached for copies).	Informational - see below for specific information topics and discussions.	None
OBJECTIVES, METHODOLOGIES AND INCLUSION & EXCLUSION CRITERIA	Dr. Fildes explained the process of manufacturing DCLHB™, its associated risks, objectives for the study, methodology for selecting patients and he detailed the inclusion and exclusion criteria - reviewing each individually.	Members acknowledged understanding of information. NO concerns voiced nor recommendations/changes/action.	None

DCLHB™ Minutes - Admin.
June 4, 1997
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TOPIC	DISCUSSIONS	CONCLUSION/ACTION	FOLLOW-UP
CONSENTS	The Abbreviated and Informed Consent Forms and accompanying algorithms were reviewed in detail.	Members recommended the following: 1. Include in the Abbreviated consent form a list of the risks and benefits associated with DCLHB™, as well as a description of the penalty (if any) for withdrawing from the study.	Forward consent forms with modifications to District Attorney's office for review & approval, then to ClinTrials and IRB.
PUBLIC DISCLOSURE PLAN	Dr. Fildes provided a step by step review of the proposed Public Disclosure Plan including the Grand Rounds presentation by Dr. Ed Sloan. He discussed the news articles and circulated samples of articles published at other study sites. In addition, the need for a Public Hearing was discussed. Members present felt that a hearing should be held and members in the community with a vested interest (i.e., M.A.D.D., Religious Leaders, County Commissioners, Law Enforcement, County Health District, RMS, etc.) should be invited. Minutes from these and all meetings regarding DCLHB™ will be maintained and forwarded to ClinTrials when completed. Dr. Fildes will be on vacation in July so he stated that he would not initiate the Public Disclosure Plan or Grand Rounds by Dr. Sloan until August at the earliest (6 weeks out). Only one public hearing will be held and a 24 hour telephone line will be installed to allow community members to call to ask questions or express concerns. These will be documented as well.	Actions Needed: 1. Dr. Fildes will confirm date with Dr. Sloan for Grand Rounds presentation - once confirmed - public time line for completion of public disclosure and initiation of study 2. Forward summary of DCLHB™ study (in lay terms) to the County Commissioners (Hospital Board of Directors), similar to the information presented today, in order to keep them informed 3. Forward samples of the news articles to Mr. Pugh, Asst. Administrator - Marketing and Public Relations, and District Attorney 4. Install 24 hour phone line	

DCLHbTM Minutes - Admin.
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<u>TOPIC</u>	<u>DISCUSSIONS</u>	<u>CONCLUSION/ACTION</u>	<u>FOLLOW-UP</u>
BUDGET	Dr. Fildes reviewed the Budget for the study. No questions.	Budget Approved	None
SUMMARY	Dr. Fildes summarized the information presented and the recommendations made by the members present.	Members verbalized Administrative support for the study. Forward copy of minutes to ClinTrial.	Copy of minutes to ClinTrial Copy of minutes to those in attendance Copy of minutes to Director of Lab and the Pharmacy Contact

There being no further business, the meeting was adjourned at 4:00 pm

Respectfully Submitted,



Connie Clemmons-Brown, RN
Clinical Manager, Trauma
Study Coordinator

cc: William Hale, Chief Administrative Officer
Gwen Shockley, CRA - ClinTrials Research

University Medical Center
1800 West Charleston Blvd., Las Vegas, NV 89102
Contact: Trish Lampro
Telephone: (702) 383-2090

FOR IMMEDIATE RELEASE

**UMC HAS BEEN ASKED TO EVALUATE A NEW TREATMENT
FOR SERIOUSLY INJURED PATIENTS WHO ARE ADMITTED TO THE
TRAUMA CENTER WITH SEVERE LOSS OF BLOOD**

LAS VEGAS, N.V., September 17, 1997 -- University Medical Center has been asked to evaluate a new patented product developed by Baxter Healthcare Corporation which has the potential as a blood substitute during the emergency treatment and recovery period. The blood substitute is derived from human red blood cells and is heated and filtered to make it safe from viruses.

Dr. Edward Sloan, M.D., M.P.H., FACEP, an Associate Professor from the University of Illinois, will lead a discussion on a new treatment for seriously injured patients. Dr. Sloan will conduct this discussion on "Oxygen Carrying Solutions in the Treatment of Hemorrhagic Shock" on Thursday, September 18th at 5 pm in the UMC Education and Ambulatory Care Center (2040 West Charleston Blvd. - 6th floor).

UMC would like to make this potential blood substitute available to those patients who are facing a life-threatening situation for which standard therapy offers little hope. The FDA requires UMC to inform the public and receive public input before a decision is made to allow for this treatment. A public hearing will be conducted October 3rd at 5 pm located at 2040 West Charleston Blvd.

UMC is the state's leading teaching hospital and provides the community with most comprehensive medical services available in Southern Nevada. For more information about this presentation, please contact Trish Lampro at 383-2090.

###

Nevada Business Journal
Attn: Liz Young
2127 Paradise Road
Las Vegas, NV 89104

KBLR TV Channel 39
Attn: Betina Bert
5000 West Oakey, #B
Las Vegas, NV 89102

Las Vegas Review Journal
Attn: Annette Caramia
1111 West Bonanza Road
Las Vegas, NV 89106

Nevada Business Journal
Attn: Connie Brennan
2127 Paradise Road
Las Vegas, NV 89104

KVBC TV Channel 3
Attn: Robert Martinez
1500 Foremaster Lane
Las Vegas, NV 89101

KLAS TV Channel 8
Attn: Kyle Iboshi
3228 Channel 8 Drive
Las Vegas, NV 89109

KNUU- AM/KNEWS Radio 970 AM
Attn: Fred Lewis
2001 East Flamingo Road, #101
Las Vegas, NV 89109

KLUC Radio 98.5 FM
Attn: Melanie McKay
6655 West Sahara Avenue, Ste. D208
Las Vegas, NV 89118

KKLZ Radio 96.3 FM
Attn: Dennis Mitchell
4305 South Industrial Road
Las Vegas, NV 89103

KDOL Radio 1280 AM
Attn: Gabriel Borja
953 East Sahara Avenue
Las Vegas, NV 89104

Las Vegas Chamber of Commerce
Attn: Lisa Wise-McLeary
3720 Howard Hughes
Las Vegas, NV 89109-0937

Las Vegas Review Journal
Attn: Frank Fertado
1111 West Bonanza Road
Las Vegas, NV 89106

Las Vegas Sun
Attn: Jeff Schumacher
800 South Valley View
Las Vegas, NV 89107

KBLR TV Channel 39
Attn: Marlene Monteolivo
5000 West Oakey, #B
Las Vegas, NV 89102

KLAS TV Channel 8
Attn: Jim Wiggam
3228 Channel 8 Drive
Las Vegas, NV 89109

KTNV TV Channel 13
Attn: Denise Whitman
3355 Valley View
Las Vegas, NV 89102

KVVC Radio 105.1 FM
Attn: Kevin Malone
1500 Foremaster Lane
Las Vegas, NV 89101

KHWY Radio 99.5
Attn: Keith Hayes
101 Convention Center Drive, P -109
Las Vegas, NV 89109

KBGO Radio 93.1 FM
Attn: Vikki Wood
1130 East Desert Inn Road
Las Vegas, NV 89109

KFMS Radio 101.9 FM
Attn: Ted Marvelle
1130 East Desert Inn Road
Las Vegas, NV 89109

KHWK Radio 92.7 FM
Attn: Bob Wynters
PO Box 1669
Las Vegas, NV 89049

KMXB Radio 94.1 FM/KMZQ Radio 100.5 FM
Attn: Cindy Weiner Schloss
6655 West Sahara Avenue, Ste. C-216
Las Vegas, NV 89102

KWNR Radio 95.5 FM
Attn: Roy West
1130 East Desert Inn
Las Vegas, NV 89109

KINC TV Channel 15
Attn: Gabriel Quiroz
500 Pilot Road, Ste. D
Las Vegas, NV 89119

Newsletter "County Chronical"
Attn: Michael Papa George
500 Grand Central Parkway, 1st Floor
Las Vegas, NV 89115

View Newspapers
Attn: Kirk Kern
PO Box 70
Las Vegas, NV 89125

KRLV Radio 1340 AM
Attn: Lisa Lupo
1515 East Tropicana Avenue, Ste. 240
Las Vegas, NV 89119

Las Vegas Review Journal
Attn: Jim Laurie (Photography Department)
1111 West Bonanza Road
Las Vegas, NV 89106

KVBC-TV Channel 3
Attn: Beckie Bower (Weekend Assignment Editor)
1500 Foremaster Lane
Las Vegas, NV 89101

KVVU TV Channel 5
Attn: Matt McCombe
25 TV 5 Drive
Henderson, NV 89014

KKVV Radio 1060 FM
Attn: Bill Ball
3185 South Highland Drive, Ste 13
Las Vegas, NV 89109

KOMP Radio 92.3 FM
Attn: Andy Kaye
PO Box 26629
Las Vegas, NV 89126

KXNT Radio 840 AM
Attn: Tom Humm
6655 West Sahara Avenue, Ste. D 208
Las Vegas, NV 89119

Channel 4 "Clark County Chronicals"
Attn: Dave Linder/Hilarie Grey
500 Grand Central Parkway
Las Vegas, NV 89155

Las Vegas Business Press/Las Vegas Senior
Attn: Steve Green
3335 Wynn Road
Las Vegas, NV 89102

Latitude Newspapers
Attn: Ed Dodrill
2949 East Desert Inn Road, #7
Las Vegas, NV 89121

Nevada Association of Hospitals and Health Systems
Attn: Jeanette Belz, CEO
4600 Kietzke Lane, Ste. A 108
Las Vegas, NV 89502

KLAS TV Channel 8
Attn: Stacey Welling (Weekend Assignment Editor)
3228 Channel 8 Drive
Las Vegas, NV 89109

KTNV TV Channel 13
Attn: Eric Darensburg (Weekend Assignment Editor)
3355 Valley View
Las Vegas, NV 89102

MD News Magazine and Radio Show
Attn: George Geller
3919 Parkhaven Drive
Las Vegas, NV 89120

KTNV TV Channel 13
Attn: Fred DeSousa
3355 Valley View
Las Vegas, NV 89102

Writer
Debbie Hall
3550 South Paradise Road, #368
Las Vegas, NV 89109

KFMS-FM 101.1
Attn: Bob Fisher
1130 East Desert Inn Road
Las Vegas, NV 89109

BOARD OF TRUSTEES

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Mary J. Kincaid, Vice Chair
Yvonne Atkinson Gates
Lorraine T. Hunt
Lance M. Malone
Myra Williams
Bruce L. Woodbury



*Care How Much We Know
Know How Much We Care.*

September 26, 1997

Sunrise Congregation of Jehovah's Witnesses
1881 N. Walnut Road
Las Vegas, NV 89115

A public hearing will be held by the Trauma Service of University Medical Center of Southern Nevada for the purpose of providing an opportunity for public comment regarding the use of Diaspirin Cross Linked Hemoglobin (DCLHb™) in the treatment of patients with severe, traumatic hemorrhagic shock. UMC has been asked to evaluate a new treatment for seriously injured patients admitted to its Trauma Center with severe loss of blood.

BAXTER Healthcare has developed a patented product which has potential as a blood substitute during the emergency treatment and recovery period. The blood substitute is derived from human red blood cells and is heated and filtered to make it safe from viruses.

The U.S. Food and Drug Administration (FDA) requires new drugs and therapies to be proven effective with volunteer human patients before approval for marketing. The FDA has recently ruled that, under strict circumstances, unconscious patients whose life is in danger and for whom there is no alternative with a good chance of success. Patients or their families will be notified at the earliest opportunity of their inclusion in the research study. Obviously, patients with know objection to the use of blood products and blood transfusions will not be included in this study.

We welcome your participation and input at the public hearing scheduled for:

DATE: Friday, October 3, 1997
TIME: 5:00 - 6:00 pm
LOCATION: 2040 W. Charleston Boulevard
Las Vegas, NV 89102

Comments may also be communicated to the Trauma Service by calling: (702) 383-3729 and leaving a message.

UNIVERSITY MEDICAL CENTER

1800 W. Charleston Blvd. • Las Vegas, Nevada 89102 • (702) 383-2000

An Equal Opportunity (Including the Handicapped) - Affirmative Action Employer

LISTING OF JEHOVAH'S WITNESSES CONGREGATIONS

<u>CONGREGATION</u>	<u>PHONE NUMBER</u>	<u>E/U CALL</u>
SUNRISE CONGREGATION OF JEHOVAH'S WITNESSES 1881 N. WALNUT ROAD LAS VEGAS, NV 89115	453-1277	Reminder call 10/03/97
PARADISE AND SUNSET CONGREGATION OF JEHOVAH'S WITNESSES 2520 E. PATRICK LANE LAS VEGAS, NV 89120	736-7450	Reminder call 10/02/97 & 10/03/97 - no answer
KINGDOM HALL OF JEHOVAH'S WITNESSES 5025 DONNIE AVENUE LAS VEGAS, NEVADA 89130	645-4590	Reminder call 10/03/97
JEHOVAH'S WITNESSES 5546 W. OAKLEY BOULEVARD LAS VEGAS, NV 89102	877-1172	Reminder call 10/03/97
JEHOVAH'S WITNESSES 601 ARROWHEAD TRAIL HENDERSON, NV 89015	565-8220	Reminder call 10/03/97
GREEN VALLEY CONGREGATION OF JEHOVAH'S WITNESSES 3090 MOUNTAIN VISTA LAS VEGAS, NV 89121	454-3090	Reminder call 10/03/97

BOARD OF TRUSTEES

Erin Kenny, Chair
Mary J. Kincaid, Vice Chair
Yvonne Atkinson Gates
Lorraine T. Hunt
Lance M. Malone
Myrna Williams
Bruce L. Woodbury



*Care How Much We Know.
Know How Much We Care.*

September 2, 1997

Sandy Heverly
STOP D.U.I.
3321 Sunrise Avenue, Suite 107
Las Vegas, NV 89101

Dear Ms. Heverly:

A public hearing will be held by the Trauma Service of University Medical Center of Southern Nevada for the purpose of providing an opportunity for public comment regarding the use of Diaspirin Cross Linked Hemoglobin (DCLHb™) in the treatment of patients with severe, traumatic hemorrhagic shock. UMC has been asked to evaluate a new treatment for seriously injured patients admitted to its Trauma Center with severe loss of blood.

BAXTER Healthcare has developed a patented product which has potential as a blood substitute during the emergency treatment and recovery period. The blood substitute is derived from human red blood cells and is heated and filtered to make it safe from viruses.

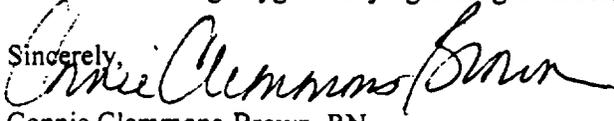
The U.S. Food and Drug Administration (FDA) requires new drugs and therapies to be proven effective with volunteer human patients before approval for marketing. The FDA has recently ruled that, under strict circumstances, unconscious patients whose life is in danger and for whom there is no alternative with a good chance of success. Patients or their families will be notified at the earliest opportunity of their inclusion in the research study. Obviously, patients with known objection to the use of blood products and blood transfusions will not be included in this study.

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DATE: Friday, October 3, 1997
TIME: 5:00 - 6:00 pm
LOCATION: 2040 W. Charleston Boulevard
Las Vegas, NV 89102

Comments may also be communicated to the Trauma Service by calling: (702) 383-3729 and leaving a message. In addition, I have attached a flyer announcing a Grand Rounds presentation by Dr. Edward Sloane concerning oxygen carrying hemoglobin solutions. Your attendance is welcomed.

Sincerely,


Connie Clemmons-Brown, RN

UNIVERSITY MEDICAL CENTER

1800 W. Charleston Blvd. • Las Vegas, Nevada 89102 • (702) 383-2000

An Equal Opportunity (Including the Handicapped) - Affirmative Action Employer



TEMPLE NEIGHBORS

A Community Newsletter from Temple University Health Sciences Center

DECEMBER 1997

Temple Children's Update

With Dr. Howard Grant, CEO



North Philadelphia will soon be home to a new medical center for children. The doors of the Temple University Children's Medical Center will open in January.

Temple Children's will provide an array of services to the children in the community. We want people to know that Temple Children's is not just a hospital. The nine-story, 60-bed facility, joined to Shriners Hospitals For Children, will offer more than beds, nurses and physicians. We plan for Temple Children's to serve as a home for a variety of outreach, preventive and health maintenance programs for the families, community organizations and institutions that are the heart of this community.

We will be active in all outreach and related educational programs. A major focus of Temple Children's will be to tackle the problems that persist in the lives of children in North Philadelphia and the surrounding communities. We need to increase immunizations and prenatal care, and decrease the incidence of lead poisoning in this community.

Our team of pediatricians, pediatric surgeons and other specialists are on board to serve the community with quality care and services. We are determined to treat every child and family with dignity and respect. To accomplish these objectives as efficiently as possible and maintain low medical costs, we will partner with other hospitals, as well as pool the resources of Temple's main hospital and Shriners Hospitals. Our expectation is to see about 30,000 ambulatory patients per year.

To assure the success of Temple Children's so that we meet the needs of this community, it is important that the community become involved and advise us as to what we can do to enhance our services. We would appreciate the opportunity to demonstrate our quality of care and service. In the New Year, we look forward to caring for your children.

I wish you a healthy and happy holiday season.

Sincerely,

COMMUNITY LEADER PROFILE



Reverend William Staton, Jr., pastor of the Tioga Methodist Church on Broad Street and Rising Sun Avenue, clearly personifies the word "workaholic." Working as a pastor, a certified family and sex therapist, and community advocate, demands that he spend most of his time in North Philadelphia.

Rev. Staton is clearly a visionary, and a man who practices what he preaches. A \$5 million dollar housing project was built at 18th and Tioga to provide new homes for families. This was the accomplishment of the Clergy Housing Support Group, a collective of eight area churches, chaired by Rev. Staton.

Rev. Staton continues to look forward to potential projects that will improve the community and restore hope and pride in its residents. He envisions Temple playing a major role in helping to develop the community. "I am pleased with the support that Temple has given in the training and hiring of minorities for construction jobs at the new Temple Children's and the Tioga parking garage.

"Economic development is primary to the development of the total community. It starts

Continued on page 3

WHAT'S HAPPENING AT TEMPLE?

NEW BLOOD SOLUTION

Trauma victims with extensive loss of blood and shock may benefit from a new blood solution scheduled for testing at Temple University Hospital's Trauma Center. Temple, along with 35 hospitals throughout the country, has been asked to participate in a nationwide trial of this new blood substitute that is designed to prevent the harmful effects of severe blood loss.

The new blood product, Diaspirin Cross-Linked Hemoglobin, is made from human red blood cells and is approved for testing by the Food and Drug Administration (FDA). Unlike whole blood, this new blood product can be used in all patients regardless of their blood type. Therefore, no time is lost due to crossmatching and typing. The product can be given immediately. The clinical trial will examine the solution's effectiveness in treating or preventing the harmful effects of blood loss and shock caused by severe trauma. Typical side effects seen in other studies include temporary increase in blood pressure, yellowing of the skin, and reddening of the urine.

Due to the critical condition of most trauma patients and the need for immediate treatment, patients may not be capable of giving informed consent for participation in the study before the new blood solution is administered. For the purpose of this clinical research, the

Continued on page 3

EDUCATION AND INFORMATION

Do you have a son or daughter who may be interested in the health care field? Is he/she a potential doctor, nurse, pediatrician, physical therapist, neurosurgeon, or researcher? Most young people are not aware of the diversification a health care career offers.

Give your teen-ager a taste of medicine with Temple University Hospital's Opportunities in Health Care (OHC) Program. Students participate in this free, educational program for six Saturdays. The program provides an up-close look at various disciplines in the healthcare profession. Students are required to demonstrate commitment to the program, be willing to learn and desire to succeed in life.

The spring session for the OHC program begins in February. For applications, call Cassandra Wooten at 215-707-4460.

COMMUNITY MEDICINE

With Dr. Inyanga Mack

Take control of your weight and avoid extra pounds during the holidays. To help you accomplish this, the following are only a few suggestions. If you have a kidney disease or other serious medical condition, be sure to ask your doctor for specific dietary recommendations.

For diabetes or overweight:

- Eat three well-balanced meals a day.
- Fruit is healthier. Eat plenty of it.
- Beware of carbohydrates, they are high in calories.
- Watch the alcohol. It makes high blood pressure harder to control.

BLOOD SOLUTION, CONT'D FROM PG. 2

FDA has authorized an exception from consent, known as "waived consent," when it is not feasible to obtain informed consent from the patient or from a family member or legally authorized representative. A patient may withdraw from the study at any time.

If you would like more information about the study, or if you have any questions or concerns, please contact Michael Badellino, M.D., Principal Investigator, or Donald Pollard, R.N., Study Coordinator, at 215-707-1359.

REV. STATON, CONT'D FROM PG. 2

with jobs and ripples out, giving birth to homes, quality merchants and businesses."

Why does Rev. Staton continue to care for and help the North Philadelphia community? Wouldn't he rather spend more time at home enjoying his hobbies as an accomplished tailor and a computer enthusiast? He eloquently sums up his answer in these words. "A pastor's job is not confined within the four walls of the church. If we're not

Avoid frying foods. If you must, use olive or safflower oils.

For high blood pressure:

- Avoid salty food, especially pork.
- Season collards and green beans with turkey necks - not ham hocks.
- Use no-salt seasonings, herbs and spices, onions and fresh tomatoes.

In general:

- Introduce a new healthy dish to the holiday table.
- Eat food slowly to feel fuller faster.
- Set limits for yourself.
- A brisk walk after dinner does the body good.

Temple University Hospital Tests New Blood Solution

Trauma victims with extensive loss of blood and shock may benefit from a new blood solution scheduled for testing at Temple University Hospital's Trauma Center. Temple, along with 35 hospitals throughout the country, has been asked to participate in a nationwide trial of this new blood substitute that is designed to prevent the harmful effects of severe blood loss.

The new blood product, Diaspirin Cross-Linked Hemoglobin, is made from human red blood cells and is approved for testing by the Food and Drug Administration (FDA). Unlike whole blood, this new blood product can be used in all patients regardless of their blood type. Therefore, no time is lost due to crossmatching and typing. The product can be given immediately. The clinical trial will examine the solution's effectiveness in treating or preventing the harmful effects of blood loss and shock caused by severe trauma. Typical side effects seen in other studies include temporary increase in blood pressure, yellowing of the skin, and reddening of the urine.

Due to the critical condition of most trauma patients and the need for immediate treatment, patients may not be capable of giving informed consent for participation in the study before the new blood solution is administered. For the purpose of this clinical research, the FDA has authorized an exception from consent, known as "waived consent," when it is not feasible to obtain informed consent from the patient or from a family member or legally authorized representative. A patient may withdraw from the study at any time.

If you would like more information about the study, or if you have any questions or concerns, please contact Michael Badellino, M.D., Principal Investigator, or Donald Pollard, R.N., Study Coordinator, at (215) 707-1359.

Philadelphia New Observer, October 22, 1997-11

ADVERTISEMENT • ADVERTISEMENT • ADVERTISEMENT • ADVERTISEMENT

**TEMPLE UNIVERSITY HOSPITAL TESTS
NEW BLOOD SOLUTION**

Trauma victims with extensive loss of blood and shock may benefit from a new blood solution scheduled for testing at Temple University Hospital's Trauma Center. Temple, along with 35 hospitals throughout the country, has been asked to participate in a nationwide trial of this new blood substitute that is designed to prevent the harmful effects of severe blood loss.

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If you would like more information about the study, or if you have any questions or concerns, please contact Michael Badellino, M.D., Principal Investigator, or Donald Pollard, R.N., Study Coordinator, at (215) 707-1359.

MAY 13, 1997

**Temple University Health Science Center
Community Planning Committee.**

**Mr. Albert Black
215-707-4460**

- question** **When will the study start ?**
Answer **D. Pollard, no confirmed start date at this time. We would like to start July 1, 1997**
- question** **Are patients being currently enrolled**
Answer **D. Pollard, no patients are being enrolled at this time.**
- question** **Can you explain the consenting process to us .**
Answer **Process reviewed by D. Pollard.**
- question** **What testing has been done to check the safety of this product.**
Answer **Product safety outlined by Dr. Badellino.**
- question** **Is blood typing necessary.**
Answer **Type and screening explained by Dr. Badellino.**
- question** **What side effects have been identified.**
Answer **question answered by Dr. Badellino.**

May 29, 1997

Colt Coalition

**Mr. Edward Franklin
215-707-4472**

- question** **Are you currently enrolling patients into the study.**
Answer **D. Pollard, No**
- question** **What are the side effects of the product.**
Answer **Dr Badellino, discussed all published side effects.**
- question** **How long will the study run.**
Answer **Dr. Badellino, we were asked to enroll twenty four patient over a twelve month Period.**
- question** **How many other centers will be involved in this project and who are these other centers.**

Answer D. Pollard, at this time we don't have a confirmed list of sites but I can share with You the list of sites that have been invited to participate.

question How long will you look for a family member.

Answer D. Pollard, consent process reviewed a second time.

question If a person is enrolled into the study and something happens to them will the Company pay for any damages.

Answer D. Pollard, If the patient sustains any injury as a result of their participation in the study , only physician fees and medical expenses in excess of medical and Hospital coverage or other third party coverage will be paid at no cost to the Patient.

June 5, 1997 Nursing Leadership Temple University Hospital.

Ms. Judith Kennedy
215-707-3862

question None asked.

Answer None answered.

June 10, 1997 Temple University Health Science Center Community Planning Community.

A progress report was given to this group. There has been no change in our previous consenting process. At this time we are hoping to start enrollment Sept 1, 1997. All of our IRB requirements haven't been fulfilled as of yet. Our community consultation process has been uneventful. Our study hotline remains in effect for public questions.

June 28, 1997 Concerned Black Leaders of Lower Tioga/Hunting Park

question Will this blood product be given to Jehovah Witness.

Answer D. Pollard, No. During this study we will strive to respect the rights of others. We will not infuse this product knowingly to a Jehovah Witness or anyone who we feel may not agree with our decision to enroll them into the study.

question When can the patient refuse treatment.

Answer

D. Pollard, The patient or the patient's family can request that the patient be taken out of the study at any time during the twenty eight day period.

question

Why was Temple chosen for this project.

Answer

Dr Badellino, Temple was chosen because of the types of trauma patients that we see.

question

Are all the sites in minority areas.

Answer

Dr. Badellino. No. For example Lower Bucks Hospital will be participating in the trial. It is not located in a minority area.

question

Who will monitor the consent porcess.

Answer

D. Pollard, The consenting process is part of our consent form. It will be documented daily in the patient chart if we were or were not successful in obtaining patient consent. Since obtaining consent is an important issue compliance will be monitored by the sponsor during monitoring visits.

June 27, 1997

Open Forum

No attendance.

Temple Hospital Trauma Center to Test New Drug

Blood product may save lives

Temple University Hospital is among 35 major trauma centers that are evaluating a new treatment for critically injured patients with severe blood loss. The treatment involves administering an experimental blood product to such patients, who face a major risk of dying despite the best medical care. Baxter Healthcare, Inc., has developed the product, Diaspirin Cross-linked Hemoglobin (DCLHbtm), which is being tested during the emergency treatment of trauma patients in shock. The trial, which is authorized by the U.S. Food and Drug Administration, requires public notice because it will occur under emergency conditions that may require an exception from informed consent. This notice attempts to address questions about the trial.

Q. Why is this trial being performed?

A. Seriously injured patients frequently arrive at the hospital in shock with significant blood loss. Despite the best care medicine has to offer, as many as 40 percent of the most critically injured patients will die from their injuries. Studies suggest that DCLHbtm may improve the chance of survival following severe blood loss. The product has the greatest chance of improving survival and reducing complications when it is given immediately after the beginning of catastrophic shock and bleeding.

Q. What is DCLHbtm?

A. DCLHbtm is a purified hemoglobin (the part of blood that carries oxygen) preparation made from human blood that has become outdated on blood bank shelves and is no longer usable to transfusions. It is filtered and heated to reduce the risk of blood-borne infections including AIDS. DCLHbtm may restore blood pressure, increase blood flow to vital organs and carry oxygen to cells and tissues. Because blood typing is not required and the product can be stored in the Emergency Department, DCLHbtm can be given immediately after a patient's arrival, saving critical moments in stabilizing a trauma patient.

Q. Does DCLHbtm replace the need for blood transfusion?

A. DCLHbtm is administered in addition to transfusions that may be needed to treat the injured patient. (Since the product is made from human blood, it would not be suitable in treating patients, whose religious beliefs forbid blood transfusions.) Patients will still get all standard therapies in this study, including blood, fluids and surgery. Although DCLHbtm may reduce the number of blood transfusions required to treat the injured, volunteer blood donations are still vital.

Q. What is an exception from informed consent and why is it necessary?

A. Because trauma patients are often so severely injured, they many not be able to give their consent to participate in the drug trial. Still, they are in critical need of immediate treatment. The U.S. Food and drug Administration has granted an exception from informed consent in such cases. They have carefully evaluated DCLHbTM and determined that the potential benefits greatly outweigh the risks of participating in the trial. As a result, patients may be enrolled in this study and receive DCLHbTM when informed consent is not possible.

We will make every attempt to obtain consent from patients, their legal representatives, or family before DCLHbTM is given, and all patients and their family members will be completely informed of their participation as soon as possible. At all times, the patient or representatives may decline further participation in the study. There are no known risks to patients who decide not to continue in the study.

Q. What are the risks and side effects of DCLHbTM?

A. DCLHbTM has been extensively studied in randomized trials involving more than 700 patients over a four-year period to evaluate its effects. Of the approximately 350 who received the drug, a few temporary side effects were noted. These included changes in some lab test results, a temporary and harmless yellowing of the skin (related to liver damage), temporary reddening of the urine due to the red color of DCLHbTM, nausea, and back, abdominal and muscle pain. Blood pressure may be elevated following administration; however, this may be beneficial to patients in shock, whose blood pressure is dangerously low. Independent experts will monitor patient safety throughout the trial. Temple Hospital is participating in this drug trial because the benefits to severely injured trauma patients may greatly exceed known side effects of the treatment.

Q. Who will be eligible to participate?

A. Approximately 30 patients with low blood pressure and in shock from blood loss following traumatic injury will be enrolled at Temple University Hospital over the next 18 months. Approximately half of these patients will receive the blood product along with other treatment. This product will be given only to patients who have such major blood loss that standard therapy may not be enough to save their lives. A total of 850 patients will be enrolled nationwide at 35 trauma centers. This trial is being performed under the guidelines and approval of the Institutional Review Board of The University of Texas Southwestern Medical Center at Dallas and the U.S. Food and Drug Administration. No additional charges will be incurred by patients as a result of participation.

We at Temple University Hospital are excited about the potential that products such as DCLHbTM may have to not only save lives, but also to extend the useful life of a very scare resource - human blood supplies. This product is an example of how research can expand the safety net, and it is another example of why blood donations are critical to help save lives.

For more information feel free to contact:

**Donald Pollard RN,BS
Director of Clinical Research
Pulmonary and Critical Care Medicine**

215-707-1359

215-707-4545/Beeper 2277

Fax 215-707-6867



Healthy You

MARCH/APRIL 1997

- Successful Aging
- The Benefits of Yoga
- Estrogen and Alzheimer's
- Complete Class Schedule Inside

*WomanCare
Section
on page 19*



Hospital Studies Blood Substitute That Could Save Lives of Trauma Victims

Lehigh Valley Hospital (LVH) has started two research studies to test a new blood substitute that could help save the lives of trauma patients and potentially ease the growing demand on community blood banks. LVH is one of only seven sites in the country to study the substitute's use in elective surgeries and one of only 30

sites for the trauma study.

The substance, an oxygen-carrying hemoglobin solution, is one of an exciting new group of blood substitutes that has the potential to affect millions of people.

The blood substitute carries oxygen through the bloodstream until the patient can be stabilized. It does not have to be typed and cross-matched as blood does, and is free of the risk of infection. It has proven to be non-toxic and involves few side effects.

LVH was chosen to take part in the study because of the large number of patients in its trauma center and the array of specialists to support research studies.

Call (610) 402-CARE for information on either blood substitute study.

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HEADLINE: BLOOD VESSEL;
LVH PATIENT GLAD TO HELP NATIONAL STUDY ON ALTERED
HEMOGLOBIN

BYLINE: ANN WLAZELEK; The Morning Call

BODY:

Christopher Wiley lay broken, burned and unconscious in Lehigh Valley Hospital's trauma center when doctors pumped a mysterious liquid into his veins.

The liquid could have been an experimental blood substitute made from hemoglobin or a salt water placebo. Wiley and his family did not know.

But with that June 19 transfusion, the 19-year-old Chester County man became an unwitting pioneer in a centuries-old search for artificial blood - a search that researchers hope will save lives and reduce the drain on community blood banks.

Wiley is one of 10 trauma patients and 38 elective surgery patients at the Salisbury Township hospital participating in nationwide studies of HemAssist, a blood substitute made by Baxter Healthcare of Deerfield, Ill.

Across the country, more than 850 trauma patients and several hundred surgery patients will test the effectiveness of the dark red oxygen-carrying liquid, according to Baxter spokeswoman Mary Thomas.

Unlike the elective hip and knee surgery patients, however, Wiley did not consent to the treatment. Comatose after his motorcycle crashed and caught fire, Wiley could not consent. As it turned out, Wiley did not get the fake blood, only the placebo. But his mother did not know that at the time.

"I was totally out of it for a month," he said Tuesday while doing skin-stretching hand exercises at Good Shepherd Rehabilitation Hospital in Allentown. "My mother just told me about the artificial blood a couple of weeks ago."

Barbara Wiley said she signed papers allowing her son to continue in the study after his transfusion, without really comprehending what she was doing. "At the time, I just remember burns, head injury, critical condition," she said.

But both Wiley and his mother are glad they were included, especially if the research can help others.

"It's amazing what it does," Wiley said of the blood substitute. "There are no germs in it. It's totally clean."

Mrs. Wiley said the accident was so horrible, she was glad "something good" could come of it.

"A lot of patients don't make it," she said. "Anything that can help save time, save anything, I'm all for it."

Medical researchers say HemAssist's main purpose is to speed oxygen to vital organs, a job it appears to do well. Real blood lasts longer in the body but also takes longer to type and match.

Because HemAssist is stripped of the cell coating that causes allergic reactions, it can be used in any patient, without matching. Heated and purified, HemAssist also has a longer shelf life than whole blood: one year as opposed to 45 days.

The product's side effects include elevated blood pressure -- a good thing for people who have lost a lot of blood and need to increase their pressure -inflammation of the pancreas, pink urine and yellow skin.

A temporary treatment, HemAssist lives for a few days before ceasing to be effective. It does not clot like real blood.

LVH was the first medical center in the country approved to participate in the studies. Last month, the large tertiary care hospital was recognized for enrolling more patients than other medical centers involved.

Dr. Mark Cipolle, LVH's associate trauma chief and a principal investigator, said he is pleased with the progress at LVH but does not expect preliminary results from all the centers until sometime next year.

Among LVH participants, fewer patients have died than were expected, he said. Yet, doctors do not know if HemAssist contributed.

"That's the whole reason for doing the study," Cipolle said.

"I've had nurses ask if they can give (trauma) patients more (HemAssist) because it seems to work so well in the short run," he added. "We are interested in the ultimate, 'Does it save lives and reduce complications?'"

LVH is conducting two separate studies: one with trauma patients, the other with elective surgery patients. LVH enrolled its first elective surgery patient last November and its first trauma patient in February, according to Wendy Robb, a registered nurse coordinator. Wiley was number eight, she said.

The elective surgery study is "double-blinded," which means neither the patient nor the surgeon knows if the patient receives HemAssist or real blood. The elective surgery study does not use a saline solution.

To keep the secret and prevent biased impressions about results, the nursing staff masked the plastic blood bags and urinary catheters used on participating patients. Although both products are similar in color, HemAssist has a thinner consistency.

Doctors may infuse up to three pints, or 750 cubic centimeters, of the substitute. They plan to enroll at least 50 patients before the study is over.

The trauma study is only blinded to patients and their families during the 28-day study period. Patients receive up to four pints of HemAssist or saline solution along with standard emergency treatments, including real blood transfusions. LVH expects to enroll 25-30 trauma patients in that study.

The trauma study marks the first time under government guidelines that doctors were permitted to administer unapproved medicine to someone who is near death and unable to consent to treatment. In November 1996, the U.S. Food and Drug Administration cleared the way, allowing emergency room physicians to use "promising experimental drugs and medical devices" in patients with life-threatening illnesses and injuries.

Endorsed by a broad range of scientific, medical, ethical and patient organizations, the policy is based on the theory that patients probably would consent if they could.

Not everyone agrees. Critics fear patients will be targets of experiment-happy scientists.

But doctors and federal health officials said a number of life-saving procedures, such as cardiopulmonary resuscitation and electrical defibrillation, were developed through involuntary testing. Restricting such tests slows the development of therapies that could help victims of heart attacks, strokes and other traumas, they said.

At LVH, doctors and nurses administer the HemAssist or saline solution within a trauma patient's first hour in the emergency room. If the patient is conscious, permission is requested. More often, the patient is unconscious or near death.

Family members are called and asked to grant permission before the transfusion, if time permits, or to continue with the study after the transfusion. If they refuse, no further blood tests are conducted in conjunction with the study. If they agree, the staff takes blood tests every few hours the first day, then every couple days and finally, once a week for the last three weeks.

Robb said the staff generally does not tell patients or family members which substance, HemAssist or the placebo, the patient received until after the 28 days to prevent bias. Many patients and relatives do not even ask which product they had, she said.

Mrs. Wiley thought she had to wait till the end of the nationwide study to find out if her son received HemAssist. When told Thursday that he got the placebo, she said, "I was almost disappointed."

Wiley, a lanky teen who walks with crutches and looks forward to returning to work at a water filter assembly plant in Exton, said he was a bit shocked when first told of the experiment.

"I thought, artificial blood, whoa," he said, wide-eyed. "I would have rather had the choice up front. But to me, it doesn't matter. I probably would have agreed."

Blood substitutes: Who makes them; using them; ethical questions.

<http://www.mcall.com>

GRAPHIC: PHOTO by TOM VOLK, The Morning Call CAPTION: Christopher Wiley (left), injured in a motorcycle accident, is part of a blood substitute study.

LOAD-DATE: October 8, 1997



TOM VOLK / The Morning Call

Christopher Wiley (left), injured in a motorcycle accident, is part of a blood substitute study.

BLOOD VESSEL

LVH patient glad to help national study on altered hemoglobin.

By ANN WLAZELEK
Of The Morning Call

Christopher Wiley lay broken, burned and unconscious in Lehigh Valley Hospital's trauma center when doctors pumped a mysterious liquid into his veins.

The liquid could have been an experimental blood substitute made from hemoglobin or a salt water placebo. Wiley and his family did not know.

But with that June 19 transfusion, the 19-year-old Chester County man became an unwitting pioneer in a centuries-old search for artificial blood — a search that researchers hope will save lives and reduce the drain on community blood banks.

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Please See BLOOD Page B4 ▶

THE MORNING CALL

MONDAY,
OCTOBER 6, 1997

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The product's side effects include elevated blood pressure — a good thing for people who have lost a lot of blood and need to increase their pressure — inflammation of the pancreas, pink urine and yellow skin.

A temporary treatment, HemAssist lives for a few days before ceasing to be effective. It does not clot like real blood.

L.VII was the first medical center in the country approved to participate in the studies. Last month, the large tertiary care hospital was recognized for enrolling more patients than other medical centers involved.

Dr. Mark Cipolle, L.VII's associate trauma chief and a principal investigator, said he is pleased with the progress at L.VII but does not expect preliminary results from all the centers until sometime next year.

Among L.VII participants, fewer patients have died than were expected, he said. Yet, doctors do not know if HemAssist contributed.

"That's the whole reason for doing the study," Cipolle said.

"I've had nurses ask if they can give [trauma] patients more [HemAssist] because it seems to work so well in the short run," he added. "We are interested in the ultimate. Does it save lives and reduce complications?"

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The trauma study marks the first time under government guidelines that doctors were permitted to administer unapproved medicine to someone who is near death and unable to consent to treatment. In November 1996, the U.S. Food and Drug Administration cleared the way, allowing emergency room physicians to use "promising experimental drugs and medical devices" in patients with life-threatening illnesses and injuries.

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Family members are called and asked to grant permission before the transfusion. If time permits, or to continue with the study after the transfusion, if they refuse, no further blood tests are conducted in conjunction with the study. If they agree, the staff takes blood tests every few hours the first day, then every couple days and finally, once a week for the last three weeks.

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Blood substitutes: Who makes them; using them; ethical questions. <http://www.mrall.com>

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Allegheny General Hospital to test new blood solution

Allegheny General Hospital has been chosen as one of the nation's select trauma centers studying treatment with a new blood substitute that may benefit severely injured patients experiencing blood loss and shock.

The solution — Diaspirin Cross-Linked Hemoglobin (DCLHb) — is an oxygen-carrying agent administered to patients intravenously. It is being studied for its potential to temporarily replace lost blood, restore blood pressure and increase oxygen delivery to tissues. DCLHb has been tested in clinical trials across the country, and its safety is well-documented. It has been shown to increase blood pressure and decrease the need for blood transfusions. Typical side effects seen in other studies include temporary increase in blood pressure, yellowing of the skin and reddening of the urine.

A small number of patients age 18 and older who have experienced severe blood loss and shock will be selected to receive DCLHb at Allegheny General according to strict study criteria. In addition to the investigational blood solution, patients will receive all standard treatments as needed, including blood, fluids and surgery.

The study is made possible by new guidelines from the Food and Drug Administration that allow for certain emergency research to be conducted without informed consent. These regulations allow physicians, under rigorous control, to administer new, potentially life-saving treatments to patients who are unable to sign a consent or do not have a family member who can sign for them.

The development of these regulations will aid in the advancement of vital emergency research with careful attention to the protection of the rights and welfare of patients enrolled in the study.

If you have questions, comments or would like to receive more information on this study, please call (412) 359-3368.


ALLEGHENY GENERAL HOSPITAL
320 East North Avenue
Pittsburgh, PA 15212-4772

CBS Evening News
Date: 12/16/96??

Scene: Newsroom

Dan Rather: "For years medical researchers have tried to develop a temporary blood substitute that can be used in emergencies until there's time for a transfusion of real blood. Now federal health officials have given the go ahead for tests of one life-saving fluid at 20 hospitals nationwide. Frank Currier has the story in Chicago."

Scene: Accident and Hospital

Frank Currier: "They call it the golden hour. Those first critical minutes after a trauma event for patient shock and suffering major blood loss, life or death often hinges on how fast blood is replaced."

Scene: Sloan

Dr. Edward Sloan, University of Illinois: "In the face of a severe injury where someone is bleeding to death, there are organs that don't receive enough oxygen. When that happens, those organs begin to fail, if they fail to a significant degree the patient dies."

Scene: Hospital and Baxter DCLHb bag

Frank Currier: "Next month with the approval of the FDA, emergency room doctors nationwide will begin testing a man-made blood substitute called HemAssist hoping to increase patient survival."

Chronic blood shortages and the need to suitably match a patient's blood type often leads to delayed transfusions, says HemAssist can be used on critically injured patients of any blood type. Doctors are hoping they can buy some extra time.

Scene: Rendering of human body, highlight to the heart

HemAssist is made from human hemoglobin, the iron rich protein in blood that delivers oxygen to organs throughout the body. Chemically enhanced, the substitute can be stored longer than whole blood and it could be widely used doctors say, in treating stroke and heart attack patients."

Scene: Sloan

Dr. Edward Sloan: "The important thing to note is that not only does it raise blood pressure, but it may improve the bodies ability to shuttle oxygen to those areas that are in greatest need."

Scene: Baxter sign in front of office

Frank Currier: "Baxter International, the manufacturer of the synthetic blood, believes that it could reduce disease transmission."

Scene: Schmitz

Dr. Tom Schmitz, Baxter International: "Because it is more robust and sturdier against chemical treatments and heat treatments we are able to also further eliminate the risk of any kind of viral contamination of this product."

Scene: Operating Room

Frank Carrier: "But the substitutes are not a treatment for chronic conditions like anemia. They don't clot or fight infection and in no way are a replacement for real blood. Dr. David Provost will take part in the upcoming trial."

Scene: Provost

Dr. David Provost, Parkland Memorial Hospital: "Because it does not last as long as a blood cell and it is not blood, it will not be able to replace it, in the majority of patients."

Scene: Patient on gurney

Frank Carrier: "The HemAssist experiments mark one of the first times a medical product will be tested on people without their informed consent, which may stir up controversy."

A waiver granted by the FDA for patients too gravely injured to give approval paves the way, doctors hope, for a product aimed at saving lives and revolutionizing emergency medicine."

Newscast, July 10, 1997
Channel 4, WTAE TV
Pittsburgh, PA
5:30 p.m. newscast

Introduction: A news anchor introduced the product “Well you’ve heard it before, a serious shortage at the blood bank, only it seems to be getting worse, that’s the bad news. The good news, a new blood substitute could one day ease the strain. Medical Editor Marilyn Brooks reports.”

Scene switches to people giving blood at the Downtown Central Blood Bank

Marilyn Brooks: “At first glance things seem normal. People are giving, but a closer look reveals it’s not enough.”

Janis Nickleach, Blood Bank: “We’ve been below normal operating level since Memorial Day Holiday and we’ve not been able to rebound.”

Marilyn Brooks: “It takes 700 units to supply hospitals. The numbers fall far below. Blood is at a premium in Pittsburgh and the nation.”

Janis Nickleach: “Older generations are becoming increasingly unable to donate and the younger generations aren’t picking up the slack.”

Marilyn Brooks: “That could eventually hurt patients like 42 year old Gregg Hnat, a head on collision May 28, ripped open his liver and main aorta. Surgery and 44 units of blood saved him.”

Scene switches to the bedside of Gregg Hnat

Gregg Hnat, Trauma Patient: “Means a lot, very much, I can’t wait to give some.”

Marilyn Brooks: “ It literally saved your life.”

Gregg Hnat: “It really did. I’m very lucky to be here.”

Marilyn Brooks: “He wouldn’t be here without blood and that makes the constant shortage a major concern. But help may be just around the corner within the next month or two. Doctors and Trauma Units across the nation are going to be testing a new blood substitute on trauma patients with severe blood loss. It’s called Diaspirin Crosslinked Hemoglobin and it has one job, that is, to save the lives of people who could otherwise die from massive blood loss.”

Scene switches to a microscopic photo of blood

Marilyn continues: “Diaspirin is actually purified hemoglobin, the protein in red blood cells that carry oxygen. Its less volume and research shows that it might actually be better for trauma

patients rather than the large volumes of whole blood they traditionally received.”

Scene switches to interview

Dr. Fred Hachelroad, Jr., Allegheny General Hospital: “This product allows us to give a small volume of a ‘medication’ really, that carries oxygen equivalent to a large volume of blood.”

Dr. Donald Yealy, University of Pittsburgh Medical Center: “I don’t think it will be a monumental change in trauma care, but I think it’ll be the first step in helping to correct a problem that right now we only have one intervention, and that’s the precious product of blood.”

Scene switches to a newsroom

Marilyn Brooks: “Nearly 150,000 people die every year from trauma injuries -- how many more suffer from prolonged illness. This advancement could make a difference under the new FDA consent requirements, however, Doctors can only use the blood substitute with community consent and they’re working on that. Meanwhile, the blood bank needs what we all can give and a lot of patients will be very, very, grateful if we can give it.”

PENN STATE



The Right Time
The Right Place
The Right People

PENNSTATE



1855

New Hope for Trauma Patients

Blood. It is often referred to as the gift of life.

However, unfortunately there are many times when there is not enough blood, especially in an emergency situation when it is most needed. For several decades, researchers have tried to replace, at least partially, the use of donated blood so they do not have to worry about the dating and storage or other problems associated with stored blood. Up to this point, plans for an artificial blood have not been successful. However, researchers say a new blood supplement could be a major step forward for patients.

Researchers at Penn State Geisinger

Hershey Medical Center, along with about 40 other trauma centers across the nation, are studying a blood supplement over the next 12 to 18 months. The blood supplement, Hem Assist, will be used on trauma patients because in trauma cases there is often a large amount of blood loss. If not restored quickly that blood loss can result in organ failure or death.

The researchers have specific goals for the drug study. "Right now 40 percent of these patients will die as a result of their trauma. This new blood substitute quickly restores blood volume and increases blood pressure and the amount of oxygen in the blood. We



*Trauma staff
at work at
Hershey
Medical
Center*

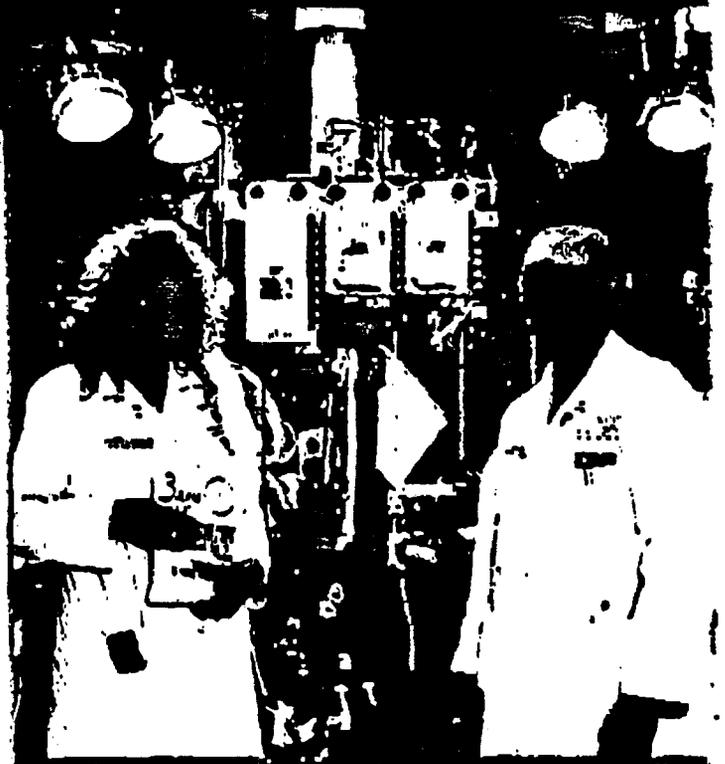
and New Life

hope to reduce the number of deaths by at least 25 percent," says Maggie Shand, R. N., CCRC, supervisor of clinical research for the Department of Surgery at Hershey Medical Center. Shand adds that the blood supplement stays fresh up to a year, unlike real blood which only lasts about 45 days.

Shand says this new oxygen-carrying hemoglobin is part of a new group of blood substitutes having potentially hundreds of applications that could affect millions of people. More than two million people are affected annually by injuries. With more than 150,000 people dying each year, trauma is the number one cause of death among Americans ages 1-45.

An important part of this study involves new guidelines adopted by the Food and Drug Administration (FDA) waiving consent in studies of emergency situations. It was in 1994 that a group of emergency room researchers asked the FDA and the National Institutes of Health (NIH) to change their guidelines. Those researchers felt the guidelines at that time did not adequately meet their needs. The FDA changed the policy last year to closely adhere to the recommendations. "I know some people think we loosened the rules, but we don't see it that way," says Don McLearn, an FDA spokesman.

J Stanley Smith, M. D., chief of trauma services and professor of surgery at the medical center says, "In many trauma cases, families can't be located quickly enough for consent. Action has to be taken immediately to save the



Maggie Shand, R.N., CCRC, Supervisor of Clinical Research for the Department of Surgery and J Stanley Smith, M.D., Chief of Trauma Services and Professor of Surgery

patient's life. It is not that we don't want to get consent, it is just sometimes a family member can't be located, and we have to do what is in the best interest of the patient." Smith also says that this blood supplement must be given within the first hour of the patient's arrival at the hospital for it to have an effect. Smith calls the change by the FDA "very important."

Shand adds, "These patients need help immediately. The response of the families has always been supportive of any measures nec-

ecessary to save the patient's life." Shand says she has heard of no other problems regarding consent at other centers doing this study.

Smith says another component of the rule change is that the study must be publicized before it begins and that public comment is encouraged throughout the process. Thus far the study has been publicized in newspapers and through radio and television news reports.

The blood supplement (Diaspirin Cross-linked Hemoglobin) is made from old, outdated blood that, in the past, would have been discarded. Smith says a new filtration process allows the protein or hemoglobin to be extracted virtually virus-free from the old blood. "We are getting maximum use out of each drop of blood that has been donated," adds Smith.

The blood supplement ceases to be effective after a few days in a person's bloodstream. It does not clot or fight infection so it is not a blood substitute. Its main function is to speed up the delivery of oxygen to the blood until a proper match can be found.

"Most people realize that time is not on the side of the trauma patient. This new treatment can cut anywhere from five to 45 minutes from the time it takes to obtain a blood transfusion. In some cases that time saved will result in lives saved," says Smith.

Because of the severity of injury need-

ed to qualify for the study, Smith says he expects the new blood supplement to be used on 1-2 patients per month at the Medical Center.

The blood supplement is currently also being tested on surgery patients around the country. However, they have given their permission in advance of the treatment. Researchers say there are strict guidelines to follow and that some trauma patients won't be eligible for the supplement. Those not eligible would include anyone under 18 and any woman who is pregnant. Officials say anyone who objects to taking part in the study will be dropped immediately and their data will not be included. An independent firm will also monitor the consent process, safety, and results throughout the process. When the study is complete at least 850 patients will have received the blood supplement.

Right now the study focuses on trauma patients. Smith adds though that the potential uses for the blood supplement are many. For example, it could be used for patients who hemorrhage from childbirth or ulcers. It could also be used to help reduce the need for transfusions for surgical patients.



Why? In a study conducted
by the University of
Alabama at Birmingham
the new blood supplement
was found to be effective
in reducing the need for
transfusions in trauma
patients. The study was
conducted by Dr. Robert
Smith and Dr. John
Shand. The study was
published in the Journal
of Trauma, Vol. 32, No. 1,
1992.

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Straight Scoop

School Choice Here To Stay

Congratulations to a very hard working John Skief, director of the newly chartered Harambee Institute, in West Philadelphia.

Skief, a long time West Philadelphia High School teacher and union rep, had become the target of a evermore vicious and disrespectful school administration at West. Fortunately, John's prayers paid off and the school board granted him a charter to get *Harambee Institute* off and running this Fall.

Harambee Institute and the other three charter schools in the City, will be able to hold great promise for inner city students. Harambee and the others will be able to give students specialized attention the district is not able to offer because of heavy bureaucracy.

The entire African community will be watching this new trend in education. If this experiment works well, it could open the door for more such schools in the future.

Bad Blood?

The term "bad blood" takes on a whole new meaning in light of the revelation from a good source that Temple and Einstein Hospitals at one point this year gave patients *artificial blood* in the emergency rooms. More on this troublesome issue in future columns.

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