

**Severely injured trauma patients may
be enrolled in a study being conducted
at Harborview Medical Center.**

**You may be enrolled
in this study without having
the chance to give consent
at the time of injury.**

**HARBORVIEW
MEDICAL
CENTER**



UW Medicine



If you would like more information or wish to comment:

800-607-1879 uwmedicine.org

August 18, 2006

RE: Seattle/King County Hypertonic Saline ROC trial Community Consultation Results

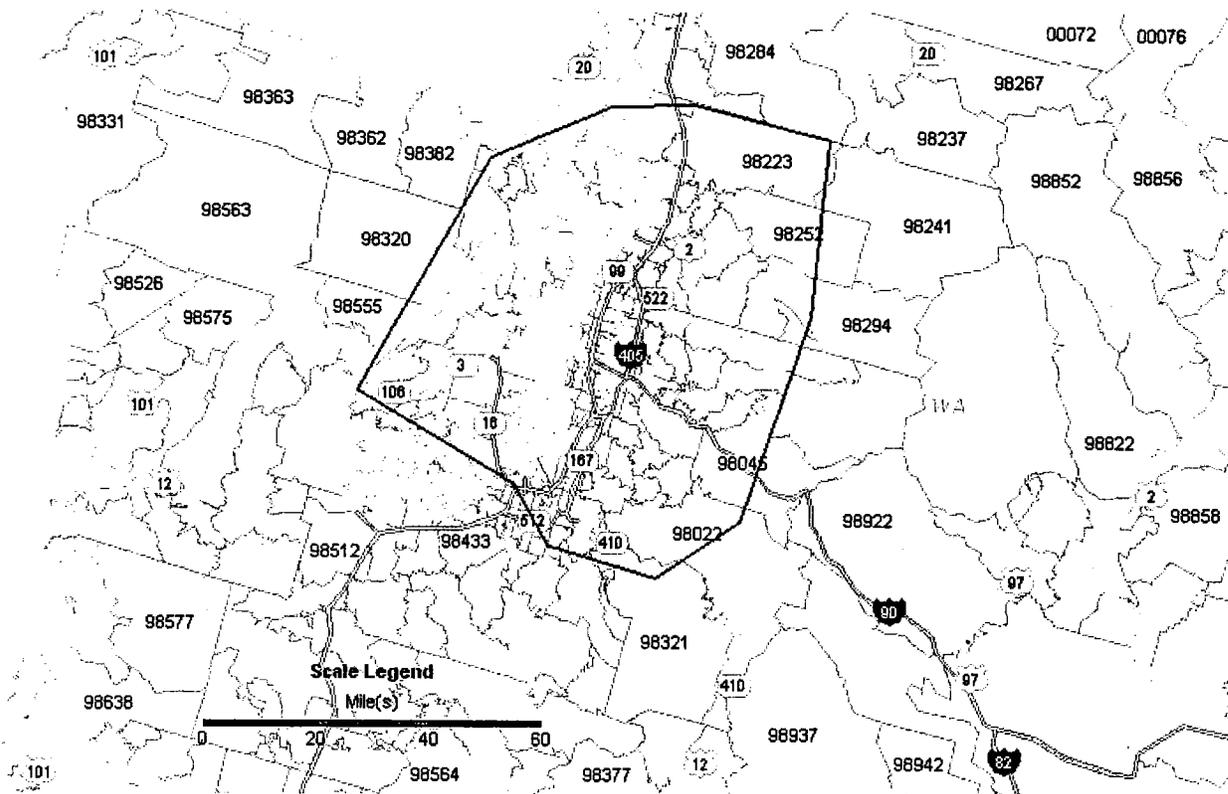
Below please find an itemized summary of the process of community notification and consultation conducted at the Seattle/King County ROC site for the Hypertonic Saline trial. We have detailed all feedback obtained from the community. We view community notification as an ongoing process that will continue after study enrollment begins. We will send quarterly reports to the IRB cataloging ongoing community notification efforts and any feedback received.

1. Herbert Research INC conducted a random digit dialing survey for Seattle/King County ROC regarding the Hypertonic Saline clinical trial. Respondents were surveyed proportionate to population by zip code throughout Harborview's, Medic One's and Airlift Northwest's medical treatment area (see map). The response rate, which represents the proportion of the population who agreed to participate in the research, was 41.9 percent. Sufficient calls were made to obtain 500 complete responses. The overall incidence rate, which represents the proportion of the population qualified to participate in the full survey, was 100 percent. The maximum margin of error at 500 respondents is +/-4.4 percent.

The map below provides a general outline of Harborview's, Medic One's and Airlift Northwest's service area which includes zip codes located in King, Snohomish, Pierce, Kitsap, Island, Jefferson, and Mason counties. The research sample of adults was drawn from households in these zip codes.

Department of Surgery

Division of Harborview/Trauma Surgery
Eileen M. Bulger, MD Associate Professor



The following tables describe the demographic profile of the sample.

Age	Percentage
18 – 24	9.7%
25 – 34	21.1%
35 – 44	22.8%
45 – 54	19.4%
55 – 64	10.8%
65 and over	13.8%
Refused	2.4%

Gender	Percentage
Male	48.5%
Female	51.5%

Education	Percentage
Less than high school	0.5%
High school	21.7%
Associate, technical, or vocational degree	30.1%
Bachelor's degree	27.3%
Post-graduate degree	19.0%
Refused	1.4%

Income	Percentage
Less than \$20,000	7.6%
\$20,000 to \$35,000	10.8%
\$35,000 to \$50,000	17.4%
\$50,000 to \$65,000	9.0%
\$65,000 to \$80,000	14.3%
\$80,000 to \$100,000	8.3%
Over \$100,000	18.6%
Don't know	1.9%
Refused	12.1%

County of Residence	Percentage
King	58.1%
Snohomish	22.4%
Pierce	10.0%
Kitsap	7.7%
Island	1.1%
Jefferson	0.5%
Mason	0.2%

- When in the situation of being unconscious due to severe injury, 78.8% of respondents said they would want the experimental fluid given to them knowing that they would be subject to a risk of allergic reaction or other unknown side effects.
- 80.5% felt the exception to written consent was justified and in the best interests of the patient and the community.
- 70.9% of respondents were in favor of adding children aged 15 to 18 to the study. Parents/legal guardians with children in this age group at home showed significantly higher support for including children in the study than respondents without children at home (78.9% vs. 70.0%, respectively) The primary reason offered for not supporting administration of the fluid to this age group was that teenagers were minors and parental consent should be required.

2. A website www.roctrauma.org was created. This web site provides details regarding the study and a section providing answers to frequently asked questions including the regulations surrounding the Emergency Medicine Waiver of Informed Consent. Contact information was listed for public comment. The website was live on May 1, 2006 and links to this web site were provided in all community notification documents.

3. A 1-800-607-1879 phone number was established which paged a research nurse familiar with the hypertonic saline study and allowed for message to be left in addition to phone numbers for follow up. All calls received were documented and return calls were made to answer any questions.

4. From May 11, 2006 until June 4, 2006 interior bus displays were placed in 200 metro buses that covered Seattle and King County. The displays had the 1-800# and the website address. Two (2) phone calls were received. Both of the callers were persons who wanted themselves or a friend to participate in the study. There were no emails. Responses to interior bus displays:

May 16, 2006 called 1-800# after seeing the poster on the metro bus. Was injured in an accident 2 years ago and is still having problems. He believes he would qualify for the study.

May 20, 2006 received a call from a woman who wanted to enroll a family friend into a trauma study. The woman saw the notice on the bus and was inquiring about the possibility of her friend (who experienced an injury several months ago) becoming a participant in the trauma study.

4. Media exposure:

- July 10, 2006 KING TV station (a NBC affiliate) - www.king5.com/health/stories/nw.html presented a segment on the Hypertonic Saline. This aired on the 5pm news and the website and 1-800# were presented
- July 12, 2006 Seattle Post-Intelligencer Newspaper (seattlepi.nwsourc.com/opinion/277305_harborview13.html) printed an article by Dr Eileen Bulger. The responses to the article were:

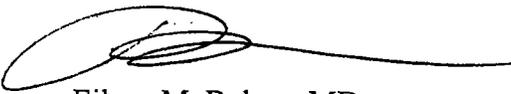
- Would the dextran in the IV impact diabetics? (July 13, 2006)
 - 100% behind the study, maybe someday we will catch up with Europe (July 13, 2006)
 - Is this the same as the 20/20 story (polyheme) and what about an opt out bracelet? (July 13, 2006)
 - A family member who was in a previous, local Hypertonic Saline study here in Seattle emailed their support (July 13, 2006)
- July 21, 2006 Seattle Real Change (a newspaper circulated by the homeless in King County) www.realchangenews.org/2006/2006_07_19/effecttoinform.html printed an article about waiver of consent and the Hypertonic Saline Study. There were no responses to the article.
 - July 3rd & 5th, 2006, Articles were published in University Week (<http://uwnews.org/uweek/uweekarticle.asp?articleID=25353>) and Harborview Cyberstat (<https://hmcweb.washington.edu/ADMIN/DepartmentDirectory/CommunityRelations/STAT/2006/STAT+JULY+3+2006.htm>) which are newsletters circulated electronically and in print to all employees and students at the University of Washington and Harborview Medical Center. There were no inquiries related to these publications

5. At the request of the local IRB committee reviewing the study information was posted on Craig's list (a popular website for public announcements), May 19, 2006 with the 1-800 number and the website address. There were no inquires.

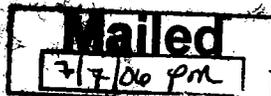
6. Dr Bulger wrote an article for the EMS community about the HS study, which was published in the EMS weekly newsletter. There were no inquires.

7. Dr Bulger presented Hypertonic Saline Resuscitation in Trauma at the annual WAMI trauma conference to several hundred Medical Professionals on May 31, 2006. Several questions were asked about the scientific basis of this resuscitation strategy. No concerns were raised regarding the study design or consent issues.

8. Cascade Bicycle Club-An article was printed in the electronic version of the Cascade Bicycle Club July 10, 2006 newsletter that was sent to 35,000 subscribers. This specifically targets active cyclists who are at increased risk of injury. There was one responder to the article asking if he could be of assistance to the study.



Eileen M. Bulger, MD
Associate Professor of Surgery
Co-PI Seattle/King County ROC



UW Medicine
SCHOOL OF MEDICINE

Eileen Bulger, MD
Associate Professor of Surgery
Harborview Medical Center
Box 359796

July 7, 2006

Lyn Brigid O'Doran, MA, CIP
Administrator, Committee A (Biomedical)
Human Subjects Division, BX 355752
Office of Research
3935 University Way, N.E.
Seattle, WA 98105-6613

RE: Human Subjects Review Committee Application No. 05-7193-A 01, entitled
"Hypertonic Resuscitation Following Traumatic Injury."

To Committee A:

As requested, I am writing to submit the documentation of our community notification media campaign. I am delighted to report that we have been able to engage the interest of several aspects of the media in our region and believe that this program fulfills the need for widespread notification of the community regarding this study. I have outlined below each media venue and the timeline for release and have attached the appropriate documentation. We have not received any additional feedback from the community at this time but will continue to monitor this closely and report to the IRB any comments or inquiries made in response to our media campaign. We view the process of community notification as an ongoing one that needs to continue after the study starts. We will thus continue to seek opportunities to notify the community and obtain additional feedback and will keep the IRB advised of this process through our quarterly reports.

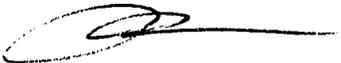
Summary of Media Campaign

1. Television: We have completed an interview with King 5 News that also includes an interview with a former trauma patient who was enrolled in our previous hypertonic saline trial. This is scheduled to air on Healthlinks during the evening news at 5pm on Monday July 10th. The reporter from King 5 felt that this would provide a wider audience than Friday evening, which was the alternative. They will include a link to our web site and our 1-800 number on their web site version of the story. It will likely re-air several times that evening as well.

2. Newspaper: We have written an Op Ed piece for the local papers, which was initially offered to the Seattle Times, but they could not commit to a time frame to run it. We now have a commitment from the Seattle Post-Intelligencer to publish it sometime in the next two weeks. I have attached the draft of this piece and we will forward you the final article when published. We are also pursuing the Puget Sound Business Journal for a similar story and have been contacted by a reporter for Real Change News, which will likely publish a story in the near future.
3. Bus Advertisements: As you know, we posted advertisements in all King County transit busses for the month of May and received only two calls both of which were from people who either wanted to be in the study or wanted to know how to enroll a loved one who had been injured in the study.
4. Web Advertising: Study information was posted on Craig's list last month with a link to our web site for additional information. We have received no community response from this posting.
5. University of Washington/ Harborview notification: An article appeared in cyber STAT last week, which is the Harborview electronic newsletter circulated to all HMC employees. This week an article was posted through U Week, which is circulated to all faculty, students, and staff of the University of Washington. The Cyber STAT newsletter is attached. The link for the U week story is: <http://uwnews.org/uweek/uweekarticle.asp?articleID=25353>.
6. Notification of the Medical Community: In addition to the articles circulated to Harborview and UWMC employees, we have conducted in service sessions with the physicians and nurses at HMC who will care for these patients. We also had the opportunity to present the study at the recent regional WWAMI trauma conference, which was attended by over 500 nurses, physicians, and paramedics interested in trauma care. We have also conducted a series of presentations to the EMS community including all medical directors, airlift employees and regional paramedic providers.
7. Cascade Bicycle Club: We have been in communication with the director of the Cascade Bicycle Club. They have agreed to run a brief description of the study with a link to our web site and 1-800 number in their electronic newsletter. The initial mailing goes to their primary membership of 8,000 cyclists and will be sent on Monday July 10th. They will send a secondary mailing to 35,000 associate members on July 17th. The draft of this text is attached. We were limited to four sentences.

In summary, I believe that this campaign reaches the community through a number of media venues and fulfills the requirements for community notification. We believe that this study should now be allowed to proceed with patient enrollment. Thank you for your thoughtful review of this application.

Sincerely,



Eileen M. Bulger, MD

STAT

HARBORVIEW
MEDICAL
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UW Medicine

A publication for the staff of Harborview Medical Center

July 3, 2006

Harborview shines in ranking of Seattle's best doctors

In its July cover story, Seattle Metropolitan Magazine recognizes Harborview as one of the nation's premier burn and trauma treatment centers and credits UW Medicine for creating "an innovative environment that draws talented practitioners and goads them to keep up on new advances."

The magazine lists 315 specialists in 77 fields as Seattle's best doctors based on a survey mailed to 5,000 local physicians. Congratulations to these Harborview doctors for being selected by their peers as top in their profession:

Itamar Abrass, *Geriatric Medicine*
Scott Barnhart, *Occupational Medicine*
Virginia Broudy, *Hematology*
David Byrd, *General Surgery*
Michael Copass, *Emergency Medicine*
Richard Ellenbogen, *Neurological Surgery*
Jordan Firestone, *Occupational Medicine*
Patrick Fleet, *Nephrology*
John Harlan, *Hematology*
Vishesh Kapur, *Sleep Medicine*
Arthur Lam, *Anesthesiology*
W.T. Longstreth Jr., *Neurology*

Fred Mann, *Radiology*
Wayne McCormick, *Geriatric Medicine*
Joseph Merrill, *Addiction Medicine*
Frederick P. Rivara, *General Pediatrics*
Peter Roy-Byrne, *Psychiatry*
Michael Ryan, *Nephrology*
John Sheffield, *Internal Medicine*
David Spach, *Infectious Diseases*
Kenneth Steinberg, *Critical Care*
Christina Surawicz, *Gastroenterology*
Nicholas B. Vedder, *Plastic Surgery*
Nathaniel Watson, *Sleep Medicine*

Photographer Spike Mafford exhibits "Braille" at Harborview

As part of the Harborview art program's series of temporary public art exhibitions, photographs from Seattle artist Spike Mafford's "Braille Portfolio" are currently on view in the Ground West Lobby, cafeteria and foyer of the Research & Training Building.

In a departure from conventional digital photography, Mafford applies text in the form of Braille (clear, raised plastic dots) to the surface of each image. This text provides poetic interpretations of the scenes depicted, so that the photographs can be understood and appreciated by individuals with reduced or impaired vision as well as by the fully sighted.

Even though he initially struggled with the taboo against touching art, Mafford gradually accepted that he would have to break this rule to make the work accessible to new audiences. Now, he encourages people to touch and welcomes the physical changes that result when fingers move over the photographs. "I like the idea of people reaching out to touch the image; in a sense, I am reaching out to touch the viewer, and I like the idea of that reach returning."

Mafford's work will remain on display throughout the summer. For more information about the artist or his work, contact Peggy Weiss at pweiss@u.washington.edu.



Give blood!

Look for the Puget Sound Blood Center bus at Harborview this week on Ninth Avenue. Hours are 10 a.m. to 12:30 p.m. or 1:45 p.m. to 4 p.m. Thursday, July 6 and 1 p.m. to 4 p.m., Friday, July 7.

Funding allocation requests due July 7

The deadline to submit funding requests to the Funding Allocations Committee is Friday, July 7. All Harborview staff and faculty are encouraged to submit funding requests for projects that would enhance patient care and comfort at Harborview.

Contact Jan Harrison at jh27@u.washington.edu or (206) 543-6403 for an application or more information.

Continued on other side

Novak receives award

Dr. Charles Novak, Harborview professor of anesthesiology, has received the "Distinguished in Government Award" from the American Society of Anesthesiologists for his contributions to the specialty and patients. He received the award in May at the organization's legislative conference.

STAT summer schedule

In July and August, STAT will be published every other week on the following dates: July 3, July 17, July 31, Aug. 14 and Aug. 28.

Please submit articles by 5 p.m. Tuesday for the following week's edition. After the Labor Day holiday, STAT will return to weekly issues.

The STAT is published weekly for Harborview Employees. Send articles to stat@u.washington.edu or Box 359711. The editor reserves the right to edit for length, clarity and style. Submit articles by 5 p.m. Tuesday for the following week's edition.

Research study to evaluate new treatment for severe trauma

Harborview researchers believe that a new intravenous fluid has the potential to improve chances of survival from accidents involving severe blood loss and traumatic brain injury. The fluid, called Hypertonic Saline/Dextran (HSD), is a concentrated salt solution with or without a sugar component. It will soon be tested in a research study in Seattle and nine other communities in the United States and Canada.

"Trauma is the leading cause of death for Americans between one and 44 years of age," says Dr. Eileen Bulger, a UW associate professor of surgery and investigator for the study at Harborview. "We hope this study helps us learn the best ways to improve survival chances for patients who suffer severe trauma."

The Food and Drug Administration and the UW Human Subjects Review Committee have given researchers permission to do this study and enroll patients without their consent because HSD must be administered shortly after injury when patients may be unconscious and family members not immediately available. Once it is possible to do so, all participants or family members will be asked to give their informed consent to continue in the study.

During the three-year study period, HSD fluid will be carried by paramedics in Seattle and King County and by Airlift Northwest. It will be given to approximately 400 patients ages 15 and over.

Public comment on the study is welcome. For more information, go to the study's Web site at <http://www.roctrauma.org> or call 1-800-607-1879.

Good Job! Workshops for job and communication skills

Harborview's Organization Development & Training Department is offering a series of workshops in July to strengthen professional effectiveness and job satisfaction.

All staff may attend. Workshops take place from noon to 12:50 p.m. in 1EH 149, across from the Cashier's office. Bring your brown bag lunch. Registration is not required.

Date	Workshop
July 7	Creative Stress Management
July 14	Job Skills Exploration
July 21	Giving and Receiving Feedback
July 28	Innovative Thinking and Career Development

Harborview team exceeds goal in Race for the Cure

Forty-seven Harborview employees and supporters participated in the Susan G. Komen Breast Cancer Foundation Race for the Cure, **June 17**, at Qwest Field. The team had 11 breast cancer survivors and raised \$8,405, easily surpassing their goal of \$7,000.

Team members included Heidi Sitton, captain, Bimla Bembry, Linda Brandeis, Phyllis Carlton, Bria Chakofsky-Lewy, Carmen Cunningham, Shireesha Dhanjreddy, Laura Houston, Patty Kieffer, Susan Onstad, Margie Peyovich, Becky Pierce, Martine Pierre-Louis, Jan Rabang, Lynn Schnapp, Mary Skogan, Teresa Stettner, Cara Swenson, Sarah VanBuskirk and Rosa Villalobos.

Eldercare workshop

The UW Retirement Association will offer an Eldercare Workshop from 10:30 a.m. to 5:30 p.m., **Saturday, July 22**, at the UW Bothell Campus. This workshop is open to the public as well as members of the UW community. Registration deadline is **July 14**.

Led by Seattle Times columnist Liz Taylor, the workshop is appropriate for family members who have or anticipate taking on primary or secondary care and oversight responsibilities for care of an older or disabled adult, which may include legal and financial responsibilities.

For more information, contact retiremt@u.washington.edu, or go to <http://depts.washington.edu/retiremt/center/pages/workshops.htm>.

New Research Program Aims to Improve Survival of Accident Victims

Imagine yourself trapped in a car on Interstate 5 after a head on collision. You are unconscious and have lost a significant amount of blood. You may have a severe brain injury. When paramedics arrive, they start intravenous fluids, critical to keeping you alive on the way to the hospital. The intravenous fluids currently used have been unchanged since their development in the 1960s.

UW physicians based at Harborview Medical Center believe that a new intravenous fluid has the potential to improve your chances of survival. The fluid is a concentrated salt solution with or without a sugar component called Hypertonic Saline/Dextran (HSD). It will soon be tested in Seattle and nine other communities in the United States and Canada as part of a research study sponsored by the Resuscitation Outcomes Consortium with funding from the National Institutes of Health.

Hypertonic fluids are expected to help accident victims survive by resulting in more rapid improvement of blood pressure, improved blood flow to the injured brain and decreased likelihood of high pressure in the brain. They may also decrease the risk of infection and lung injury by altering the immune response.

HSD is already approved for use in 14 European countries including the United Kingdom, France, Germany, Sweden, Norway and Denmark. It has been tested previously in eight clinical trials in the U.S. and shown to improve survival. Potential side effects include allergic reaction to dextran, seizures due to very high salt levels in the blood and rapid increase in blood pressure leading to more bleeding. None of these side effects has been seen in the previous clinical trials.

Would you want paramedics to give you HSD for life-threatening injuries following an accident? When asked this question in a recent telephone survey, more than 78 percent of Seattle area respondents said they would welcome this treatment.

The Food and Drug Administration and the UW Human Subjects Review Committee have given researchers permission to do this study and enroll patients without their consent because HSD must be administered shortly after injury when patients may be unconscious and family members not immediately available. Once it is possible to do so, all participants or family members will be asked to give their informed consent to continue in the study.

During the three-year study period, HSD fluid will be carried by paramedics in Seattle and King County and by Airlift Northwest. It will be given to approximately 400 patients ages 15 and over with severe blood loss due to either blunt trauma (e.g., injuries caused by motor vehicle crashes) or penetrating trauma (e.g., bullet or stab wounds). It will also be given to patients with evidence of severe traumatic brain injury.

In 1970, Seattle became a model for emergency care in the field with the creation of Medic One at Harborview. We're confident the new study will contribute to our continued leadership role in setting the best medical standards worldwide for pre-hospital emergency care.

For more information, go to the study's Web site at <http://www.roctrauma.org> or call 1-800-607-1879. Public comment is welcome.

Dr. Eileen Bulger is an attending physician at Harborview Medical Center and a UW associate professor of surgery.

New Research Study May Improve Outcome after Severe Injury

Investigators from the University of Washington and Harborview Medical Center are launching a new research study aimed at patients who are injured with severe blood loss or brain injury. If you are involved in a major cycling accident, you may be enrolled in this study by the paramedics or flight nurses who care for you. The study involves the administration of a new intravenous fluid containing a concentrated salt solution with or without a sugar component called dextran, which may improve blood flow and reduce organ injury after trauma. The University of Washington welcomes your feedback on this study for more information please visit our web site at www.roctrauma.org or call 1-800-607-1879.

Hello, my name is _____, and I'm a research assistant for Hebert Research, an independent research firm in Bellevue, Washington. This call does not involve sales of any kind, now or in the future. We are currently conducting a survey on behalf of the University of Washington and Harborview Medical Center to obtain community opinions and views on a study involving severely injured patients. The survey will take approximately five minutes, during which time I will describe the research study to you and ask you for your opinions on it. I will also ask you a few personal questions regarding your education and income level. You do not have to answer any questions that you object to, and you may stop the survey at any time. The University of Washington and Harborview Medical Center will use your opinions to help determine whether the study is acceptable to the community. Would you be willing to offer your opinions and answer some questions after I give you details about the medical study? Your answers will be kept anonymous. Are you eighteen years old or older? **[IF NOT, ASK TO SPEAK TO SOMEONE EIGHTEEN YEARS OLD OR OLDER; REINTRODUCE YOURSELF]** Thank you!

[READ THE FOLLOWING PRIOR TO ASKING SURVEY QUESTIONS]

An experimental intravenous fluid is being tested in a study involving patients with severe injuries, such as those in severe auto accidents, who have a 25-50% chance of dying from their injuries. Usually, patients in a study must provide written consent for participation after being told about the study, its risks and its potential benefits. In the case of severe injury, it is not always possible for patients to give written consent, because they may be unconscious, and their families may not always be available to speak for them.

The U.S. Food and Drug Administration allows for certain studies to be performed without written consent in emergency settings but only if patients have a high risk of dying without treatment, cannot communicate because of their illness and don't have family available to speak for them. When there is no other known treatment available to improve their chance of survival, patients may be given an experimental agent but only if it has been approved in advance by an independent University group set up to review these situations. We would like your opinion on one such study that is proposed involving severely injured patients.

Injury is the leading cause of death in children and younger adults. The usual cause of death in these patients is blood loss or severe head injury. Sometimes a patient will survive the injury but die several days later due to organ failure of their heart, lungs, liver or kidneys. Researchers at Harborview Medical Center are trying an experimental intravenous fluid that may prevent organ failure and improve survival after severe injury. This fluid may also improve outcome after brain injury.

This intravenous fluid has been used in previous clinical studies with no adverse events and is currently approved for use in Europe. As with any medication there is the risk of allergic reaction or other unexpected side effects.

RECEIVED
Human Subjects Division

FEB 08 2006

UW

Previous studies suggest that this fluid is most effective if given as the first intravenous fluid after the injury. As a result, this study fluid will be given by the paramedics at the scene of the accident and consent to continue enrollment in the study will be obtained in the hospital. We are considering whether to allow the study fluid to be given by the paramedics without written consent. We would like to ask you some questions about your opinion on this.

1. At any moment, we are all at risk of serious injury, especially in an automobile. If you were severely injured, such that you had a 25-50% chance of dying with standard treatment, would you want this experimental fluid given to you without written consent, knowing that it might improve your chance for survival or recovery from head injury, but that there is a risk of allergic reaction or other unexpected side effects?
 1. Yes
 2. No
 3. Don't know
 4. Refused

2. Do you believe that this exception to written consent is justified and in the best interests of the patients and community or not?
 1. Yes **[SKIP TO Q4]**
 2. No
 3. Don't know
 4. Refused

3. What is your reason for concern? **[SKIP TO Q5 AFTER ANSWERING]**
 1. Fear of the possibility of side effects
 2. Patients should not lose the right to provide consent for themselves
 3. Other _____ **[SPECIFY]**
 4. Don't know
 5. Refused

4. Why do you feel this exception to consent is justified? _____
 1. It is in the best interest of the patient
 2. It is in the best interest of the community
 3. It is in the best interests of both the patient and the community
 4. Don't know
 5. Refused

5. Injury is the leading cause of death in teenagers, ages 15-18 years, and because they have the same risk and benefits with the study fluid as adults, do you think it is appropriate to include 15-18 year old children in this study?

1. Yes

2. No.....what is the objection _____

3. Don't know

4. Refused

6. Do you have any additional comments about giving this drug without written consent by the patient? _____ **[RECORD VERBATIM]**

The following questions are only to make sure that we have a representative sampling of the community's opinions. Your answers will be kept anonymous

7. What is your age? _____

8. What is your race? **[RECORD ONE RESPONSE]**

- | | |
|------------------------------------|----------------------------------|
| 1. Caucasian/White | 9. Mixed Race |
| 2. African American/Black | 10. Other _____ [SPECIFY] |
| 3. Asian | 11. Don't know |
| 4. Hispanic | 12. Refused |
| 5. American Indian/Native American | |

13. What is the highest level of education you have completed?

1. Less than high school
2. High school
3. Associate, Technical or Vocational degree
4. Bachelor's degree
5. Post-graduate degree
6. Refused

14. What is your occupation? _____

15. What is the zip code where you live? _____

16. Into which of the following categories does your approximate annual household income fall?

- | | |
|-------------------------|--------------------------|
| 1. Less than \$20,000 | 6. \$80,000 to \$100,000 |
| 2. \$20,000 to \$35,000 | 7. Over \$100,000 |
| 3. \$35,000 to \$50,000 | 8. Don't know |
| 4. \$50,000 to \$65,000 | 9. Refused |
| 5. \$65,000 to \$80,000 | |

Are you the parent or legal guardian of a child or children ages 15-18 years? _____

THAT CONCLUDES OUR SURVEY. THANK YOU VERY MUCH FOR YOUR TIME AND COOPERATION.

GENDER:

1. MALE

2. FEMALE

DATE: _____

INTERVIEWER: _____

Community presentation
power point

**Prehospital Clinical Research:
The Resuscitation Outcomes Consortium
(ROC) Studies**



Seattle and King County Medic One with
Harborview Medical Center

ROC Overview

ROC was created to conduct clinical
research in the areas of

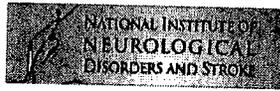
- traumatic injury
- cardiopulmonary resuscitation



Who are the sponsors? (U.S.A.)



National Heart, Lung and
Blood Institute



N.I.N.D.S.



U.S. Department
of Defense



Who are the sponsors? (Canada)



CIHR IRSC
Canadian Institutes
of Health Research



CIHR IRSC
Canadian Institutes
of Health Research



Finding Answers. For Life.



RECEIVED
Human Services

IFEB 06 2003

UW

Who will conduct the research?



- Alabama Resuscitation Center
- Dallas, TX
- Iowa City, IA
- Milwaukee, WI
- Pittsburgh, PA
- Portland, OR
- Ottawa/OPALS/B.C.
- San Diego, CA
- Seattle/King County, WA
- Toronto, ON

**Hypertonic Resuscitation Following
Traumatic Injury**



Eileen M. Bulger, MD, FACS
Sandy Hanson RN, MN



The Need for Trauma Care Research

- Leading cause of death for ages 1 to 44 yrs
- In the next 30 minutes in the United States:
 - 6 people will die
 - 1000 people will have a disabling injury
 - \$24 million will be spent to care for these patients
- Every year over 500,000 patients suffer a traumatic brain injury of these:
 - 100,000 will die
 - 90,000 will suffer a severe long term disability

Why do Trauma Patients Die?

	Acute <48 hours	Early 48 hours to 7 days	Late > 7 days
Brain Injury	40%	64%	39%
Blood loss	55%	9%	0%
MOFS	1%	18%	61%

**Sauaia et al, J Trauma, 1995*

What is Blunt Trauma?

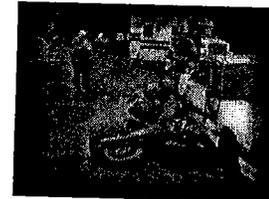
80% of Trauma Patients seen at Harborview

- #1 Motor Vehicle & Motorcycle crashes
- #2 Pedestrians & bicyclists struck by cars
- #3 Falls
- #4 Assaults with blunt objects



Trauma Care Begins in the Field

- Prehospital Care
 - Airway management
 - IV Fluid Administration
 - Spinal Immobilization



Intravenous Fluids

- Given to help replace blood loss and support blood flow to important organs
- Low blood pressure suggests severe blood loss and requires ongoing fluid replacement

Current Practices for Hypovolemia

- Management of hypovolemic shock (low blood pressure) involves giving IV fluids very quickly to the trauma patient

Clinical Problem (Traumatic Brain Injury)

- Early deaths (2-7 days) resulting from Traumatic Brain Injury are increased due to
 - Inadequate brain perfusion, which leads to
 - Another injury as a result of poor delivery of need nutrients
 - Oxygen
 - Glucose



Hypertonic Saline/Dextran

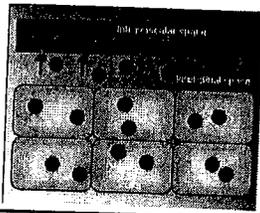
- An experimental IV fluid that is more concentrated
 - 7.5% saline
 - 6% dextran-70
- Has many potential benefits for trauma patients but needs to be studied



How does HS work?

- Rapid fluid shift from inside the cells to the blood vessels
- Very effective volume expander

- Eat a package of saltines
- Fluid shifts

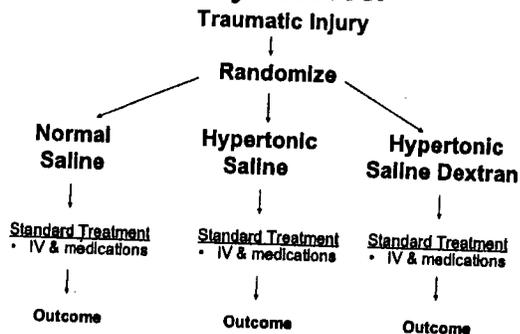


Purpose of the Study

- To determine if Hypertonic Saline with and without Dextran:
 - Improves overall survival
 - Improves outcome in victims of severe brain injury
- ...compared to Normal Saline.



Study Protocol



Sample size

- Hypovolemic shock cohort will include approximately 3700 patients over 3.5 years
- Traumatic brain Injury study will include approximately 2100 patients over 1.5 years



Hypertonic Saline: Advantages

- Rapid improvement in blood pressure for the bleeding trauma patient
- Improved blood flow to the injured brain
- May alter the response of the immune system after injury



Potential Side Effects from Hypertonic Saline

- Potential for allergic reaction to the dextran
- VERY high salt levels in the blood can lead to seizures
- Rapid increase in blood pressure could lead to increase bleeding

Not seen in previous trials of trauma patients



Entry Criteria for HSD Study

- Age \geq 15yrs (110 lbs or more if age unknown)
- Blunt or Penetrating Trauma patients
- Low blood pressure
- Altered mental status



Study Design

- Collect data for hospital course for all patients to see if those who receive HSD have improved outcomes
- Follow the neurologic status for patients with brain injury for up to 6 months to see if HSD effects their outcome
- Study the White blood cells from blood samples to see how HSD affects their function.

Participating in a Research Study

- To participate in most research studies patients or their families need to sign a consent form.

Waiver of Consent

- The federal government allows emergency studies to be done with a waiver of informed consent if:
 - The patient is in a life-threatening situation and cannot provide consent
 - Family are not immediately available to provide consent
 - Treatment may benefit the patient with reasonable risks
 - The study could not be done without the waiver
 - The community agrees to participate

Community Involvement

- Telephone survey (500 households)
- Community meetings
- Press releases w/ contact number
- Physician & paramedic education

Regulatory Oversight

- University of Washington Institutional Review Committee
- Food & Drug Administration
- National Institutes of Health
- Data Safety and Monitoring Board

What to do if you do not want to participate

- Opt-out bracelet
 - Must be on the person when they have the accident
- If circumstances allow the Medics might be able to read a prepared script and there might be the option to say NO
 - First focus is the injured patients care

For More Information

- web site:
www.washington.edu/medicine/hmc/overview/studies/esd.html
- Or contact us:
 - Phone: 1-800-506-1309
 - Email: hsdstudy@u.washington.edu

Questions

?

Power Point for Prehospital providers

Prehospital Clinical Research: The Resuscitation Outcomes Consortium [ROC]



"Insert your base hospital name / Service provider name here"

OBJECTIVES

After the presentation you should be able to describe:

- What ROC is
- Purpose of Hypertonic Saline Trial
- Inclusion/Exclusion criteria
- Possible adverse effects
- Proper notification and documentation of cases

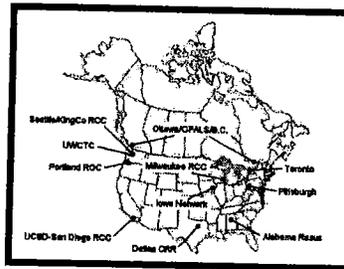


ROC Overview

- ROC was created to conduct clinical research in the areas of cardiopulmonary resuscitation and traumatic injury
- Trials may evaluate existing or new therapies as well as clinical management strategies (i.e.: new drugs, new fluids, new techniques...)



Who will conduct the research?



- Birmingham, AL
- Dallas, TX
- Iowa City, IA
- Milwaukee, WI
- Pittsburgh, PA
- Portland, OR
- Ottawa/OPALS/B.C.
- San Diego, CA
- Seattle/King Co., WA
- Toronto, ON

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Who are the sponsors? (U.S.A.)



National Heart, Lung and Blood Institute



N.I.N.D.S.



U.S. Department of Defense



Who are the sponsors? (Canada)



Department of Research and Development Canada



CIHR IRSC
Canadian Institutes of Health Research



Finding answers. For life.



Trauma Study

Hypertonic Resuscitation following Traumatic Injury



Purpose

- To determine if Hypertonic Saline with and without Dextran:
 - › Improves overall survival
 - › Improves outcome in victims of severe brain injury
- ...compared to Normal Saline.



Hypertonic Saline (HS) Trial

Trauma patients:

1. Blunt or penetrating trauma patients in hypovolemic shock (28 day survival)
2. Blunt trauma patients with severe traumatic brain injury (long term neurologic outcome)

Randomized to receive 250cc IV of study fluid



HS Trial

Three arm, randomized, blinded trial comparing:

- Hypertonic saline / Dextran (7.5% saline / 6% Dextran 70) – HSD
- Hypertonic saline (7.5% saline) – HS
- Normal saline (0.9% saline) – NS

... as the **initial** resuscitation fluid administered in the prehospital setting

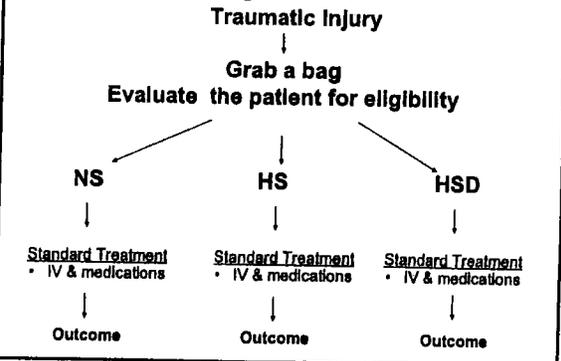


Randomization and Blinding

- Randomization: Similar to “flipping a coin”
- Randomization assures results reflect study intervention and do not occur from bias or chance
- Blinding reduces chance of bias
- Just grab a bag and go!



Study Protocol



Sample Size

- Hypovolemic shock cohort :
~ 3700 patients over 3.5 years
- Traumatic brain injury cohort:
~2100 patients over 1.5 years



Background

- Trauma is the leading cause of death in North Americans between the ages of 1 and 44 years (150,000+ in U.S.)
- The majority of these deaths result from hypovolemic shock or severe brain injury



Death following Trauma

- 50 % of deaths occur at scene (CNS injury & blood loss)
- 30 % in first 48 hrs (secondary brain injury)
- 20 % following ICU stay (ARDS; MOFS)



Hypovolemic shock

- Rapid blood loss
↓
Inadequate perfusion
↓
Poor delivery of O₂
↓
Inflammatory cell activation



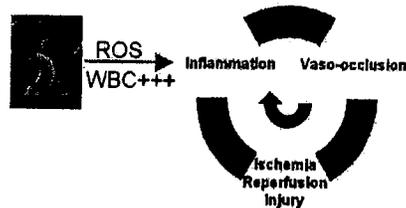
Clinical Problem: Hypovolemia

- Patients in shock develop systemic tissue ischemia that leads to reperfusion injury at the time of fluid resuscitation.



Clinical Problem: Hypovolemia

- Reperfusion of ischemic tissue causes an inflammatory response resulting in organ injury.



Clinical Problem: Hypovolemia

- Inflammatory response contributes to:
 - **ARDS** (Acute Respiratory Distress Syndrome) and
 - **MOFS** (Multiple Organ Failure Syndrome)
- ...which are responsible for over 20% of trauma related deaths.



Clinical Problem: Traumatic Brain Injury

- Early deaths (2-7 days) resulting from Traumatic Brain Injury are increased due to
 - Inadequate cerebral perfusion, which leads to
 - Secondary Ischemic Injury (cerebral edema, ↓ blood flow, ischemia, ↑ICP...)



HS: Potential Benefits in TBI

- May aid in the rapid restoration of cerebral perfusion &
- Prevent extravascular fluid sequestration &
- Limit secondary brain injury



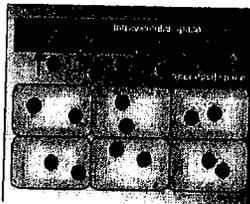
Hypertonic Saline: Advantages

- Rapidly restores tissue perfusion
- Recent studies show that hypertonicity significantly :
 - alters the activation of inflammatory cells
 - may reduce subsequent organ injury and decrease nosocomial infection



How does HS work?

- Pulls fluid into vessels
 - Increases serum osmotic pressure
 - Redistributes fluid from the interstitial to the intravascular space



What does HS do?

- Rapidly restores intravascular volume
 - with a smaller volume of fluid
 - decreased accumulation of extravascular volume

Volume Infused (ml)	Type of fluid	Volume expansion (ml)
1000	D5W	100
1000	LR	250
500	Pentastarch	500
250	7.5% Saline	1000

Rizoli, J Trauma 2003

Dextran

- Glucose polymers.
- Very effective volume expander.
- Dextran prolongs the increase in serum osmotic pressure, which leads to the redistribution of even more fluid from the interstitial to intravascular space.
- Extends the hemodynamic effects of HS from 1 to up to 4 hours.



Potential risks

Seizure activity

- Associated with HIGH levels of serum sodium (>170mEq/L) or too rapid correction of elevated sodium levels.
- Data from previous clinical trials suggest that levels greater than 170mEq/L are rarely seen.



Potential risks

- Rare reports of allergic reactions to Dextran.
- When administering the study fluids monitor for anaphylaxis:
 - Edema
 - Urticaria
 - Wheezing

Not seen in previous trials of trauma patients



Reporting!

- **Any evidence of allergic reaction or seizure activity following administration of the study fluid is to be reported and documented as a serious adverse event**
 - Stop infusion immediately
 - Treat patient appropriately



Here's what you have to know!



Inclusion Criteria

- Age ≥ 15yrs (≥ 50 kg if age unknown)
 - Blunt or Penetrating Trauma patients with...
 - Hypovolemic shock:
 - SBP ≤ 70 mmHg OR
 - SBP 71-90 mmHg AND HR ≥ 108 bpm
- AND / OR**
- Blunt Trauma patients with...
 - Traumatic Brain Injury
 - Prehospital GCS ≤ 8



GCS criteria ≤ 8

- Goal is to enroll pts with **SEVERE TBI**
 - › 8 is the critical score
 - › 90% ≤ 8 are in coma

***Coma is defined as: (1) not opening eyes, (2) not obeying commands, and (3) not uttering understandable words.

Case study: GCS 8

- 42y/o female s/p motor vehicle crash with open femur fracture. SBP 94/60, HR 144, RR 36.

•Eyes open briefly to painful stimuli E = 2
•Groans, no verbalization V = 2
•Pulls away from IV start, doesn't follow commands M = 4
GCS 8

Case study: GCS 6

- 32 y/o tree topper, who fell 30' onto concrete. SBP 154/94, HR 122, RR 8. Blood from both ears, abrasion on forehead, RLE deformity, RUE open fracture.

•Doesn't open eyes E = 1
•No verbal response to stimulation V = 1
•Withdraws to pain, non-purposefully M = 4

GCS 6

Case study: GCS 8

- 27 y/o unhelmeted male, s/p motor cycle crash at highway speed. Deformity of L femur noted, L periorbital ecchymosis. SBP 138/74, HR 128, RR 10.

•Eyes open to voice, but close without constant verbal stimuli E = 3
•Moaning, doesn't follow commands V = 2
•Flexes arms with sternal rub. M = 3
GCS 8

Exclusion Criteria

- Known or suspected pregnancy
- Age <15
- Ongoing CPR
- Administration of > 2 litres of IV fluids
- Severe hypothermia (suspected T <28C)



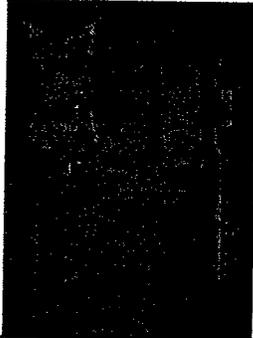
Exclusion Criteria

- Drowning or hanging
- Burns > 20%
- Isolated penetrating injury to the head
- Inability to obtain intravenous access
- Time of call received at dispatch to study intervention > 4 hours



HSD Study Kit Contents:

- Study fluid
- Extra labels with the bag number
- ID bracelet with bag number
- Info card with incl/excl criteria & contact numbers



Why Don't You Need Patient Consent?

- Exception from informed consent in emergency circumstances
- Patients are facing a life-threatening situation, may be unethical to attempt consent in ROC study setting
- Patients will receive info sheet while in hospital and will be consented for follow-up interview



How Are You Protected?

- Employer and Medical Director approval
- Other
 - NIH's U.S. Government-mandated Protocol Review Committee
 - Data and Safety Monitoring Board
 - FDA / Health Canada approval
 - Research Ethics Board approval
 - Institutional Review Board approval



Notify Us!

When you enroll a patient, you must:

- Apply the arm band to the pts. wrist
- Apply the study labels to the run record and ED paperwork
- Call the 800 number provided and leave a message saying you've enrolled a patient (date, location, IV Bag #)
- Bags must be collected in ER



Documentation

- Ensure that SBP and/or GCS are well documented
- Apply stickers with bag # to the run report and the hospital paperwork
- Report any unusual events or concerns



FAQ's

1. If I finish the study fluid bolus (250cc) and the patient is still hypotensive, can I give him more fluids?

YES, after the study fluid has been given you can continue with your local fluid administration orders.



FAQ's

2. If I need to continue with fluid administration (i.e. 20ml/kg) do I include the initial 250cc of study fluid in the total calculated amount?

YES: ex: 80kg patient x 20ml/kg = 1600 cc (- 250 cc of study fluid) = 1350cc left to administer.



FAQ's

3. Local standards are to discontinue a fluid bolus at a systolic BP of 90 mmHg and run TKVO. What if the pressure goes above 90 and I am still running the 250cc of study fluid?

Once you start the study fluid **YOU MUST FINISH IT**. This protocol supersedes the local orders. After the study fluid bolus is finished re-evaluate your patient and proceed as needed.



FAQ's

4. What do I do if the study fluid has not finished infusing by the time I reach the ED?

You must make sure the entire 250cc of study fluid is given to the patient.

Thank you for helping us find better ways to treat our patients!

ANY QUESTIONS?



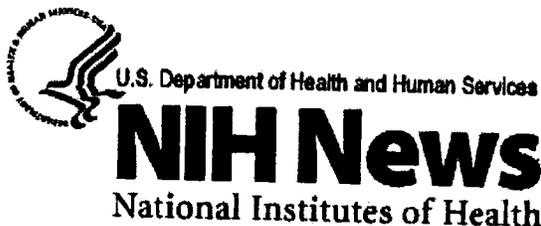
Insert your logo here



Resuscitation Outcomes Consortium

Exception to informed consent

- **Community consultation**
- **Public notification**
 - › **Opt out option – ID bracelet available**
- **Prehospital script**
 - › **If feasible**



Master Copy	<input type="checkbox"/>
Committee Copy	<input type="checkbox"/>
Investigator Copy	<input type="checkbox"/>

National Heart, Lung, and Blood Institute

<http://www.nhlbi.nih.gov>

FOR IMMEDIATE RELEASE
March 24, 2006

CONTACT: NHLBI Communications Office
(301) 496-4236
E-mail: nhlbi_news@nhlbi.nih.gov

New Federally Funded Research Program Aims to Improve Survival from Cardiac Arrest and Severe Trauma

A young mother is unconscious and bleeding from internal injuries caused by a highway accident. A soldier is severely injured in a roadside explosion. A 50-year-old man suffers a cardiac arrest as he gets ready for work. For the "real" counterparts of these made-up case histories, the chance of survival from life-threatening injury and cardiac arrest is dismally low. Many more could survive if only they could be sustained long enough to reach a hospital alive. However, most cardiac arrest victims die before they reach the hospital, and traumatic injury is a top killer in North America. With the launch of a massive research program funded by the National Institutes of Health (NIH) and other federal and Canadian agencies, scientists hope to learn the best ways to improve survival chances from cardiac arrest and severe trauma.

The "Resuscitation Outcomes Consortium" (ROC) will conduct collaborative clinical trials of promising new treatments for cardiac arrest (the stopping of the heartbeat) and severe traumatic injury. Along with Emergency Medical Services (EMS) agencies, ROC will involve public safety agencies, regional hospitals, community healthcare institutions and medical centers in 11 regions in the United States and Canada and as many as 15,000 patients over a 3-year period. Communities involved in ROC will learn about the study in a comprehensive community education effort to be conducted over the next 6 months to a year.

"Surviving traumatic injury and cardiac arrest is a serious public health issue. Tens of thousands of Americans die each year from sudden cardiac arrest and trauma. The good news is that there is a growing body of research – basic research and small studies -- that suggests a significant number of these people can be saved," said Elizabeth G. Nabel, M.D., director of the National Heart, Lung, and Blood Institute (NHLBI) of the NIH, the lead federal sponsor of the research effort.

Other funding agencies include the U.S. Department of Defense, the NIH's National Institute of Neurological Disorders and Stroke, the Institute of Circulatory and Respiratory Health of the Canadian Institutes of Health Research, Defence Research and Development Canada, the Heart and Stroke Foundation of Canada, and the American Heart Association. The initial funding commitment to the Consortium is \$50 million.

"This is the first time we have used large-scale clinical trials to improve the treatment of patients with traumatic injury and cardiac arrest. Similar studies in patients with heart attack and heart failure have answered questions about the best treatments. As a result, we've seen greatly improved survival for these disorders. That's what we want to do with cardiac arrest and traumatic injury," said Myron Weisfeldt, M.D., professor and chair of internal medicine at Johns Hopkins University and chair of the steering committee for the research effort.

All of the interventions to be tested in the new program will have been shown in smaller, single center studies to be safe and to potentially have a life-saving effect. According to Weisfeldt, the

Consortium's testing of new techniques will provide the large-scale proof of effectiveness needed to support widespread adoption and use.

An important goal of the ROC will be the evaluation of interventions in terms of benefit to cognitive outcomes, as the ultimate goal of resuscitation is to return victims to their prior functional capacity.

The first treatments to be tested will be highly concentrated forms of a saline solution similar to the body's own fluids. Typically, in the crucial early minutes before blood transfusions can be safely administered in hospital, trauma patients receive normal saline solution intravenously in the field to compensate for blood loss and buy time. In the new trial, trauma patients with either signs of blood loss or severe brain injury will receive one of three saline solutions -- standard normal saline, high concentration saline, or high concentration saline with dextran, a circulation-enhancing substance. The two concentrated solutions are designed to compensate for blood loss more effectively, lessen excessive inflammatory responses and prevent brain swelling. These effects in turn could potentially lead to a reduction in organ failure for patients with major blood loss and improved function for patients with brain injury.

The second study will test a device to enhance blood flow during CPR. This device is a one-way valve that fits between the airbag used to introduce air into a person in cardiac arrest and the flexible plastic tube that goes through the nose or mouth and into the lungs to help with breathing. The valve can also be used with a facemask that goes over the patient's nose and mouth. During CPR, the one-way valve creates a small vacuum inside the patient's chest, which increases the return flow of blood to the heart.

Other possible future studies include testing of new drug approaches to aid resuscitation from cardiac arrest and evaluation of novel strategies to control hemorrhage.

There are an estimated 330,000 out-of-hospital cardiac deaths each year in the United States. Most of these are from sudden cardiac arrest, although the exact numbers are not known. In cardiac arrest, the heart stops beating effectively, blood does not circulate and no pulse can be felt. The victim collapses suddenly into unconsciousness. Heart attacks, which are caused by a blockage of a coronary artery, can sometimes lead to cardiac arrest. A common underlying cause of sudden cardiac arrest is an abrupt disorganization of the heart's rhythm called ventricular fibrillation, which can be triggered by a heart attack or can just represent a catastrophic rhythm disturbance. Unless cardiac arrest victims are treated within minutes (by defibrillation to shock an abnormally beating heart back into normal rhythm or CPR followed by or in conjunction with other procedures), they will die.

Severe injury is also a major public health problem. It is the number one killer of both children and young adults up to age 44. As a disease of young people, it is also the leading cause of life years lost. In 2002, there were over 161,000 fatal injuries in the United States. The leading causes of death following injury are brain injury, blood loss, and organ failure from excessive inflammation.

In addition to rigorous review by an NHLBI-convened independent review group, the clinical trials of the new Consortium will be conducted under strict FDA guidelines that allow for patients in life-threatening situations to participate in research without individual consent at enrollment. The guidelines specify criteria that must be followed for a study to have an exception from informed consent. These include:

- Approval by an institutional review board (IRB), a committee of experts and lay people established to review research.
- Consultation with the community.
- Public disclosure of the study's design before the study begins and when the study is over to share results.
- Notification of patients who were involved in the research.
- Oversight by an independent group of experts charged with monitoring the research for safety.

Each site's IRB will decide how best to inform the community, recommending approaches that might include town meetings, newspaper notices, random digit dialing surveys, and meetings with groups at high risk of either cardiac arrest or trauma – such as local motorcycle clubs. In order to inform future studies involving exceptions from informed consent, the community consultation process used in ROC will be evaluated in at least one ancillary study.

"There is a high probability of benefit for patients participating in these trials," said Joseph Ornato, M.D., the Consortium's co-chair for cardiac arrest and chairman of the Department of Emergency Medicine at the Virginia Commonwealth University Medical Center in Richmond, VA. "Not only have these therapies been shown to be potentially life-saving, but also EMS personnel involved in the research will be trained in the most up-to-date and effective methods of emergency treatment."

According to Tracey Hoke, M.D., Sc.M., NHLBI project officer for the ROC, "A federal exception of informed consent can only be granted when patients are in a life-threatening situation, when obtaining individual informed consent is impossible, and when current therapy is unproven or unsatisfactory. The most critical stipulation of the exception is that there must be the potential for direct benefit to the patients enrolled. In the case of ROC, this means that preliminary evidence of direct survival benefit must be shown prior to the development of any trial."

"These initial studies, and those that follow, will change the way all providers of trauma care, military and civilian, care for the most critically injured," said COL John Holcomb, MD, the consortium co-chair for trauma, and the Commander of the US Army Institute of Surgical Research, San Antonio, TX. "For the first time we will know, based on large and well designed studies, what interventions really make a difference."

In a typical study scenario, a first responder will arrive at the scene of the cardiac arrest or trauma and confirm the patient's diagnosis. The emergency medical technician (EMT) will then assess whether the patient meets the entrance criteria for the study and if so, treat the patient with the study intervention.

Since the studies will be blinded, the EMTs in the field will not know which treatment the patient receives. For example, in the first consortium study testing the concentrated saline solutions, all solutions of saline to be administered to patients will look alike, although they will be numbered for later identification and analysis by the study's scientists.

In addition to the clinical trials, the Consortium is also currently enrolling patients into a database of all cardiac arrest and trauma events. "This is the first multi-city comprehensive database with information about how field treatment leads to patient survival," said George Sopko, M.D., deputy project officer on the study and a medical officer with NHLBI.

The study is coordinated by investigators at the University of Washington, Seattle, Principal Investigator: Al Hallstrom, Ph.D.

The participating cities include:

- Birmingham, AL: The Alabama Resuscitation Center is coordinated through the University of Alabama at Birmingham (Central and possibly Northern Alabama). Principal Investigator: Tom Terndrup, M.D.

- Dallas, TX: The Dallas Center for Resuscitation Research is coordinated through the University of Texas Southwestern Medical Center (Dallas and surrounding cities to participate). Principal Investigator: Ahamed Idris, M.D.

- Iowa City, IA: The University of Iowa Carver College of Medicine-Iowa Resuscitation Network is coordinated through the University of Iowa (includes 10 cities throughout Iowa). Principal Investigator: Richard Kerber, M.D.

- Milwaukee, WI: The Milwaukee Resuscitation Research Center is coordinated through the Medical College of Wisconsin. Principal Investigator: Tom Aufderheide, M.D.
- Ottawa, Ontario/Vancouver, BC (counts as two regions): The University of Ottawa/University of British Columbia Collaborative RCC is coordinated through the Ottawa Health Research Institute, University of Ottawa, Ontario and St. Paul's Hospital, University of British Columbia (includes additional 20 cities). Principal Investigator: Ian Stiell, M.D., Co-Principal Investigator: Jim Christenson, M.D.
- Pittsburgh, PA: The Pittsburgh Resuscitation Network is coordinated through the University of Pittsburgh Medical Center (includes several suburbs). Principal Investigator: Clif Callaway, M.D., Ph.D.
- Portland, OR: The Portland Resuscitation Outcomes Consortium is coordinated through the Oregon Health and Science University (includes 4 counties). Principal Investigator: Jerris R. Hedges, M.D., MS.
- San Diego, CA: The UCSD-San Diego Resuscitation Research Center is coordinated through the University of California, San Diego (entire county). Principal Investigator: David Hoyt, M.D.
- Seattle and King County, WA: Seattle-King County Center for Resuscitation Research at the University of Washington. Principal investigator: Peter Kudenchuk, M.D.
- Toronto, Ontario: The Toronto Regional Resuscitation Research out of hospital Network is coordinated through the University of Toronto (includes areas surrounding Toronto). Principal Investigator: Arthur Slutsky, M.D., Co-Principal Investigators: Laurie Morrison, M.D. and Paul Dorian, M.D.

To interview NHLBI's Dr. Tracey Hoke, ROC project officer or NHLBI's Dr. George Sopko, ROC deputy project officer, contact the NHLBI Communications Office at 301-496-4236. To interview Dr. Weisfeldt or Dr. Jeremy Sugarman, ROC ethicist and Harvey M. Meyerhoff Professor of Bioethics and Medicine with the Phoebe R. Berman Bioethics Institute and Department of Medicine Johns Hopkins University, call David March, Media Relations and Public Affairs, Johns Hopkins Medicine at 410-955-1534. To interview Dr. Ornato, call 804-828-7184. To interview COL Holcomb, call 210-916-2720.

Part of the National Institutes of Health, the National Heart, Lung, and Blood Institute (NHLBI) plans, conducts, and supports research related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases; and sleep disorders. The Institute also administers national health education campaigns on women and heart disease, healthy weight for children, and other topics. NHLBI press releases and other materials are available online at: www.nhlbi.nih.gov.

The National Institutes of Health (NIH) — The Nation's Medical Research Agency — includes 27 Institutes and Centers and is a component of the U. S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical, and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit <http://www.nih.gov>.

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Harborview Injury Prevention and Research Center

CONTACTS:

Larry Zalin
Harborview Injury Prevention and Research Center
(206) 744-9459
zalin@u.washington.edu

Susan Gregg-Hanson (to speak with Dr. Eileen Bulger)
Harborview Medical Center
(206) 731-6397
sghanson@u.washington.edu

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Human Subjects Division

APR 04 2006

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For immediate release:

New Federally Funded Research Program Aims to Improve Survival from Severe Trauma

Hypertonic resuscitation – a concentrated intravenous (IV) dose of saline, with or without dextran, a sugar solution – has the potential to help survivors of cardiac arrest and trauma by improving blood flow and delivery of oxygen to the injured brain while decreasing high pressure in the brain, a common problem for patients with brain injury. This therapy is being tested in a research study at 10 hospitals in the U.S. and Canada, including University of Washington (UW) physicians based at Harborview Medical Center.

“Trauma is the leading cause of death for Americans between 1 and 44 years of age,” says Dr. Eileen Bulger, a UW associate professor of surgery and investigator for the study at Harborview. “We hope this study helps us learn the best ways to improve survival chances for patients who suffer severe trauma.”

The hypertonic saline study will include patients aged 15 years and older who are being treated for blunt trauma (e.g., injuries caused by motor vehicle crashes), penetrating trauma (e.g., bullet or stab wounds), and traumatic brain injury.

Care for those who experience trauma begins in the field, with paramedics and flight nurses providing airway management, spinal immobilization and IV fluids. Given to help replace lost blood and support blood flow to vital organs, IV fluids are especially important for patients who have suffered brain injuries. Current pre-hospital treatment includes two liters of an IV saline solution having a similar concentration to human plasma.

The experimental hypertonic saline with dextran (HSD) or without (HS) solution is more concentrated than the current treatment and may offer potential benefits to victims of cardiac arrest and trauma, including more rapid improvement of blood pressure, improved blood flow to the injured brain while decreasing the high pressure in the brain, and an altered immune system response which may decrease the risk of infection and acute respiratory distress syndrome.

HSD is already approved for use in 14 countries, including the United Kingdom, France, Germany, Sweden, Norway and Denmark. **It has been the subject of eight previous clinical trials in the U.S., all of which showed improved survival with HSD, but these studies had an insufficient number of subjects or involved patients with primarily penetrating trauma.**

There will be approximately 400 patients enrolled from our region. One third will receive traditional resuscitation, one third will receive HS, and one third will receive HSD. All other aspects of medical and surgical care will be the same for all of the groups.

Because HSD/HS must be immediately after injury, it is not possible to obtain informed consent from patients, or their family members. The Food and Drug Administration and the UW's Human Subjects Review Committee has given the researchers permission to do this study and enroll patients without their consent due to the emergency nature of their illness and the potential benefit of this treatment. All participants (or family members) will be asked to give their informed consent to continue in the study once it is possible to do so. A recently completed community survey of residents from King County and the surrounding region suggest support for the study with 77% of respondents indicating that they would consent to receive the study fluid if injured and 71% believe it is appropriate to include 15 – 18 year old patients.

Potential side effects of HSD and HS include possible allergic reaction to dextran, seizures due to very high salt levels in the blood, and rapid increase in blood pressure leading to more bleeding. None of these side effects have been seen in previous clinical trials.

The study is being funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health (NIH), the lead federal sponsor of the research effort. Other funding agencies include the U.S. Department of Defense; the NIH's National Institute of Neurological Disorders and Stroke; the Institute of Circulatory and Respiratory Health of the Canadian Institutes of Health Research; Defence Research and Development Canada; the Heart and Stroke Foundation of Canada; and the American Heart Association.

Harborview Medical Center and the University of Washington welcome public comment on the HSD study. Further information can be found on the study's web site: <http://www.washington.edu/medicine/hmc/overview/studies/esd.html> (available June 18) or by leaving a message at 1-800-506-1309 or 206-341-4721.

###

Web site wording

Hypertonic Saline May Help Victims of Blunt Trauma

Researchers at the University of Washington based at Harborview Medical Center, as part of the Resuscitation Outcomes Consortium, will be testing a concentrated form of intravenous saline with and without dextran (a sugar solution) to improve the outcomes and quality of life for victims of trauma.

Hypertonic saline with dextran (HSD) or without (HS) has been tested in smaller studies in the U.S. and has shown an improved survival, but the numbers were too small to make HSD a standard of care in the trauma population. HSD is approved for use in 14 European countries.

HSD/HS is more concentrated than standard treatment and may offer potential benefits including more rapid improvement of blood pressure, improved blood flow to the brain while at the same time decreasing pressure in the injured brain. HSD/HS may also alter the immune system response, which may decrease the risk of infection and acute respiratory distress syndrome.

Some of the information provided in the website may be difficult to understand. If this is the case please view the consent form located under the "consent form" tab or contact us via e-mail: XXXXXXXXXXXX or at 1-800-XXXXXXXX where you will be able to leave a voice message.

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Research

Eileen M. Bulger, MD, associate professor of surgery at the University of Washington is a trauma surgeon at Harborview Medical Center. She has given the following community presentation in the King County Area.

[Download Slide Presentation](#)

(Microsoft PowerPoint 471K)

Six months after the trauma patients identified as having a head injury have left the hospital there will be a follow up questionnaire.

[Download the Questionnaire](#)

(Microsoft Word 49K)

Consent Forms

Consent form for HSD study

(Microsoft Power Point 46K)

Telephone questionnaire

(Microsoft Word 195K)

Contact Information

Name: Sandy Hanson, RN, Research Coordinator

Phone: 1-800-XXXXXXXX (This is a message line)

E-mail: XXXXXXXXXXXXXXXXXX

Address: Harborview Medical Center Department of Surgery
325 Ninth Avenue
Box 539796
Seattle, WA 98104-2499

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- How may people experience trauma?
- What's the immediate treatment for a trauma patient?
- How can the survival rate be improved?
- Why are we doing another study?
- How will the Resuscitation Outcomes Consortium study at the University of Washington be conducted?
- Which trauma victims will be treated with HSD/HS?
- Who will be included in the study?
- Are there potential risks in the study?
- Will a trauma victim's records be kept confidential?
- How are trauma victims and their families informed about this research?
- Why has the FDA changed its rules on informed consent?
- Does the HSD/HS study meet the FDA requirements for waiver of informed consent?
- Will the victim's family know that the patient was part of the HSD/HS study?
- Who are the investigators for this study?

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How many people experience Trauma?

Trauma is the leading cause of death among Americans between the ages of 1 and 44 years. Blunt trauma includes motor vehicle collisions, pedestrians and bicyclists struck by cars, falls, and assaults with blunt objects. Penetrating trauma includes bullet or stab wounds. The majority of deaths after trauma results from hypovolemic shock (low blood pressure from blood loss) and severe brain injury. Patients in hypovolemic shock develop a state of systemic tissue ischemia (decreased oxygen and blood flow to the tissues) with a subsequent reperfusion injury at the time of fluid resuscitation.

What's the immediate treatment for a Trauma patient?

Conventional resuscitation of these patients involves the intravenous administration of a large volume of isotonic or slightly hypotonic (lactated ringers) solutions beginning in the pre-hospital environment. Previous studies have suggested that an alternative resuscitation fluid, hypertonic saline with dextran (HSD) may reduce mortality in these patients; but these have not been conclusive. Furthermore, HSD may have specific advantages in the brain-injured patient, as it may aid in the rapid restoration of cerebral perfusion, prevent extravascular fluid sequestration, and thus, limit secondary brain injury. In addition, recent studies have demonstrated that hypertonicity significantly alters the activation of inflammatory cells, which may result in a reduction in subsequent organ injury following whole body ischemia/reperfusion and ultimately decrease nosocomial infection rates. This study is designed to evaluate the clinical outcome of patients following blunt traumatic injury with hypovolemic shock, who receive lactated ringers (LR) vs. HSD resuscitation. In addition, we plan to focus specifically on neurologic outcome in the subset of patients with brain injury and on the effect of HSD resuscitation on the responsiveness of inflammatory cells.

How can the survival rate be improved?

Most deaths after trauma result from blood loss or severe brain injury thus we need better therapies to support patients with severe blood loss and reduce injury to the brain. HSD or HS has the potential to help in both these circumstances, but more study is needed. Patients that survive their initial injury are also at risk to develop excessive activation of their immune system than can result in injury to their organs, most commonly the lungs. This is called Acute Respiratory Distress Syndrome (ARDS). HSD has been shown to alter the inflammatory response early after injury and thus may reduce the risk of ARDS as well.

Why are we doing another study?

HSD has been successfully used on humans in Europe and in small clinical trials in the US. In fact a hypertonic saline with dextran study was completed in July of 2005. The study was conducted here in King and Snohomish County. There were 209 patients enrolled in the study and while the numbers were too small to show any impact in

mortality and there was no difference in the development of adult respiratory disease syndrome (ARDS) between those who did get HSD and those who did not. HSD did help those patients who were severely injured and required 10 or more units of blood in the first 24 hours after their injury. The information obtained in this Seattle trial was used in the design of a large-scale, North American hypertonic saline study. This hypertonic saline study of severely injured trauma victims in the United States and Canada, will be conducted by the Resuscitation Outcomes Consortium (ROC). The ROC is a research group that involves 11 different communities in the United States and Canada, including University of Washington physicians at Harborview Medical Center. Over 5000 trauma patients will be enrolled in the ROC study; approximately 500 patients will be enrolled here in Seattle and King County.

How will the Resuscitation Outcomes Consortium study at the University of Washington be conducted?

Trauma victims with low blood pressures will be identified by pre-hospital providers (paramedics and flight nurses) and randomized either to receive 250 cc HSD, 250 cc HS, or 250 cc of isotonic solution (normal saline). Normal Saline is the current standard of care. The ambulances and helicopters will be supplied with the IV bags from the pharmacy.

The US Food and Drug Administration, the National Institutes of Health and the Human Subject Ethics Review Board of the University of Washington have approved this study.

Which trauma victims will be treated with HSD?

This will be a randomized study. One third of the patients in the study will receive hypertonic saline with dextran, one third will receive hypertonic saline without dextran and one third will receive normal saline. Neither the victim nor the physician or paramedic will know whether the hypertonic saline or the normal saline was given. Randomization is necessary to assure that research findings do not occur from bias or chance

Who will be included in the study?

- The trauma victims must be at least 15 years old.
- Must have had a blunt, penetrating or a traumatic brain injury.
- Have hypovolemic shock defined as a systolic blood pressure less than 70mmHg or between 70 and 90mmHg with tachycardia (HR >108 beats/min)
- Have an altered mental status (unconscious)
- The participant must be transported directly to Harborview Medical Center either by ambulance or helicopter.

Are there potential risks in the study?

HSD administration has been tested in nine previous clinical trials (over 900 subjects) with no adverse effects reported.

Theoretical (but not reported) risks associated with HSD therapy:

Anti-platelet effect of dextran could potentially impair coagulation. The reported effects of dextran on coagulation occur with significantly higher doses than proposed in this study.

Allergic reaction to dextran.

Seizure activity from severe hypernatremia (Serum sodium = 170 meq/L). Levels this high are rarely seen.

Will a trauma victim's records be kept confidential?

Yes, information gathered in the process of this study will remain confidential by the University of Washington research team, the King County area paramedics, the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). The NIH is funding this study, along with the Department of Defense and other agencies here in the United States and Canada. There is also a Federal Certificate of Confidentiality to protect the data from this study.

How are Trauma victims and their families informed about this research?

Obtaining an "informed consent" from victims of serious trauma is difficult as the participant is often unconscious and the family is not immediately available. To allow researchers to possibly improve the survival rate of individuals suffering from life-threatening injury, the US Food and Drug Administration (FDA) has issued guidelines for the waiver of consent under emergency circumstances, as long as the research has the

prospect of direct benefit to the patient. However, consent information is provided to the patient, legal representative and the family as soon as possible.

In an attempt to inform as many people as possible before the research begins, the researchers are required to disclose to the public the nature, risks and benefits of the study. This is being done through a variety of means:

This website.

Advertising on public buses

News stories.

Consultation with the administrative staff of the King County area paramedics.

Consultation with community leaders.

Community survey

A random sample of 500 King County area households were called in March 2006 and asked their opinion of waiver of consent and whether or not they would want hypertonic saline given to them without their consent. 77% of respondents indicated that they would like to be enrolled in the trial.

Why has the FDA changed its rules on informed consent?

The FDA has issued these regulations to allow research, designed to improve medical treatment, to occur under emergency circumstances in which obtaining informed consent is not feasible while doing everything possible to protect the rights and safety of human subjects.

Does the HSD study meet the FDA requirements for waiver of informed consent?

Yes, the University of Washington research study meets these requirements:

A life-threatening situation with unproven or unsatisfactory treatment where research is necessary to improve outcome. Trauma causing hypovolemic shock or severe

severe traumatic brain injury is an immediately life-threatening condition with unsatisfactory treatment.

Obtaining informed consent is not feasible because the patient is unresponsive and treatment must begin immediately if there is any hope for survival.

Participation in research has the prospect of direct benefit because the situation necessitates an intervention, science supports the potential of direct benefit and the risks of the research are reasonable compared to the medical condition.

The research could not practicably be done without waiver of informed consent.

The potential therapeutic window is short (in the case of resuscitative fluid must be given within minutes)

The University of Washington's Human Subject's Ethics Review Board approves the consent document and procedures for the subject or legal representative.

Will the victim's family know that research was part of the HSD study?

Yes, the University of Washington research study meets these requirements:

A life-threatening situation with unproven or unsatisfactory treatment where research is necessary to improve outcome. Trauma causing hypovolemic shock or severe traumatic brain injury is an immediately life-threatening condition with unsatisfactory treatment.

Obtaining informed consent is not feasible because the patient is unresponsive and treatment must begin immediately if there is any hope for survival.

Participation in research has the prospect of direct benefit because the situation necessitates an intervention, science supports the potential of direct benefit and the risks of the research are reasonable compared to the medical condition.

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***Harborview Medical Center
Waiver of Consent Research Report
April, 2006***

Prepared by:

**Kenneth Klima, Research Director
Karen Marotz, Research Analyst**

U.S. Corporate Office

13629 Bel-Red Road
Bellevue, WA 98005

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Waiver of Consent Research
April 2006**

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Goal and Objectives

Research Goal:

The goal of this research was to provide unbiased community input for use in gaining approval for the implementation of a waiver of consent in administering a newly developed fluid to trauma patients in a clinical study.

Research Objectives:

The following objectives were addressed in conducting research for Harborview Medical Center:

1. Assess the proportion of the adults living in Harborview's service area who, if severely injured, would want to receive an experimental fluid without providing written consent.
2. Evaluate the extent of the belief that the exception to written consent is justified and in the best interests of the patient and community.
3. Assess the concerns of those respondents who do not believe the exception to written consent is justified.
4. Determine the reasons respondents have for believing the exception to written consent is justified.
5. Evaluate the level of support for including children, aged 15-18 years, in the study.
6. Develop a demographic profile of the respondents.

Methodology

A total of 500 surveys were completed for Harborview Medical Center. Respondents were surveyed proportionate to population by zip code throughout Harborview's medical treatment area (see map). The response rate, which represents the proportion of the population who agreed to participate in the research, was 41.9 percent. The overall incidence rate, which represents the proportion of the population qualified to participate in the full survey, was 100 percent. The maximum margin of error at 500 respondents is +/-4.4 percent.

The data were analyzed using generally accepted univariate measures of central tendency and dispersion. A complete list of responses to open-ended questions will be found in the Appendix.

Hebert Research has made every effort to produce the highest quality research product within the agreed specifications, budget and schedule. The customer understands that Hebert Research uses those statistical techniques, which, in its opinion, are the most accurate possible. However, inherent in any statistical process is a possibility of error, which must be taken into account in evaluating the results. Statistical research can predict consumer reaction and market conditions only as of the time of the sampling, within the parameters of the project, and within the margin of error inherent in the techniques used.

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Statistical Weighting

Statistical weighting is a technique that is commonly used in survey research to compensate for sampling and response error. During the process of data collection and immediately after its completion, statistical tests were run to identify demographic factors that cause variance in variables of interest and then these sample parameters were compared with known population parameters to determine if the sample was representative of the population. Demographic data from the U.S. Census was obtained in order to identify population parameters. Demographic sample parameters were compared with population parameters and adjustments were made to account for response bias. To compensate for potential sampling bias, weights were calculated and applied to the survey sample to ensure that various demographic sub-groups were properly represented. In the final weighting analysis, it was concluded that the sample was representative of the population within the following critical parameters: zip code, gender, and age.

Explanation of Multivariate Analysis

Multivariate analysis was conducted in order to examine differences among respondents according to specific pre- and post-classified segments, or groupings. Multivariates included:

- Age
- Education
- Gender
- Race

Multivariate analysis is an advanced statistical technique used in the testing of hypotheses and measuring the degree of association between variables. It involves Chi Square, analysis of variance and appropriate tests of independence and association.

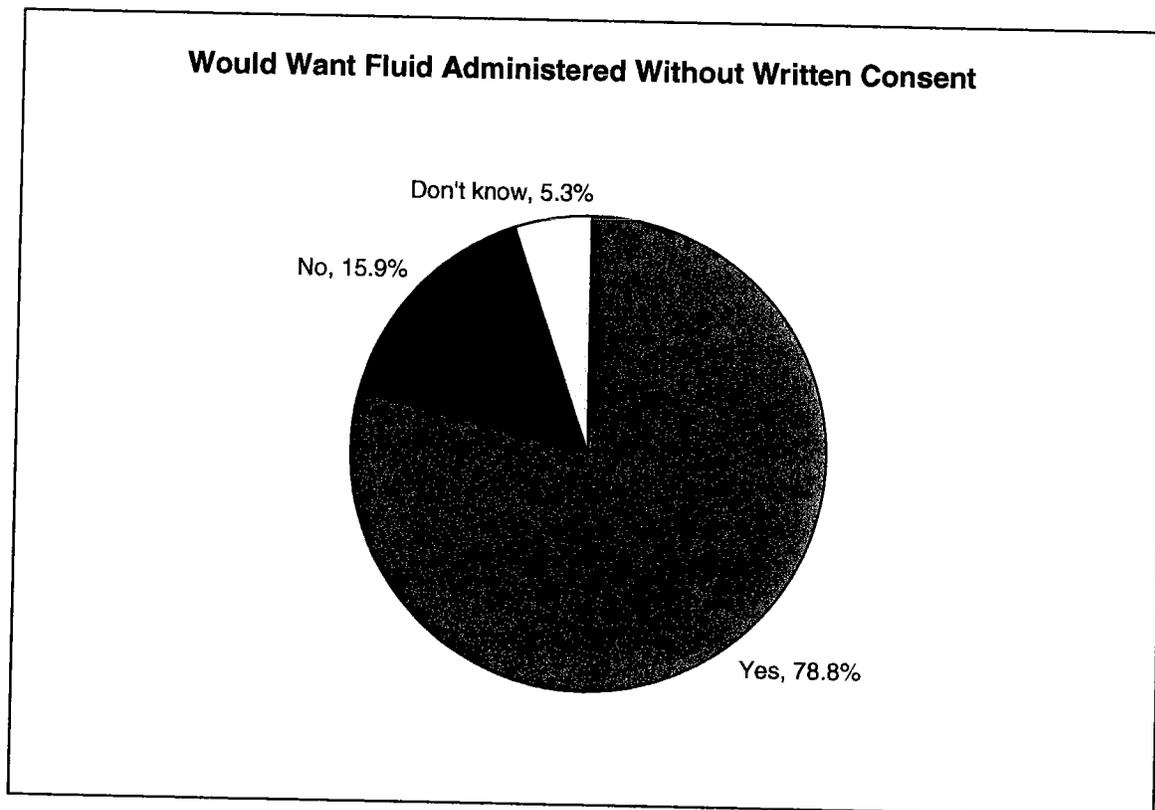
Interpretations and inferences set forth in the analysis are intended to provide an independent statistical perspective. The statistical procedures utilized were applied with a 0.95 confidence level for estimating values and/or providing significant inferences. This means that if a study were repeated 100 times, 95 times out of 100 the answers would vary by no more than the margin of error. A 0.05 significance level was used as the criterion to test hypotheses. At 0.05, there is no more than a 5 percent likelihood that the answers occurred by chance. The smaller the significance level, the less likely the answers occurred by chance – for example, a 0.001 means it is 1 in 1000 the answers occurred by chance. Multivariate findings, when they are significant and meaningful, are indicated at the end of each section.

In addition to measures of significance in which differences have been determined at the 0.05 level, a measurement of association will also be reported. These measurements vary between 0 and 1. A measurement of 0 indicates the variable in question does not explain (or is not associated with) the dependent variable, and a measurement of 1 indicates that the variable explains all of the dependent variable. This level of association is called Cramer's V, and it is what is reported throughout the report.

Support for Administration of Fluid without Written Consent

Respondents were first provided with background information about the nature of the study, the reasons for use of the experimental fluid, the conditions under which it would be administered without consent, and the type of fluid being administered. They were then asked if they personally would want the fluid administered without providing written consent if they were found in the relevant situation.

More than three-quarters (78.8%) of respondents said they would want the fluid administered to them without written consent if they were unconscious, family was not reachable, and they had a 25 to 50% chance of dying. Only 15.9% of the respondents said they would *not* want the fluid administered. 5.3% of respondents said they did not know. The community is highly in favor of receiving the experimental fluid in a situation where written consent cannot be provided.



No significant differences in responses were found by gender indicating the desire to receive the experimental fluid was equally strong for both men and women. However, significant differences did arise by education, race/ethnicity and age.

Respondents with less education (up to an Associate, Technical or Vocational Degree) were significantly more in favor of receiving the experimental fluid without written

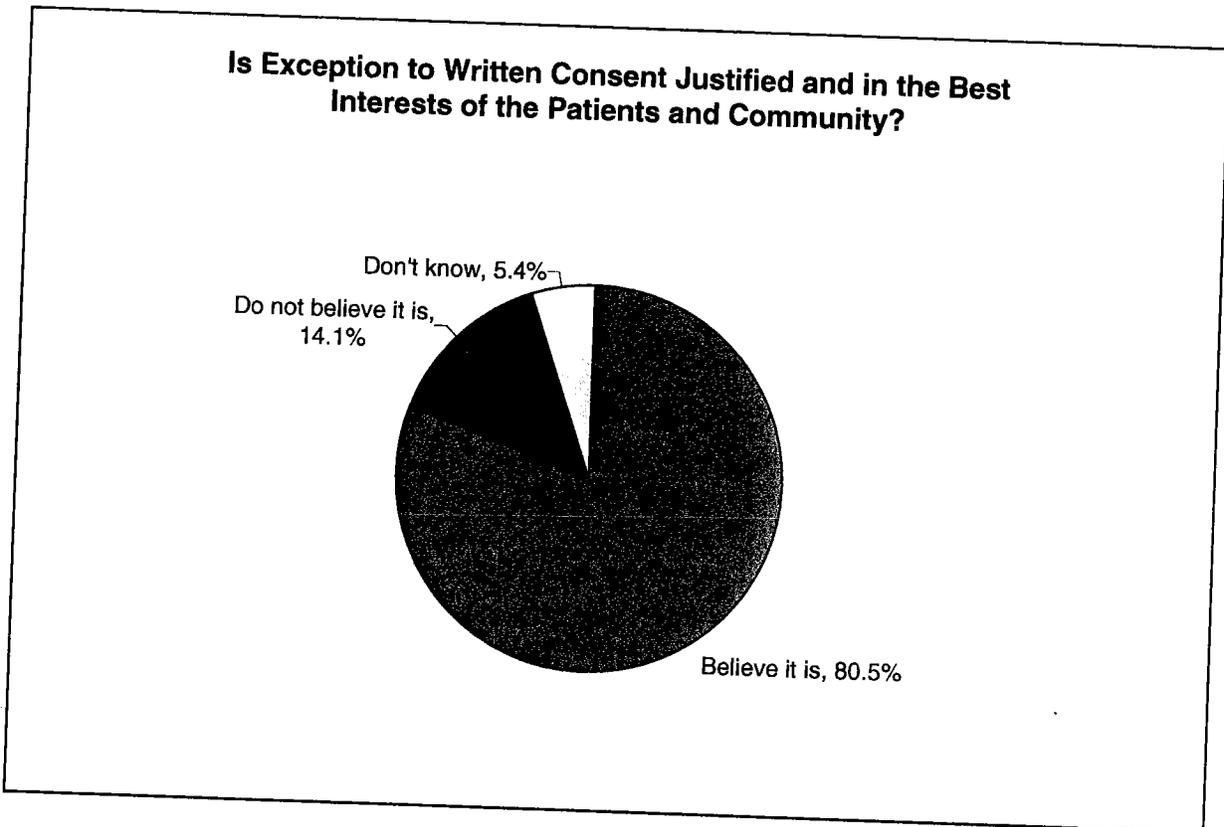
consent than respondents with a higher education level ($p = .001$, Cramer's $V = .177$) although the percent in favor of receiving the fluid remained high across all groups (above 75.9%).

Non-Hispanic White respondents were significantly more in favor of receiving the experimental fluid without written consent than all other races (80.5% vs. 70.0%, ($p = .005$, Cramer's $V = .146$).

Respondents between the ages of 45 and 54 and those over the age of 85, were significantly less likely to want the experimental fluid administered without written consent (68.8% and 66.7%, respectively) compared to all other age groups ($p = .021$, Cramer's $V = .164$). The percentages for each age group more in favor of receiving the experimental treatment were: 18 to 24—91.7%, 25 to 34—82.9%, and 75 to 84—84.6%.

Exception to Written Consent is Justified

80.5% of respondents believed the exception to written consent was justified and in the best interests of the patient and the community. 14.1% of respondents said it was not justified. The community showed a very strong belief that the exception to written consent is justified.



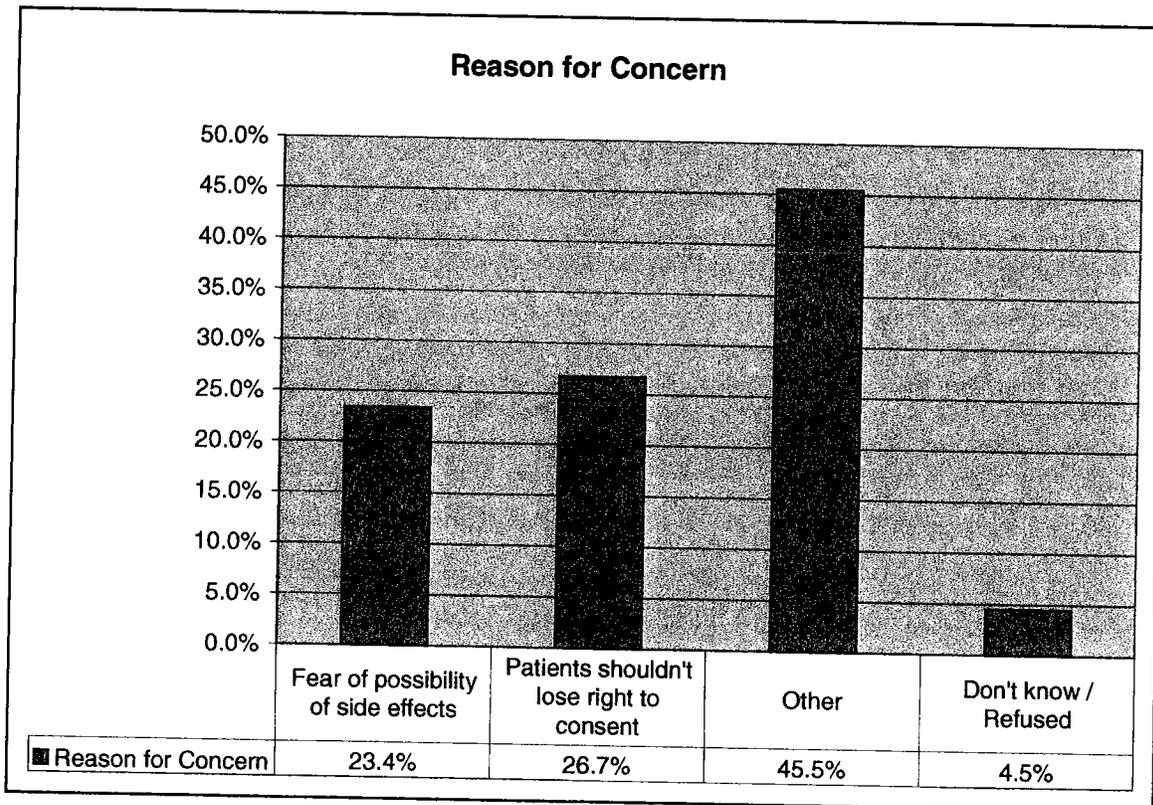
No significant differences in responses were found based on education level or gender. Significant differences did arise by race/ethnicity and age.

A significantly higher percent of Non-Hispanic White respondents believed the exception to written consent was justified than all other races (82.9% vs. 70.0%, $p = .005$, Cramer's $V = .163$).

Respondents in the age ranges of 45 to 54, 55 to 64 and over 85 believed the exception was justified in lower proportions (69.1%, 72.2% and 66.7% respectively) compared to all other age groups ($p = .001$, Cramer's $V = .176$). The percentages for each age group more in favor of receiving the experimental treatment were: 18 to 24—100%, 25 to 34—89%, 35-44—78.9%, 65 to 74—79.4%, 75 to 84—84.6%.

Respondents who Did Not Believe the Exception was Justified
Concerns about Administration Without Written Consent

The respondents who did not believe the exception to written consent was justified (14.1%) or did not know whether consent was justified (4.5%) were asked the reason for their concern. Of this combined sub-group, 26.7% (5.0% of total sample) thought patients should not lose the right to provide consent for themselves, and 23.4% (4.4% of total sample) said they feared the possibility of side effects. Another 45.5% (8.5% of total sample) provided other reasons which included issues about the competence of paramedics in administering the fluid, moral or religious concerns, fears related to the fluid being “experimental”, and a belief that the risk of death had to be higher to warrant receiving an unproven treatment. Examples of these concerns appear on the next page; the full list of responses will be found in the appendix.



Other concerns:

Paramedics:

- *Skill of a paramedic is not like a doctor. It should be on the doctor not the paramedics.*
- *The allergic reaction. The paramedics are not doctors. My concern is, would they be able to stop the allergic reaction? I don't know if paramedics have the choice to do that.*
- *The judgment of the people that are administering it— because they would be paramedics not doctors.*
- *Are the paramedics able to make this decision?*
- *With paramedics giving the fluid with no consent is opening the door for a lawsuit.*

Moral or Religious Concerns:

- *I'm a Jehovah's Witness; I don't believe in any blood or blood products even if I died. I need to be assured it does not contain blood or blood products.*
- *A moral issue because people need to have a say for those things to happen and not just inject this into you while you are unconscious.*
- *They may have religious reasons for not having that fluid given.*
- *It's stepping on a lot of personal feelings of people; whether religious or not.*

Experimental Nature of the fluid:

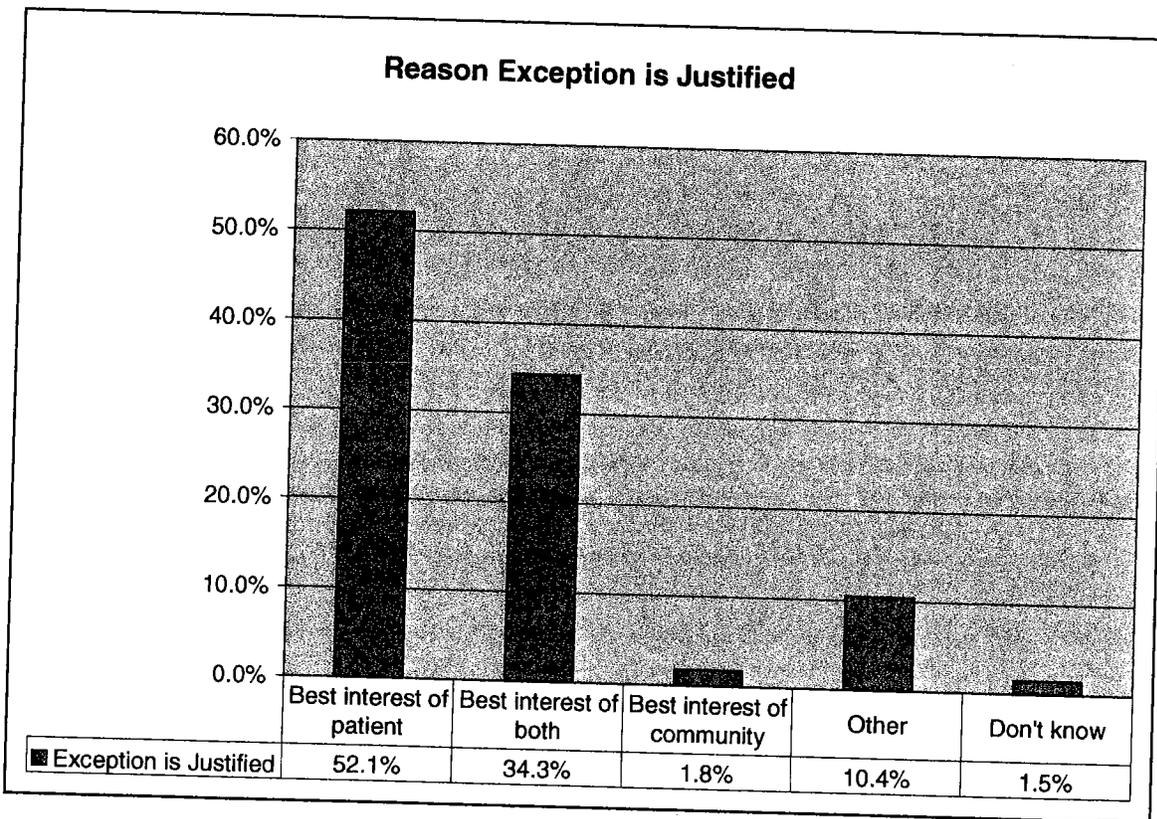
- *If it is experimental, the patient or family needs to be contacted.*
- *Any drug not approved by the FDA should get written permission.*
- *It should be used on prisoners in jail.*
- *I'm afraid of being a guinea pig, especially on experimenting.*
- *How thoroughly has the fluid been tested?*
- *I don't like the idea of being given something I don't know about.*
- *Not knowing what could go wrong by using this fluid. I don't know what the fluid is.*

Risk is Not High Enough:

- *Not with that percentage, above 50% chance of dying, then yes I could see it.*
- *A 25% to 50% chance is a broad range; I don't know how an EMT can judge that.*
- *It's 25% to 50%; if it's more than 50% it's one thing to test the product, but less than 50% is not a good number to test on people.*
- *That is quite a large margin...being 50/50. I think I would want just standard treatment.*
- *It's not enough risk of a life at 25% to 50%. There's a 50/50 chance they'll be alright without the test drug.*
- *I have 50% chance of living with the current technology and you don't know what this other drug is going to do.*

Reasons Exception to Consent is Justified

Respondents who stated the exception to consent was justified (80.5%) were asked to describe the reasons for this belief. More than half (52.1%) said it was in the best interest of the patient; 34.3% felt it was in the best interest of both the patient and the community. Only 1.8% felt it was only in the best interest of the community. Ten percent (10.4%) said it was justified for some other reason. Reasons in this category dealt with trust in the decisions made by the medical professionals, the fact that the fluid has been proven safe and successful in Europe, and that medical experimentation is valuable to both help patients and gain knowledge. Selected responses in the "Other" category appear below; the full listing of "Other" response will be found in the appendix.



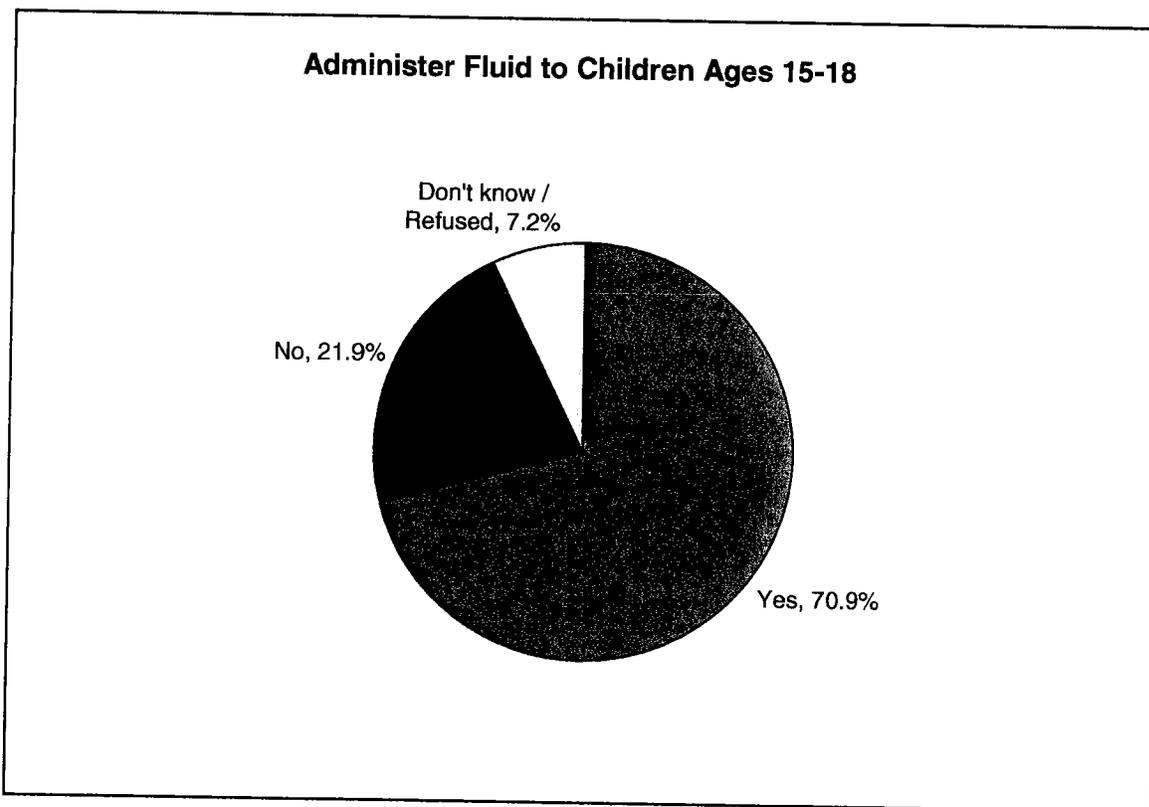
Other reasons:

- *It's an emergency situation and I'm presuming oral consent may be given.*
- *It depends on the severity of the injury and it should only be up to 25% of a person's chance to survive when given. Some people may have some moral hesitations concerning this.*
- *To allow new knowledge to be gained with the use of this.*
- *It's worth a try. If it's a matter of life or death, you have to make these split decisions.*

- *If you are injured and there are medical people there, you should trust them to make the right decision.*
- *If there are no family members around the incident, it's justified if it is primarily safe with positive results; they should just go ahead and do it.*
- *There must be experiments.*
- *The allergic reaction is small compared to the benefits; at least that's what I'm assuming.*
- *I don't have anyone to speak for me. I have a daughter that lives north, but she wouldn't be able to come and make a decision. There are a lot of people whose family live far.*
- *It was used in Europe and it should be also used here as well. Europe is far more advanced in medical research so we should trust that.*
- *Because it has to be decided immediately, and because it has been approved in Europe and there are no statistics of bad side effects.*
- *It's already used currently in Europe so it's not just something that somebody just thought of recently anyway.*

Support for Administration of Experimental Fluid to Children Ages 15-18

Respondents were asked whether they believe it is appropriate to include children ages 15 to 18 in this study. 70.9% of respondents said it is appropriate to include the age group while 21.9% said it is not. 7.2% said they did not know or refused to answer the question. Parents and legal guardians of children ages 15 to 18 were significantly more in favor of including children in the study compared to respondents without children in this age group (78.9% and 70.0%, respectively; $p < .001$, Cramer's $V = .360$). The community shows a high level of support for adding children ages 15 to 18 to the research study.



Non-Hispanic Whites showed significantly higher support for including children in the study compared to all other races/ethnicities (73.4% and 58.9%, respectively; $p = .001$, Cramer's $V = .179$).

Significant differences were also found by age. Respondents between the ages of 75 and 84 were significantly more in favor of including children (76.9%) compared to respondents over the age of 85 and between the ages of 18 and 24 (47.6% and 60.4%, respectively; $p = .010$, Cramer's $V = .161$).

Reasons for Not Including Children in the Study

Respondents who said that it would not be appropriate to include 15 to 18 year-old children in the study were asked to explain their reasons. The concerns of respondents with children in this age group at home were very similar to those without children. The main idea presented is that children in this age group are still underage and parents should be consulted for a decision. Respondent concerns are listed below according to whether or not the respondent was a parent/legal guardian of a child aged 15 to 18 years old.

Concerns of Parents/Legal Guardians:

- *I think they should have a say in their treatment of themselves.*
- *Eighteen is old enough to make that consent, they are adults. But younger, not so. At eighteen, most kids are out of the house so they don't need their parents' consent, but younger ones need parents' consent for everything.*
- *Nine times out of ten, and I'm generalizing, you can get a hold of their parents. With adults, you may not have a family member available.*
- *I think that is a decision from the parent. The family unit needs to be considered.*
- *I think you need parental consent first. They are minors and it's not the standard treatment, but an experimental treatment that you're giving.*
- *The fact that there may be more complications that may happen, like allergic reactions and the fact that those children or teenagers are younger in age and have not lived as long compared to a very mature 30 or 40 year old adult, and the condition of that type of body. Parents need to be contacted for that type of situation.*
- *If somebody's there to assess what's going on at the time, that's okay.*
- *I am in favor of medicine that has been proven, and not patients used as a guinea pig for experimental medication.*
- *I think a parent should have the option to make that decision at the time.*
- *They are too young and need parental consent. They also have a better chance of surviving anyway because of their age and do not need experimental drugs.*
- *I've seen too many parents take care of disabled children 24 hours a day and I know that is tough.*

Concerns of Non-Parents/Legal Guardians:

- *When I'm talking about myself, someone as old as I am who's had a good life, if something happened, too bad. I've had a chance at life, but a 15-18 year old hasn't and I wouldn't want to make a decision like that.*
- *I think they are too young and can't give their permission. Their parents should give their permission.*
- *Just in case there might be something wrong with the fluid, that five years from now could damage or harm the children.*

- *I still feel the parents or guardians should be able to determine whether they get the fluid or not.*
- *There's too many other things going on with teenagers—they take drugs and other things they are doing—it is harder to track down what they are doing. And, parents have different thoughts about their children. I'm more leery on a child then a teenager to receive this fluid...you never know.*
- *Not without authorization. At that age group, someone should be available to authorize it.*
- *They are not of age of legal consent and need parental permission for them because they can't make that decision for themselves if involved.*
- *They are minors and it's a legal matter; they don't have the consent and they need their parents consent first. The child also needs to speak out first regardless of the circumstances before they receive this fluid.*
- *Well, I believe that the parent should give consent, and if the parent is not available then the fluid should not be used.*
- *They should be adults or have parental consent*

Additional Comments

Respondents were given an additional opportunity to make any further comments about the study. Respondents both in favor of and against administration of the experimental fluid offered additional comments. One common concern involved questions about the judgment and qualifications of paramedics in assessing the likelihood of the patient dying (25%-50%) or in determining that this experimental fluid should be administered. Some felt more comfortable with a doctor making the decision. Other fears involved the potential for side effects and allergic reactions, and concerns over human beings serving as "guinea pigs." Some thought the fluid should have FDA approval before being administered. Some said they need to know more about it.

On the positive side, many respondents said they would want all possible measures taken to help them, and that medical professionals should be trusted to make the right decisions. Additionally, respondents stated that experiments such as these are necessary in order to advance knowledge. Finally, some respondents were reassured that the fluid had been approved in Europe and that it was not an entirely new treatment.

A selection of responses appear below; the full range can be found in the appendix.

Want More Information:

- *No, I'd like to read more about it! I've worked in emergency before and some paramedics I just wouldn't trust to do that!*
- *Well, I'd be interested to know what is, but I think it would be worth the risk.*
- *Where did the fluids come from? What kind of fluids are they? How long has Europe been using it? I would want to know more about what fluids they are using and a better description of the fluids. I think the public should know. My husband was in a coma for 31 days, and without other people making decisions, he wouldn't be.*
- *I am a dental hygienist and I think that it is pretty scary to give something experimental without consent. I must also say that I cannot say that I would be able to give answers as to if I would let it be given to me. I do not have enough information about what the fluid is.*
- *I would like to know what it is.*
- *I don't know enough about the drug, but if it saves lives and someone is nearly dying, then it would be beneficial to them.*
- *I don't know enough about this drug, even beyond your explanation, to comment further.*

FDA Approval:

- *I wouldn't risk giving any drug without approval from AMA, FDA, or the proper authority. Now days, doctors and health care workers have to be so careful. I know it's not too positive. Overall from what I know and hear, I wouldn't*

administer this drug. I would be afraid to administer this drug if I was physician or paramedic. I feel sorry for the medical profession because they are under strict guidelines and rules. We just have to go by that.

- *I do not believe that any drug should be given without FDA approval. Why not get full approval and then there would not be need for consent, especially if it turns out to be an effective drug.*

Side Effects and Allergies:

- *I have allergies, so I don't think I would want them to give it to me, but if it would save someone's life and they have a little bit of time to make a decision, then they should use it.*
- *I don't want to answer that because I don't know anything about the fluid. In my case, I have diabetes and high blood pressure, so I say no to my case.*
- *I have allergies, so that's the only issue that I have. I have had side effects. I would certainly do it for other members of my family. I would want to know if they have something on hand to take care of allergic reactions. I would want to know if they are prepared for allergic reactions. I am all for the new science, and victims who don't have a voice.*
- *I have a big family history to allergies. My grandmother, mom and I are Celiacs which is an autoimmune disease. So, depending on what is in the fluid, it could kill or harm us instead of helping us.*

25% to 50% Chance of Dying:

- *If it's more than 50%, it's one thing to test the fluid, but less than 50% of a chance of dying is not a good time to try the fluid. Let's say if they survive from a 45% death rate. If you were to do it again with the fluid then they die because of the new fluid because it's a test—it would be a horrible thing. I think that this fluid should be tested by doctors in non-critical condition patients in supervised labs to make sure that there are minimal allergic reactions. Children definitely should not be tested on without consent. What, are they lab rats, are you kidding?*
- *If my child was in an accident, I would not want them to give him experimental drugs. Only if they are 50% to 60% sure it would work, and there are no long term effects.*
- *25% is a high risk. If it was much more risk in the person expiring in minutes, or greater risk in them dying or being permanently injured, I would go with it. If it was 75%, I would go with it. It would have to be much greater. Having a family and all, my wife would probably go with it. I have a lot of allergic reactions to food and medications. I don't take them without a doctor's approval. Even then, I am cautious. What would this experimental drug cost? Would poor people be lab mice? Saving lives is important, but it depends on how the doctor comes across.*
- *How do they know that a person with a 25% chance of living would survive? And, it should be up to someone that is in the field to decide for the injured.*
- *How would the paramedics know who the parents would be? If there was no verbal consent or relative consent, then give the fluid. A 25% chance that the patient would die and the hospital were 20 minutes away is different than if a person were bleeding and the hospital was farther away.*

- *You can't get written consent. Haven't they tried this in Iraq? Giving this without written consent seems to be the only way to get it to work. If you have a 25% chance of dying, you're probably not mentally around to sign a consent form. It's when you give it to younger children, I worry. Presumably, the paramedics are trained to administer it. The ones that I have met have pretty good judgment. I was wondering if it has been tested on adults in Iraq. I seem to remember reading something about this. There is more than one fake blood. How does the body get rid of it? Is it used routinely in Europe or is it just available experimentally?*

Paramedics:

- *I could see where it could be beneficial, but I would have to be very cautious. I hope the paramedics do not leave out other options; they must be really sure that the patient really needs it. They need to be really sure that it is necessary.*
- *I have a lot of allergies to drugs so I don't know if they can tell what drugs will affect them. I worked for the National Ski Patrol but left it due to liabilities and could be personally sued, so I would hate to see the paramedic put in that position. So, this would have to be approved through legislation.*
- *I wonder about the paramedics using it. I'd feel better if there was a doctor that knew what he were doing and had more training.*
- *It has to be done where paramedics are not held liable. Legal issues. People are lawsuit happy. For myself, it's fine for me. They are very well-trained. Medic One people are very well-trained. I don't see anything wrong with it here. If you can get around the legal ramifications, go for it.*
- *Sounds like the paramedic is making the decision and it's troubling to me because I'm not sure he's totally qualified. If it becomes routine, then he'd just do it. And, are there adverse effects on someone that is totally healthy that would not really need it?*
- *The paramedics who will make that decision are not as schooled as the people at the trauma center, and that concerns me.*
- *Well, I have reservations about giving that power to paramedics, since they're not necessarily qualified doctors. They're not qualified to make an assessment if a patient's life is such at risk.*

Europe:

- *How long they have been using it in Europe? And if people had an allergic reaction to it? How many people have had long or short term side effects?*
- *I think it's a good idea. That it could help with organs days later could help you live, and it's being used in Europe.*
- *I think there should be an investigation to adverse effects. What is the status of adverse events in Europe?*
- *I want to know how often it's been used in clinical trials. How often do people have allergic reactions? I just wanted to know the outcome when used in practice in Europe; how successful it is.*

- *I want to see if it's already working in other countries effectively; and, you already mentioned to me that it's already currently used in Europe, and it's working well there.*
- *I would like to see the statistics from Europe or those who have used it. I would like to know the bad side effects that are possible. I wouldn't want to prolong my child's life or my life if I was going to be a vegetable.*

Other Favorable Remarks:

- *I agree with it because people who are in high risk of dying could benefit from it. If it helps, I think it's a good cause.*
- *I am a registered nurse. I think that they really need to make sure that there have been good clinical trials that are proven. If it is not well proven, it should not be used.*
- *I don't like giving up your right, but if you are unconscious, it's probably fine to receive this new drug. Only you have control over your own body and what to do with it, but when you're down and out and you don't have the ability to communicate with family members that are standing nearby you at the accident scene to state how you feel, then go ahead and receive it.*
- *I feel it's a fair thing for them to receive. I know I wouldn't mind. At a certain point, I've instructed my family that I don't want to be kept on life support. Initially they make their diagnosis, if fluid would help them in the long term, but if I don't respond in a reasonable amount of time, I don't want to be kept alive in the long term. I've raised five children. Today, both parents are working, and the kids need some chance. They should give every reasonable chance of medication to try to save their life.*
- *I guess if every avenue were exhausted as to getting permission and allowing that to happen, and a last ditch effort was done, then yes. All family members should be contacted before giving somebody fluid. If the public knew enough about it, then it would be a good thing. If you keep people in the dark as to what it is, then there would be people who would not agree with it. The more people know about something, the more they are willing to consent.*
- *I had a daughter that was in a car accident and there wasn't anybody there to give consent to whatever they gave her, so I say if it saves your life, do it.*
- *I have a son that drives to his job 30 or 40 miles every day back and forth, and if he ever got into an accident, I don't mind that they inject this new fluid to save his life, with the exception if he kept on living, he doesn't become a vegetable head after the crash.*

Other Concerns:

- *I do not think that anything experimental should be given without consent. There are plenty of losers in jail that you can just use.*
- *My personal opinion is that I wouldn't want that. I don't really have another opinion. I wouldn't want it that way; I wouldn't want some drug I didn't know about.*

- *This drug is not fully approved or, like you mentioned, because of possible side effects and allergic reactions that might occur; so, it's not officially safe free or proven yet.*
- *I haven't studied this, but in general I don't believe in giving medications without consent. I don't see this as a compelling reason.*

Respondent Profile

The following tables describe the demographic profile of the sample. As indicated in the methodology section, the sample was statistically weighted to heighten representativeness. The frequencies in the tables below are the weighted frequencies.

Children 15-18 years old	Percentage
Yes	14.4%
No	84.9%
Refused	0.7%

Age	Percentage
18 - 24	9.7%
25 - 34	21.1%
35 - 44	22.8%
45 - 54	19.4%
55 - 64	10.8%
65 and over	13.8%
Refused	2.4%

Gender	Percentage
Male	48.5%
Female	51.5%

Education	Percentage
Less than high school	0.5%
High school	21.7%
Associate, technical, or vocational degree	30.1%
Bachelor's degree	27.3%
Post-graduate degree	19.0%
Refused	1.4%

Income	Percentage
Less than \$20,000	7.6%
\$20,000 to \$35,000	10.8%
\$35,000 to \$50,000	17.4%
\$50,000 to \$65,000	9.0%
\$65,000 to \$80,000	14.3%
\$80,000 to \$100,000	8.3%
Over \$100,000	18.6%
Don't know	1.9%
Refused	12.1%

County of Residence	Percentage
King	58.1%
Snohomish	22.4%
Pierce	10.0%
Kitsap	7.7%
Island	1.1%
Jefferson	0.5%
Mason	0.2%

Occupation listings can be found in the appendix.

Key Findings

- When in the situation of being unconscious due to severe injury, the vast majority of respondents (78.8%) said they would want the experimental fluid given to them knowing that they would be subject to a risk of allergic reaction or other unknown side effects. An even higher percentage of respondents (80.5%) felt the exception to written consent was justified and in the best interests of the patient and the community. The community is clearly in strong favor of receiving the experimental fluid without providing written consent.
- Respondents were strongly reassured regarding the safety of the fluid because it is currently approved for use in Europe. This served to mitigate fears of “experimental” research being conducted on human subjects. Generally, respondents felt that since the effect of this fluid is to preserve and promote life, it should be tried.
- Concerns expressed by respondents over use of the fluid included whether paramedics were able to make the proper judgment of the severity of injuries and need for administering it, uncertainty because of a lack of information, the need for prior FDA approval, and the fear of side effects and allergic reactions. Respondents emphasized that every effort should be made to gain the patient’s consent or the consent of the family.
- Respondents showed strong support for adding children aged 15 to 18 to the study (70.9% were in favor). Parents/legal guardians with children in this age group at home showed significantly higher support for including children in the study than respondents without children at home (78.9% vs. 70.0%, respectively) The primary reason offered for not supporting administration of the fluid to this age group was that teenagers were minors and parental consent should be required.

**UNIVERSITY OF WASHINGTON and HARBORVIEW
MEDICAL CENTER - WAIVER OF CONSENT RESEARCH**

Questionnaire – March, 2006

Hello, my name is _____, and I'm calling on behalf of the University of Washington and Harborview Medical Center from Hebert Research, an independent research firm in Bellevue, Washington.

May I speak to someone who is at least 18 years of age? Thank you.

[IF NECESSARY, REINTRODUCE YOURSELF]

This call does not involve sales of any kind, now or in the future. We are currently conducting a survey on behalf of the University of Washington and Harborview Medical Center to obtain community opinions and views on a study involving severely injured patients.

Taking part in this survey is voluntary and will take approximately five minutes, during which time I will describe the research study to you and ask you for your opinions on it. In addition, I would like to ask you a few personal questions regarding your education and income level. You do not have to answer any questions that you object to and you may stop the survey at any time. The University of Washington and Harborview Medical Center will use your opinions to help determine whether the study is acceptable to the community. Would you be willing to offer your opinions and answer some questions after I give you details about the medical study? Your answers will be kept anonymous.

Introduction: [READ]

First, I am going to describe the research study to you.

An experimental intravenous fluid is being tested in a study involving patients with severe injuries, such as those in severe auto accidents, who have a 25-50% chance of dying from their injuries. Usually, patients in a study must provide written consent for participation after being told about the study, its risks and its potential benefits. In the case of severe injury, it is not always possible for patients to give written consent because they may be unconscious, and their families may not always be available to speak for them.

The U.S. Food and Drug Administration allows for certain studies to be performed without written consent in emergency settings but only if patients have a high risk of dying without treatment, cannot communicate because of their illness and don't have family available to speak for them. When there is no other known treatment available to improve their chance of survival, patients may be given an experimental agent but only if it has been approved in advance by an independent University group set up to review

these situations. We would like your opinion on one such study that is proposed involving severely injured patients.

Injury is the leading cause of death in children and younger adults. The usual cause of death in these patients is blood loss or severe head injury. Sometimes a patient will survive the injury but die several days later due to organ failure of their heart, lungs, liver or kidneys. Researchers at Harborview Medical Center are trying an experimental intravenous fluid that may prevent organ failure and improve survival after severe injury. This fluid may also improve outcome after brain injury.

This intravenous fluid has been used in previous clinical studies with no adverse events and is currently approved for use in Europe. As with any medication, there is the risk of allergic reaction or other unexpected side effects.

Previous studies suggest that this fluid is most effective if given as the first intravenous fluid after the injury. As a result, this study fluid will be given by the paramedics at the scene of the accident and consent to continue enrollment in the study will be obtained in the hospital. We are considering whether to allow the study fluid to be given by the paramedics without written consent. We would like to ask you some questions about your opinion on this.

1. At any moment, we are all at risk of serious injury, especially in an automobile. If you were severely injured, such that you had a 25-50% chance of dying with standard treatment, would you want this experimental fluid given to you without written consent, knowing that it might improve your chance for survival or recovery from head injury, but that there is a risk of allergic reaction or other unexpected side effects?
 1. Yes
 2. No
 3. Don't know
 4. Refused

2. Do you believe that this exception to written consent is justified and in the best interests of the patients and community or not?
 1. Yes **[SKIP TO Q4]**
 2. No
 3. Don't know
 4. Refused

3. What is your reason for concern?
 1. Fear of the possibility of side effects
 2. Patients should not lose the right to provide consent for themselves
 3. Other **[SPECIFY]**
 4. Don't know

5. Refused

[SKIP TO Q5]

4. Why do you feel this exception to consent is justified?

1. It is in the best interest of the patient
2. It is in the best interest of the community
3. It is in the best interests of both the patient and the community
4. Other **[SPECIFY]**
5. Don't know
6. Refused

5. Injury is the leading cause of death in teenagers, ages 15-18 years, and because they have the same risk and benefits with the study fluid as adults, do you think it is appropriate to include 15-18 year old children in this study?

1. Yes
2. No
3. Don't know
4. Refused

6. **[ASK IF Q5=2]** What are your reasons for that response?

7. Do you have any additional comments about giving this drug without written consent by the patient? **[VERBATIM]**

DEMOGRAPHICS

The following questions are only to make sure that we have a representative sampling of the community.

8. What is your age? **[RECORD NUMBER]**

9. What is the highest level of education you have completed?

1. Less than high school
2. High school
3. Associate, Technical or Vocational degree
4. Bachelor's degree
5. Post-graduate degree
6. Refused

10. What is your occupation? **[VERBATIM]**

11. What is the zip code where you live? **[RECORD NUMBER]**

12. Are you the parent or legal guardian of a child or children ages 15-18 years old?

1. Yes
2. No
3. Don't Know
4. Refused

13. What is your racial or ethnic identification? **[RECORD ONE RESPONSE]**

1. White, non-Hispanic
2. Black, non-Hispanic
3. Alaskan Native or American Indian, non-Hispanic
4. Asian or Pacific Islander, non-Hispanic
5. Spanish or Hispanic, any race
6. Multicultural (parents represent different racial ethnic groups)
7. Other [Do not specify]
8. Refused
9. Don't know

14. Into which of the following categories does your approximate annual household income fall?

1. Less than \$20,000
2. \$20,000 to \$35,000
3. \$35,000 to \$50,000
4. \$50,000 to \$65,000
5. \$65,000 to \$80,000
6. \$80,000 to \$100,000
7. Over \$100,000
8. Don't know
9. Refused

THAT CONCLUDES OUR SURVEY. THANK YOU VERY MUCH FOR YOUR TIME AND COOPERATION.

POSTCODE GENDER:

1. MALE
2. FEMALE

DATE: _____

INTERVIEWER: _____

Appendix

Specified Verbatim Answers

Q3. What is your reason for concern? OTHER:

- If the person is insured or not.
- Are the paramedics able to make this decision?
- I don't know enough about it to make a decision.
- Not with that percentage, above 50% chance of dying, then yes I could see it.
- If the trial and the person are young enough, there should be someone there for consent.
- I'm a Jehovah's Witness; I don't believe in any blood or blood products, even if I died. I need to be assured it does not contain blood or blood products.
- A moral issue because people need to have say for those things to happen and not just inject this into you while you are unconscious.
- I want to make sure that I might have quality of life; I don't want to be a vegetable.
- As I understand it, the fluid will be given at the site and there they will not take the time to locate the person who could give consent.
- Not enough information; it could do more harm than good.
- People who have will testaments established who already made that against having to be resuscitated when one passes away.
- If it is experimental, the patient or family needs to be contacted.
- The allergic reaction, the paramedics are not doctors. My concern is, would they be able to stop the allergic reaction? I don't know if paramedics have the choice to do that.
- A 25% to 50% chance is a broad range; I don't know how an EMT can judge that.
- Any drug not approved by the FDA should get written permission.
- It is an experimental drug and I am leery of being used as a guinea pig.
- It's 25% to 50%; if its more than 50% its one thing to test the product, but less than 50% is not a good number to test on people.
- The skill of paramedic is not like a doctor; it should be on the doctor not the paramedics.
- Percentage of death isn't high enough to justify using this agent.
- It should be used on prisoners in jail.
- I don't know what the fluid is made of.
- I'm afraid of being a guinea pig, especially on experimenting.
- A lot of these accidents are caused by drunks and he kills a nice family, and the drunk is alive, and taxpayers pay to keep him alive, I say let him slide.
- I don't think medication is always the best option.
- Some people would rather die than live on machines or in a coma.
- The chance of death isn't high enough to warrant an experimental treatment.

- *If someone's severely injured, it may be more costly to keep them alive.*
- *How thoroughly has the fluid been tested?*
- *I don't like any colleges. At the UW, they're too liberal and communist.*
- *They may have religious reasons for not having that fluid given.*
- *If a child is severely injured, the parents should have the say in what would happen to them*
- *I would want to know more about what the drug is. One could get that from any doctor. I would want to know who was doing it. It's an incomplete question.*
- *I don't like the idea of being given something I don't know about.*
- *Not knowing what could go wrong by using this fluid. I don't know what the fluid is.*
- *Not having enough information on what is in the fluid. If there was information and it was something good, then yes, I would like to see that happen.*
- *It opens the door for other decisions to be made for you that you would not necessarily make for yourself under other conditions.*
- *If the patient dies due to this, there would be a lawsuit.*
- *The age of the person who is injured, combined with the fact that the drug is experimental and not officially patented, and side effects-free through research at this moment.*
- *Having the paramedic on the side of the street making that decision.*
- *It's stepping on a lot of personal feelings of people, whether religious or not.*
- *If it's a 25% chance of dying, is it significant but not the last possibility? It's a tough question.*
- *The risk is not high enough.*
- *That is quite a large margin...being 50/50. I think I would want just standard treatment.*
- *Not enough risk of a life at 25% to 50 %. There's a 50/50 chance they'll be alright without the test drug.*
- *A fear of being hooked up to a machine if I'm brain dead.*
- *The judgment of the people that are administering it because they would be paramedics and not doctors.*
- *They could have bad reactions.*
- *A human should not be used as a guinea pig. Giving consent to it because I work in medical research and I work with medical equipment and I don't agree with that.*
- *With paramedics giving the fluid with no consent is opening the door for a lawsuit.*
- *There is a small chance of suffering*
- *If it has been shown where it worked and about the allergic reactions, what happened.*
- *I have 50% chance of living with the current technology and you don't know what this other drug is going to do.*
- *They should give them the best chance that they got.*

Q4. Why do you feel this exception to consent is justified? OTHER:

- *I have had friends that were in a car accident.*
- *It's an emergency situation and I'm presuming oral consent may be given.*
- *It depends on the severity of the injury and it should only be up to 25% of a person's chance to survive when given. Some people may have some moral hesitations concerning this.*
- *All new things need to be tried out. They could use it on me if I was ever in an accident.*
- *Sometimes the family members of the accident victim are not present at the time of the accident, so they should just go ahead and do it.*
- *I'd like to know the percentage of allergies. If it was low and this increases your risk of surviving, then why wouldn't you?*
- *To allow new knowledge to be gained with the use of this.*
- *The patient can't make a decision if they are injured, and they have a better chance with the fluid then without.*
- *It's worth a try. If it's a matter of life or death, you have to make these split decisions.*
- *In case it is life threatening; it's best for the patient.*
- *It was used in Europe and it should be also used here, as well. Europe is far more advanced in medical research in that country so we should trust that.*
- *The family is not being able to be notified about this right away so they should go ahead and do this.*
- *In an emergency, you don't have time to get consent.*
- *Because it has to be decided immediately, and because it has been approved in Europe and there are no statistics of bad side effects.*
- *It could save a life and save money.*
- *Time is of the essence. I rode in an ambulance for a while and have been involved in these cases. If there had been anything saving 1 out of 20, it would have been worth it.*
- *Only if there is nobody that can take responsibility or authorize it. If it will enhance recovery and no one is there to authorize it, then it should be used.*
- *If you are injured and there are medical people there, you should trust them to make the right decision.*
- *There is a lack of education in the community. People don't always know this is available for their benefit.*
- *If there are no family members around the incident, it's justified; if it is primarily safe with positive results, they should just go ahead and do it.*
- *If its FDA approved and if it gives a better chance at life, I definitely would not be opposed to it.*
- *Assuming the treatment is effective, it's good for both community and the patient*
- *There must be experiments.*
- *Medical science advances and increases the chance of life.*
- *Consent is not possible in this case.*

- *The emergency nature of the situation.*
- *Because a previous study has been done on it and has not shown any allergic reaction, and early-on treatment is beneficial.*
- *It's already used currently in Europe, so it's not just something that somebody just thought of recently anyway.*
- *Based on the information you just gave me and my own personal knowledge of medical and research information, because I am a dental hygienist for a living and my husband is an EMT.*
- *I don't have anyone to speak for me. I have a daughter that lives north, but she wouldn't be able to come and make a decision. There are a lot of people whose family live far.*
- *I strongly agree that the faster you get treatment, the better chance you have for a larger amount of recovery.*
- *If the doctors think it's okay*
- *Because sometimes other people can't be there.*
- *The good outweighs the chances of allergic reaction. It would be in cases where it is traumatic and that it would be the judgment of the paramedic.*
- *Without experimentation, you can't go forward or advance unless you try these new products...or the reason to think of being sued, which just brings you backwards in progress.*
- *Doctors are more knowledgeable; that's why they went to school and studied it. So, they know what they are doing and I trust them.*
- *I am all for research. I don't see how else to really learn.*
- *The allergic reaction is small compared to the benefit, at least that's what I'm assuming.*
- *If it improves your chances, then it should be tried.*

Q6. What are your reasons for that response [Inappropriate to include teenagers]?:

- *I think they should have a say in the treatment of themselves.*
- *When I'm talking about myself, someone as old as I am who's had a good life, if something happened, too bad. I've had a chance at life, but a 15 to 18 year old hasn't, and I wouldn't want to make a decision like that.*
- *I think they are too young and can't give their permission. Their parents should give their permission.*
- *Just in case there might be something wrong with the fluid... five years from now that could damage or harm the children.*
- *No. Not really. I don't know. No.*
- *Because they are under age; there must be a guardian.*
- *If it's an emergency situation, you would have to use it. They would, I think, need written consent.*
- *I still feel the parents or guardians should be able to determine whether they get the fluid or not.*
- *There's too many other things going on with teenagers—they take drugs and other things they are doing—it is harder to track down what they are doing. And, parents have different thoughts about their children. I'm more leery on a child than a teenager to receive this fluid...you never know.*
- *I think you can get consent from relatives and so forth. I don't believe in giving medications without consent.*
- *Their reaction to it and what it will do for them. I'm pretty naive to the medications and what it will do for them. We don't know what they are and how well they are tested. I know we have to start somewhere. Is it something that will drive them to death, or help them? I think it should be used on people who agree to be their guinea pig on it. I think if that is used and someone dies from it, it could create lawsuits and be devastating to the family.*
- *Not without authorization. At that age group, someone should be available to authorize it.*
- *No, it's not fair for the same reason. A person should be able to give their consent.*
- *They are not of age of legal consent, and need parental permission for them because they can't make that decision for themselves, if involved.*
- *Because the parents should make that decision of consent.*
- *Nobody should have the right taken...no matter what*
- *They are minors and it's a legal matter; and, they don't have the consent and they need their parents' consent first. The child also needs to speak out first, regardless of the circumstances, before they receive this fluid.*
- *Eighteen is old enough to make that consent; they are adults. But younger not so. At 18, most kids are out of the house so they don't need their parents' consent, but younger ones need parents' consent for everything.*
- *Well a fifteen year old doesn't apply; he needs consent. I myself would exclude a fifteen to 17 year old...I would make a lawsuit.*

- *The parental consent is what I believe is the first priority, whether it be over the telephone or written. The parents need to know that their child was in an accident and then approve it verbally over the phone.*
- *They need to have the concern of their parents, legal guardians or family.*
- *They are below the age of consent and not responsible for their own being. They do not have the reasoning to grant consent.*
- *Some parents are real sue happy.*
- *I don't want to continue with this.*
- *Seems better to experiment on older adult*
- *I think it should be tested on adults, and then after all the questions have been asked, then children can be involved.*
- *I am concerned with the adverse reactions and the risks. You could be fine for awhile, and then something may happen.*
- *You look at the situation where the result might be a coma...that a side effect would be responsible for.*
- *If it's experimental, the patient or the family needs to consent.*
- *I don't think it should be given without parents' consent*
- *I do not think minors should apply.*
- *Nine out of ten times, and I'm generalizing, you can get a hold of their parents. With adults you may not have a family member available.*
- *Well I believe that the parent should give consent, and if the parent is not available, then the fluid should not be used.*
- *I think that is a decision from the parent. The family unit needs to be considered*
- *Because it needs to have the consent of parents, I don't think somebody else should make that choice of the parent. 50% will and the other 50% won't. 50% chance the child doesn't live...I see suing and court problems. Somebody's head is going to roll if the child doesn't live.*
- *I think they should get parental permission. With any study involving children under 18, you cannot not have parental permission.*
- *They are still minors*
- *For the ethical reasons of doing experimental trials on people without their consent. I don't think it matters whether they are 25 or 85.*
- *Again, if they can't give their consent, they should not be given something they aren't able to consent to.*
- *If it's more then 50%, its one thing to test the fluid. But less than 50% of a chance dying is not a good time to try the fluid. Let's say if they survive from a forty five percent death rate. If you were to do it again with the fluid then they die because of the new fluid because it's a test, it would be a horrible thing. I think that this fluid should be tested by doctors in non-critical condition patients in supervised labs to make sure that there are minimal allergic reactions. Children definitely should not be tested on without consent. What are they, lab rats? Are you kidding?*
- *Because I'm not sure of the side effects.*
- *I feel that the paramedics' skill is not as good as the doctors, and that the fluids should be given by the doctors and not the paramedics in case of a reaction to it.*

- *Mostly because if something went wrong, their parents are going to be suing.*
- *So many people are allergic to so many things; I'm concerned about a bad allergic reaction to it. I would want it personally.*
- *I want to know what they are experimenting with. It's against my ethics using experimental methods on kids.*
- *Just that they are not adults and that it should only affect adults*
- *It's up to their parents.*
- *They're still a minor*
- *They should be adults or have parental consent*
- *A sixteen-year-old's chances of wrecking a car are up there, due to speed, drugs, alcohol, and poor judgment; they go out and kill people. But, they're young and resilient, and they tend to survive.*
- *Because in case they are unconscious, it is not fair to treat unconscious people as a nobody.*
- *I think they are too young for the medication.*
- *If they die that night, the parents will sue. It's always someone else's fault. They would protect themselves.*
- *I think you need parental consent first. They are minors and it's not the standard treatment but an experimental treatment that you're giving.*
- *Same as before*
- *Parents may not be able to understand enough for their child's benefit.*
- *The fact that there may be more complications that may happen like allergic reactions, and the fact that those children or teenagers are younger in age and have not lived as long time wise as compared to a very mature 30 or 40 year old adult and the condition of that type of body. Parents need to be contacted for that type of situation.*
- *I wouldn't be sure what else would be in their systems. If there's no family to tell you, they wouldn't be able to tell the person giving it. It's a high risk thing to do.*
- *Not if they can't get parents' consent...unless doctors decide in that case that no other treatment is useful*
- *They shouldn't be able to make that choice until they're 18. I would need to know more about it.*
- *I wouldn't do it at all. I just think that even though the intentions are good, without proper authority, you are setting yourself up for malpractice suit.*
- *I believe there are special rules on testing on minors. There is almost always a family member to speak for a teenager, an adult who can make the decision. I don't see why you have to include them in the study because you said they are the same as adult participants. You can include them in the future when the adult testing is over.*
- *They should ask for the parent's consent. A teenager has the parents to decide what's best. They know their allergies.*
- *They would have to have consent given previously. Just because they are under age and the parents would have to. If it was me, I would want to be part of the decision on anything being done.*

- *Just that they are too young; it's just that at that age it doesn't seem right. With parental input, they may not want that given to them.*
- *If somebody's there to assess what's going on at the time, that's okay.*
- *I am in favor for medicine that has been proven and not patients used as guinea pigs for experimental medication.*
- *I'm a parent, and I know everything that's going on. If it's necessary they would have it written on a wristband or driver's license.*
- *There may be law suits if children are given treatment without consent.*
- *Because a child could die, being less advanced in growth like adults.*
- *I feel that children being minors, their parents have more control over their lives and what they do and how they act. I would like to see results that it works on adults before testing on children.*
- *They may have a bad reaction. People's reactions are different when they're younger.*
- *I don't want to lose control over anything. When you start to lose control over something like this, you lose control over everything.*
- *I think a parent should have the option to make that decision at the time.*
- *I don't think they think they are too young. That's why we draft them.*
- *The parents have the right to say, one way or the other, to say if they should have it or not.*
- *It's experimental and it hasn't been approved, along with parental consent of the child's parents I think is needed first.*
- *They should have parental consent because they are their legal guardians*
- *I don't think they are old enough.*
- *There should be a way to get a hold of an adult*
- *Since it is experimental, you should not use it on people who are more vulnerable. Children and their bodies are changing, and are more susceptible to changes than adults.*
- *It wouldn't matter if it was a child or whatever age, the families need more information. I feel negatively towards research on people when there is not enough information to make an educated decision on this. And, I don't think it should be left up to the medical community. It should be left up to a family member.*
- *It's stepping on a lot of personal feelings of people, whether religious or not.*
- *Because they have a long life ahead of them and it's only 25% to 50%; it would have to be 75 percent on a child. You don't want to lose a life just because it's experimental.*
- *I don't... I just don't think it's right. I don't know.*
- *The part the side effects...not knowing what it would do. It could be anywhere from hiccups to diarrhea.*
- *They are too young and need parent consent. They also have a better chance of surviving, anyway, because of their youth and do not need experimental drug.*
- *Because I would approve for myself, but do not wish to speak for anyone else.*
- *I think that at that age there is more control exercised by the parents. Someone in the family situation should be notified, and the decision made by them.*

- *The same for them, the risk is not high enough.*
- *I think at that point, it is the parental decision. I don't think it's the right thing to do. The scope is far too wide being 25% to 50%. If it was narrowed to somewhere around 85% to 90% chance of dying, I think you would have a case. I think that is a pretty rash decision to make on first judgment. You said that this was the first drug administered, so it would even be before an IV. I think that is pretty early in the treatment.*
- *I think their chances of survival are better; they're younger and stronger.*
- *They are minors. It's already a risky thing for adults, and it might be riskier for them. It doesn't sound good to me. I don't think the risks outweigh the benefits. What are the longer term effects? How does it affect the costs of health care?*
- *The kids still don't know responsibility. They are still young enough not to be included.*
- *I think their parents should be involved. I would hate to give up my parental rights.*
- *Not without parental consent. Who knows what people's reaction is going to be with something that isn't totally tested. It's just giving someone something experimental without permission. Everything with medication has its bad side effects. I don't like taking medication. I take as little as possible. People have so many more allergies these days, and who knows what kind of effects it will have on them.*
- *Yes, with parental consent and no, without. Parents know the medical health of their kids better than any paramedic that comes on the scene.*
- *Mostly because we don't know effect for children; I'd rather see in the population first. It's not ok to give without a parental consent*
- *Their bodies are still developing along with their brains. They are not developed enough to handle the treatment.*
- *It would be the emergency people that are doing the administering. The oxygen is given in the ambulance and they start IV. They use things that are commonly known not to cause problems. That's plenty of emergency care. If they are so severely injured, that is all they should get. The fact that they get emergency treatment of any kind, that's plenty of care. I think there needs to be a higher evaluation made instead of the emergency personnel.*
- *Well, they could be allergic, and I think kids do not apply to this study. It could kill them.*
- *They don't have a reason to perform this arbitrarily.*
- *If it was my 15 to 18 year old, who know what reaction there would be for a person that age compared to a 50 year old. If it was never used on the 15 to 18 age group, then I don't know if I want that given to my child.*
- *If there a slim chance of surviving, then they should have it*
- *I've seen too many parents take care of disabled children 24 hours a day and I know that is tough.*
- *It's a gross invasion of privacy to decide for me or a child that age, and it's experimental anyway. It's an invasion of privacy, someone is playing God.*

- *I wouldn't want anyone giving anything that is experimental to my kid. If it's something proven and used, it should be approved and given. If it's an experimental thing and no one knows what will happen, it shouldn't be given.*
- *I think their parents should be notified and the parents should make those decisions. They aren't adults yet, and they can't make those decisions. That is the parent's right to make those decisions for them. It's an experimental procedure. Because it's being used in another country, it doesn't necessarily meet our guidelines. There are a lot of drugs that in a couple years down the road, they find it isn't so great. It causes lawsuits, deaths, and costs.*
- *Because of the possible side effects. The parents would probably know if the child had allergies or anything like that.*

Q7. Do you have any additional comments about giving this drug without written consent by the patient?

- *No additional comment (223)*
- *25% is a high risk. If there was much more risk of a person expiring in minutes or a greater risk of dying or being permanently injured, I would go with it. If it was 75%, I would go with it.*
- *It would have to be much greater. Having a family and all, my wife would probably go with it. I have a lot of allergic reactions to food and medications. I don't take them without a doctor's approval. Even then, I am cautious. Would this experimental drug cost? Would poor people be lab mice? Saving lives is important, but it depends on how the doctor comes across.*
- *A patient can't give their consent if they are unconscious, and you would think the health care providers would do whatever they could. What is this drug? I guess you would hope that you are never in that situation.*
- *There is a risk of allergic reaction that the patient might react to it, and they should have some alternative medicine to treat that when they give the new fluid afterwards. If the scale is tipped below the patient's health recovery status then the drug should be used I think.*
- *An EMT should not give this shot without prior consent.*
- *Any new drug that comes along needs to be proven, and there will be positives and negatives when going through a trial phase for example like penicillin, which has saved so many lives regardless of a few side effects that some people got while trying it. If it takes a while for a new drug to go through trial and error phases but will get better in the long run, so be it for our sake.*
- *As long as it has justification and is backed up by data, it sounds like a good experiment*
- *As long as it's been thoroughly reviewed by the university, I'm okay with it being given.*
- *As long as it's in an emergency situation.*
- *As long as there hasn't been anything withheld about the drug. The Dioxin Company didn't let on to the side effects and dangers in the drug given. It is definitely worth the risk to use the fluid.*
- *As long as they follow the guidelines; set up a board and in cases where there's no one to speak for them or they can't speak for themselves, then yes.*
- *As long as they know what the side effects are, what the benefits could be, and the extent of it all around.*
- *As long as it is in a situation where they can't get permission, as you described.*
- *It would be good for certain people.*
- *It doesn't feel their right, but if there was a higher chance of the patients dying, then it would be alright to give it without written consent.*
- *I don't think that people should lose their written consent or have power of attorney to speak for them.*
- *Each person is their own case. Each person is completely different. People have different lifestyles. It's a different situation for different persons. It's a difficult*

situation for each. People have different diets. People have different educations. The food, drink, and drugs are very important for everyone.

- Going by face value of what you are reading to me, it sounds okay, but there is part of me like my family history with hospital problems and patient rights issues. But on the other side, I believe they are trying to help people. This is very thought provoking.
- I've worked as a paramedic and see that there's a better chance of surviving an accident and feel that it would save lives without consent.
- How do they know that a person with a 25% chance of living would survive? And, it should be up to someone that's in the field to decide for the injured.
- How long have they have been using it in Europe? If people had an allergic reaction to it, how many people have had long or short term side effects?
- How much research has already been done? There are people who wouldn't want this, especially if something doesn't go right. I think they would be open to lawsuits. I think emergency people are damned if they do and damned if they don't. People seem to want to blame someone for anything that happens.
- How would the paramedics know who the parents would be? If there was no verbal consent or relative consent, then give the fluid. A 25% chance that the patient would die and the hospital was 20 minutes away is different than if a person was bleeding and the hospital was further away.
- I really hope that it works.
- I agree with it because people who have a high risk of dying could benefit from it. If it helps, I think it's a good cause.
- I am a dental hygienist, and I think that it is pretty scary to give something experimental without consent. I must also say that I cannot say that I would be able to give an answer as to if I would let it be given to me. I do not have enough information about what the fluid is.
- I am a registered nurse. I think that they really need to make sure that there have been good clinical trials that are proven. If it is not proven well, it should not be used.
- I believe it save lives.
- I believe that previous procedures should be followed because new experiments can be dangerous.
- I believe that this experimental drug could lead to a problem that is truly solved. I also think that ideally consent should be sought first. It would be the ideal situation. I also think that the parent should have some knowledge and be able to make a decision.
- I can't think of anything. It's a no-brainer. I know someone on the island who had a heart attack and a Russian doctor on the island gave him a Russian drug. Now, he is up and feeling fine. He couldn't give consent either.
- I could see where it could be beneficial, but I would have to be very cautious. I hope the paramedics do not leave out other options and must be really sure that the patient needs it .They need to be really sure that it is necessary.

- *I do not believe that any drug should be given without FDA approval. Why not get full approval and then there would be no need for consent, especially if it turns out to be an effective drug.*
- *I do not think that anything experimental should be given without consent. There are plenty of losers in jail that you just use.*
- *I don't know enough about it.*
- *I don't know enough about the drug, but if it saves lives and someone is nearly dying, then it would be beneficial to them.*
- *I don't know enough about this drug even beyond your explanation to comment further.*
- *I don't like giving up your right, but if you are unconscious, it's probably fine to receive this new drug. Only you have control over your own body and what to do with it, but when you're down and out and you don't have the ability to communicate with family members that are standing nearby you at the accident scene to state how you feel, then go ahead and receive it.*
- *I don't think it should be done.*
- *I don't want to answer that because I don't know anything about the fluid. In my case I have diabetes and high blood pressure, so I say no to my case.*
- *I feel it's a fair thing for them to receive. I know I wouldn't mind. At a certain point, I've instructed my family that I don't want to be kept on life support. Initially they make their diagnosis if fluid would help me in the long term, but if I don't respond in a reasonable amount of time, I don't want to be kept alive in the long term. I've raised five children. Today, both parents are working, and the kids need some chance. They should give every reasonable chance or medication to try to save their lives.*
- *I guess, if every avenue were exhausted as to getting permission and allowing that to happen, and a last ditch effort was done, then yes. All family members should be contacted before giving somebody fluid. If the public knew enough about it, then it would be good thing. If you keep people in the dark as to what it is, then there would be people who would not agree with it. The more people know about something, the more they are willing to consent.*
- *I had a daughter who was in a car accident and there wasn't anybody there to give consent to whatever they gave her, so I say if it saves your life, do it.*
- *I have a big family history to allergies. My grandmother, mom and I are Celiacs which is an autoimmune disease. So, depending on what is in the fluid, it could kill or harm us instead of helping us.*
- *I have a lot of allergies to drugs, so I don't know if they can tell what drugs will affect them. I worked for the National Ski Patrol but left it due to liabilities and could be personally sued so I would hate to see the paramedic put in that position. So, this would have to be approved through legislation.*
- *I have a son that drives to his job 30 or 40 miles every day back and forth and if he ever got into an accident, I don't mind that they inject this new fluid to save his life with the exception if he kept on living, and that he doesn't become a vegetable head after the crash.*

- *I have allergies, so I don't think I would want them to give it to me, but if it would save someone's life and they have a little bit of time to make a decision, then they should use it.*
- *I have allergies, so that's the only issue that I have. I have had the side effects. I would certainly do it for other members of my family. I would want to know if they have something on hand to take care of allergic reactions. I would want to know if they are prepared for allergic reactions. I am all for the new science and victims who don't have a voice.*
- *I have had a head injury. I had to have surgery and was not able to sign; my boys were there and were able to sign. Yes, it is important. If I had not had surgery, I wouldn't be here. I had a brain aneurysm.*
- *I have met a lot of paramedics, and I think that they can sustain life until a patient arrives at a hospital. I believe that the paramedics should have the okay to administer this experimental drug without consent.*
- *I have the highest esteem for Harborview. My son was in a car accident and was near death, Harborview did a wonderful job of saving his life. If the doctors think that the drug is helpful and useful, I fully support their decision.*
- *I have to say that anything that is put out into the field has been tested. I happen to know because I use to be a paramedic. If it is at the stage of being administered by paramedics, then it is for emergent use. I know that doctors' licenses are on the line and they are not just going to give the paramedics something willy-nilly. I believe that anything that is going to save lives I am all for. I am now a leukemia patient and would love something experimental for my self.*
- *I haven't studied this, but in general I don't believe in giving medications without consent. I don't see this as a compelling reason.*
- *I just pray that it works and so they can continue to use it.*
- *I just think it's appropriate for adults and with kids, too. That is my personal belief, and I don't know what other people will say.*
- *I just want to be on the cautious side and make sure that the side effects weren't that often. The chances of helping should be better than the harmful effects.*
- *I just would like to know the side effects that could occur.*
- *I know there are certain religions that prevent this, and I still don't know what the fluid is.*
- *I mean, there obviously has been testing going on. For me, it's okay to save the person in a critical event.*
- *I need to know more about it to make a decision.*
- *I only approve of this under exceptional situations.*
- *I only support this if they guarantee some sort of quality of life.*
- *I really think that Harborview and the UW have highly trained staff and I believe that their judgment is to be trusted.*
- *I sort of object to anything that says I don't need to give written consent.*
- *I think it's a great thing they're doing the research on it; I hope it goes through. It sounds like it's some sort of synthetic volume enhancer. I was a medic in Iraq and all they give for something like low blood pressure is Saline.*

- *I think children should be treated like adults; however, if at all possible, the parents should be given a choice.*
- *I think if it's for the community's sake something should be written up for minors legally by the state and voted on by the community for approval ahead of time. My second remark is this experimental IV drug should be only administered in worst case scenarios without permission; It's the severity of the injury and that the patient would die without it and also would die trying to get to the hospital. Because insurance status is never known in accidents, for payment approval if someone is in an accident, proof should be given that this is the only way to save the life of the patient. I think Harborview Medical Center is really great and so is the U of W!*
- *I think if you gave this, wouldn't the hospital or whoever be open to big time lawsuits? If something happened due to the fluid, wouldn't there be lawsuits?*
- *I think in the elderly, if they have an emblem for no heroic measure to maintain life that is apparent, then do not take those measures for survival. In other cases it is rated permissible.*
- *I think it is an idea and it sounds like it would really be a good idea and as long as the side effects do not out way the study.*
- *I think it is a bad idea.*
- *I think it is good idea. If it would keep you from dying until you got to the hospital, then that would be okay.*
- *I think it should be known to the public so they know what the risks are and what might be happening in such an event. They could wear something if they didn't want to be given this drug.*
- *I think it should be on a trial basis and then after 6 months, it should be noted to what the advantages and disadvantages are so the public is given the pros and cons. If the public approves after seeing the results then it can be approved.*
- *I think it's a good idea because it's life saving and we want to save as many people as we can.*
- *I think it's a good idea and that it could help with organs days later and could help you live, and it's being used in Europe.*
- *I think it's an invasion of privacy. The state is taking a stand on life and death, and the state does not belong in that business. The state has a lot of latitude right now.*
- *I think it's underhanded in that you can do the research without consent. As far as patient rights, it bothers me.*
- *I think people need to be made aware of the side affects. Like organ donors, they should have a card on them as to whether they want this fluid to be used or not. And, if there is no card on the injured person, then let the medical team do the best that they can at that time. I feel when random studies fall out, there are relatives involved with legal tangles and lawsuits of unlawful death. We need more information to understand this fluid and register whether we would want it or not.*
- *I think that any drug given can cause allergic reaction, and you never know what the reaction will be. I personally have allergic reactions and doctors do not know*

what to do. I do not think paramedics should be given permission; they are not doctors. Wait until they get to the hospital

- *I think that any drug that would help survival is good.*
- *I think that anything that saves lives is okay with me.*
- *I think that anything that can be done to save lives should be done.*
- *I think that fluid is safer than blood. You might catch someone's illness through the blood. I had surgery a few years ago, and I gave them a couple pints of my blood, so I was able to get my blood back.*
- *I think that it is a good idea to save a life or at least make an attempt. I could only hope for the best*
- *I think that it would be a fine study and I believe that they should do more on women and children. It has been noted that medication amounts were not right and women and children die for no reason. I also know of a new product that is in Iraq where they throw this white powder on a bleeding patient and it stops bleeding. So new advancement is great, and I am sure approval for experiment will come soon.*
- *I think that people have a right to say whether or not they want to participate in experimental procedures. I think that it's good that the drug is being experimented and researched. I think there is a risk involved and people should be aware of this.*
- *I think that teenagers are really susceptible to accidents and this would really be good for them.*
- *I think that there are concerns with regards to religious beliefs. I would also hesitate to include minors in this situation. I am not sure I would want something given to my children even though I do not have any.*
- *I think that it will save lives.*
- *I think that you are opening up yourselves for lawsuits. I think this is just an insanely law suit society. People sue the fast food restaurants for making them fat. Who told them they had to eat that?*
- *I think the agency using it would be opening itself to law suits. A lot of people would want to know what they are given. It's a real iffy area. If this did not contain blood or blood byproducts, then yes, I would be all for it.*
- *I think there should be an investigation to adverse effects. What is the status of adverse events in Europe?*
- *I think they should try to keep a person alive however they can, whether someone can consent or not.*
- *I think you have to have a record of it being successful in a percentage of cases. If someone were to sue, the hospital would probably be liable.*
- *I want to know how often it's been used in clinical trials. How often people have allergic reactions? I just wanted to know the outcome when used in practice in Europe and how successful it is.*
- *I want to know what's in the fluid. You feel like a lab rat with these experimentation things. I think life is precious, but we are not made to be experimented with on our bodies. I think when it's time to go, it's time to go.*

Don't experiment with humans or animals, it's not right. When God wants me to go, he wants me to go.

- I want to see if it's already working in other countries effectively and you already mentioned to me that it's already currently used in Europe, and it's working well there.*
- I wonder about the paramedics using it. I'd feel better if there was a doctor that knew what he was doing and had more training.*
- I would agree more to have that drug given if it was approved in the United States the first time. I'm a little leery of things that are not officially approved or haven't been through many years of research to be proven.*
- I would approve of this only if the FDA approves it for research. I hope it's as good as you say it is.*
- I would be curious if it has been government approved.*
- I would change the percentage, maybe 35% to 40%.*
- I would like to know what is in the fluid, but as long as it helps people, then I guess it is okay.*
- I would like to know what the solution is. Is it any worse than neutral. If it's benign, I would approve. But if sides effects are great than I do not approve.*
- I would like to see the statistics from Europe or those who have used it. I would like to know the bad side effects that are possible. I wouldn't want to prolong my child or my life if I was going to be a vegetable.*
- I would like to talk about organ donating. The boy that was killed during the Mardi gras trying to save a woman had all his organs donated. This is his third anniversary. His sister is getting married and inviting all recipients of organs donated to her wedding. I say that I totally believe in the experiment.*
- I would say if a patient needs help and it is a critical situation if you withhold treatment just because of a patient's inability to give consent, it's not logical, it doesn't make sense to me! It's a life saving treatment. My daughter had a stroke and she received treatment and was in a coma for a year and a half and then she got married! So I'm a believer that anything should be done for that person at that moment!*
- I would say in general I would want the information on the drug available on the internet. The more I could look at it, the better. There may be hidden motivations, like the pharmaceutical company pushing a drug that is marginal. I don't trust the experts; let the free society figure it out.*
- I would say only in an emergency situation.*
- I would take anything at my age! I'm feeling good considering I've had a stroke!*
- I would want anything the save my life.*
- I would want more research to continue and determine the safety of it.*
- I would want to know what the side effects are before I consented to something.*
- I wouldn't risk giving any drug without approval from AMA, FDA, or the proper authority. Now days, doctors and health care workers have to be so careful. I know it's not too positive. Overall, from what I know and hear, I wouldn't administer this drug. I would be afraid to administer this drug if I was physician*

or paramedic. I feel sorry for the medical profession because they are under strict guidelines and rules. We just have to go by that.

- I, again, feel that if the patient might be happy as result of taking the medication or not. I have a friend whose daughter was put into a coma.*
- I'd be curious of the statistics of allergic reactions. If it were low, I'd have no qualms about it, if it were high, I would.*
- I'd be interested in finding out information in the European studies. Outside of the possible allergic reactions, I think it would be a good thing to do.*
- I'd like to see what success they have now in their clinical studies. I'd like to know more about it. I don't know what age groups and if it could be used on children. I would like to know more about what side effects there might be. I would like to know why it hasn't been approved here. Why was it approved in Europe?*
- If I understand you correctly, there is less than 50% survival.*
- If it is approved in other countries, then there is nothing wrong with it.*
- If it can increase the chances for survival by any percentage, then they should do it.*
- If it was a head injury or a serious one and it would save lives, then they should give it a try.*
- If it would help in survival before instant death, it might be okay.*
- If it's an adult, especially if they are elderly, I'd say go for it. I know I'd want that for me, especially if there was nothing else. If you're going to die without it, then why not try it?*
- If it's going to save a life, I'm all for it. I'm a diabetic. Thank God for the paramedics. They have saved my life. Anything that needs to be done at the moment, by all means do it. I suppose you will have those who will sue. I think that's pretty pathetic. They are thinking about how to get rich fast. I think if it happened to me or any member of my family, I say do it. The paramedics are a godsend and let them do what they are trained to do. If it saves somebody's life, isn't it worth it? The only way they are going to find out if this stuff works, is to use it.*
- If it is life or death, there shouldn't even be a question; it should just be something that's done!*
- If it's more than 50%, it's one thing to test the fluid, but less than 50% of a chance of dying is not a good time to try the fluid. Let's say if they survive from a 45% death rate. If you were to do it again with the fluid then they die because of the new fluid because it's a test—it would be a horrible thing. I think that this fluid should be tested by doctors in non-critical condition patients in supervised labs to make sure that there are minimal allergic reactions. Children definitely should not be tested on without consent. What, are they lab rats, are you kidding?*
- If my child was in an accident, I would not want them to give him experimental drugs, only if they are 50% to 60% sure it would work, and there is no long term effects.*
- If paramedics or doctors tried to inject this into me...if I was in this similar situation...because I currently have auto immune liver disease and they would not*

know the side effects of giving this to me with not enough knowledge on how this would affect me with my liver disease.

- If patient is alert, the patient should take part in decision making process*
- If people can live normal lives and can bare children, I think that it is ok.*
- If somehow the public could know about the side effects, so if they know about someone in that situation, they could be knowledgeable. The only time you hear about this is if they are severely hurt. If someone is severely hurt, you only hear about half of the stuff that's being said, anyways.*
- If the patient cannot give written consent before the parents can.*
- If the patient is incapacitated and unconscious, then by all means.*
- If the patient is unconscious and their family can't be reached, you have to do it. Every second counts.*
- If the people know what they are doing, then I would trust their judgment.*
- If there has never been testing done on children, I wouldn't want this used. I think it's at the discretion of the attending physician, if the patient looks like they are going to die anyways. I wouldn't want an experimental drug that has never been tested at all or used on patients.*
- If there is a way to save a life, everything that needs to be done should be done.*
- If there is someone present who is a family member, but they don't want them to have the intravenous fluid, that should be respected.*
- If there's a chance it would save a life, I think it should be used without consent.*
- If they are coming up with something that offers you better life quality and helps you heal faster, you should go ahead and do it.*
- If they handled it differently with how to go about it. Approach the populace as they do organ donors on a driver's license, where people could give written consent. Or ID card for youths. Something where they have been aware and give consent ahead of time.*
- If they are on the table, they should try it. If they are going to die the doctor should make the decisions of the patients.*
- If this is going to save his life and his brain, yes, give it to my son. They can fix anaphylactic shock. I wish the paramedics didn't always have to use it; I would like it to be used by a doctor, but you gotta do what you gotta do.*
- If this is something new, I think they should try it out and see if it works.*
- If this were going to be done, I wouldn't keep it under wraps. People should know that this fluid is being used on them; people don't like surprises. It sounds like the hospital is checking public reaction before doing this.*
- If you can't get a hold of their parents and it's hard to do, if it's going to help, by all means go ahead and do it. If I was a paramedic and thought there was a failure of some sort, I would want it given to me or any other family member.*
- If you have a 50% or more chance of dying you should not have a written consent of the patient, but again if you have less than 50% chance of dying than you should have the consent of the patient.*
- I'm assuming oral consent is there. Written consent may not be practical at the scene. Once you're at the hospital, then getting written consent is appropriate.*

- *I'm concerned about the ACLU. They can bring on a lawsuit by giving it to people without their consent.*
- *I'm hesitant that EMT people are going to authorize it because I just think an experimental treatment should be under a doctor's supervision.*
- *I'm just trusting you in what you are telling me and it should be used. I have a lot of faith in the hospital you are referring to, and we would all like to survive if caught in that situation.*
- *I'm just wondering to what length they are going to find a family member. Is it one phone call and that's it? Then again, it has to be given right away! I'm going to have to think about this! If it was me, I would want it.*
- *I'm not to sure anyone should get the drug without consent, due that it is in its experimental phase due to side effects.*
- *I'm surprised with all the hooplas of personal security these days. You can't even pick up prescriptions for other people, anymore.*
- *In extreme cases where they have a chance of not making it or they could have future brain damage, it should be given.*
- *It's a huge ethical question. So, if they are injured, it would save lives.*
- *It has to be done where paramedics are not held liable. Legal issues. People are lawsuit happy. For myself, it's fine for me. They are very well-trained. Medic One people are very well-trained. I don't see anything wrong with it here. If you can get around the legal ramifications, go for it.*
- *It has to be proven in other countries before it could be given here in the United States without written consent.*
- *It makes sense! If there is no written consent, but it can save many lives.*
- *It's scary, but I know that if you need blood in hurry....*
- *It seems like a dangerous road to go down if this is something we see a lot. Boundaries become blown.*
- *It should be publicized so people can have knowledge, and know more about the drug and the possible side effects.*
- *It sounds like a good thing. I have a concern about the side effects. Side effects can sometimes be worse than doing nothing at all.*
- *It would be beneficial to do a study on the allergic reactions to this agent. How to counter act the allergic reactions. The paramedics could recognize the allergic reactions.*
- *It would be in the best interest, opposed to not knowing what would happen if they didn't get it.*
- *It would be interesting to know more about it, and find out the viability of it. If it's being used in Europe, what are the reports on it? It would be good to see the percentages on the success rates.*
- *It would depend on weather the patient is going to make a successful comeback. If they just stay alive and be a vegetable, it's not worth it.*
- *It's about time...a good idea...something worth trying.*
- *It's wonderful. Since it's a supplement, it works well for the people that need a blood transfusion.*

- *I've got no objections to that in case of emergencies. It sounds like it's on the threshold of accidents and injuries. Auto accidents are pretty prevalent around the country. They should check to see if it has much interaction with alcohol in their system.*
- *My agreement with that approach is conditional on the researchers and not on the conflict of interests. They could be bias and might be putting people at risk.*
- *My concern is how severe does the injury need to be if consent is not possible? To what extent do teenagers...how much effort will be used in finding consent for the teenager?*
- *My concern is if they allowed it and it were justifiable, they could extend that onto other drugs as well.*
- *My only concern in an auto accident is that doctors give what would be the best treatment, what's been around the most. If given in lieu of blood, natural blood product should be preferred to using the experimental fluid. It could be expensive with manufacturing. All the doctors would agree with conventional fluid if blood is not available. If the public said yes, they would be less likely to get the conventional product because of expense.*
- *My only problem at all is that I hope the people administrating the drug should be monitored so they don't get carried away.*
- *My personal opinion is that I wouldn't want that. I don't really have another opinion. I wouldn't want it that way; I wouldn't want some drug I didn't know about.*
- *No, because most people are not going to have that written consent. If the person who meets the accident has the qualifications they should give the fluid.*
- *No I don't. I think if it's life or death, anything should be done to save their life. It could be me.*
- *No I don't. I kind of gave you my thoughts on this. Sometimes you can be allergic to a drug, but the second time you won't.*
- *No, I'm not in favor until more research is done. They were still using faldomine in Europe when the birth defects came up. Just because Europe is using a medicine doesn't guarantee its safety.*
- *No. They shouldn't be given it unless a family member or the person themselves is there; there shouldn't be no heroics*
- *No, I think it's a good idea if it benefits the patient's life.*
- *No, but I feel that a member of a family member or guardian should have a say on what is going into the patient, and that no one should be poked for no reason and not knowing what it is.*
- *No. I believe it is something that the hospital is trying to help the patient and the hospital. I don't believe they mean any harm. So, I think this is a good idea.*
- *No, I'd like to read more about it! I've worked in emergency before and some paramedics, I just wouldn't trust to do that!*
- *No, not at this time.*
- *No, other than it could be sustaining your life and most people want to live.*
- *No, sounds good to me.*

- *No, I don't think so, because the patient can't give consent and it's a life or death situation, yes. Let the paramedics give it to them.*
- *No, I have no problem with it.*
- *No, I think there is a good understanding of the benefit. Anything that improves the condition of life as we know it is most desirable.*
- *No, if they follow the guidelines you read.*
- *No. I can't really think of anything. If you're incapacitated, it's up to the emergency personnel to make the call on the advice of the physician they are communicating with. Each circumstance is different.*
- *No. I just hope they have good luck with it. I've been to Harborview and I know how good they are!*
- *No. If they're not given the fluid, they'll die anyway, so why not give them the fluid and improve their chances of living? It's approved in Europe, so why not give it to them here?*
- *No. No. If there's a chance, then why not?*
- *No. I think it is important in a life saving incident; there is no time to waste.*
- *No. It is experimental and it is not a definite cure. I would have second thoughts on that.*
- *No. I think that in many cases, even with consent, people get into situations they regret, with new treatments coming out.*
- *No. I'm glad I don't have to make those decisions, though.*
- *None, other than my reservations that I have already expressed. If it's the only way that you can save a life, then you should go ahead and do it. But this seems to be the only way this can be tested and proven. If the qualified people believe it will benefit people, then I believe so as well. Apparently this fluid is such that if it's given right at the scene of the accident, like all of the other treatments, it will improve their chances of surviving*
- *Not knowing anything about this fluid, have there been any reports about any major side effects? If it's good for an adult, it's good for a 15 to 18 year old. If a person is unable to give consent and there is no other adult to make that decision, as a human kind we are to look after each other. More doctors need to be funded for research. There needs to be more research. The FDA is very slow in approving things.*
- *Not really, no. I just agree that it should be used, life or death. An EMT would know; they have contact with emergency room.*
- *Only concern is that I don't know about the drug and am afraid of the side effects.*
- *Only if...there should be written consent, but if not they should go ahead. It's a legal issue.*
- *Only if they eliminate hospital stays and give a better chance for survival.*
- *Only if you can't give consent and nobody can speak for you.*
- *Only wish that they would make the public more aware of the side effects, and the pro and cons of the drug, and how it would affect the patient after the trauma.*
- *Other than it could save their life, I don't think any patient is ready to die.*
- *Our son was involved in an accident and if he was injured, you would still need permission from a grown up to do it. To give that to him.*

- *People just die anyway. Give them a chance.*
- *Personally I don't have any problems with it. In the medical field, the risk of being sued might come up. That's a legal situation. In any emergency situation, I think the most should be done for the patient.*
- *Probably not, probably not.*
- *Research doesn't progress unless some chances are taken. But if chances were taken with my family, I don't know if I could live with that. I'd have no qualms using this agent, if the person was going to die for sure without administering it. I wouldn't want to use it, if they were going to come back a vegetable. I believe in assisted suicide, because it's not passionate to keep people alive with some things. I think their quality of life wouldn't be good, and quality of life is important. We put our pets to sleep if they aren't good, but we can't do this to the people we love.*
- *Set up enough guidelines to prevent as much negative potential as it's administered. Safety is the number one issue.*
- *I would want to know more about the fluid.*
- *Side effects. I need more information.*
- *Since it is currently used in Europe, I'm okay with it.*
- *Some kind of education effort should be made prior, so that people with objections can opt out of that. The community of interest should be known and an educational effort should be made, and it should allow people to opt out.*
- *Some people have been in accidents where they may have been saved if something could have been done sooner. I support saving lives. If people are not careful lawsuits can happen.*
- *Someone is playing God; it's something that is experimental and they haven't asked that person. It's a judgment call with no input from the family. It's an invasion of privacy.*
- *Sounds like the paramedic is making the decision, and it's troubling to me because I'm not sure he's totally qualified. If it becomes routine, then he'd just do it. And, are there adverse effects on someone that is totally healthy that would not really need it?*
- *The biggest thing is it would depend on how severe the allergic reactions are and what they are. If they carry something with them so they [the paramedics] would know, and they could do something about it immediately. How fast can they tell? If they could administer something immediately, if they have an allergic reaction. If they check for allergy bracelets and necklaces. I assume if this is something they are going to experiment with, they would check wallets and stuff for information on allergies.*
- *The concept of informed consent is iffy anyway. You cannot explain the full ramifications to a patient, and they could argue later in court that they had not been fully informed. I think this study should be done and I am hopeful it will turn out to be very helpful since, in any trauma, injury or disease, the first few minutes are the crucial time for treatment.*
- *The doctors know better than anyone.*
- *The only hesitancy I would have is if there were unreported side effects that may cause more damage than help. For instance, yes, you live, but you become a*

vegetable. Yes, you live but it could lead to cancer. It's a great idea if it's well researched and every aspect was looked at.

- The only thing I would say is there are so many areas that we are being tracked by the government, that we are required to give our own opinion about something. It seems wrong that anyone that can give fluids without consent in a life or death situation*
- The only thing is that complete information is given to the guardian so they know what has been given to the child.*
- The only thing is that it is experimental; we could try it on animals but since it works in Europe, why do we need to test it here? I hope there is nothing wrong with it.*
- The paramedics who will make that decision are not as schooled as the people at the trauma center, and that concerns me*
- The person giving the fluid would definitely have to be very qualified for this.*
- The problem with lawsuits by the people that are still alive...that it was given without permission.*
- There are a lot of teenagers on the road these days and they to get into accidents. I was an RN for 35 years and I worked in the emergency room. Accidents do happen and sometimes your choices are limited. I think that anything that allows for a better option for survival is ok.*
- There has to be a way...a mechanism of exhausting the attempts of contacting family. When they are negative, you can give the fluid.*
- There should be some consent from somebody. If not from the patient, it should come from the family. It doesn't sound like a great idea, to me.*
- There's a liability factor; there's a chance to be sued. That's what happens if it's no consent, or is there a Good Samaritan law?*
- There's always going to be an aftermath of religion and second thought of relatives and so forth. But, they are not privy to all the information the paramedics have and it's best to keep a life going.*
- They better make sure there's not going to be a handicap or whatever; I'd rather be dead than not have quality of life but have my life prolonged.*
- They should do some studies on children under 18. They should have some documentation and studies before they give this to children under 18.*
- They would need to do a preliminary allergy test before they administer it to the patient. It is very easy to do. I would want them to do a skin test for allergic reaction. Other than that, if they do a preliminary reaction test, I would be much more inclined that they go ahead and administer the fluid if it's really beneficial.*
- This drug is not fully approved or, like you mentioned, because of possible side effects and allergic reactions that might occur so it's not officially safe-free or proven yet.*
- This fluid gives people the possibility to live. I welcome studies like this. I am a cancer survivor and I like to do medical studies.*
- This is really a tough call because some people want to live no matter what their quality of life may be. But I still think we should have written consent.*

- *Try to find consent for the patient that they would be asked but I realize it would also save lives if they couldn't find one to give it without consent.*
- *Just a verbal consent. They have to receive some kind of consent unless they are unconscious*
- *It should probably be publicly made known so that people know about it.*
- *understanding only use in a life and death situation*
- *We have to know what the liquid is about. What's in it? What are the consequences of having it? Is it safe? We need to know what they're giving us.*
- *Well, I have reservations about giving that power to paramedics, since they're not necessarily qualified doctors. They're not qualified to make an assessment if a patient's life is such at risk.*
- *Well, I'd be interested to know what it is, but I think it would be worth the risk.*
- *Well, there is always the risk of it not being given without the consent of the parent and guardian. If given without consent they may feel there would be a problem and they may sue. There are religions that object if anything is given. They may file a lawsuit.*
- *Well, if it's pretty well proven at saving lives, I say yes.*
- *What are the European results? I just would need to know more about it and what are the results. If it's saving lives in Europe, we should use it here.*
- *What happens if it is given and the patient does not really need it? I would also like to know how close to being approved it is. I believe that as long as there is no misuse or downfalls with reaction I am all for the experiment.*
- *What if it kills them? Who gets the blame? The paramedic?*
- *What percentage of the population in Europe reacts to this drug? Whether it's good versus bad reaction to it, and also if it is treatable afterwards.*
- *Whatever this fluid is, I would want to know about it. I would want to know about it, so I could have an opinion about it. So much is hypothetical without knowing much about it.*
- *When is this drug going to checked off and deemed it will be safe? I have great faith in the efforts in the medical community. I would testify the need to use experimental drugs. I would want them, and permit them to use this on me. I would assume the study is going to continue and eventually be a wonderful thing that could be offered to the American public.*
- *When you talk about allergies, would this fluid be the kind to cause allergies in general or is this something new?*
- *Whenever you're administering drugs or substitutions without overt consent of the patient, you run the risk of violating their rights. You also run the risk of introducing antibodies into somebody's person without their knowledge or understanding. That is a controversial or dangerous line to cross. However, given all the parameters of people to respond, it makes sense to me to revive a life so those persons could be responded to. The people administering this must have knowledge and training to watch for any adverse side effects. Some folks might object due to religious reasons and/or own views on medical and resuscitation. People might have standing instructions not to revive.*

- *Where did the fluids come from? What kind of fluids are they? How long has Europe been using it? I would want to know more about what fluids they are using and a better description of the fluids. I think the public should know. My husband was in a coma for 31 days, and without other people making decisions, he wouldn't be alive.*
- *Who would be giving the drug? How well is the paramedic trained?*
- *Whoever there that makes the decision that saves the patient; they need to have a publication to let people know how to save lives.*
- *With the 50% chance of surviving or better, then I don't think it should be done. But, if you have more than 50% chance of dying, I would agree to all of it.*
- *Without a court order, it should be illegal.*
- *I wonder why it has been approved in Europe and not in America, yet. It should only be given by a doctor and not a paramedic because the paramedic's skills are not that good.*
- *Would it cost too much to start a campaign that would let people know about this program, so someone could carry something to say they have parental consent? I don't know whether it would be feasible or not.*
- *Would it open up the avenue for lawsuits later?*
- *I would like to know what it is*
- *Yeah it would be...if it's a benefit to mankind, you should test this fluid without consent. It's already approved in Europe; I mean, why not?*
- *You can't get written consent. Haven't they tried this in Iraq? Giving this without written consent seems to be the only way to get it to work. If you have 25% chance of dying, you're probably not mentally around to sign a consent form. It's when you give it to younger children, I worry. Presumably, the paramedics are trained to administer it. The ones that I have met have pretty good judgment. I was wondering if it has been tested on adults in Iraq. I seem to remember reading something about this. There is more than one fake blood. How does the body get rid of it? Is it used routinely in Europe or is it just available experimentally?*
- *You have to try something. It can't be totally bad if it is used somewhere else.*
- *You should get written consent if they're conscious. If they're unconscious, you should do the best you can; that's what a hospital is for.*
- *You would need to be sure that the benefits outweigh the risks.*
- *You're talking about a patient who can't do anything, they need to survive. If they think it'll work, I'd do the Good Samaritan thing, try everything they could.*

Q10. What is your occupation?

- Accountant/CPA (8)
- Activity Director, nursing home
- Administrator (7)
- Architect/Engineer/Draftsman (11)
- Artist/Entertainer/Writer/Musician/Pro Athlete (4)
- Bank Teller/Bookkeeper/Cashier
- Banker/Controller/Financial Analyst (6)
- Bartender/Cook/Waiter/Waitress/Flight Attendant/Baker/Caterer (2)
- Business Owner (18)
- Business, Non-Managerial Professional/Business Consultant (4)
- Buyer/Purchasing Agent
- Caregiver
- Carpenter/Electrician/Painter/Plumber/Machinist (2)
- Casino Dealer
- Chief
- Child Care Worker/Housekeeper/Maid/Teacher's Aide/Dishwasher (6)
- Client Service Specialist
- Computer Consultant
- Computer Programmer/Systems Analyst (8)
- Computer/Data Entry/Key Punch Operator (3)
- Construction (3)
- Corporate Recruiter
- Correctional Officer
- Costco Worker
- Customer Service
- Delivery/Route Man/Driver (5)
- Dental Assistant/Nurses Aide/Medical Assistant (3)
- Dental Hygienist
- Doctor (10)
- Engineer (7)
- Economist/Mathematician/Scientist
- Exhibit Designer
- Fabricator
- Factory Machine Operator
- Factory/Railroad Worker/Miner/Blacksmith/Ferrier/Elec. Assembler/Miner
- Finance Director
- Fireman/Guard/Policeman/Fish & Wildlife/Forest Ranger (2)
- Fisherman/Gardener/Lumberman/Landscaper/Mill Worker (4)
- Hair Dresser
- Homecare Provider
- Homemaker/Housewife/Househusband (47)

- Hospital Clerk
- Insurance (2)
- Insurance Adjuster/Real Estate Appraiser/Actuary/Loan Processor (2)
- Janitor (2)
- Journeyman/Electrician
- Kitchen Manager
- Laborer (3)
- Lawyer/Paralegal (3)
- Legal and Tool Inspector
- Lumber Processor
- Mailroom/Messenger/Postal Worker (3)
- Manager (5)
- Market Gardener
- Marketing (3)
- Math Tutor
- Mechanic (3)
- Medical Technician/Paramedic/Registered Nurse/Therapist/Dietician (13)
- Mental Health Therapist
- Mortgage Consultant
- Mortgage Banker
- Music Instructor
- Musician and Recording Engineer
- Not able to Work/Disabled (3)
- Nurse (5)
- Nurse's Aide
- Pastor/Minister (3)
- Photographer
- Plumber
- Professor (3)
- Project Coordinator
- Real Estate
- Receptionist/Secretary (2)
- Religious/Social Worker/Counselor (3)
- Research Associate
- Reservationists
- Retired (164)
- Sales - Industrial/Wholesale (2)
- Sales - Insurance, Real Estate, Services/Travel Agent (4)
- Sales - Retail/Florist (3)
- Sales Associate/Clerk (2)
- Sales Representative (2)
- Self Employed (2)
- Service Director
- Spanish-English Translator

- Student (14)
- Supervisor
- Teacher (21)
- Toxicologist
- Transportation Coordinator
- Unemployed (9)
- Utility Lineman/Service man
- Veterinarian Hospital Technician



General Health channel

<http://www.ivanhoe.com>

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Saving Trauma Patients

SEATTLE, Wash. (Ivanhoe Broadcast News) -- He's back to teaching this model-making class, and Chris Stanley knows it's a miracle after a terrible accident two years ago. Stanley was riding his bike on a busy road when he was hit by a car. "I slid up on the hood of the car, hit the windshield, and pushed that in," he says. "My helmet was destroyed."



He flew 85 feet and landed without it.

Stanley's severe head injury allowed him to qualify for a new study. It's already being used in Europe, and now a national study is testing an experimental treatment to see if it can help improve survival rates for trauma patients.

Paramedics usually give trauma patients an IV filled with salt to replace lost blood. The level of salt is about the same as what's in the bloodstream. In the new study, patients got a more concentrated dose of saline or a placebo.



"In a patient who has lost a lot of blood, you can rapidly restore their blood pressure by giving this concentrated salt that then draws extra fluid out of their tissues into their bloodstream," Trauma Specialist Eileen Bulger, M.D., of Harborview Medical Center in Seattle, tells Ivanhoe.

Early results show the high doses of salt -- called hypertonic saline -- also improve blood flow to the brain, reduce brain swelling, and can decrease the risk of infection.

Dr. Bulger says, "Our goal is for the people who have lost a lot of blood to see if we can actually improve survival."

Hypertonic saline has been tested in smaller studies with and without a sugar solution. Results showed an improved survival but the numbers were too small to make the treatment a standard of care for trauma patients. Hypertonic saline is currently being used in 14 European countries.

Stanley doesn't know yet if he got the hypertonic saline or the placebo. He's just thankful for his amazing recovery. He says, "Just being able to speak, being able to walk, being able to think coherently are miracles."



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