



## **Hypertonic Saline**

### **Basic Study Description:**

The goal of the Hypertonic Saline Trial is to determine whether giving hypertonic saline fluid intravenously to patients with symptoms of severe bleeding or head injury in the field will improve their survival or neurologic recovery. Patients with injuries and either a low blood pressure or in shock will receive either one cup of normal saline (water with the saltiness of the blood which is currently the standard of care), hypertonic saline (more concentrated salt water), or hypertonic saline with dextran (more concentrated salt water with a sugar molecule added).

The research is being conducted by the Resuscitation Outcomes Consortium, a recently formed network of 11 regional centers throughout the US and Canada and a central data coordinating center. Approximately 5,800 patients are expected to be enrolled over several years.

### **1. Why are you doing the study?**

Severe injury is a major public health problem. It is the number one killer of both children and young adults up to age 44, and the leading cause of life years lost, because it is a disease of young people. About 175,000 fatal injuries occur each year in North America. For every patient who dies, there are at least 2 other patients who are severely disabled. The leading causes of death following injury are brain injury, blood loss, and organ failure from excessive inflammation.

Treatment for severe injury must be initiated quickly in the field because 50% of deaths occur at the scene, 30% in the first two days, and 20% after a long stay in an intensive care unit. Very few treatments have been scientifically tested. More research must be done to guide treatment for this common, disabling and potentially lethal health problem.

### **2. What is the potential benefit of hypertonic saline therapy?**

Current treatment uses normal saline (water as salty as the blood) to replace blood volume but animal and human studies suggest that hypertonic saline may save lives. Initially hypertonic saline acts to quickly draw fluid into the vascular space from the surrounding tissues to restore blood pressure. It has also been shown to reduce swelling of the injured brain and to diminish the early inflammation that is associated with late deaths in the intensive care unit.

### **3. Why are you using 2 different preparations, one with dextran?**

Previous studies have used a solution of hypertonic saline mixed with dextran sold as RescueFlow, but it is not known if the dextran is helpful. Hypertonic saline alone

is simpler to manufacture or use. Scientific testing will tell us which is the better resuscitation fluid for patients with serious injury.

#### **4. What are the risks of using hypertonic saline?**

We will compare the number of adverse effects with the standard normal saline versus the hypertonic solutions. Possible adverse effects that our study will monitor include:

- high sodium (salt) levels that may cause seizures requiring medical treatment,
- the potential for blood clotting problems leading to increased bleeding,
- skin irritation at the site of the infusion or a rash,
- a drop in blood pressure, increase heart rate and trouble breathing as might be seen with an allergic reaction..

#### **5. Why can consent not be obtained before the fluid is given?**

Patients who are seriously injured may be confused, unconscious or in shock . In this situation where the patient is unable to give consent, regulations have been developed by the FDA to allow for exception from consent.

#### **6. Is it ethical to conduct research on someone who can't consent?**

We take the responsibility of conducting this kind of research seriously. The following steps were taken for this study:

- First, the participating sites and coordinating center were selected based in part on their prior success at conducting high-quality prehospital emergency care research.
- Second, prior smaller studies were reviewed and showed evidence of promise for success of the new resuscitation treatment over the current standard of care.
- Third, the study was reviewed and approved by an independent committee of the National Institutes of Health before study initiation.
- Fourth, the study was reviewed and approved by the Food and Drug Administration (FDA) before study initiation and will continue to be monitored for safety issues by the agency during the study's conduct.
- Fifth, the FDA regulations require that the community, where the research is being conducted, be notified and consulted before the study is started

A local independent group called an Institutional Review Board (IRB) reviews the process of the community notification and consultation, and reviews the study for safety and any other issues of concern before approving the study for local implementation.

Another independent group including experts in medicine, ethics, statistics, and clinical trial methods must also be appointed to monitor the safety of the patients throughout the course of the study. This is called a Data Safety Monitoring Board (DSMB). This group has access to the study outcome data and can recommend changes including stopping the study at any time if there is any indication of safety issues or that the study is not progressing as planned. All adverse events are reported to the DSMB, the FDA and the local IRBs.

Patients and families are notified of their participation in the research as soon as feasible either in person, by phone or mail.

**8. Have there been any other recent studies of hypertonic saline?**

Yes, there have been recent studies: one in Australia and one in Toronto, Canada both, studying the effects on patients with brain injury, and one in Seattle studying the effects of the fluid on inflammation in patients with shock (low blood pressure). In all, there have been 9 preliminary trials (<900 subjects). Three of these were equivocal and six were favorable. These trials showed no adverse events that were related to the resuscitation fluid. However, these studies were too small to draw definitive conclusions about the use of this therapy.

# COMMUNITY MEETINGS

*A new national research study may involve you.*

Oregon Health & Science University (OHSU) would like your input on a national research study that may be conducted in the Portland area.

The study will determine whether a different type of salt solution than the one currently given to people with severe injuries at the scene of an accident can improve survival rates.

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For more information, please visit the study Web site at [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc) or call OHSU at **503 494-7015** or **888 370-2888**.

*OHSU is an equal opportunity, affirmative action institution.*

## Your thoughts?

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We want to hear your thoughts, questions or concerns about this study at the following community meetings:

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**Monday, May 8 – 7 p.m.**

Southwest Washington Medical Center  
Health Education Center  
600 N.E. 92nd Ave. • **Vancouver, Wash.**

**Tuesday, May 9 – 7 p.m.**

Washington County Public Services  
Building Auditorium  
155 N. First Ave. • **Hillsboro**

**Wednesday, May 10 – 7 p.m.**

OHSU Auditorium (old library)  
3181 S.W. Sam Jackson Park Road  
**Portland**

**Monday, May 15 – 7 p.m.**

Clackamas County Fire District #1  
Oak Lodge Station 3  
2930 S.E. Oak Grove Blvd. • **Milwaukie**



April 28, 2006

Dear Elected Official:

This letter and fact sheet are designed to inform you about a clinical trial that may be conducted by Oregon Health & Science University in the Portland-metropolitan area. OHSU is part of the National Institutes of Health-funded Resuscitation Outcomes Consortium (ROC). The consortium comprises 11 regional health centers across the United States and Canada that are conducting clinical trials to find promising scientific and clinical advances to improve resuscitation outcomes.

The goal of the first ROC study is to determine whether a different type of intravenous resuscitation fluid than usual, given at the scene of an accident to individuals with severe bleeding or life-threatening head injuries, can improve their outcomes.

Because individuals eligible for this study will be unable to provide informed consent due to the nature of their injuries, the study will be conducted under Food and Drug Administration regulations that allow research in certain life-threatening situations without authorization. The federal regulations that allow this waiver of consent require community notification to ensure the public is aware of the study.

To that end, the public is encouraged to attend one of the following community meetings where the potential benefits of the study will be explained. These open meetings will allow the public a chance to ask questions and share their opinions about the study.

- **Monday, May 8, 7 p.m. at the Southwest Washington Medical Center Health Education Center, 600 N.E 92<sup>nd</sup> Ave., Vancouver, WA**
- **Tuesday, May 9, 7 p.m. at the Washington County Public Services Building Auditorium, 155 N. First Ave., Hillsboro**
- **Wednesday, May 10, 7 p.m. at the OHSU Auditorium (old library building), 3181 S.W. Sam Jackson park Road, Portland**
- **Monday, May 15, 7 p.m., at the Clackamas County Fire District #1 Oak Lodge Station 3, 2930 S.E. Oak Grove Blvd., Milwaukie**

ROC ultimately will consist of multiple studies during the course of several years, testing new or alternative drugs, tools and techniques for resuscitation. OHSU will work directly with emergency medical services (EMS) agencies and hospitals in Multnomah, Clackamas, Washington and Clark counties to conduct this important research.

We hope these documents will provide you with the information you need in the event your constituents contact you regarding this potential study. Please contact me directly if you would like to discuss this study and implications for our community. To learn more about the study, visit [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc).

Sincerely,  
Jerris Hedges, M.D.  
Co-Principal Investigator  
Vice Dean  
Professor of Emergency Medicine

Oregon Health & Science University School of Medicine

April 28, 2006

Dear Community Leader:

Oregon Health & Science University would like to encourage the public to attend one of several upcoming community meetings to discuss a clinical trial that may be conducted in the Portland-metropolitan area.

OHSU is part of the National Institutes of Health-funded Resuscitation Outcomes Consortium (ROC). The consortium comprises 11 regional health centers across the United States and Canada that are conducting clinical trials to find promising scientific and clinical advances to improve resuscitation outcomes.

ROC will consist of multiple studies during the course of several years, testing new or alternative drugs, tools and techniques. OHSU will work directly with emergency medical services (EMS) agencies and hospitals in Multnomah, Clackamas, Washington and Clark counties to conduct this important research.

The goal of the first ROC study is to determine whether a different type of intravenous resuscitation fluid than usual, given at the scene of an accident to individuals with severe bleeding or life-threatening head injuries, can improve their outcomes.

Because individuals eligible for this study will be unable to provide informed consent due to the nature of their injuries, the study will be conducted under Food and Drug Administration regulations that allow research in certain life-threatening situations without authorization. The federal regulations that allow this waiver of consent require community notification to ensure the public is aware of the study.

The following community meetings will allow the public a chance to ask questions and share their opinions about the study:

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- **Tuesday, May 9, 7 p.m. at the Washington County Public Services Building Auditorium, 155 N. First Ave., Hillsboro**
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- **Monday, May 15, 7 p.m., at the Clackamas County Fire District #1 Oak Lodge Station 3, 2930 S.E. Oak Grove Blvd., Milwaukie**

I would appreciate it if you could share this information with your neighborhood association members. For more information about the study, visit [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc) and share your opinions about the study by filling out a short survey. If you are interested in scheduling a presentation at an upcoming meeting, please call Denise Griffiths at 503 494-7015. Enclosed please find a short article that could be included in your newsletter.

Sincerely,  
Jerris Hedges, M.D.  
Co-Principal Investigator  
Vice dean  
Professor of Emergency Medicine  
Oregon Health & Science University School of Medicine

QuickTime™ and a  
Photo - JPEG decompressor  
are needed to see this picture.

May 2,

2006

Contact: Liana Haywood, 503 494-8231; [haywoodl@ohsu.edu](mailto:haywoodl@ohsu.edu)

## **OHSU SEEKS COMMUNITY INPUT ON STUDY TO IMPROVE SURVIVAL FROM TRAUMATIC INJURIES**

*Study is part of a national consortium to find the best methods for resuscitation outcomes at the site of injury*

**PORTLAND, Ore.** – Oregon Health & Science University is part of the National Institutes of Health-funded Resuscitation Outcomes Consortium (ROC). This group of 11 regional medical centers across the United States and Canada seeks to find promising scientific and clinical advances to improve survival from cardiac arrest and severe trauma.

The ROC will consist of multiple studies during the course of several years, testing new or alternative drugs, tools and techniques. OHSU will work directly with emergency medical services (EMS) agencies and hospitals in Multnomah, Clackamas, Washington and Clark counties to conduct this important research.

The current standard of care for treating people with traumatic injuries in the field is to intravenously administer saline (water with the same salt content as blood). The first ROC study will determine whether hypertonic saline (water containing more salt than blood) or hypertonic saline with dextran (an added sugar molecule) will improve survival or brain function recovery. It is believed hypertonic saline will allow blood flow to be restored with a smaller amount of fluid than regular saline, which will avoid overcrowding blood vessels and reduce inflammation following injury.

Because individuals eligible for this study will be unable to provide informed consent due to the nature of their injuries, the study will be conducted under Food and Drug Administration regulations that allow research in certain life-threatening situations without authorization. The federal regulations that allow this waiver of consent require community notification to ensure the public is aware of the study. To that end, OHSU will hold four community meetings, one in each county where the study will take place, to offer the public a chance to ask questions and share their opinions about the study. (See meeting dates at the end of the release.)

“We are dedicated to finding the best ways to handle medical emergencies, and the only way to do this is to actually try experimental procedures in the field. Only then will we know what the best procedures are,” said Jerris Hedges, M.D., OHSU’s principal investigator, professor of emergency medicine and vice-dean in the OHSU School of Medicine.

To be eligible for the study, subjects must have severe injuries with either low blood pressure or an altered mental state. OHSU expects most eligible subjects to be involved in motor vehicle accidents. Women with an obvious pregnancy and individuals under arrest at the time of the accident will not be enrolled.

Following a traumatic accident, EMS will arrive on the scene and determine whether the individuals involved meet the criteria for the hypertonic saline study. If they do, EMS will start an intravenous (IV) delivery of

saline. EMS agents will not know whether they are providing regular saline or hypertonic saline. All bags will be bar-coded and scanned so it can be determined later whether the individual received the study solution. If the patient needs more fluid before arriving at the hospital, EMS agents will provide regular saline. No one will receive more than one bag (equal to one cup) of hypertonic saline. Subjects enrolled in the study, and their family members, will be informed of their participation as soon as possible.

“Patient safety is our highest concern. All study protocols will be reviewed before implementation by an independent panel of scientists chosen by the NIH, but not participating in the study design. Each community also will perform its customary review of the study protocols before implementation,” said Mohamud Daya, M.D., OHSU study investigator and associate professor of emergency medicine in the OHSU School of Medicine. “Finally, a second independent panel of scientists (Data and Safety Monitoring Board) will monitor each trial for safety purposes.”

Recent studies of hypertonic saline and hypertonic saline with dextran done in Australia, Canada and the United States have shown no adverse reactions from the treatment, but have all been too small to draw definitive conclusions. The group of medical centers working together as part of the ROC will allow more people to be studied across rural and urban settings. The ROC will provide the necessary infrastructure to conduct multiple collaborative trials to aid rapid translation of promising scientific and clinical advances to improve resuscitation outcomes.

The sooner treatment can be provided following an accident, the better the rate of survival. The ROC will allow EMS providers to study proposed new treatments for traumatic injuries at the scene of an accident, where people are most likely to benefit from them. OHSU hopes to begin enrolling patients in the hypertonic saline study this summer.

The community meetings will be held:

**Monday, May 8, 7 p.m. at the Southwest Washington Medical Center Health Education Center, 600 N.E 92<sup>nd</sup> Ave., Vancouver, Wash.**

**Tuesday, May 9, 7 p.m. at the Washington County Public Services Building Auditorium, 155 N. First Ave., Hillsboro**

**Wednesday, May 10, 7 p.m. at the OHSU Auditorium (old library building), 3181 S.W. Sam Jackson Park Road, Portland**

**Monday, May 15, 7 p.m., at the Clackamas County Fire District #1 Oak Lodge Station 3, 2930 S.E. Oak Grove Blvd., Milwaukie**

The community may learn more information about the ROC and the hypertonic saline study by visiting [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc) where they are encouraged to fill out a short survey, or by calling study coordinator Denise Griffiths at 503 494-7015 or 888 370-2888.

## **LOCAL INVESTIGATORS PROCEED WITH STUDY TO IMPROVE SURVIVAL FROM TRAUMATIC INJURY**

Local investigators have received approval to move forward with a study that aims to determine whether a type of resuscitation fluid that is different from normal saline can improve survival rates in severely injured people. The study is the first of multiple studies OHSU-led investigators from local EMS agencies and hospitals will conduct in partnership with the National Institutes of Health-funded Resuscitation Outcomes Consortium (ROC). The planned start date is November 1, 2006.

The current standard of care for treating people with traumatic injuries in the field is to intravenously administer saline (water with the same salt content as blood). This study will determine whether hypertonic saline (water containing more salt than blood) or hypertonic saline with dextran (an added sugar molecule) will improve survival or brain function recovery. It is believed that hypertonic saline will allow blood flow to be restored with a smaller amount of fluid than regular saline, thereby reducing overexpansion of blood vessels and reducing inflammation following injury.

Individuals eligible for this study will have suffered serious injuries, and will therefore be unable to provide informed consent. Because of this, the study will be conducted under Food and Drug Administration (FDA) regulations that allow treatment research in certain life-threatening situations without the individual's consent before treatment is started.

As part of the FDA regulations allowing exception to informed consent studies, the investigators were required to conduct a campaign to notify and consult with the community about the study. That campaign included random phone surveys, public meetings in each of the four participating counties, ads in local newspapers, letters sent to neighborhood associations and elected officials, a news release to local media that generated news coverage, and presentations at meetings of minority and other community organizations.

The study was reviewed and approved by an independent panel of scientists chosen by the NIH, but not participating in the study design. The FDA approved the study and will continue to monitor it for safety purposes. Locally, groups called Institutional Review Boards (IRBs) are required to review and approve these studies following the community consultation campaign. IRB's of OHSU, Legacy Emanuel Hospital, Southwest Washington Medical Center and Multnomah County and Oregon State Public Health all reviewed and approved the hypertonic saline study.

To be eligible for the study, subjects must have severe injuries with either low blood pressure or an altered mental state due to head injury. Most eligible subjects will have been injured as a result of motor vehicle crashes. Women who are obviously pregnant, children, and individuals under arrest at the time of the incident will not be enrolled.

Any community member who does not want to be included in this hypertonic saline study, or in future ROC studies that are carried out without individual advanced informed consent, can obtain a bracelet allowing them to opt out of all such studies. The bracelet will resemble a medical alert bracelet, and paramedics in the four participating counties will be trained to look for them. To obtain a bracelet, call OHSU study coordinator Denise Griffiths at 503 494-7015.

More information about the Resuscitation Outcomes Consortium and the hypertonic saline study can be found at [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc)



Date: October 16, 2006

Contact: Tamara Hargens, 503 494-8231; hargenst@ohsu.edu

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**WHO:** Researchers and emergency medicine providers representing Oregon Health & Science University and Legacy Emanuel trauma departments; as well as Portland-metro and Vancouver, Wash., emergency medical services and fire district providers will be in attendance.

**WHERE:** The Governor Hotel, 614 S.W. 11<sup>th</sup> Ave., Portland

**WHEN:** Tuesday, Oct. 17, 11 a.m.

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## **OHSU PROCEEDS WITH STUDY TO IMPROVE SURVIVAL FROM TRAUMATIC INJURIES**

*Study is part of a national consortium to find the best methods for resuscitation outcomes at the site of injury*

**PORTLAND, Ore.** – Oregon Health & Science University has received approval to move forward with a study that aims to determine whether a different type of resuscitation fluid than normal saline can improve survival rates in severely injured people. The study is the first as part of OHSU's partnership in the National Institutes of Health-funded Resuscitation Outcomes Consortium (ROC).

ROC is a group of 11 regional medical centers across the United States and Canada seeking to find promising scientific and clinical advances to improve survival from cardiac arrest and severe trauma. The ROC will consist of multiple studies during the course of several years, testing new or alternative drugs, tools and techniques. OHSU will work directly with EMS agencies and hospitals in Multnomah, Clackamas, Washington and Clark counties to conduct this important research.

The current standard of care for treating people with traumatic injuries in the field is to intravenously administer saline (water with the same salt content as blood). This study will determine whether hypertonic saline (water containing more salt than blood) or hypertonic saline with dextran (an added sugar molecule) improves survival or brain function recovery. It is believed that hypertonic saline will allow blood flow to be restored with a smaller amount of fluid than regular saline, thereby reducing overexpansion of blood vessels and reducing inflammation following injury.

The individuals eligible for this study will be severely injured, and therefore unable to provide informed consent. Because of this, the study will be conducted under Food and Drug Administration (FDA) regulations that allow research of emergency treatments in certain life-threatening situations without the patient's pretreatment consent.

As part of the FDA regulations allowing exception to informed consent studies, OHSU was required to conduct a campaign to notify and consult with the community about the study. That campaign included random phone surveys, public meetings in each of the four participating counties, ads in local newspapers, letters sent to neighborhood associations and elected officials, a news release to local media that generated news coverage, and presentations at meetings of minority and other community organizations.

The study was reviewed and approved by an independent panel of scientists chosen by the NIH, but not participating in the study design. The FDA approved the study and will continue to monitor the study for safety purposes. Locally, groups called Institutional Review Boards (IRBs) are required to review and approve these studies following the community consultation campaign. IRBs of OHSU, Legacy Emanuel Hospital, Southwest Washington Medical Center and Multnomah County and Oregon State Public Health all reviewed and approved the hypertonic saline study.

“We undertake this study after intense local and national review. The results of the study will likely guide the future choice of resuscitation fluid to be used by paramedics across all of North America,” said Jerris Hedges, M.D., principal investigator, Greater Portland ROC site, professor of emergency medicine and vice dean in the OHSU School of Medicine.

To be eligible for the study, subjects must have severe injuries with either low blood pressure or an altered mental state due to head injury. OHSU expects most eligible subjects to be injured as a result of motor vehicle crashes. Women who are obviously pregnant, children 14 and under, and individuals under arrest at the time of the incident will not be enrolled.

Following a traumatic injury, emergency medical services personnel (paramedics) will arrive on the scene and determine whether the individuals involved meet the criteria for the hypertonic saline study. If they do, paramedics will start an intravenous (IV) delivery of a resuscitation fluid. Paramedics will not know whether they are providing regular saline, hypertonic saline or hypertonic saline with dextran. All bags will be bar-coded and scanned so it can be determined later whether the individual received one of the study solutions. If the patient needs more fluid before arriving at the hospital, paramedics will provide additional regular saline. No one will receive more than one small bag (about one cup) of hypertonic saline. Subjects enrolled in the study, and their family members, will be informed of their participation as soon as possible.

“We are dedicated to finding the best ways for our local paramedics to treat emergencies, and the only way to do this is to actually test experimental procedures in the field. Only then can we determine the best procedures,” said Hedges.

Any community member who does not want to be included in this hypertonic saline study, or in future ROC studies that are carried out without individual advanced informed consent, can obtain a bracelet that gives them the choice to opt out of all such studies. The bracelet will resemble a medical alert bracelet, and paramedics in the four participating counties will be trained to look for them and exclude any person, wearing this bracelet, from the study. To obtain a bracelet, call OHSU study coordinator Denise Griffiths at 503 494-7015.



## News and Information

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More information about the Resuscitation Outcomes Consortium and the hypertonic saline study can be found at [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc)

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22-June-2006

**Portland RCC Summary of Open Community Meetings:**

**Date: May 8, 2006**

**Location: Southwest Washington Medical Center (SWMC) in Clark County**

Attendees: 4 members of the research team, 1 member of the Multnomah County Public Health IRB, 1 member of the SWMC IRB, 1 member of the OHSU IRB, 2 members of Vancouver Fire, 1 member of TVF&R, 1 member of Clark Regional Emergency Services Agency (CRESA), 6 members from the community.

Dr. Hedges gave a 45 minute presentation on the trauma system in the Portland/Vancouver area, the ROC and the Hypertonic Saline Study. After the presentation, there was a question and answer session of approximately 1 hour. There were some very good questions:

- 1) Are the fluids being used in Iraq?
- 2) Why is enrollment only for ages  $\geq 15$  yrs?
- 3) Are there current fluids being used now for head injured patients that help decrease swelling, such as mannitol?
- 4) The patient will get only one bag of the fluid?
- 5) Are there diabetic issues with the Dextran? What about high blood pressure?
- 6) Why are you studying both the HSD and the HS?
- 7) Will comparing this number of fluids slow down the results of the study?
- 8) How long will the study run?
- 9) What about particular groups who do not want EMS treatment? How will this affect them?
- 10) Have there been any adverse events or side effects ever in using these fluids?
- 11) Who's funding this research?
- 12) Can a patient withdraw from the study after they've been informed of being enrolled?
- 13) Will the website be updated continuously with changes and/or new information?

**Concerns:**

There was one person who voiced her concern about not being able to consent to be enrolled into the study. However, she felt the study was important and had no other suggestions on how to do this differently. She did mention having a way to opt out, for those who would not want to be enrolled, would be a good idea. Overall, the group was positive about the study.

**Other Suggestions:**

There were suggestions on other ways to get the information out to members of the community. Those were to contact neighborhood association presidents who have ways to get this out to all members in their neighborhood. Placing ads in student newspapers at local colleges.

22-June-2006

**Date: May 9, 2006**

**Location: Public Health Services Building in Washington County**

Attendees: 4 members of the research team, 1 member of the Multnomah County Public Health IRB, 1 member of the OHSU IRB, 1 member of TVF&R, 1 member of Washington County EMS, 2 members from the community.

Dr. Hedges gave a 45 minute presentation on the trauma system in the Portland/Vancouver area, the ROC and the Hypertonic Saline Study. After the presentation, there was a question and answer session of approximately 30 minutes.

Questions:

- 1) Will some people get standard treatment, some get HS and some get HSD?
- 2) Who is going to be carrying the fluids?
- 3) How long will the study run?
- 4) Is there a specific number of patients you need to enroll?
- 5) Can a family member opt out for the patient?
- 6) What defines a family member?
- 7) Are there religious groups that have issues with this study?
- 8) How many people will be enrolled in the Portland/Vancouver area?
- 9) Are you meeting with minority groups such as Asian and Hispanics?
- 10) If some one does not want to be in the study, how can they opt out?

Concerns:

No concerns about the study. Of the two members from the community, both seemed positive about the study moving forward.

**Date: May 10, 2006**

**Location: Oregon Health & Science University, Old Auditorium**

Attendees: 3 members of the research team, 1 member of the Multnomah County Public Health IRB, 1 member of the OHSU IRB, 1 member from the community.

Dr. Daya gave a 45 minute presentation on the trauma system in the Portland/Vancouver area, the ROC and the Hypertonic Saline Study. After the presentation, there was a question and answer session of approximately 30 minutes.

Questions:

- 1) When does the patient stop receiving the study fluid?
- 2) Who determines if a patient gets the study fluid?
- 3) How will they know which patient will get the fluid?
- 4) Is there any worry at all that the HS fluid is no better than the current treatment?
- 5) How long will the study run and how many subjects are anticipated to be enrolled?
- 6) Have other sites started this study?
- 7) How often will you look at the data to see if one fluid is better than another?

22-June-2006

Concerns:

Overall, the one member of the community who attended felt good about the study, but she felt the fluid should be given to all trauma patients and not just those that would meet the inclusion criteria. She was not comfortable with the fact that some patients would get it and others wouldn't.

**Date: May 15, 2006**

**Location: Clackamas County Fire District #1, Oak Grove Station 3**

Attendees: 3 members of the research team, 2 member of the Multnomah County Public Health IRB, 1 member of the OHSU IRB, 3 members from the community.

Dr. Hedges gave a 45 minute presentation on the trauma system in the Portland/Vancouver area, the ROC and the Hypertonic Saline Study. After the presentation, there was a question and answer session of approximately 40 minutes.

Questions:

- 1) How do the paramedics know if the patient should be enrolled?
- 2) When do you anticipate starting the study?
- 3) What happens if the majority of the community is not in favor of the study?
- 4) Is there usually a better turn out for these open forums?
- 5) What other studies have gone through this process?
- 6) How much time does it take for the medics to assess the patient before they are enrolled and given the fluid?
- 7) Is there a limit to other fluids given prior to a patient getting the study fluid?
- 8) How long does it take the medics to figure out age and weight of an adolescent before the can be enrolled into the study?
- 9) What kind of response have you received from the EMS community?
- 10) Some of the slides seem a little too technical for the lay community. Can these be changed a bit to make it more understandable, such as what an IRB is?

October 16, 2006

Dear Community Leader:

You recently received a letter from Oregon Health & Science University detailing a proposed clinical trial to be conducted on severely injured people at the scene of the injury. We greatly appreciate the opportunity we have had to discuss this study with you. We acknowledge that the Hidden Springs Neighborhood Association has voiced concerns regarding studies done using the FDA-guidelines for exception to informed consent. After receiving input and creating a practical mechanism for individuals to opt out of the study, should they so desire, the ROC investigators will move forward with the study here and at other North American ROC sites.

The investigators are part of the National Institutes of Health-funded Resuscitation Outcomes Consortium (ROC). The consortium comprises 11 regional health centers across the United States and Canada conducting clinical trials to find promising scientific and clinical advances to improve resuscitation outcomes. ROC will consist of multiple studies during the course of several years, testing new or alternative drugs, tools and techniques. The investigative team, affiliated with emergency medical services (EMS) agencies and hospitals in Multnomah, Clackamas, Washington and Clark counties, will conduct this important research starting November 1, 2006.

The goal of the first ROC study is to determine whether a type of intravenous resuscitation fluid that is different from fluid usually given at the scene of a traumatic injury to individuals with severe bleeding or life-threatening head injuries can improve their outcomes.

Individuals eligible for this study will have suffered serious injuries, and will therefore be unable to provide informed consent. Because of this, the study will be conducted under Food and Drug Administration (FDA) regulations that allow treatment research in certain life-threatening situations without the individual's consent before treatment is started.

As part of the FDA regulations allowing exception to informed consent studies, the OHSU-led investigative team was required to conduct a campaign to notify and consult with the community about the study. That campaign included random phone surveys, public meetings in each of the four participating counties, ads in local newspapers, letters sent to neighborhood associations and elected officials, a news release to local media that generated news coverage, and presentations at meetings of minority and other community organizations.

Any community member who would prefer not to be part of this or other exception to informed consent studies can obtain a bracelet that gives them the choice to opt out of all such studies. The bracelet will resemble a medical alert bracelet, and EMS personnel in the four participating counties will be trained to look for them and exclude any person, wearing this bracelet, from the study. To obtain a bracelet, call OHSU study coordinator Denise Griffiths at 503 494-7015.

I would appreciate it if you could share this information with your neighborhood association members. For more information about the study, visit [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc).

Sincerely,  
Jerris R. Hedges, M.D.

Principal Investigator, Greater Portland ROC site  
Vice Dean, School of Medicine  
Professor of Emergency Medicine  
Oregon Health & Science University

December 19, 2006

You have requested an opt-out bracelet from the Hypertonic Saline prehospital study. Enclosed is your opt-out bracelet.

The bracelet resembles a medical alert bracelet, and EMS personnel in the four participating counties (Clark, Clackamas, Multnomah and Washington) have been trained to look for them and exclude any person wearing this bracelet from the study.

The study is scheduled to begin January 2<sup>nd</sup>, 2007. The study will go for approximately 18 to 24 months. We will send you a letter to let you know the study has ended so you know when you can stop wearing the bracelet.

For more information about the study please contact us at [roc@ohsu.edu](mailto:roc@ohsu.edu); 503-494-7015 or visit our local website at [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc).

Sincerely,

ROC Study Team  
Department of Emergency Medicine  
Oregon Health & Science University

October, 2006

Dear Elected Official:

You recently received a letter from me about a proposed Oregon Health & Science University clinical trial to be conducted on severely injured people at the scene of the injury. I wanted to let you know that OHSU has received approval to move ahead with the study and the planned start date is November 1, 2006.

OHSU is the lead local entity in the National Institutes of Health-funded Resuscitation Outcomes Consortium (ROC). The consortium comprises 11 regional health centers across the United States and Canada conducting clinical trials to find promising scientific and clinical advances to improve resuscitation outcomes. ROC will consist of multiple studies during the course of several years, testing new or alternative drugs, tools and techniques. OHSU will work directly with emergency medical services (EMS) agencies and hospitals in Multnomah, Clackamas, Washington and Clark counties to conduct this important research. Collaborative investigators from many local hospitals will assist with the studies.

The goal of the first ROC study is to determine whether a type of intravenous resuscitation fluid that is different from the fluid usually given at the scene of a traumatic injury to individuals with severe bleeding or life-threatening head injuries can improve their outcomes.

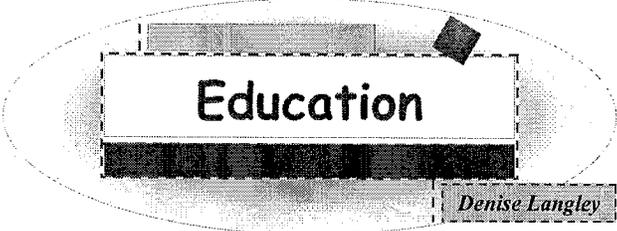
Individuals eligible for this study will have suffered serious injuries, and will therefore be unable to provide informed consent. Because of this, the study will be conducted under Food and Drug Administration (FDA) regulations that allow treatment research in certain life-threatening situations without the individual's consent before treatment is started.

As part of the FDA regulations allowing exception to informed consent studies, OHSU was required to conduct a campaign to notify and consult with the community about the study. That campaign included random phone surveys, public meetings in each of the four participating counties, ads in local newspapers, letters sent to neighborhood associations and elected officials, a news release to local media that generated news coverage, and presentations at meetings of minority and other community organizations.

Any community member who would prefer not to be part of this or other exception to informed consent studies can obtain a bracelet that gives them the choice to opt out of all such studies. The bracelet will resemble a medical alert bracelet, and EMS personnel in the four participating counties will be trained to look for them and exclude any person, wearing this bracelet, from the study. To obtain a bracelet, call OHSU study coordinator Denise Griffiths at 503 494-7015.

I hope this letter provides you with the information you need in the event your constituents contact you regarding this study. Please contact me directly if you would like to discuss this study and its implications for our community. To learn more about the study, visit [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc)

Sincerely,  
Jerris R. Hedges, M.D.  
Principal Investigator, Greater Portland ROC site  
Vice Dean, School of Medicine  
Professor of Emergency Medicine  
Oregon Health & Science University



## Education

Denise Langley

# Press Release

## OHSU STUDY TO IMPROVE SURVIVAL FROM TRAUMATIC INJURIES BEGINS

*Study is part of a national consortium to find the best methods for resuscitation outcomes at the site of injury*

**PORTLAND, Ore.** – A study to determine whether a different type of resuscitation fluid than normal saline can improve survival rates in severely injured people will begin in the Portland metropolitan area this month. The study is the first as part of OHSU's partnership in the National Institutes of Health-funded Resuscitation Outcomes Consortium (ROC).

The study was delayed so all hospitals in the consortium which could potentially receive subjects enrolled in the study could further standardize monitoring procedures. The Food and Drug Administration (FDA) asked that all hospitals have someone familiar with the study on staff and that sodium levels of enrolled subjects be checked regularly after admission.

The current standard of care for treating people with traumatic injuries in the field is to intravenously administer saline (water with the same salt content as blood). This study will determine whether hypertonic saline (water containing more salt than blood) or hypertonic saline with dextran (an added sugar molecule) improves survival or brain function recovery. It is believed that hypertonic saline will allow blood flow to be restored with a smaller amount of fluid than regular saline, thereby reducing overexpansion of blood vessels which might worsen bleeding or swelling and by reducing inflammation following injury.

The individuals eligible for this study will be severely injured, and therefore unable to provide informed consent. Because of this, the study will be conducted under FDA regulations that allow research of emergency treatments in certain life-threatening situations without the patient's pretreatment consent.

The study was reviewed and approved by an independent panel of scientists chosen by the NIH, but not participating in the study design. The FDA approved the study and will continue to monitor the study for safety purposes in conjunction with local Institutional Review Boards (IRBs).

"We undertake this study after intense local and national review," said Jerris Hedges, M.D., principal investigator, Greater Portland ROC site, professor of emergency medicine and vice dean in the OHSU School of Medicine. "The results of the study will likely guide the future choice of resuscitation fluid to be used by paramedics across all of North America. The potential benefit to citizens of the greater Portland area and beyond is great."

To be eligible for the study, subjects must have severe injuries with either low blood pressure or an altered mental state due to head injury. OHSU expects most eligible subjects to be injured as a result of motor vehicle crashes. Women who are obviously pregnant, children 14 and under, and individuals under law enforcement arrest at the time of the incident will not be enrolled.

Any community member who does not want to be included in this hypertonic saline study, or in future ROC studies that are carried out without individual advanced informed consent, can obtain a bracelet that opts them out of all such studies. The bracelet resembles a medical alert bracelet, and paramedics in the four participating counties are trained to look for them and exclude any person wearing this bracelet from the study. To obtain a bracelet, email [roc@ohsu.edu](mailto:roc@ohsu.edu) and provide your full name and mailing address.

More information about the Resuscitation Outcomes Consortium and the hypertonic saline study can be found at [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc).

PC  
Answer:

**Interventional radiology procedure for  
clot retrieval may be considered.**

# PULSE CHECK



PC  
Question:

**What intervention other than tPA can be done for stroke patients with symptom onset less than 8 hours?**

## NEWS, NOTES & REMINDERS

### CALENDAR

- **January 3**  
PSN Training Onsite
- **Jan 2 & 5**  
**0700 & 1500**  
ED Staff Meetings
- **January 28-31**  
24th Annual NW Winter Conference in Emergency Medicine - Sunriver

### ED Staff Meetings

There are four scheduled staff meetings next week. Important information will be shared about some changes coming up in January.

### PHONE / ADDRESS UPDATE

A new printout of staff phone numbers was put in the Schedule Book today. If you have changed your number and updated it with HR it should be current on the new list. If not, please send an e-mail to "address change" and submit the current information.

### 24th Annual Northwest Winter Conference in Emergency Medicine

Sunriver, Oregon  
January 28-31, 2007

Conference details and online registration:  
[www.ocep.org](http://www.ocep.org)

The goal of this year's conference is to provide practitioners of emergency medicine with the latest information on current concepts and emerging trends in emergency care. This year's conference will concentrate on the diagnosis and management of emergency conditions in the fields of toxicology, trauma, ophthalmology, stroke, and brain injury, as well as updates on epidemiology, wilderness medicine, emergency sedation and analgesia, and orthopedics.

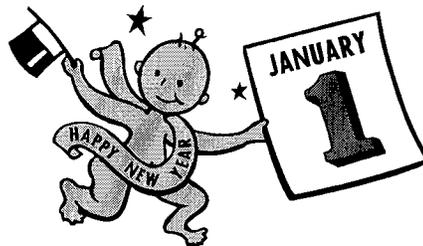
### CONFERENCE SCHEDULE

Doernbecher Auditorium, 11th floor Jan 3, 2006		
7:00	Trauma Conference	
8:00	M&M	DeTorio Huh West
9:00	First Trimester Disorders	Mashkuri
10:00	Abdominal Trauma - Blunt and Penetrating	Palmer
11:00	Board Review - GI Emergencies	Daya O'Connor
12:00	Sick Cell Disease	Ismach

### ROSE AWARDS



Kirsten Borglum  
Ed Palmer  
Holly Eller  
Pat O'Dea  
Jennifer Ehlers  
Patrick Hickey  
Courtney Cambreleng (3)



### Emergency Communication Center

#### STATS

Dec 21, 2006 to Dec 27, 2006

Ambulance Patients	- 166
EMS Consults (by MD)	- 57
Total requests to call MD	- 720
Avg time for ECC to handle	- 01:25
Total physicians paged	- 745
Total time for call returns	- 06:56
Transfer patients	119
Trauma Entries	65

This Week

From Judi

## Greetings, All -

I am delighted to announce that Makenzy Byrum will be assuming Janie's position as our ED Internship Coordinator. In her new role Makenzy will be assuming responsibility for the orientation of our newly hired staff, the placement of our many students and also for being OHSU's representative to our local ENA Consortium. She will begin her orientation immediately - please join me in congratulating her and welcoming her to her new role.

Also stepping up to assist us will be Mirinda Miller who has almost completed her graduate nursing degree. She will assist Denise and I in the tracking of your annual competencies and education requirements and she will serve as a departmental representative to several of our EPIC workgroups. I am sincerely grateful to both Makenzy and Mirinda for their interest in providing this support to our department.

As delighted as I am about this announcement, I am as sincerely saddened to acknowledge that today really is Kit's last day in our department. Kit has been such an invaluable and unique resource to both the OHSU and our greater community - to say that his shoes can be filled by no other is an absolute truth. That is, at least, in Kit's way - his possessed compilation of intellect, personality and skill is truly one of a kind and we have all been so fortunate to have had the opportunity to learn from and enjoy him.

Kit's long list of accomplishments includes being the leader of the automation of our department. From the initial implementation of EmStat, to the addition of modules over the years to our ultimate implementation of CPOE and Nurse Doc last Spring, Kit's leadership and skill established and sustained our identity as one of our organization's leaders in electronic implementation.

Kit's skills in the area of information technology also had influence beyond the boundaries of our department. He was a pioneer in bringing Geographic Information Systems to OHSU and incorporating them into our daily operations.

His understanding of geographically referenced information supported the establishment and subsequent movement of our trauma line and our involvement with the CDC on many projects related to disease outbreak and tracking. Most recently he has been involved in efforts to establish OHSU as a pilot hospital for Biosense - a behind the scenes software program supported by the federal government that assists in the early identification of disease-specific or bioterrorism events.

Kit's vision and innovation also led to the creation of our Emergency Communications Center. In it's multiple roles (Trauma Communications, Regional Hospital, Transfer Center and Medical Resource Hospital) our Comm Center operates under the highest quality standards and has been nationally recognized. We are a leader in disaster preparedness in our region and the reliability of our Comm Center lays the foundation for our entire community's response.

Kit's work for the Department of Emergency Medicine has also had influence along many lines. He was the first database administrator for the department and participated in multiple research and quality improvement efforts. The Resuscitation Outcomes Consortium (ROC) that is now embarking on a multi-center trial, benefited from his insight and direction in implementing their epidemiologic data system, purchasing and setting up the ROC server and hiring their data manager.

Most of all, Kit was a great friend to all of us. He has been described as an "experienced and familiar face in our department, unflappable under a multitude of tense situations and problems". "A wonderful friend, teacher and colleague whom we are all sad to see go and whom we will all miss greatly".

He certainly was a best buddy of mine who taught me something about something every time we spoke. My career is richer for knowing him and I will miss him always as I know will all of you.

In closing, the poem on the previous page for Kit....our skillful seafarer off to sail the winds of life.

- Judi

### Average Daily Patient Census in the ED Dec 21 - Dec 27

99

#### NURSING OPPORTUNITIES

Website for the current RN openings:  
[www.OHSUnursing.com](http://www.OHSUnursing.com).

In-Unit positions are posted in the Staff lounge hallway.

#### TIMEKEEPING NEWS

If your vacation request has been approved you can go ahead and make the entry into KRONOS, even if it's months away.

#### MEETING SCHEDULE 7:00 AM

ED Charge RN	- 1st Thurs
ED Staff	- 2nd Tues
CNA	- 3rd Thurs
HUC/Paramedic	- 4th Thurs, alternating

UBNPC - 1st Tues, 5-7:00 pm

The ED is a  
Fragrance-Free  
Zone

Editor: Sandy Huston  
[hustons@ohsu.edu](mailto:hustons@ohsu.edu)

**January 2, 2007**

## **OHSU STUDY TO IMPROVE SURVIVAL FROM TRAUMATIC INJURIES BEGINS**

*Study is part of a national consortium to find the best methods for resuscitation outcomes at the site of injury*

**PORTLAND, Ore.** –A study to determine whether a different type of resuscitation fluid than normal saline can improve survival rates in severely injured people will begin in the Portland metropolitan area this month. The study is the first as part of OHSU's partnership in the National Institutes of Health-funded Resuscitation Outcomes Consortium (ROC).

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“We undertake this study after intense local and national review,” said Jerris Hedges, M.D., principal investigator, Greater Portland ROC site, professor of emergency medicine and vice dean in the OHSU School of Medicine. “The results of the study will likely guide the future choice of resuscitation fluid to be used by paramedics across all of North America. The potential benefit to citizens of the greater Portland area and beyond is great.”

To be eligible for the study, subjects must have severe injuries with either low blood pressure or an altered mental state due to head injury. OHSU expects most eligible subjects to be injured as a result of motor vehicle crashes. Women who are obviously pregnant, children 14 and under, and individuals under law enforcement arrest at the time of the incident will not be enrolled.

Any community member who does not want to be included in this hypertonic saline study, or in future ROC studies that are carried out without individual advanced informed consent, can obtain

a bracelet that opts them out of all such studies. The bracelet resembles a medical alert bracelet, and paramedics in the four participating counties are trained to look for them and exclude any person wearing this bracelet from the study. To obtain a bracelet, email [roc@ohsu.edu](mailto:roc@ohsu.edu) and provide your full name and mailing address.

More information about the Resuscitation Outcomes Consortium and the hypertonic saline study can be found at [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc).

## Men's Wellness and Screening event deemed a success

Nearly 100 men attended the Legacy Men's Wellness and Screening event as compared to 40 in 2003, but let's hear from some of the men. Their comments included "friendly, relaxed setting," "informative lectures," "quick and efficient," and "well organized."

All attendees took advantage of the low-cost prostate and cardiac screenings and more than half received stroke risk mini-assessments.

Learning about men's health can be complex, but was made easier by free lectures, including prostate cancer by Michael Kaempf, M.D., cardiac risk factors by David Schroeder, M.D., and healthy eating by Marci Reed, dietitian. Men's health literature, including colorectal cancer prevention, also was available for free.

The fifth annual Men's Wellness and Screening was a collaborative effort among Legacy's Cancer Services, Heart Services and Comprehensive Stroke Program. Support comes from Good Samaritan Foundation, Emanuel Medical Center Foundation and Legacy Laboratory Services.

Thanks go to the 18 Legacy staff who helped with the men's event and to the Legacy Lab staff who processed the blood work. Paul Dorsey, genetics counselor, and Charlyn Wilson, R.N., Cancer Services, coordinated the event. ✖

Prostate cancer can kill. In fact, it's the No. 2 cause of cancer deaths in American men. About 218,890 new cases of prostate cancer in the U.S. will be diagnosed this year, and about 27,050 men will die of this disease. Especially at risk are African-Americans age 45 and older, men age 50 and older and any man with a family history of prostate cancer.

*The American Cancer Society*

## Oral cancer topic of free talk



R. Bryan Bell, M.D.,  
DDS, FACS

Nearly 31,000 Americans will be diagnosed with oral and oropharyngeal cancer this year. Early disease detection, public awareness and the latest advances in diagnosis, treatment and reconstruction are among the topics of the *free* community presentation, *Oral Cancer*. The speakers are R. Bryan Bell, M.D., DDS, FACS, and Katie Gavula, M.S., CCC-SLP, Legacy Rehabilitation Services. Wednesday, March 7, 7-8:30 p.m., Legacy Emanuel Hospital, MOB West. Call 503-335-3500 to register or for more information. ✖

## Saline trial studies survival rates of trauma patients

Legacy Clinical Research is participating in a National Institutes of Health (NIH) study to compare the pre-hospital administration of hypertonic saline to the current standard therapy of normal saline—in order to determine the affect of each saline therapy on the survival rate of trauma patients.

Most deaths that occur at accident scenes or within 48 hours of injuries result from extremely low blood pressure or severe brain injuries, which is why first responders give IV fluids to trauma victims. These fluids replace lost blood and support blood flow to vital organs.

Currently, normal or isotonic saline IV fluids are administered at the accident scene; however, some small studies indicate that the more highly concentrated dose of hypertonic saline could improve trauma patient survivals and outcomes—thus, the reason for the NIH study.

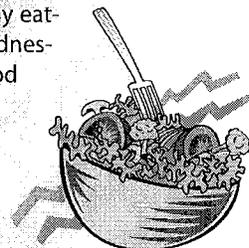
The NIH study works this way. Trauma patients and their families are notified of their participation in the study, as soon as feasible upon arrival at the hospital. Patients with life-threatening injuries most often aren't able to give their consent before receiving IV fluids in the field. Surveys show that more than 75 percent of the general public approves of this sort of waiver of consent when experimental treatments may improve their survival and outcomes.

However area residents who don't want to receive the experimental hypertonic saline therapy may *opt out* now. To alert first responders or others involved in their potential emergency care, they can receive a free medical ID bracelet specifying *no hypertonic saline* by sending an e-mail to roc@ohsu.edu.

The NIH study is being conducted in collaboration with OHSU and Southwest Washington Medical Center. ✖

### Heart Healthy Eating

Presented by Legacy Heart Services and Whole Foods Market, *Heart Healthy Eating* classes offer the latest information and tools for heart-healthy eating every day. The two classes are Wednesdays, 6-8 p.m., March 7 at Legacy Good Samaritan Hospital, and March 14 at Whole Foods. The cost is \$20, which includes a light meal provided at the second session. Call 503-335-3500 to complete the required registration.



# PULSE CHECK



**PC Question:** What two or three words work wonders?

## NEWS, NOTES & REMINDERS

### CALENDAR

- **July 17, 2006**  
CNA Retreat
- **July 27/28**  
ACLS Provider Course
- **July 28**  
ACLS Renewal Course

### CONFERENCE SCHEDULE

Doernbecher Auditorium, 11th floor  
**June 28, 2006**

7:00	Trauma	
------	--------	--

NO  
EMERGENCY  
MEDICINE  
CONFERENCES

Congratulations to the following physicians who this month celebrate the completion of their three-year Emergency Medicine Residency at OHSU:

Ryan Allen  
Nikolas Jones  
Kiran Beyer  
Ramsey Herrington  
Michael Kremkau  
Nathan Magaret  
Lesley Ogden  
Cathy Wang

### ACLS CERTIFICATION

The Department of Emergency Medicine will be conducting ACLS classes in July. Contact Mona Gonzales at 4-6993 or [gonzalem@ohsu.edu](mailto:gonzalem@ohsu.edu) if you are interested in signing up.

### MISSED E-MAILS

The disk failure of GroupWise post office RSCHPO1 earlier this week impacted the [address@ohsu.edu](mailto:address@ohsu.edu) mailbox which comes into HR Records. If any of you sent e-mails to that mailbox between 7:00 PM Friday and 5:30 a.m. Tuesday, please resend.

Congratulations to Dirk Devries, Emergency Transport Coordinator, upon the completion of his Master's studies in Technical Writing.

Dirk has diligently been pursuing his schooling over the past 15 years while working in the ED Communications Center.



### METRO'S HAZARDOUS WASTE EVENT

There's still time tomorrow to bring household items for proper disposal. Check out the website for details.

[http://ozone.ohsu.edu/greenteam/pages/event\\_hw.shtml](http://ozone.ohsu.edu/greenteam/pages/event_hw.shtml)

### ROSE AWARD WINNERS



Lu Painter  
Shelly Reeves  
Mercedes Wilson  
Laura Balmes  
Samantha Sinclair  
Kathleen Manseau  
Bonnie Jensen

### EMERGENCY MEDICINE CHAIR SEARCH

The Search Committee has invited three candidates to return for second interviews. The final three candidates are Robert O'Connor, Tom Aufderheide and John Ma.

### Emergency Communication Center

#### STATS

June 16, 2006 to Jun 22, 2006

Ambulance Patients	- 150
EMS Consults (by MD)	- 60
Total requests to call MD	- 681
Avg time for ECC to handle	- 00:56
Total physicians paged	- 711
Total time for call returns	- 06:22
Transfer patients	- 126
Trauma Entries	- 72

## NEWS, NOTES & REMINDERS, (CONT'D)

### RESEARCH STUDY

#### Hypertonic Resuscitation Following Traumatic Injury Study

Oregon Health & Science University is part of the National Institutes of Health-funded Resuscitation Outcomes Consortium (ROC). The consortium comprises 11 regional health centers across the United States and Canada that are conducting pre-hospital clinical trials to find promising scientific and clinical advances to improve resuscitation outcomes.

ROC will consist of multiple studies during the course of several years, testing new or alternative drugs, tools and techniques. OHSU will work directly with emergency medical services (EMS) agencies and hospitals in Multnomah, Clackamas, Washington and Clark counties to conduct this important research.

The goal of the Hypertonic Resuscitation Trial is to determine whether giving hypertonic saline fluid intravenously to pre-hospital patients with symptoms of severe bleeding or head injury in the field will improve their survival or neurologic recovery. Patients with injuries and either a low blood pressure or in shock will receive either 250cc of normal saline, hypertonic saline, or hypertonic saline with dextran.

Because individuals eligible for this study will be unable to provide informed consent due to the nature of their injuries, the study will be conducted under Food and Drug Administration regulations that allow research in certain life-threatening situations without authorization. The federal regulations that allow this waiver of consent require community notification to ensure the public is aware of the study.

For more information, please visit [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc) or call the study coordinator, Denise Griffiths, at 503 494-7015 with questions.

### EMSTAT / CPOE

- 1) ED Staff entering Imaging & Vascular lab orders in A2K, please include all details written by the MD in the EmStat order in A2K orders. This information is vital for the Imaging & Vascular Lab Techs to perform the correct study.
- 2) Medication Orders: Remember all medications in the EmStat medication list are listed by generic name with a few exceptions including Aspirin and Kayexalate. Please look for the generic medication name before entering a medication in the custom medication box.
- 3) There is a CPOE Leadership Meeting next Wednesday. Sherri would appreciate your feedback on how EmSTAT CPOE/NC is going in the ED.

### OVERTIME, MISSED MEAL, MISSED BREAK LOG

The purpose of this log is to document all overtime, missed meals and missed breaks. The Charge Nurse is to be notified by halfway through the shift about potential missed meals or missed breaks and will make a decision about what is to be done. The Charge Nurse is to be contacted during their active shift. The overtime, missed meal or missed break is to be entered on the log and initialed to signify that the Charge Nurse has been involved in the plan. The employee is to complete the clocking transaction by phone. Please do not put it on the online timekeeping correction form; this is a transaction that employees can handle by phone once the Charge Nurse has been involved. Periodic audits are done to check for compliance.

### CLOCKING TRANSACTIONS

Your clocking transactions need to occur in the department when you are ready to work and when you are ready to leave. Do not phone in from other areas.

### ED REGISTRATION - Joan Wild

As of July 1, 2006 the 'Genetic Opt Out' rule will be in effect. OHSU will be mailing the information to existing patients. ED Registration (Admitting) will be offering and obtaining the patient's signature for new patients to OHSU. ED Registration will handle this form in the same manner they currently do the NPP (Notice of Privacy Practice.) ED Clinical will want to include this form when sending the charts to HIS for scanning into LCR Web. The form will be an official document for the patient's visit.

### Co Payment Process Update!!

Here are 'OUR' numbers to date for June 2006

# of Orange Sheets placed	-	786
# of patients back to Reg	-	53
# of those patients that paid	-	27
Amount collected	-	\$1,355
# of letters mailed	-	436
# of payments received by mail	-	114
Amount received by mail	-	\$5,495
Total for June 06 so far!!	-	\$6,900

We have one more week to go and are about \$1,150 below last month at the same time - we definitely have time to meet and exceed May's total. A heartfelt thank you to all participants for their continuation in making this process successful.

Joan Wild  
ED Registration Manager

## Education

Denise Langley

### Eloped, AMA and EMTALA

What is the difference between discharging a patient out of EmStat as Eloped vs AMA? Does it matter which one you use? The answer may surprise you.

E  
L  
O  
P  
E  
D

. . . is when a patient leaves **prior** to being seen by an MD or NP. This is the patient who decides they no longer want to wait in the waiting room and slip out. This also applies to the patient who makes it back to a room and then leaves before a physician enters the room.

A  
M  
A

. . . occurs after a patient has been evaluated by a physician or NP, and then leaves against medical advise

There is a federal law (**EMTALA**) that dictates "The hospital shall take all reasonable steps to secure the individual's written informed consent to refuse such examination and treatment". It's not enough to document "left without being seen". Include "refused medical screening", "signed AMA", "refused to sign AMA".

What do you do if the patient asks about costs or their co-pay at Triage when deciding if they are going to be seen or not? **Any** discussion or signage relating to payment prior to the medical screening is an EMTALA violation.

Practice a scripted response and be truthful. "I understand you're concerned but the federal government states that I cannot talk to you about financial costs before your medical screening. After you have seen a doctor or nurse practitioner we can provide the phone number of someone to talk to about this and we understand your concerns."

Each EMTALA violation is subject to penalty of **\$50,000** and is not covered by the hospital's malpractice insurance.

#### CRITICAL LAB VALUES:

Read-back policy: The lab is required to call and report critical values to an RN or MD. They also have to provide their first and last name. On our end, we are required to **read back** the critical value reported, then provide our first and last name.

#### ADDITIONAL LAB INFORMATION:

Monday nights the ACCESS machine, which runs troponins, goes down for maintenance. This takes about an hour. The lab will call the Charge Nurse prior to the maintenance for coordination of patient care. During these times, a red top and a green top should be drawn if a troponin is needed. The red top can be sent to the VA by the lab for emergent troponin levels during down times.

#### PEDIATRIC TUBES:

There continues to be problems with troponins sent on pedi tubes. The lab cannot run these anymore. They result in false positives due to the fibrinogen levels in the tubes. Chemistry and CBC results take longer when sent in pedi tubes. There is more hands-on manipulation required, and different equipment used which all results in longer turn around times. Think twice about sending a pedi tube on children over 3 years.

**LAST LAB REMINDER** - The lab tracks improper ratios (INR/PTT), clotted samples, wrong tube, mislabeled, quantity not sufficient and hemolyzed specimens. One area we could improve is the improper ratios. Don't draw the INR/PTT first. There is a significant air pocket in those tubes and when drawn first they stop filling before the fill line. However, this is not a problem when they are drawn second, third or fourth.

**STEMI KIT:** A new "kit" option has been added to the Acute and Resus Pyxis. Along with the RSI meds, there is an option to select **STEMI kit**. It contains the following medications to choose from: aspirin, metoprolol, heparin, nitroglycerin, and plavix.

**NEW SCALE AT TRAIAGE:** The handles make it easier for unsteady folks to stand on the platform, the platform is larger with more foot room, and the high end range meets the needs of our bariatric patients. Remember to record all weights in kilograms.

**DISPOSAL THERMOMETERS:** You asked for it - you are getting it! New, **faster disposable thermometers for our Peds patients**. We trialed several brands and selected a better product. The thermometer goes to the VAC committee this month which, when approved, will bring the product into the hospital.

This Week

# In the ED



Words are sacred.  
 They deserve respect.  
 If you get the rights ones,  
 in the right order,  
 you can nudge the world a little.

- Tom Stoppard, British playwright

A couple of small, but very useful additions this week:

- ◆ A clock was added on the wall by the psych rooms; and,
- ◆ An extra light was added in the Point of Care testing area.

On Monday a film crew was producing a Spanish-language video following a "patient" from EMS into our ED and spending time in the Observation Unit. Dr Sabbaj had a starring role in the video.

We hosted a group of nurses and architects from Providence Everett, Washington on Tuesday. They're building a new ED and are doing site visits. They were particularly interested in our ED Observation Unit. Cassie gave them a tour and answered questions and the group spent time with Judi and Dr. Sabbaj.



Thanks to all the people on those days who made our visitors feel so welcome.

- Karen



## You Got Caught Caring



Lindsey Kleps, NP

Lindsey gives her patients undivided attention. When a patient complained about the coffee Lindsey took the time and her own money to make the patient as comfortable as possible by buying her a Starbucks cup of coffee. She went the extra mile to make her patient feel well cared for and comfortable.

### JUNE FOCUS

- T - Timely Team Work
- R - Rapid level assessment
- I - Initiate, Identify, Implement and Involve the triage service team
- A - Ask, Assess and Assign
- G - "Get and Go"
- E - Execute flow, Evaluate "waiters", Effectively work the lobby with Enthusiasm and Energy

Average Daily Patient  
 Census in the ED  
 Jun 15 - Jun 21

99

### NURSING OPPORTUNITIES

Website for the current RN openings:  
[www.OHSUnursing.com](http://www.OHSUnursing.com).

In-Unit positions are posted in the Staff lounge hallway.

### TIMEKEEPING NEWS

Pay Period 13 ends Sunday at midnight. Check your timecards. Matt has been working on recent KRONOS access problems. If they persist send him an e-mail with exact computer ID.

### MEETING SCHEDULE 7:00 AM

- ED Charge RN - 1st Thurs
- ED Staff - 2nd Tues
- CNA - 3rd Thurs
- HUC/Paramedic - 4th Thurs, alternating

UBNPC - 1st Tues, 5-7:00 pm

PC Answer: Thank you! *Good work!* I appreciate you! Great Job! You rock! Thanks a lot! WELL DONE! That was awesome! You're great! What a Team!

Editor: Sandy Huston  
[hustons@ohsu.edu](mailto:hustons@ohsu.edu)

>>>NewsBank -- service provider for Vancouver Columbian Archives <[newslibrary@newsbank.com](mailto:newslibrary@newsbank.com)> 06/23/06 3:36 pm  
>>>

Vancouver Columbian

Columbian, The (Vancouver, WA)

May 7, 2006

Experiment, study to use crash victims

Author: TOM VOGT, Columbian staff writer

Section: Clark County/region

Page: c1

Estimated printed pages: 3

Article Text:

Most people who participate in medical studies get a chance to weigh the pros and cons of a new drug or technique being used on them.

It's called informed consent. It's hard to get when an unconscious accident victim has been rescued from a crumpled car.

That's an issue Oregon Health & Science University researchers must deal with in a nationwide study that will involve people in Clark County with traumatic injuries.

Local paramedics and EMTs and regional hospitals also will participate.

Researchers want to know if a different type of saline solution, administered intravenously at an accident site, will improve survival or recovery of brain function.

The biggest thing we struggle with is giving enough fluid so you don't have an organ problem, said Roxy Barnes, the Vancouver Fire Department's administrator of emergency medical services.

If we give too much fluid, it causes swelling in the brain, which creates more problems with a brain injury. We have to give enough to keep the blood pressure up; but if we overshoot, there is the potential of causing more damage to the brain, she said.

The Food and Drug Administration allows research in some life-threatening situations without patient approval, but researchers must make sure the community is aware of the study.

OHSU will hold a community meeting Monday at Southwest Washington Medical Center to get public opinion. The session will be at 7 p.m. in the Health Education Center of the hospital, 600 N.E. 92nd Ave.

Similar meetings will be held in Multnomah, Clackamas and Washington counties, where OHSU also will conduct the research. The study, funded by the National Institutes of Health, includes 11 regional medical centers in the United States and Canada.

People with traumatic injuries now receive intravenous saline solution, which is water with the same salt content as blood about 0.9 percent.

We don't know if it is the best solution, said Dr. Mohamud Daya, an associate professor of emergency medicine at OHSU. We've done it for a long time.

But a small amount of data from human tests, and data from animal testing, suggests that a more concentrated solution 7.5 percent salt will give trauma victims a better chance of survival, he said.

It is believed the extra-salty, or hypertonic, saline will allow blood flow to be restored with a smaller amount of fluid than regular saline; it will avoid overcrowding blood vessels and also reduce inflammation.

With the normal fluid we use now, only a portion stays in the vascular space. A lot leaks out, Daya said. If I give 1,000 cc, maybe a quarter stays in the vascular space. With the hypertonic, I give less: 250 cc; that's like a cup of water.

At the same time, the extra-salty solution pulls fluid from cells into the blood vessel system, Daya said, so with 250 cc, you get the equivalent of 1,000 cc in the vascular space.

Drawing fluid away from tissues also helps people with traumatic brain injuries.

That actually reduces brain swelling, Daya said.

There also will be another version of the hypertonic saline. An added sugar molecule, dextran, seems to make the solution more effective.

To be eligible for the study, subjects must have severe injuries with either low blood pressure or an altered mental state. OHSU expects most eligible subjects to be involved in motor vehicle accidents. Pregnant women and individuals under arrest at the time of the accident will not be eligible.

If accident victims meet the criteria, emergency medical responders will start an intravenous delivery of saline from a supply designated for the study. Those not eligible will get a standard saline solution. All bags will be bar-coded.

No one will receive more than one bag of hypertonic saline. Subjects enrolled in the study, and their family members, will be informed as soon as possible.

The study is expected to begin in June.

Tom Vogt can be reached at 360-759-8008 or [tom.vogt@columbian.com](mailto:tom.vogt@columbian.com).

If you go

What: Community meeting to get public opinion on trauma study overseen locally by OHSU.

When: 7 p.m. Monday.

Where: Health Education Center at Southwest Washington Medical Center, 600 N.E. 92nd Ave.

Information: [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc) or call 888-370-2888.

# PULSE CHECK



PC  
Question:

What is Echolalia?

## NEWS, NOTES & REMINDERS

### CALENDAR

- **November 11, 2006**  
Fall Trauma Conference
- **October 23, 2006**  
ED Staff Meetings  
0700 and 1500
- **December 8, 2006**  
Emergency Department  
Winter Appreciation Event

### CONFERENCE SCHEDULE

Doernbecher Auditorium, 11th floor  
**Oct 25, 2006**

7:00	Trauma Conference	
8:00	M&M	Spiro Denninghoff Bryan Dente
9:00	Megacode	Spiro
10:00	Approach to Pediatric Fever	Meckler
11:00	Pediatric Literature Review	Disney
12:00	Chief Resident Update	Patel Torres

#### Downtime Notification for:

**Timekeeping (TACS to TTE) Conversion**  
Saturday, October 21, 2006, 9:00 - 9:30 am

Reason: Redirect timekeeping phone lines from the old TACS machines to the new TTE machines.

Impact: No access to the TACS system during this time.

#### OHSU Benefits of Upgrade:

We will double our total number of current available phone lines. The additional phone lines will eliminate the busy signals that some employees have experienced during peak clocking times.

The new system, called TTE (Time Telephone Entry) will also provide us with the ability to use new clock code functionality called transfer codes. Please see the updated clock code list posted in various locations in the department. You will notice, some of the existing clock codes have been changed and added to the transfer code list.

For example: clock code 60, previously identified as Doubleback is now transfer code 805. To clock Doubleback an employee first enters clock code 85 and then selects transfer code 805. The new transfer codes not only offer us more clocking flexibility, they will also reduce timekeeper intervention with employees working in multiple work rule capacities, and offer departments a greater ability to more accurately report and budget for specific types of hours.

#### FLU VACCINATIONS:

Employee Health is encouraging all employees to receive flu vaccines at clinics running Tuesdays and Wednesdays Oct. 10 – Nov. 8, 9 a.m. to 3 p.m. in Physicians' Pavilion room 140.

Employee Health is encouraging all employees to receive flu vaccines, not only for their own health but to minimize the risk of spreading the influenza virus to patients. This is important even if you are not in a direct patient care position.

Employee Health will offer flu clinics Tuesdays and Wednesdays from Oct. 10 through Nov. 8 for employee vaccinations. Flu clinics will be held from 9 a.m. to 3 p.m. in the Physicians' Pavilion room 140. Walk-in hours at the Employee Health offices are always Wednesdays from 7 a.m. to 4 p.m. in the Multnomah Pavilion 1SE.

### Emergency Communication Center

#### STATS

Oct 12, 2006 to Oct 19, 2006

Ambulance Patients	-	209
EMS Consults (by MD)	-	78
Total requests to call MD	-	876
Avg time for ECC to handle	-	01:23
Total physicians paged	-	889
Total time for call returns	-	08:36
Transfer patients	-	161

## NEWS & NOTES

### COMPASSIONATE QUILTERS

A friendly reminder that there will be sewing, cutting, ironing, tying, eating, drinking all happening on November 4th in 14b20!!! A good time was had by all at our first session in August.

The quilts make such a huge difference for families and staff--it is a profound experience being able to give a quilt and change the atmosphere in a room!!!

Join this dedicated group of volunteers to help make lap quilts. Saturday, Nov. 4, from 9 a.m. to 4 p.m. (or for as long as you are able) in UHS 14B20. For more information e-mail Paula Huelskamp at huelskam@ohsu.edu with a subject line "Compassionate Quilts." You don't need to know how to sew!

### OPEN ENROLLMENT MONTH

October is Open Enrollment month for your benefits. Packets have been delivered to the department. Review the options carefully. A separate mailing was sent to your home address with the benefit plan information you have now. Choices made during October will go into effect in January. The options presented in this year's packet have been chosen by a multi-representational group.

### SOUTH WATERFRONT SHUTTLE

While the Portland Aerial Tram will not be running until early 2007, OHSU has provided a way to get to the South Waterfront campus in the interim.

**Two 24-passenger shuttles** are now running **every 15 minutes** between CHH and the hill. Shuttles will run on a direct route with no stops in between the two campuses. The trip takes 10-15 minutes. Shuttles will be equipped with mobility devices. Shuttles will be distinguished from the regular OHSU shuttle with proper CHH signage.

For any questions regarding the shuttle, please contact Chuck Stiller, Manager - Logistics @ 8-1387 or [stillerc@ohsu.edu](mailto:stillerc@ohsu.edu)

## Dinner and Silent Auction Fundraiser

### To Benefit the Bone Marrow Transplant of Dr. Michael Shertz

OHSU EM Resident, Class of 1999

St. Vincent Emergency Physician, Med Director for WA County SWAT Team, and Medical Director for several local Fire Departments, as well as, a Veteran of the US Army Special Forces

Dinner and Auction will be held at:

**The Marriott Hotel, Waterfront**

**1401 SW Naito Parkway**

**Friday, November 3, 2006**

**Cocktails and Silent Auction begin at 6:00pm**

**Dinner to Follow**

**\$100.00 per ticket**

Tickets can be purchased at any Emergency Room Secretary's desk at St. Vincents, via phone or email to either Claudette VanDomelen (Claudette.VanDomelen@providence.org, 503-693-7773) or Mary Hazel (sleepymary@aol.com, 503-359-5102.) Please make checks payable to Providence St. Vincent Fundraiser.

## EMERGENCY PREPAREDNESS

### DIASTER NEWS

Oct 15 - Hawaiian Earthquake 6.9

Oct 17 - Earthquake off the coast of Northern California 4.9

There have been 181 earthquakes within the ring of fire (in the last week) greater than 4.0.

As we saw in the Hawaiian quake, power was lost for hours. Many stores were closed and the few that were open only took cash. Do not plan on the ATM's or banks being available also. They run on power and need people available to refill and do the accounting. Just a reminder to keep cash with your emergency supplies. This should be cash that you put away and forget about. The amount of money should depend on family size and needs.

There are no warnings before an earthquake, so prepare now.

# Education

*Denise Langley*

## **Important Date - Mark your Calendar Now**

**Nov. 11 - Fall Trauma Conference** - The entire agenda, speaker line-up and registration is available on-line at <http://www.ohsu.edu/trauma/education/tnc/> - There is going to be a great group of speakers this year, and the conference is a bargain (free for OHSU trauma care providers).

Congratulations to the new 16 CENS in our department. It is a big accomplishment to have 30% of our staff now nationally certified and recognized as experts in their field.

### **Current List of Active CEN Nurses, as of 10/20:**

Carol Bonnono	Jill Carter	Allie Draper	Holly Eller	Jenn Francis
Brent Goodness	Jerrie Jaquith	Denise Langley	Mark Shene	Melinda Hartenstein
Tina Larson	Cassie Richard	Bill Schueler	Michelle Togni	Samantha Sinclair
Jamie Sutherland	Jason Tofel	Sarah Mortensen		

If your certification is current please turn in a copy of your test results page to Sandy so the information can be entered in ResQ. The \$500 bonus for FTE nurses with current CEN will be tabulated during Pay Period #24 (Nov 13-26).

► Link for the D&C policy is now available for referencing

<http://ozone.ohsu.edu/healthsystem/POLICYMANUALS/Clin01Care/Clin01-38.html>

► Skills Day packets - need to be turned in by Oct 31st.

► Starting Nov. 1st - qualifying pre-hospital trauma patients will be enrolled in a hypertonic saline study. They are identified by the purple band on their wrist/ankle. If they arrive with the bag still hanging - do not throw it away. There is a collection container in the paramedic room for these. Also, if the patient goes to the OR with the bag hanging it needs to be collected from them and put in the container in the ED. There are posted notices with more information around the dept. More information elsewhere in this newsletter.

► "Continuing the Care - holding ICU patients in the ED" - a six week in-service blitz will start in November with weekly topics on some of our more common ICU patients that we end up holding in the ED. We have some very excited and knowledgeable ICUs excited about sharing this information with you. Think of it as a mini crash course in ICU care.

► Discharging a patient to the cath lab - As the final disposition of the patient will be determined after the cath, the patient should be discharged in EMSTAT, from the ED, when going to the cath lab. To do so indicate **discharge to clinic** and the **floor preference is cath lab. Service is Cardiology.**

This eliminates billing problems, holding beds for patients whom will not be admitted, and other coverage issues. If there are questions please see Louise.

## RESEARCH STUDY

### LOCAL INVESTIGATORS PROCEED WITH STUDY TO IMPROVE SURVIVAL FROM TRAUMATIC INJURY

Local investigators have received approval to move forward with a study that aims to determine whether a type of resuscitation fluid that is different from normal saline can improve survival rates in severely injured people. The study is the first of multiple studies OHSU-led investigators from local EMS agencies and hospitals will conduct in partnership with the National Institutes of Health-funded Resuscitation Outcomes Consortium (ROC). The planned start date is November 1, 2006.

The current standard of care for treating people with traumatic injuries in the field is to intravenously administer saline (water with the same salt content as blood). This study will determine whether hypertonic saline (water containing more salt than blood) or hypertonic saline with dextran (an added sugar molecule) will improve survival or brain function recovery. It is believed that hypertonic saline will allow blood flow to be restored with a smaller amount of fluid than regular saline, thereby reducing overexpansion of blood vessels and reducing inflammation following injury.

Individuals eligible for this study will have suffered serious injuries, and will therefore be unable to provide informed consent. Because of this, the study will be conducted under Food and Drug Administration (FDA) regulations that allow treatment research in certain life-threatening situations without the individual's consent before treatment is started.

As part of the FDA regulations allowing exception to informed consent studies, the investigators were required to conduct a campaign to notify and consult with the community about the study. That campaign included random phone surveys, public meetings in each of the four participating counties, ads in local newspapers, letters sent to neighborhood associations and elected officials, a news release to local

media that generated news coverage, and presentations at meetings of minority and other community organizations.

The study was reviewed and approved by an independent panel of scientists chosen by the NIH, but not participating in the study design. The FDA approved the study and will continue to monitor it for safety purposes. Locally, groups called Institutional Review Boards (IRBs) are required to review and approve these studies following the community consultation campaign. IRB's of OHSU, Legacy Emanuel Hospital, Southwest Washington Medical Center and Multnomah County and Oregon State Public Health all reviewed and approved the hypertonic saline study.

To be eligible for the study, subjects must have severe injuries with either low blood pressure or an altered mental state due to head injury. Most eligible subjects will have been injured as a result of motor vehicle crashes. Women who are obviously pregnant, children, and individuals under arrest at the time of the incident will not be enrolled.

Any community member who does not want to be included in this hypertonic saline study, or in future ROC studies that are carried out without individual advanced informed consent, can obtain a bracelet allowing them to opt out of all such studies. The bracelet will resemble a medical alert bracelet, and paramedics in the four participating counties will be trained to look for them.

To obtain a bracelet, call OHSU study coordinator Denise Griffiths at 503 494-7015.

More information about the Resuscitation Outcomes Consortium and the hypertonic saline study can be found at [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc)

*This Week*

**From Judi**

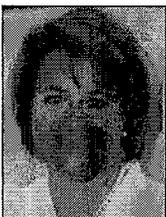
**Greetings, All -**

Kit and I spent the early part of this week in Madison WI having our first look at our future clinical information system, EPIC ASAP. Though our preliminary introduction was brief and did not include information about flow of information from the outpatient setting through the ED and on to the inpatient side, we were genuinely impressed by the ease and efficiency with which information could be entered and obtained from the record.

The system is BIG with limitless possibilities for program enhancements on the departmental or individual user level. Our immediate challenge will be to define what fits well for us in the beginning without getting ahead of ourselves. Members of our team will have differing skill levels with the navigation of the application and we will need to grow proficient together to ensure that the impact of this change on our patients is only positive.

Later and over time we can mature our sophistication with all ASAP has to offer, a process that will likely become a part of our permanent reality. We walked away feeling encouraged, excited and wanting to see more.

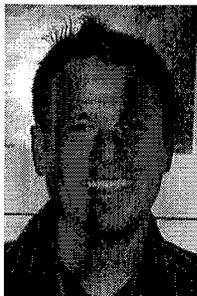
Those scheduled to work days on Nov 2 - please remember we will be fully participating in the statewide pandemic drill. "Volunteer" patients will be triaged and flowed through the department and flu vaccine will be administered to those who have not yet had it as part of the exercise. We are looking for additional staff to work between the hours of 0900-1500 so that we can actively participate while still maintaining normal operations in the department. Please consider signing up if you are available - your participation will be most appreciated and will earn you a free lunch.



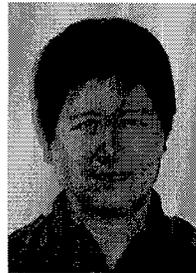
**- Judi**



**You Got Caught Caring**



*Dr. Garth Meckler*



*Dr. Jo Su*

Drs Meckler and Su have agreed to help with the training of the Peds Nursing Core Group. This support and teamwork is serving to move us closer to a specialized pediatric team. Thank you!

**Congratulations** to Misty Barrett, our resource EMT-P for day shift, who received her CCEMT-P certification. It was an **EXTREMELY** difficult exam and included a full-time 2-week course **WITH** a clinical rotation and nightly studying.

**PC Answer:** When someone repeats the speech of somebody else in an involuntary and meaningless way

**Average Daily Patient Census in the ED Oct 12 - Oct 17**

**102**

**NURSING OPPORTUNITIES**

Website for the current RN openings:  
[www.OHSUnursing.com](http://www.OHSUnursing.com)

In-Unit positions are posted in the Staff lounge hallway.

**TIMEKEEPING NEWS**

Corrections for last pay period need to be processed by Wednesday in order to be included in your next paycheck. Contact Sandy for a Payroll Adjustment form.

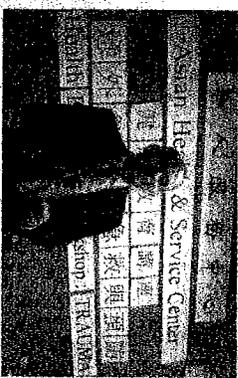
**MEETING SCHEDULE 7:00 AM**

- ED Charge RN - 1st Thurs
- ED Staff - 2nd Tues
- CNA - 3rd Thurs
- HUC/Paramedic - 4th Thurs, alternating

UBNPC - 1st Tues, 5-7:00 pm

**The ED is a Fragrance-Free Zone**

Editor: Sandy Huston  
[hustons@ohsu.edu](mailto:hustons@ohsu.edu)



華人服務中心健康教育講座，教你認識危及生命創傷的急救與預防，及介紹新出急救藥物高張生理食鹽水。

詳見第A2版

# 危及生命創傷的急救與預防 華人服務中心舉行健康教育講座

【本報記者趙聯光報導】緊張關頭的緊急救援，尤其是因心臟停止跳動，或受到一份較濃縮的鹽份和糖的病人提供應急的鹽份，而且其濃度較前四包的急救鹽水，內含的鹽份和糖的鹽份不易流失，容許病人身體慢慢吸收。

在波特蘭和週邊地區，通常在接到此類急救時，均由俄勒岡醫科大學(即山頂醫院)或以馬內(McMinn)醫院展開緊急救援工作，挽救生命為大前提，現在配合高張生理食鹽水的試驗，將會對挽救急症中的危難會提高。

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左起：關美慈、Jerris Hedges醫師、Mohamud Daya醫師、計劃主管Denise Griffiths、梁永富主任

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# Proposed study seeks a better way to treat blood loss

**Trauma** | Doctors want to test hypertonic saline on accident victims in Portland and other cities

By **ANDY DWORNIK**  
THE OREGONIAN

Doctors hope that the traumatic accidents of thousands in Oregon and nationwide will answer a vexing problem: How to best help people who have lost lots of blood.

They think the answer may be using a highly concentrated saline solution in place of the less-salty liquid that trauma victims now get outside the hospital.

They plan to test the idea on people suffering severe brain injury or shock from blood loss in Portland and 10 other U.S. and Canadian cities.

Such people can't consent to usual scientific trials. So researchers hope to use a federal waiver that substitutes a community education process for individual informed consent. The researchers are holding community meetings this week and next as part of this effort to get the trial running in Portland by summer.

Finding a better blood replacement has been the holy grail of trauma medicine for years, said Dr. Muhammad Daya, one of several Oregon Health & Science University researchers leading Portland's effort to join the trial.

## Solution in the field

For practical reasons, medics can't give donated blood at trauma scenes. Blood is too fragile to carry on ambulances. And, it's hard to match donor and patient blood types at a trauma scene.

So emergency medical technicians in the field give trauma victims "normal saline" to increase their fluid level and spread oxygen in the body. That solution has less than 1 percent saline, about as salty as blood or tears. It keeps some people alive until they reach the hospital, but many people still die.

A few small studies in animals and people suggest that concentrated saline may be better than normal saline in several ways:

- Some of the normal saline infused seeps out of vessels into other body tissues. So adding a quart of saline effectively boosts circulating blood by a cup. Hypertonic saline is so salty it draws

fluids from other tissues into the bloodstream. A cup of hypertonic saline boosts blood volume by a quart, Daya said.

- About a fifth of trauma deaths happen days after the injury. The return of blood throughout the body sometimes sets off a wave of inflammation, causing many organs to fail. Some studies suggest concentrated saline is less likely to cause this "inflammatory cascade," Daya said.

## Saline study hearings

Researchers will have public meetings to describe a proposed test of concentrated saline solution on some trauma victims.

**7 p.m. today,** OHSU Auditorium, 3181 S.W. Sam Jackson Park Road, Portland

**7 p.m. Monday, May 15,** Clackamas County Fire District No. 1 Oak Lodge Station 3, 2930 S.E. Oak Grove Blvd., Milwaukie

For more information: Visit [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc) or call study coordinator Denise Griffiths at 503-494-7015 or 1-888-370-2898.

**Finding a better blood replacement has been the holy grail of trauma medicine for years.**

years.

least 5,848 patients, said the University of Washington's Bert Barderson, trauma project manager for the trial's coordinating center. No one who was obviously pregnant, younger than 15 or

under police arrest would be included in the trial.

The study will compare normal saline with two concentrated solutions, each about twice as salty as seawater. One test solution contains 7.5 percent saline. The other has that much saline and adds dextran, a sugary molecule that may extend the solution's effects. Trauma victims have equal chances of getting any of the three solutions.

## Three possibilities

If the study moves forward, paramedics will give severe trauma victims an IV holding about a cup of saline. They will not know which of the three solutions patients get; bar codes on the bags help researchers decode that later. If patients need more fluids, they will get normal saline or, if at a hospital, blood. Medics will tell patients or their family members they were enrolled in the trial as soon as possible.

Once the study ends, researchers will check which group patients were in and measure whether one solution was better at keeping victims alive or returning them to good health. As the trial runs, an independent

board will check the data every three months, stopping the test if one treatment is clearly better or worse than others.

Previous hypertonic saline studies have not shown serious side effects on people. However, researchers will watch for several problems that, in theory, concentrated saline might cause:

- Excessive sodium levels, which can cause problems including seizures. Medics always monitor sodium levels and will watch closely for problems, Daya said.
- Allergic reactions to dextran.
- Too much dilution of coagulating proteins or other blood components.
- Higher brain pressure once the infusions stop.

Barderson said researchers in other cities, including Seattle and Vancouver, B.C., are going through community education processes similar to Portland's, hoping to join the trial. Three Canadian cities, which face different medical regulations, are likely to start soonest. If no one rejects the trial, all cities probably will join by the year's end, she said.

Andy Dworник: 503-221-8239.  
[andydwornik@news.oregonian.com](mailto:andydwornik@news.oregonian.com)

# Study seeks OK on patient trials

BI May 8, 2004

**Health** | A new saline could aid the recovery of trauma victims, but they often are too injured to give consent

BY **ANDY DWORKIN**  
THE OREGONIAN

For the second time in two years, Portland-area doctors want to study a medical treatment on trauma victims too sick to agree to the experiment.

The trial would compare the normal saline solution emergency medical crews

give badly injured patients with two solutions that contain more sodium. Blood is too perishable for ambulances to carry. So medics at trauma scenes give saline to people who have lost blood, helping push fluid and oxygen to organs until patients reach a hospital.

Even with saline treatment, trauma kills more than 100,000 U.S. residents a year. Some scientists think concentrated, or hypertonic, saline will help more people survive head injuries or severe blood loss. The saltier solution may limit brain swelling and a life-threatening kind of inflammation

that can shut down organs days after a trauma. Small studies have not found bad side effects, but possible problems include dangerously high sodium levels or allergies to one of the test solutions, which contains a sugary substance.

Portland is one of 11 U.S. and Canadian cities wanting to test the hypertonic saline as part of the Resuscitation Outcomes Consortium. The group has \$50 million from the governments and nonprofit heart associations in the United States and Canada to do several studies. The saline trial could start this summer and run

three years.

Such trauma experiments present one big problem: The injured are usually unconscious, in shock or otherwise hurt so badly that they can not fully understand or agree to a medical trial. Ethics and laws usually require getting informed consent from someone to experiment on them.

A 1996 federal regulation, controversial among ethicists, allows emergency medicine tests without consent if a treatment is likely to help people with life-threatening injuries and if current treat-

Please see **SALINE STUDY**, Page B3

# Saline study: 1996 regulation gives leeway in treatment

Continued from Page B1

ments are unsatisfactory. In such cases, researchers have to teach community members about their plans and address their concerns and questions in advance.

Community members don't all have to agree for a trial to go forward. But their reaction is weighed by Institutional Review Boards, which ensure medical studies are ethical and well-designed.

Starting tonight, researchers will hold a public meeting in each of the Portland-metro counties where emergency medical services might use the concentrated saline: Clackamas, Clark, Multnomah and Washington.

"We want to make sure the community has a chance to voice any concerns about the study, while at the same time being informed about the study," said Dr. Mohamud Daya, one of the Oregon Health & Science University trauma experts leading Portland's part of the trial.

The saline study would include

trauma victims with serious brain injuries or shock from lost blood. Pregnant women, children younger than 15 and people under arrest would be excluded. Portland-area medics might enroll 50 to 100 people a year for blood loss, and three to four times that number for head trauma, Daya said.

The saline study is the third to try the federal consent waiver in Portland. The first was Public Access to Defibrillation trial, which ended in 2003. That 24-city trial showed that having defibrillators and trained users in public places, such as malls, doubles the chance that someone will survive a cardiac arrest.

Doctors at OHSU and Legacy Health Systems also had hoped to test a blood substitute, called PolyHeme, on trauma victims. But after two years of work, they dropped their bid to join the trial in December.

Ethical questions and limited community input delayed Portland researchers until it was too late to join the PolyHeme test. Four 2005 community meetings on PolyHeme drew about 75 people and only 31 formal comments. The hospitals backed off initial plans to do more education, including efforts to target minority groups, which limited comment.

The review board for Oregon and Multnomah County's public health agencies also had ethical "concerns" about the PolyHeme

## Saline study hearings

Researchers will have public meetings to describe a proposed test of concentrated saline solution on some trauma victims.

**7 tonight,** Southwest Washington Medical Center's Health Education Center, 600 N.E. 92nd Ave., Vancouver.

**7 p.m., Tuesday,** Washington County Public Services Building Auditorium, 155 N. First Ave., Hillsboro

**7 p.m., Wednesday,** OHSU Auditorium, 3181 S.W. Sam Jackson Park Road, Portland

**7 p.m., Monday, May 15,** Clackamas County Fire District No. 1 Oak Lodge Station 3, 2930 S.E. Oak Grove Blvd., Milwaukie

**For more information:** Visit [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc) or call study coordinator Denise Griffiths at 503-494-7015 or 1-888-370-2888.

trial, said Dr. Gary Oxman, Multnomah County health officer and review board member. Some worried that the blood substitute could be given in a hospital when real blood was available. And they were uneasy about bad reactions in earlier PolyHeme trials. The company that makes PolyHeme, and sponsored the trial, has since said 10 users suffered heart attacks in

an earlier study.

"PolyHeme was sort of an eye-opener for a lot of people here," Daya said.

But "a number of differences" exist between the saline study and PolyHeme, he said. "I'm hoping they will not be seen in the same light." The government, not a private company, funds the saline trial. And only one dose of hypertonic saline will be given: afterward, patients will get more normal saline or, if at a hospital, blood.

OHSU and county review boards have given preliminary approval to the saline study. They will consider final approval once the community notification work ends. Oxman said public health review board members "decided that the study is well designed and that there are no outstanding ethical issues."

Researchers will take extra steps to make sure the community is notified about the saline trial, Daya said, including special presentations for some minority groups.

One thing researchers and review boards will gauge by talking to community members is whether they should craft a way for people to decline joining the trial, Daya said. Some cities offered bracelets to people who did not want to join the PolyHeme trial, for instance.

Andy Diworkin: 503-221-8239;  
[andydiworkin@news.oregonian.com](mailto:andydiworkin@news.oregonian.com)

**From:** Liana Haywood  
**To:** Mohamud Daya; Denise Griffiths; Jerris Hedges; Terri Schmidt;  
Dana Zive  
**Date:** Wed, Jan 3, 2007 11:36 AM  
**Subject:** ROC articles

Articles from The O and The Columbian about ROC enrollment beginning.

Liana

<http://www.oregonlive.com/news/oregonian/index.ssf?/base/news/1167796503257320.xml&coll=7>

Saline study set to begin -- again

Blood - A concentrated salt solution will be tested on people too injured to give their consent to the experiment

Wednesday, January 03, 2007

ANDY DWORKIN

The Oregonian

Local medics are ready to start testing a new method of revival on trauma victims who are too badly hurt to give their consent.

Last year, Portland was scheduled to join several other U.S. and Canadian cities in testing hypertonic saline, a concentrated salt solution meant to replace lost blood. But the study was suspended while doctors worked out how to test and track patients who got the solution after they were admitted to a hospital.

Those procedures have been settled, and ambulance crews in Clackamas and Washington counties were ready to enroll trauma victims in the study as of Tuesday, said Liana Haywood, a spokeswoman for Oregon Health & Science University, which is leading the local portion of the trial. Clark County will be ready to enroll test subjects Monday, with Multnomah County joining Jan. 15.

The saline study is unusual because the people subjected to the test can't agree to the experiment beforehand. That advanced permission, called informed consent, is central to most medical experiments. But the saline solution is being used on trauma victims too badly hurt to give normal consent. So the trial is being run under a federal rule that allows lifesaving treatments to be tested on patients who can't consent.

Most people who receive the solution will probably be car-crash victims.

People who have lost lots of blood or suffered severe brain injuries will either get normal saline solution or one of two more concentrated versions given at the trauma scene. Those patients will get blood, if needed, once they get to a hospital and be told about the study once they are conscious and thinking clearly. In Portland, doctors expect to enroll 50 to 100 people a year for blood loss and three to four times that number for head trauma. Women who are obviously pregnant, children 14 and younger, and people under arrest are excluded from the trial.

Doctors hope the salty solution will help some of the 100,000-plus U.S. residents killed by trauma each year. Now, paramedics give those people a standard saline solution to replace lost blood. (Ambulances don't carry blood because it is too perishable.) Some researchers think a solution containing more salt will limit brain swelling or a life-threatening inflammation that sometimes destroys organs days after a trauma.

Earlier and smaller studies of concentrated saline have not resulted in bad side effects or proved the saltier liquid is better. Doctors do know that the concentrated solution raises the body's sodium level. The new study procedures say hospitals must test a patient's sodium level three times in the day after

they are enrolled in the trial and requires someone on the hospital staff to be knowledgeable about the study.

While no one involved will give normal consent, doctors made several presentations about the study around Portland last year to gauge the community's feedback, as required by federal law. Hospital and county administrators have also approved the test.

People who want to avoid the trial can get a bracelet to wear that signals they do not want to take part by e-mailing their name and mailing address to roc@ohsu.edu or calling 503-494-7015. About 350 people have received bracelets so far, Haywood said.

Andy Dworkin: 503-221-8239; andyworkin@news.oregonian.com

\_2007 The Oregonian

<http://www.columbian.com/news/localNews/01032007news89280.cfm>

Local paramedics set to begin national trauma study

Wednesday, January 03, 2007

TOM VOGT Columbian staff writer

A national study on trauma care is scheduled to begin Monday in Clark County after a two-month delay.

Oregon Health & Science University is overseeing the Portland-area portion of the study, to determine whether different types of saline solutions can improve survival rates in severely injured people.

The study was originally scheduled to start in November in 10 regions in the United States and Canada. It was postponed so the hospitals could standardize their methods of collecting study data.

Paramedics currently treat trauma victims with intravenous saline, which is water with the same salt content as blood: about 0.9 percent.

This study will determine whether hypertonic saline -- about 7.5 percent salt -- improves survival or recovery of brain function. A hypertonic solution with dextran, an added sugar molecule, also will be part of the study.

Most emergency-response crews in Clark County will take part. Paramedics won't know if they are providing regular saline, hypertonic saline or hypertonic with dextran.

Vancouver's two hospitals, Southwest Washington Medical Center and Legacy Salmon Creek Hospital, are study partners.

The study will continue until 3,000 patients in the 10 regions have been included.

Patients eligible for this study will be severely injured and unable to provide informed consent, so the study will be conducted under FDA rules allowing research of some emergency treatments without the patient's prior consent.

This is OHSU's first participation in the Resuscitation Outcomes Consortium (ROC) funded by the National Institutes of Health. OHSU will take part later this year in a study of a device designed to help people doing CPR get more oxygen to trauma victims.

Update

\* Previously: Two months ago, the Food and Drug Administration postponed a study of a new saline solution for trauma victims.

\* What's new: The FDA has told Oregon Health & Science University and nine other regional centers in the U.S. and Canada to start the study.

\* What's next: Most emergency medical responders in Clark County will start using the study solutions on Monday.

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Hello, my name is \_\_\_\_\_ calling on behalf of Oregon Health & Science University. This call does not involve sales of any kind. We would like to get your opinions about a medical study involving people who have been severely injured. The survey will take approximately 10 minutes. I will describe the research study and ask for your opinions on it. You can skip any questions or stop the survey at any time. Your opinions will help guide how best to inform your community about this study. Your answers will be kept anonymous. We need to speak to someone in your household who is 18 years or older. **[IF NOT, ASK TO SPEAK TO SOMEONE EIGHTEEN YEARS OR OLDER; REINTRODUCE YOURSELF]**

Is now a good time to do the survey?  
Thank you!

**[READ THE FOLLOWING PRIOR TO ASKING SURVEY QUESTIONS]**

*An experimental treatment for people with severe injuries, such as those occurring in a serious car crash is being considered in this area. Many times these injuries are so severe, the patient may not survive. Small studies have shown that the experimental treatment may be helpful, but this is not yet proven.*

*Usually, researchers ask people for consent to participate in a study. In the case of severe injury, it is not possible to give consent, because the person may be confused, unconscious or in shock. Also, family members may not be available to speak for them.*

*Research studies can be performed without consent in emergencies such as this. People may be included in a study like this only after a research ethics board has approved the study in advance. Such groups, including the one at OHSU, value the opinion of citizens like you.*

*Researchers wish to study an experimental fluid treatment that may improve a person's chances of surviving severe injury. The injured person would get either study fluid or standard fluid resuscitation. This is by chance, like flipping a coin, and is the only way to find out whether or not the new treatment is better than what is done now. The paramedics will not know which fluid treatment they are giving.*

*As with any medication, there is the risk of allergic reaction or other unexpected side effects, but this new fluid treatment has been used in previous clinical studies with no harmful effects and is currently used in Europe. The paramedics would need to give the experimental treatment at the scene of the accident without getting written consent.*

*Now I would like to ask you a few questions about this study.*

1. If you were severely injured and had a one in three chance of not surviving with the standard treatment, would you want to have this experimental treatment given to you without consent?
  1. Yes
  2. No
  3. Don't know
  4. Question refused

2. If one of your family members was severely injured and had a one in three chance of not surviving with the standard treatment, would you want this experimental treatment given to them without written consent?
  1. Yes
  2. No
  3. Don't know
  4. Question refused
  5. NA – in case respondent doesn't have family members
  
3. If there was less than 1 in 100,000 risk of an allergic reaction, would you still want the experimental treatment given to you?
  1. Yes
  2. No
  3. Don't know
  4. Question refused
  
4. If you were in a severe accident and later learned that you were in this study, would you be upset?
  1. Yes Why? \_\_\_\_\_
  2. No
  3. Don't know
  4. Question refused
  
5. Injury is the leading cause of death in people ages 15 - 44 years. Injured adolescents have the same benefits and risks from the experimental fluid as adults. Do you think it is appropriate to include 15-17 year olds in this study?
  1. Yes Why? \_\_\_\_\_
  2. No..... Why not? \_\_\_\_\_
  3. Don't know
  4. Question refused
  
6. We will tell the community about this study before it begins. What are some sources of information you use? **[Check all that apply] Yes, please read the list and wait for a response of Yes/No for each?**

1. Newspaper -	yes	no
2. Internet -	yes	no
3. Neighborhood Associations -	yes	no
4. Newsletters -	yes	no
5. Churches -	yes	no
6. Schools -	yes	no
7. Radio -	yes	no
8. Television -	yes	no
9. Other _____		
  
7. Do you have any additional comments about giving this experimental treatment to people severely injured without first getting written consent? \_\_\_\_\_ **[RECORD VERBATIM]**

I have a few more questions to ask to make sure that we have a representative sampling of your community's opinions. Your answers will be kept anonymous.

8. What is your age? \_\_\_\_\_

9. What is your gender?

1. Male          2. Female

10. Which of the following categories best describes your race/ethnicity?[**SELECT ONE**]

White 01

Black or African-American 02

Asian or Asian-American 03

American-Indian or Alaskan Native 04

Native Hawaiian or other Pacific Islander 05

Hispanic 06

Multi-racial 07

\*\*\*\*\*

Other [please specify] 080

Don't know 88

Refused 99

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

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

12. How many people live in the household? \_\_\_\_\_

13. Please stop me when I read the category that best describes your annual household income before taxes:

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

14. What county do you live in? \_\_\_\_\_

15. What is your zip code? \_\_\_\_\_

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

If you would like more information on this study, you can contact Dr. Jerris Hedges at 503-494-8220 or Denise Griffiths at 503-494-7015; [griffitd@ohsu.edu](mailto:griffitd@ohsu.edu)

There is also a website you can visit. Would you like that internet address?

[If so, provide: [www.OHSU.EDU/Emergency/ROC](http://www.OHSU.EDU/Emergency/ROC)]

Draft 5-15-06  
DG

## *Resuscitation Outcomes Consortium (ROC) Study Survey*

Hello, my name is \_\_\_\_\_ calling on behalf of Oregon Health & Science University. This call does not involve sales of any kind. We would like to get your opinions about a medical study involving people who have been severely injured. The survey will take approximately 10 minutes. I will describe the research study and ask for your opinions on it. You can skip any questions or stop the survey at any time. Your opinions will help guide how best to inform your community about this study. Your answers will be kept anonymous. We need to speak to someone in your household who is 18 years or older. **[IF NOT, ASK TO SPEAK TO SOMEONE EIGHTEEN YEARS OR OLDER; REINTRODUCE YOURSELF]**

Is now a good time to do the survey?  
Thank you!

### **[READ THE FOLLOWING PRIOR TO ASKING SURVEY QUESTIONS]**

*An experimental treatment for people with severe injuries, such as those occurring in a serious car crash is being considered in this area. Many times these injuries are so severe, the patient may not survive.*

*Usually, researchers ask a person for his/her consent before the person participates in a study. In the case of severe injury, it is not possible to get consent, because the person may be confused, unconscious or in shock. Also, family members may not be available to speak for the injured person.*

*It is legally allowable to carry out research studies without consent in emergency situations such as this. People may be included in a study like this only after a research ethics committee ("Institutional Review Board") has reviewed and approved the study.*

*Part of the ethics committee review is to get input from community members to see how they feel about the study. A written survey is one way for the ethics committee to get input. The committee will use survey results to help determine whether the study should be done.*

### **Survey Instructions**

*To answer the following questions, imagine that you (or a family member) were severely injured, and had a one in three chance of dying from your injuries.*

*It is likely that you would be confused or unconscious because of your injuries. If this happened to you today, paramedics would give you "standard" treatment to help save your life. This would include injecting a salt-water fluid into your veins. Unless you were completely alert and clearly objected, the paramedics would go ahead and start treatment without your formal consent.*

*Now...also imagine that there was an experimental treatment for severe injury being studied in the community. Earlier research has shown that this treatment is likely to be better than ordinary treatment, but this has not been conclusively proven.*

*The paramedics would treat you in pretty much the same way. But two things would be different:*

Draft 5-15-06

DG

1. *You might receive the standard treatment fluid – **OR** – you might receive an experimental fluid (a different salt-water solution with another medicine added). Which fluid you received would be determined by chance – like the flip of a coin.*
2. *You would be enrolled as a subject in the study. The study researchers would keep track of how well you recovered from your injuries while you were in the hospital.*

*Both of these things would happen without your consent. You or your family would be able to give consent later – at the hospital.*

**Survey Questions**

1. If you were severely injured as just described, would you be willing to be part of this study without consent? This includes possibly being given the study fluid without your consent.

Yes    Why? \_\_\_\_\_  
\_\_\_\_\_

No    Why not? \_\_\_\_\_  
\_\_\_\_\_

Don't know  
 Question refused

2. If there was a very small chance (less than 1 in 100,000) of your having a severe allergic reaction or another side effect from the study fluid, would you be willing to have this fluid given to you without your consent?

Yes  
 No  
 Don't know  
 Question refused

3. If you were severely injured and later learned that you had been put into this study without your consent, would you be upset?

Yes  
 No  
 Don't know  
 Question refused

If you answered "Yes," why would you be upset?

\_\_\_\_\_  
\_\_\_\_\_

4. If one of your family members was severely injured as described, would you be willing for her/him to be part of the study without consent? This would include possibly being given the study fluid without consent.

Yes  
 No  
 Don't know  
 Question refused  
 NA



Draft 5-15-06  
DG

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

- Less than high school
- High school diploma or GED
- Associate, Technical or Vocational degree
- Some college
- Bachelor's degree
- Post-graduate degree
- Refuse

5. How many people live in the household? \_\_\_\_\_

6. Which category best describes your annual household income before taxes:

- |   |   |
|---|---|
| <input type="checkbox"/> Less than \$20,000   | <input type="checkbox"/> \$80,000 to \$99,000 |
| <input type="checkbox"/> \$20,000 to \$34,000 | <input type="checkbox"/> \$100,000 or more    |
| <input type="checkbox"/> \$35,000 to \$49,000 | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> \$50,000 to \$64,000 | <input type="checkbox"/> Refused              |
| <input type="checkbox"/> \$65,000 to \$79,000 |   |

7. What county do you live in? \_\_\_\_\_

8. What is your zip code? \_\_\_\_\_

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

If you would like more information on this study, you can contact Denise Griffiths, Research Study Coordinator, at 503-494-7015; 888-370-2888; [griffitd@ohsu.edu](mailto:griffitd@ohsu.edu)

You can also visit the ROC website at [www.OHSU.EDU/Emergency/ROC](http://www.OHSU.EDU/Emergency/ROC)

**PORTLAND-VANCOUVER RESUSCITATION OUTCOMES CONSORTIUM**  
**HYPERTONIC SALINE & DEXTRAN PHONE SURVEY RESULTS:**  
**April 2006**

**Summary**

In March 2006, 186 people throughout Multnomah, Clackamas, Washington, and Clark counties were contacted for a random-digit dialing telephone survey regarding their opinions of critical issues associated with a proposed exception to informed consent study of hypertonic saline and dextran use in critically injured trauma patients. A private firm not associated with the Resuscitation Outcomes Consortium or any local ROC investigators conducted the survey. Below is a summary of the results from this survey, with detailed information and text responses (truncated at 250 characters) following the summary.

The demographics of those surveyed are as follows: 66% women, median age 54 years, 92% white, 4% black, 4% other race. Seventy percent had at least some college education.

**Results from selected questions:**

1. If you were severely injured and had a one in three chance of not surviving with the standard treatment, would you want to have this experimental treatment given to you without consent?  
YES = 77%, NO = 19%, Don't know = 4%
2. If one of your family members was severely injured and had a one in three chance of not surviving with the standard treatment, would you want this experimental treatment given to them without written consent?  
YES = 73%, NO = 25%, Don't know = 2%
3. If there was less than 1 in 100,000 risk of an allergic reaction, would you want the experimental treatment given to you?  
YES = 83%, NO = 12%, Don't know = 4%
4. If you were in a severe accident and later learned that you were in this study, would you be upset?  
YES = 17%, NO = 81%, Don't know = 2%
5. Do you think it is appropriate to include 15-17 year olds in this study?  
YES = 62%, NO = 31%, Don't know = 7%

Detailed Survey Results:

DEMOGRAPHICS

What county do you live in?

COUNT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Clac	43	23.12	43	23.12
Clark	43	23.12	86	46.24
Mult	49	26.34	135	72.58
Wash	50	26.88	185	99.46
Other	1	0.54	186	100.00

Gender

D9	Frequency	Percent	Cumulative Frequency	Cumulative Percent
male	64	34.41	64	34.41
female	122	65.59	186	100.00

What is your age?

Median 53.5 (IQR 38-64, range 19 - 91)

What racial or ethnic group do you belong to?

Q10	Frequency	Percent	Cumulative Frequency	Cumulative Percent
White	172	92.47	172	92.47
Black	7	3.76	179	96.24
Asian	3	1.61	182	97.85
American-Ind	1	0.54	183	98.39
Pacific Isl	1	0.54	184	98.92
Multi-rac	2	1.08	186	100.00

What is the highest level of education you have completed?

Q11	Frequency	Percent	Cumulative Frequency	Cumulative Percent
< hs	3	1.61	3	1.61
hs	41	22.04	44	23.66
assoc	11	5.91	55	29.57
some college	50	26.88	105	56.45
bach	50	26.88	155	83.33
post-grad	31	16.67	186	100.00

Please stop me when I read the category that best describes your annual household income before taxes.

Q13	Frequency	Percent	Cumulative Frequency	Cumulative Percent
< 20	17	9.14	17	9.14
20-35	22	11.83	39	20.97
35-50	41	22.04	80	43.01
50-65	23	12.37	103	55.38
65-80	26	13.98	129	69.35
80-100	13	6.99	142	76.34
100+	25	13.44	167	89.78
unknown	5	2.69	172	92.47
refused	14	7.53	186	100.00

What are some sources of information you use? - Newspaper

Q6A	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	32	17.20	32	17.20
YES	154	82.80	186	100.00

What are some sources of information you use? - Internet

Q6B	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	43	23.12	43	23.12
YES	142	76.34	185	99.46
UNK	1	0.54	186	100.00

What are some sources of information you use? - Neighborhood Associations

Q6C	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	131	70.43	131	70.43
YES	53	28.49	184	98.92
UNK	2	1.08	186	100.00

What are some sources of information you use? - Newsletters

Q6D	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	67	36.02	67	36.02
YES	117	62.90	184	98.92
UNK	1	0.54	185	99.46
REFUSED	1	0.54	186	100.00

What are some sources of information you use? - Radio

Q6E	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	31	16.67	31	16.67
YES	155	83.33	186	100.00

**What are some sources of information you use? - Television**

Q6F	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	19	10.22	19	10.22
YES	167	89.78	186	100.00

**What are some sources of information you use? - Churches**

Q6G	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	90	48.39	90	48.39
YES	95	51.08	185	99.46
REFUSED	1	0.54	186	100.00

**What are some sources of information you use? - Schools**

Q6H	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	101	54.30	101	54.30
YES	84	45.16	185	99.46
UNK	1	0.54	186	100.00

**SURVEY QUESTIONS:**

1. If you were severely injured and had a one in three chance of not surviving with the standard treatment, would you want to have this experimental treatment given to you without consent?

Q1	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	36	19.35	36	19.35
YES	143	76.88	179	96.24
UNK	7	3.76	186	100.00

2. If one of your family members was severely injured and had a one in three chance of not surviving with the standard treatment, would you want this experimental treatment given to them without written consent?

Q2	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	46	24.73	46	24.73
YES	136	73.12	182	97.85
UNK	4	2.15	186	100.00

3. If there was less than 1 in 100,000 risk of an allergic reaction, would you want the experimental treatment given to you?

Q3	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	23	12.37	23	12.37
YES	155	83.33	178	95.70
UNK	8	4.30	186	100.00

4. If you were in a severe accident and later learned that you were in this study, would you be upset?

Q4	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	151	81.18	151	81.18
YES	31	16.67	182	97.85
UNK	4	2.15	186	100.00

Open-ended response to YES answers:

Even though I'd want the treatment, I'd be surprised to discover that I'd received something I didn't consent to. I wouldn't like it.

For one thing you might not know if the other treatment would work, and what the chances are compared to the other treatments.

I had not been asked for my consent.

I just think you shouldn't do things to people without them knowing about it.

I just wouldn't want to be in it.

I like to know what's being put in my body even in an extreme emergency. I'm not a guinea pig. I know I'm allergic to certain things.

I might feel that my choice was taken away.

I want to have consent or I would want somebody to speak on my behalf.

I wasn't aware of it.

I would be upset I didn't know about it.

I would be upset if I received the treatment, and it was ultimately harmful to me.

I would want to know what they were doing to my body.

I'm a Christian, and I feel that God has given us doctors and nurses to go through training in order to help people get better and so to go into an experiment I would want to know that the experiment is going to happen and I feel God I

I'm kind of a control freak. I want to know what's going on at all times.

I'm not one who takes any medications that aren't fully approved. We've found the effects of medications on people when the medications weren't fully approved is usually injurious. If you're experimenting on people without their permission

I'm not sure. Mostly just not knowing about it.

If the study ended up having detrimental effects on my health, then I would be upset.

It is hard to say.

It was conducted without consent.

It was without my consent.

It's a matter of being informed, knowing what kind of procedures are being performed, and if they have been approved by the medical community.

It's just consent.

Lack of consent

No doctor administers it.

Not knowing the risks involved before being given the treatment makes me unsure.

The whole not knowing thing. The fact that it was an experiment.

There are many things we are overstepping if it's experimental and hasn't been proven.

Two out of 3 chances of surviving with the regular treatment is better than 1 out of 3.

Unless I'm choosing to sign up for a study, I don't think it's fair to be in one without my consent.

Unnerving to not know what is going into your body.

Without consent and it's experimental and it's not approved by FDA, there's too much potential for negative reactions.

**5. Do you think it is appropriate to include 15-17 year olds in this study?**

Q5	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NO	58	31.18	58	31.18
YES	115	61.83	173	93.01
UNK	12	6.45	185	99.46
Refused	1	0.54	186	100.00

Open-ended response to YES answers:

A lot of accidents with teenagers. I'd like them to have a chance.

A lot of people are getting hurt at that age.

A lot of these serious injuries involve people who have just started driving.

At that point they have adult-like bodies.

Because of the increased number of accidents with this age group

Don't know. Why not?

Everybody is different; a teenager is different than an adult. We would need to know how it would affect or not affect.

Gives a better cross section of the population.

I don't see a problem with it; they're mature at that age and they can handle the information.

I don't see that much difference in the age and if they have a chance to survive, then yes.

I don't see why it should make a difference.

I feel that based on the wide range of results and how it is impacting individuals, it should be considered for all age groups.

I guess it's more a matter of parental consent. I do have a 15 and 17 year old. It sounds like a low risk study and has a potentially good chance of having the individual survive.

I think everybody deserves a chance.

I think everybody ought to have a chance if they can benefit from it.

I think health care should be for repairing injury.

I think if it was my kids, I'd want them to have a greater chance of survival, and anything that would help that.

I think it is important to administer to both children and adults to make sure that the testing and research is accurate.

I think it seems pretty reliable since it's being used in Europe, and could save kid's lives.

I think that if you believe it is a better treatment you should use it.

I think that they are so young, they might have a better chance. Why leave them out? Not a good reason to leave them out.

I think they are close enough to being an adult.

Could be a benefit to the study.

I think they just have a better chance.

I think they should have a chance also if it something that would save lives.

I was almost killed when I was 17.

I would want them to live and have every chance they could.

I'm assuming it's for the patient's benefit.

I've been an RN for 20 years. They're old enough to be included because their bodies are developed enough.

If it has any possible benefits, go for it.

If it increases the chances, then I think it is ok.

If it is a chance that they would survive, it is worth it.

If it's a benefit to adults, these ages are close enough to being an adult.

If it's a valid study, yes they should be included.

If it's going to save their lives why not.

If no one's around to give consent for anyone to be experimented on, age shouldn't matter.

If the majority of people are 15-44, they should be included.

If they have 1 in 3 chances of not living, I think it would be fine

If they have a better chance of living then they should take it. It should be available for them to have it.

If they have the same risks and benefits, why not. If they just had a 1 in 3 chance, I would think that they would be able to get the same chance as anybody else.

If they only have the 1 in 3 chance of living, and there's nobody there to say yes or no.

If they were injured fatally and there was little chance of surviving, then yes.

If you are going to include people, you need to include all groups.

If you're going to do it, you may as well do it to everyone.

In this country we are not aggressive enough with medical things, and I think if it's to everyone's benefit that includes 15 to 17 year olds.

It seems like a safe risk.

It sounds like the benefits would exceed the risk.

It'll give them a better chance of surviving.

It's important to do whatever you need to do to save a life.

Just as much right to live as anybody else.

Just because they are younger doesn't mean they should have less options.

Life is important.

Not sure

People have problems with kids being in studies.

There's no difference between adults and kids; they need their lives saved.

Sounds like there are minimal bad effects with prominent good effects.

Sounds like there is enough proof that it works.

They should give it to them if it's going to help them.

Still looking at the same chances of dying, 15 to 17 year olds are close to adults.

That's what statistics are showing, teenagers are having more car accidents.

The benefits of the saline solution would outweigh the risks.

The idea that 18 makes an adult is arbitrary, and I think 15-17 year olds should have the same options as "adults."

The situation, and due to the non-life threatening ratio, creates an excellent chance for youngsters to have a better chance of survival.

Their benefits are the same. Nobody's giving permission to give them any other treatment that they get. Would use the best tool anyway.

Their life is just as important as an older persons.

Their risks and benefits are no different than an adult's.

These things need to be evaluated and tested and compared to what is currently done.

They almost have full grown adult bodies. The study would not be complete without them.

They are a high percentage of people involved in serious accidents and should have the same opportunity for survival.

They are a life just like anyone else.

They are alive too, doesn't matter what their age is.

They are at a high risk also.

They are highest risk for accidents.

They are human beings just like the rest of us--practically adults.

They are in more accidents than other age groups.

They are more likely to be in an accident, so they should be included.

They are more likely to be injured.

They are not experienced drivers and could be in an accident.

They are probably old enough to make a decision like that.

They are still young and should be given every shot you can give them.

They are the ones who get hurt the most in accidents.

They can be innocent bystanders. They should have a right also.

They can save anybody's live. It doesn't matter the age.

They could have a long life after that if it works.

They deserve as much as a chance as the older people.

They deserve the same chance as everybody else.

They deserve the same treatment as adults.

They deserve to get a chance to live.

They got the same blood as everyone else.

They have a longer time to live. They need to take the risk if it is going to save them.

They have a lot longer to live than I do.

They have a lot more life; they lose a lot more if they die.

They have a right to live. If you can't find their parents, then the paramedics are just doing their job. That's the age that's worse in car accidents.

They have the most accidents.

They have the same risks, and severe injury is a significant threat to them.

They make up the largest number in the ER. They also have the strongest chances of survival.

They may need a better chance to survive because they are young.

They need a chance of living just like you and I

It's not so hard to risk with kids.

They need to know.

They should be studied as well.

They should have a chance.

They typically get into trouble that they shouldn't be in, like a car wreck.

They would benefit from it, why not?

They're almost adults.

They're important too.

They're people and if this could help them they should be able to benefit from the treatment like anyone else.

They're the ones that probably get in more accidents.

They're young and they deserve every possible chance to survive.

We're all human beings and we all have our risks. If we're in accidents, it makes sense with such a low risk of allergic reaction to be a participant.

We're talking about a life saving method, and teenagers deserve that chance as much as the rest of us. Adolescents can tolerate medications better than older people.

We're talking about life.

What do they have to lose if there is a chance?

Where there is life there is hope.

What have we got to lose?

What is age?

Why not?

Why not? What would be the difference?

You want them to live. If there's a possibility that this will help them live, then it should be done.

Open ended response to NO answers:

Adolescents have more of a chance of rebounding from an accident than an adult. They are more resilient.

Again, people shouldn't be given experimental treatment when they don't know about it. Because I think so.

Consent

Don't know if it is good for kids, so it is hard for me to make that decision.

For the same reasons we talked about earlier, you are not told up front what the risks are.

I am just thinking of people who might have some religious objection to a type of treatment. I wouldn't want it to happen to a child of mine. There is a different standard for consent for minors and adults.

I don't know.

I don't think children should be used in the preliminary study.

I don't think it's appropriate for children, especially if it's not suitable for adults.

I don't think that they should be included. Kids under 18 should not participate.

I don't think they are old enough yet.

I don't think they have the capacity of understanding what is going on at their young age.

I feel like they still need a parental consent for something experimental.

I feel that younger people should have the standard solution because they are not adults.

I have an 18 year old, I would want to make that decision. If this was part of an experimental thing, I would want to make that choice.

I have mixed emotions. Should have access, but I think about the age of consent.

I just think the age.

I just wouldn't want them in it.

I think adults have a different level of responsibility.

I think that for people who would not be able to consent, and if their parents aren't there, the threshold is at a higher level.

I would just think until it's proven my preference would be to exclude younger people from it.

If that was my nephew/neice, I wouldn't want them to go through the side effects if there were any.

It comes down to being informed.

It doesn't matter what age you are.

It is experimental, not something proven to work without harm.

It would take an adult to make a decision on that.

It's an age thing. Big risks when dealing with someone who is still a minor.

Need consent, and I don't think 15 - 17 year olds are mature enough to offer consent.

No comment

No consent

No good reason

Not adults to make their own choices

Not of age

Not without consent

Parents would be upset if they found out; liability is pretty risky.

Same as before, because no doctor administers it.

Still minors and need parental consent.

Teenagers don't think too much about that.

The parents would have a problem with not having consent.

They are minors and they weren't able to make an informed decision and the family may have concerns.

They are not adults.

They are not at an age that they could give consent. They're children.

They are not of age to make that decision.

They are not of legal age yet.

They are too young to give consent.

They are under age.

They can't decide for themselves, and I don't believe children can do that.

They couldn't give their consent.

They have a parent that could give consent.

They would not have capacity to give informed consent. Not right for parents to give informed consent in this situation, for an experiment.

They're even more susceptible to an experiment gone wrong. I'd not want a child of mine being experimented upon without my knowledge. I know saline solutions are fairly common, but still. I don't question saline when I'm getting an injectio

They're just too young to take a chance on.

They're not of an age of informed consent.

They're too young at that age

We don't need to experiment on kids.

**6. Do you have any additional comments about giving this experimental treatment to people severely injured without first getting written consent?**

A doctor should be able to do whatever is necessary. A doctor is like a god.

A vote might be good, more information than what you gave me.

All the class A lawsuits are because of

prescriptions that are causing harm. I think that this should be out there. People should be told and educated first.

As long as it's something that has been legally checked out and okayed by whomever is in charge of doing it.

Chances of allergic reactions to saline are very slim. I am a nurse at OHSU. Hopefully it will make a change for the better.

For me it would be okay. For members of my family I would not want to authorize it until it's proven.

Good luck and best of chances

I don't know any other way to do it.

I don't know if there would be grounds for a law suit in case things went bad.

I don't understand it, so I can't talk too much.

I guess the biggest concern would be, if research has shown benefit as good as or better than original saline. But if it started showing greater risks they would have to discontinue ASAP. I think especially in a trauma incident, I think any

I have medical problems, so I don't know if that would be OK with the problems that I have.

I have some hesitations about it because I believe people need to know exactly what it is before it's given to them. Public needs to be more informed first.

I just think you're stepping into a dangerous area with this study, a slippery slope.

I think Europe and other places have a lot of things that they have been using that are beneficial that we need to quit resisting and think a lot more seriously about things that have had success in other places. I do get very frustrated w

I think if they know that it will have a harmful effect than they shouldn't do it.

I think it's a good idea. I just don't like when they have something experimental and don't use it because of all the nonsense they go through.

I think it's pretty risky to do something without giving consent unless the person has signed

something ahead of time, like an advanced directive. That's a very risky precedent to not have informed consent.

I think statement should start with paramedics determining if patient will be a participant. It makes a difference to me in my answers that a doctor is not making that decision.

I think that at the time that the accidents happen, the people are not in a condition to give consent. I have a daughter who works in trauma.

I think that if it's already used in Europe, then it should be a slam dunk.

I think that it is important to first attempt to get consent, but if you can't then I suppose you should test it without. It would be best to test it in an environment that is not in the field, but in other ways. Basically my biggest

I think that something needs to be printed explaining specifically what the new treatment is, what chemicals are involved, etc.

I think that sometimes consent and privacy laws have gone a little too far.

I understand in emergency situations when you have to make a decision. If it were a drug I would have more of a problem, since it's saline that's not as much of an issue for me.

I would be concerned that I have limited information on the opinions of the public. A larger sampling group would need to be surveyed.

I would imagine a relative or someone could give consent, but if it's an emergency you wouldn't have time for that.

I would like to know more about it before I make that decision.

I'd say that this is a situation where there is all benefit. If the experiment doesn't work, at least we eliminated it. And if it works, you help save lives.

I'm against clinical studies that don't get people's consent.

I'm confused because if it's a saline type solution what would it do?

I'm in favor of these new advances in medicine, and

I think it's necessary to have trials.

I'm just opposed to people receiving medications that are not approved. Unless it is elective. To administer it to someone who has no prior knowledge is not ethical.

I'm unsure about the treatment. I just lost my husband. I think that new experiments could help people.

If OHSU knows what they're doing, I guess it would be fine.

If it's an older person, I would say don't do it. I'm in my 90's and if I had an accident today I wouldn't want anything done today but any young person I would like it done.

If it's something that could help people that wouldn't have helped otherwise, I'm all for it because I'm thankful for all the knowledge we have now that we didn't used to have.

If it's the only thing that they can give to save lives, then yes, but if it's experimental, no.

If someone is severely injured, and they cannot give consent so they are at the control or mercy of the paramedics.

If there's a thorough effort to communicate this, there should be communication about risks with standard treatment compared to risks with experimental treatment. People need to recognize the risks and know if there isn't much of a different

If they don't have much chance of survival in the first place, then they need to have every option available to them.

If they want it's their choice, but I wouldn't want it in my family.

If they're that bad, it would be OK with me.

It feels like you are treading a fine line of ethical behavior. I have family members who are scientists and I understand the need for research. It seems unethical to only give the experimental treatment to some of the patients if you think

It just seems to me that the big problem is that somebody could be allergic to it. If the chance is as minimal as they project, then I think it should be used.

It might not do them any good to begin with. It might cause them to die.

It should be widely known and posted in emergency rooms. Places where you could read about it without it being a surprise later.

It would be alright. I would want them to try to save my life.

It would be beneficial to get consent, but since you can't do it, go ahead.

It would be nice to give people the option of consenting. Maybe like how the Oregon donor plan works.

It's one of those risks that you have to judge. I guess I would want the EMTs to be well enough trained to make an intelligent decision whether or not give this treatment.

Make sure the paramedics are well trained to know when it's a 1 in 3 chance.

Maybe need to study a lot before giving to patients.

More information is needed in this survey in order to be completely informed.

My sole concern is the stage at which you are doing the research.

On the ground that it is a simple treatment, I don't think it could be unethical.

People do not like things that they don't know about. People might feel uninformed.

Probably there would be a risk of people suing.

Research studies should be used with consenting adults. It's tough on this study. In other studies, people have the option.

Study should be done on all age groups.

The odds aren't good, and I don't think that it should be given to people without getting any consent and if they don't have any relatives, I don't think it's right.

The only thing I'm hesitant about, is that anytime we're quick to get into new ventures, the side effects are not showing necessarily up front, but

more in the distant future. We should have this new treatment tested for a standard number

The reason I would hesitate is I have just read some things about people getting treatments and dying from side effects, and I feel that people should be giving consent.

They probably should have consent.

## The FREQ Procedure

What county do you live in?

COUNT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	21	24.42	21	24.42
2	21	24.42	42	48.84
3	22	25.58	64	74.42
4	22	25.58	86	100.00

## Gender

D9	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	30	34.88	30	34.88
1	56	65.12	86	100.00

Which of the following categories best describes your race or ethnicity? - Asian or Asian American includes Chinese, Filipino, Japanese, Asian Indian, Korean, Vietnamese, other Asian.

Q10	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	75	87.21	75	87.21
2	1	1.16	76	88.37
3	1	1.16	77	89.53
4	2	2.33	79	91.86
6	4	4.65	83	96.51
7	1	1.16	84	97.67
99	2	2.33	86	100.00

What is the highest level of education you have completed?

Q11	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	1	1.16	1	1.16
2	14	16.28	15	17.44
3	9	10.47	24	27.91
4	21	24.42	45	52.33
5	22	25.58	67	77.91
6	18	20.93	85	98.84
9	1	1.16	86	100.00

Please stop me when I read the category that best describes your annual household income before taxes. - IWR prompt: Your best estimate is fine.

Q13	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	6	6.98	6	6.98
2	9	10.47	15	17.44
3	11	12.79	26	30.23
4	13	15.12	39	45.35
5	11	12.79	50	58.14
6	9	10.47	59	68.60
7	16	18.60	75	87.21
8	1	1.16	76	88.37
9	10	11.63	86	100.00

Now I would like to ask you a few questions about this study. If you were severely injured as just described, would you be willing to be part of this study without consent? This includes possibly being given the study fluid without your consent.

Q1	Frequency	Percent	Cumulative Frequency	Cumulative Percent
no 0	28	32.56	28	32.56
yes 1	55	63.95	83	96.51
Don't know 8	3	3.49	86	100.00

If there was a very small chance, less than 1 in 100,000, of a severe allergic reaction or another side effect from the study fluid, would you be willing to have this fluid given to you without your consent?

Q2	Frequency	Percent	Cumulative Frequency	Cumulative Percent
no 0	23	26.74	23	26.74
yes 1	61	70.93	84	97.67
Don't know 8	2	2.33	86	100.00

If you were in a severe accident and later learned that you were in this study, would you be upset?

Q3	Frequency	Percent	Cumulative Frequency	Cumulative Percent
no 0	67	77.91	67	77.91
yes 1	15	17.44	82	95.35
Don't know 8	4	4.65	86	100.00

If one of your family members was severely injured as described, would you be willing for him or her to be part of the study without consent? This would include possibly being given the study fluid without consent.

Q4	Frequency	Percent	Cumulative Frequency	Cumulative Percent
no 0	28	32.56	28	32.56
yes 1	56	65.12	84	97.67

Don't Know	8	2	2.33	86	100.00
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Do you think it is appropriate to include 15-17 year olds in this study?

	Q5	Frequency	Percent	Cumulative Frequency	Cumulative Percent
no	0	48	55.81	48	55.81
yes	1	35	40.70	83	96.51
Don't Know	8	3	3.49	86	100.00

Do you have any additional comments about giving this experimental treatment to people severely injured without first getting written consent?

	Q6	Frequency	Percent	Cumulative Frequency	Cumulative Percent
no	0	49	56.98	49	56.98
yes	1	37	43.02	86	100.00

Open ended response to No in Q1

O_Q1NO	Frequency	Percent	Cumulative Frequency	Cumulative Percent
	55	63.95	55	63.95

Open ended response to No in Q1

O_Q1NO	Frequency	Percent	Cumulative Frequency	Cumulative Percent
	3	3.49	58	67.44

DK	4	4.65	62	72.09
I am not a human guinea pig.	1	1.16	63	73.26
I don't like being experimented on.	1	1.16	64	74.42
I don't have enough information.	1	1.16	65	75.58
I don't know enough about the study or the liquid medication that is being used.	1	1.16	66	76.74
I feel like if I was able to make a decision, I would rather not. Alternative medicine is not as advantageous as the standard practice.	1	1.16	67	77.91
I have had experience with head injuries and people living in a vegetative state.	1	1.16	68	79.07
I think I or a close family member should be consulted first. Or an organ donor card could be	1	1.16	69	80.23

used as an indication of implied consent.				
I would like to know what the chances are of the fluid helping; also I would like to know the risk.	1	1.16	70	81.40
I would not want to be a part of any study.	1	1.16	71	82.56
I would rather have something tried and true.	1	1.16	72	83.72
I would want the family to have the final say.	1	1.16	73	84.88
If it is just a study, I do not want to be an experiment.	1	1.16	74	86.05
If there were another thing that would solve the problem, then I wouldn't want to be part of the study unless I was aware of the risks.	1	1.16	75	87.21
It hasn't been thoroughly researched.	1	1.16	76	88.37
It hasn't been tested, and it isn't something that they would ordinarily use.	1	1.16	77	89.53
My first impulse is to say no.	1	1.16	78	90.70
Paramedics don't have the medical training a doctor does.	1	1.16	79	91.86
People need to have a say. If people cannot speak for themselves or their family members, then I don't believe it should be done.	1	1.16	80	93.02
Possible adverse reactions for people with allergies	1	1.16	81	94.19
RF	1	1.16	82	95.35
Some doctor should not decide for me.	1	1.16	83	96.51
They would not have my medical background.	1	1.16	84	97.67
What if you were allergic to it? You might die.	1	1.16	85	98.84
You haven't told me enough.	1	1.16	86	100.00

Open ended response to Yes in Q1

O_Q1YES	Frequency	Percent	Cumulative Frequency	Cumulative Percent
	31	36.05	31	36.05
As it is now, I am already a donor so I believe in helping research.	1	1.16	32	37.21
As long as the experimental combination seems not harmful and may help, I think it would be worth participating, as my experience could help with saving others in the future.	1	1.16	33	38.37
As long as the study fluid had already been tested and did not to have any detrimental side effects. It should perform the same or better than the standard saline solution on everyone.	1	1.16	34	39.53
Because in earlier studies research has showed that it was helpful, and I would prefer every opportunity to survive.	1	1.16	35	40.70
Certainly rather take a chance on something that might be better than the standard treatment	1	1.16	36	41.86
DK	3	3.49	39	45.35
Doesn't sound like anything harmful and may have potential to help. I trust OHSU trauma program	1	1.16	40	46.51
Even though it's not conclusively proven, I trust the amount of evidence already found that says it may be better. In a life or death situation it may	1	1.16	41	47.67

be what's needed to survive.				
Hope for survival	1	1.16	42	48.84
I am an EMT and I would want every opportunity to try something that may be better than saline.	1	1.16	43	50.00
I believe in modern advances.	1	1.16	44	51.16
I guess I would want the best chance that I could get.	1	1.16	45	52.33
I had a similar experience and would wish the same for someone else.	1	1.16	46	53.49
I have been in a double blind study before. I like to contribute to science and I recognize that this is a tricky situation to be in and has to be experimented.	1	1.16	47	54.65
I have been in this situation; a bad car accident and I know that I am sensitive to certain types of medications.	1	1.16	48	55.81
I have had accidents where I fell and my family was not available. I was treated very well by the paramedics that came so I have reason to trust them.	1	1.16	49	56.98

Open ended response to Yes in Q1

O_Q1YES	Frequency	Percent	Cumulative Frequency	Cumulative Percent
I recently was injured and had a severely fractured leg. I was hurt so badly that I was not aware of my surroundings or how severe my injuries actually were. So I would be willing to have things done without my consent as long as there was	1	1.16	50	58.14
I think that it could have long term benefits for other people.	1	1.16	51	59.30
I would go along with it if it would save my life.	1	1.16	52	60.47
I would hope that it might be an improvement from existing methods.	1	1.16	53	61.63
I would like to think everything possible would be tried.	1	1.16	54	62.79
I would want to live.	1	1.16	55	63.95
I'm assuming the experimental fluid would be at least equal to the standard treatment and not harmful.	1	1.16	56	65.12
I've been close to death twice in my life and if it would save my life I would agree.	1	1.16	57	66.28
If it benefited me, I suppose that I would.	1	1.16	58	67.44
If it were assumed to have a more positive response, it may be in my best interest to receive the new treatment.	1	1.16	59	68.60
If it were beneficial, then I would think that everyone would opt for that treatment.	1	1.16	60	69.77
If it's life or death I guess it's okay. But I am scared about what is happening in Africa with experiment drugs and consent.	1	1.16	61	70.93
If there was a chance of saving life then it should be pursued. I have papers not to necessitate in my	1	1.16	62	72.09

car, at home, and with my doctor.				
If this medicine was beneficial to me, then I would be willing to try it.	1	1.16	63	73.26
If your flatline in the helicopter you have to have fluids, if there is better chance with experimental fluids to start the heart I would want that. I would want the best thing done if I weren't awake to give consent.	1	1.16	64	74.42
If you're that seriously injured, what difference would it make? I'm sure they would not intentionally give some chemicals that would make it worse.	1	1.16	65	75.58
It is important to develop new research to develop ways to take care of people and I think it should be randomly assigned for validity.	1	1.16	66	76.74

Open ended response to Yes in Q1

O_Q1YES	Frequency	Percent	Cumulative Frequency	Cumulative Percent
It might be the one chance to save your life, and if you're not able to say yes, then they may be able to make that judgment for you.	1	1.16	67	77.91
It will be better for someone else in the end. It also benefits scientific research.	1	1.16	68	79.07
It would be based on a study and guarantee more probability of surviving.	1	1.16	69	80.23
It would help save other people.	1	1.16	70	81.40
It's important to do more research to see if we could come up with better solutions.	1	1.16	71	82.56
It's important to move science forward. In an emergency, if an IV is established and there is some blood pressure, as long as some fluid is received it would be beneficial, regardless of the fluid type. Benefits outweigh the risks.	1	1.16	72	83.72
I'm a nurse and I am pretty open to a certain degree to experimenting and this seems fairly simple.	1	1.16	73	84.88
I've been in the hospital with serious injuries before, and think the doctors are much more capable of making decisions about what should be done than either myself or my family.	1	1.16	74	86.05
No reason not to participate.	1	1.16	75	87.21
The odds would be better with having the chance to get the study medication based on your prior statement about the positive findings. On the other hand, depending on how bad my injury was I might not want a better chance of survival.	1	1.16	76	88.37
The study will help to save more people later.	1	1.16	77	89.53
There is so much advancement in science these days.	1	1.16	78	90.70
They have to find a way to try new things	1	1.16	79	91.86
They're coming up with so many wonderful things these days, why not give people the chance to prove that new medicines work.	1	1.16	80	93.02
Trusting that serious background research has been	1	1.16	81	94.19

done on the experimental fluid, and given the high-risk situation, I'd participate for the good of the community.

Usually those folks know what's going on.

1 1.16 82 95.35

We have papers filed with our primary care provider to end or continue our lives with certain conditions. I feel it is important to contribute to science.

1 1.16 83 96.51

Without these types of experiments, there would be no advances in medicine.

1 1.16 84 97.67

Open ended response to Yes in Q1

O_Q1YES	Frequency	Percent	Cumulative Frequency	Cumulative Percent
You can give your consent at the hospital, and get the information at that time.	1	1.16	85	98.84
You can't wait sometimes to get in touch with the family.	1	1.16	86	100.00

Open ended response to Yes in Q3

O_Q3YES	Frequency	Percent	Cumulative Frequency	Cumulative Percent
	1	1.16	1	1.16

Open ended response to Yes in Q3

O_Q3YES	Frequency	Percent	Cumulative Frequency	Cumulative Percent
	70	81.40	71	82.56

DK	3	3.49	74	86.05
I don't like being experimented on.	1	1.16	75	87.21
I just don't think its right. I am severely allergic to penicillin and would die if it were given to me. What about the allergies associated with it?	1	1.16	76	88.37
I would be offended.	1	1.16	77	89.53
It is an experimental treatment being done without consent. Perhaps if they screened people before for allergies and possible interactions with the medicine and then were given bracelets saying that you are okay to receive the treatment and	1	1.16	78	90.70
It is without consent.	1	1.16	79	91.86
It would have to be consented to first.	1	1.16	80	93.02
My daughter decides things like that for me.	1	1.16	81	94.19
My other family members would probably not like it.	1	1.16	82	95.35

People should be of clear mind when making this type of decision.	1	1.16	83	96.51
There isn't enough known about it.	1	1.16	84	97.67
There was no implied consent given.	1	1.16	85	98.84
They have no right to do the study without you knowing. It does not seem right that they took a chance on you.	1	1.16	86	100.00

Open ended response to No in Q6

O_Q5NO	Frequency	Percent	Cumulative Frequency	Cumulative Percent
	35	40.70	35	40.70

Open ended response to No in Q6

O_Q5NO	Frequency	Percent	Cumulative Frequency	Cumulative Percent
	3	3.49	38	44.19

15-17 year olds have parents who should be responsible and decide that sort of thing.	1	1.16	39	45.35
15-17 year olds need to have people to answer for them.	1	1.16	40	46.51
Children are different and ethically should be treated differently.	1	1.16	41	47.67
DK	1	1.16	42	48.84
Don't mess with minors.	1	1.16	43	50.00
For minors, in emergencies everything should be done per protocol, without any deviations.	1	1.16	44	51.16
For the same reason that I would not want to do it.	1	1.16	45	52.33
I can't see that there are any positives in it, and the age would be an issue.	1	1.16	46	53.49
I do not agree with this study.	1	1.16	47	54.65
I don't think it's a right. They would have to first be sure that the fluid was good for people.	1	1.16	48	55.81
I don't think that it should be made any different because of age.	1	1.16	49	56.98
I think it would be more of a parent's decision until they turn eighteen.	1	1.16	50	58.14
I think it's more appropriate to do the trials on adults because they are minors and parents should be able to decide what is best for the child.	1	1.16	51	59.30
I would be worried about the parent's concerns. Personally, I would be more careful with my children than I would with subjecting myself to experimental treatments.	1	1.16	52	60.47
I would say just because it's a study and they might not know enough about it.	1	1.16	53	61.63
I would say no because they are not old enough to	1	1.16	54	62.79

make decisions in the first place. An adult should be the only person to make an informed decision. I'd want something tried and more secure to give kids the best possible hope; I would not want to take the risk with kids.

If there is risk it should not be applied to a person that age.

It hasn't been tried yet.

It is experimental and there is not enough data to support it, I would hesitate to include minors.

1	1.16	55	63.95
1	1.16	56	65.12
1	1.16	57	66.28
1	1.16	58	67.44

Open ended response to No in Q6

O_Q5NO	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Just too young	1	1.16	59	68.60
Minors are under age so the decision needs to be left to the parents.	1	1.16	60	69.77
Not until there is more data	1	1.16	61	70.93
Not without some implied consent; if treatment resulted in some disability that was as bad or worse than accident, minors would have longer to have to live with the disability.	1	1.16	62	72.09
The older you get, the less of a problem it would be, but the younger you are, the more assurance the family would need to have to make a decision.	1	1.16	63	73.26
The parent would have to give consent.	1	1.16	64	74.42
The parents should have consent.	1	1.16	65	75.58
Their age	1	1.16	66	76.74
Their bodies are readily changing and react differently. They haven't finished growing and they have an ability to mend quicker; they're just different. I don't think a minor should be involved in a study without a parent's consent.	1	1.16	67	77.91
Their parents, even though you cannot get a hold of them, should have a say in the decision.	1	1.16	68	79.07
There needs to be more conclusive evidence before involving minors.	1	1.16	69	80.23
They are minors.	1	1.16	70	81.40
They are not consenting adults.	1	1.16	71	82.56
They are not legal according to law; they do not have the same rights as adults.	1	1.16	72	83.72
They are not legally responsible for themselves yet.	1	1.16	73	84.88
They are not of legal age to make any kind of decision, parents should make that decision.	1	1.16	74	86.05
They are not old enough to give consent and nobody can give consent for them besides their parents.	1	1.16	75	87.21
They are not old enough to make an informed decision. This sort of thing should not be done to the youth; do it to us, old folks.	1	1.16	76	88.37
They are not old enough to make that decision for themselves otherwise.	1	1.16	77	89.53
They are not old enough to make that decision on	1	1.16	78	90.70

their own.

They are still growing and developing, and may be too young for that sort of thing. 1 1.16 79 91.86

They are younger and parents might get upset about them being given it. 1 1.16 80 93.02

They don't have the ability to make their own decisions. 1 1.16 81 94.19

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The FREQ Procedure

Open ended response to No in Q6

O_Q5NO	Frequency	Percent	Cumulative Frequency	Cumulative Percent
They have no legal consent. In this day and age, with cell phones and easy communication, there should be no reason why the parents could not be contacted.	1	1.16	82	95.35
They should be able to pass judgment on their own, and be more mature to make these decisions.	1	1.16	83	96.51
This is a minor; we can't use them for experiments.	1	1.16	84	97.67
We should do the study with adults and establish the treatment before trying on kids.	1	1.16	85	98.84
With an issue like this, it needs to be talked over beforehand if doing something different than normal.	1	1.16	86	100.00

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The FREQ Procedure

Open ended response to Yes in Q6

O_Q5YES	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Close enough to adult age to be alright	51	59.30	51	59.30
DK	1	1.16	52	60.47
Feel anything to save their life would be good	3	3.49	55	63.95
For the same reason as with adults.	1	1.16	56	65.12
For the same reasons as with adults.	1	1.16	57	66.28
I don't think that they're any different than using older people in the study. If it could give us more information for the future, it would be fine to use that age group.	1	1.16	58	67.44
I don't think it makes a difference.	1	1.16	59	68.60
I don't think it's much of a difference.	1	1.16	60	69.77
I think if it were thought that this was going to be in their favor, I would want them to have the treatment too.	1	1.16	61	70.93
I think that if the possible benefits outweigh the risk then why not give it to children too.	1	1.16	62	72.09
I think that it is important because it may help	1	1.16	63	73.26
	1	1.16	64	74.42

save their lives.

I think the doctors are very capable about making decisions for what is best, for adults as well as children.	1	1.16	65	75.58
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I think they are more likely to get hurt.	1	1.16	66	76.74
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I work in medical records and I believe that our age of consent is 16 years old. Medically, you are emancipated earlier than age 21.	1	1.16	67	77.91
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I would base it on expecting that OHSU should be an up-to-date, reputable association.	1	1.16	68	79.07
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I would want to give them every opportunity to survive.	1	1.16	69	80.23
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If it has the same results, it doesn't matter if it's a 15 or a 40 year old.	1	1.16	70	81.40
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If it is going to be used for children then it should be tested to see if there are different side effects.	1	1.16	71	82.56
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If it were truly beneficial, I would think that would be the standard action to take.	1	1.16	72	83.72
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If same benefits and risks, I see no reason why not.	1	1.16	73	84.88
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If we don't, then there could be some doubt if it works on that age group	1	1.16	74	86.05
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If you cant get a hold of anyone you better have something that will help him or her, even if it is experimental.	1	1.16	75	87.21
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It would compliment the study as long as the same safeguards would be in place.	1	1.16	76	88.37
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The FREQ Procedure

Open ended response to Yes in Q6

O_Q5YES	Frequency	Percent	Cumulative Frequency	Cumulative Percent
It would depend on the seriousness. If they are unconscious then the paramedics or doctor would not know what the patient is allergic to.	1	1.16	77	89.53
It's a high risk group, and I don't see consent for a minor as being different from adults consent rights.	1	1.16	78	90.70
It's better to have a chance at something that is better than standard treatment.	1	1.16	79	91.86
I'm sure they would not do anything that was harmful or without some previous testing.	1	1.16	80	93.02
Minors are often passengers in vehicles and it wouldn't be their fault it the driver got into a serious accident. Any parent would want anything possible to be done to save the child.	1	1.16	81	94.19
They are almost adults.	1	1.16	82	95.35
They can get hurt just as easily, and if it works they need the same treatment.	1	1.16	83	96.51
They deserve a fair chance too; if it were my child, I would want them to have the same chance.	1	1.16	84	97.67

They have just as much a right to live as adults.	1	1.16	85	98.84
They're practically grown.	1	1.16	86	100.00

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The FREQ Procedure

Open ended response to Yes in Q7

O_Q6YES	Frequency	Percent	Cumulative Frequency	Cumulative Percent
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	49	56.98	49	56.98
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The FREQ Procedure

A lot of people would probably not like it, but in some cases it might be necessary in order to save lives.	1	1.16	50	58.14
Again, they would have to be positive that it works first.	1	1.16	51	59.30
Everything we now accept was once experimental, so I do favor experiments.	1	1.16	52	60.47
I am worried about what this could lead to.	1	1.16	53	61.63
I don't have any problems with it.	1	1.16	54	62.79
I don't think they need written consent in this situation. As long as the medication would not be damaging to the brain, I wouldn't have any problem with this study being conducted. I know OHSU and trust them not to harm people.	1	1.16	55	63.95
I frequently do all kinds of things to treat people without consent; we must learn about new treatments somehow. Also, I have professional experience with OHSU and trust them and their trauma systems.	1	1.16	56	65.12
I know that this will be territory that is controversial, and that in order to carry it out there would have to be wide agreement among doctors that the medicine used is unlikely to be harmful. Some people are very paranoid and may not feel	1	1.16	57	66.28
I realize it's not always possible in this situation, but I prefer to have consent; I would prefer to have a family member make the decision.	1	1.16	58	67.44
I think a poll should be used in the area of the study, to canvass as large a group as possible, to see how they feel about the study before a decision is made to conduct it.	1	1.16	59	68.60
I think doctors should be given more latitude, everyone is concerned about being sued, but I think doctors should be allowed to make decisions and not be told how to do their work.	1	1.16	60	69.77
I think it is very important that things like this take place, otherwise, science cannot move forward. In this situation, there is no way to gain consent.	1	1.16	61	70.93
I think that this needs to be advertised so that people know about the study and the side effects of the medicine.	1	1.16	62	72.09

## The FREQ Procedure

Open ended response to Yes in Q7

O_Q6YES	Frequency	Percent	Cumulative Frequency	Cumulative Percent
I would go along with the study if I had to, but I would not willingly be a part of it. If the whole community decided it was right, then the majority rules, and I agree with that.	1	1.16	63	73.26
I would like to have more info in terms of allergies.	1	1.16	64	74.42
I would suggest a program like an organ donor program for getting consent for an experiment like this.	1	1.16	65	75.58
I would want more information about it.	1	1.16	66	76.74
If a doctor makes a decision that that would be the only thing to save their life, I would say yes.	1	1.16	67	77.91
If it was possible to get consent I would think OHSU would want to do that.	1	1.16	68	79.07
If it were beneficial, or a more beneficial treatment, then I wouldn't care. But I would understand that other people might be upset about not getting their consent.	1	1.16	69	80.23
If there were such a treatment under these experiments, I would hope it would be made public so people could know about it.	1	1.16	70	81.40
If you need it and your unconscious then the paramedics should do what is best for you.	1	1.16	71	82.56
In many situations, there is simply no time to get written consent. Paramedics just have to treat people right away and deal with consent issues at a later time.	1	1.16	72	83.72
Informing the public about what is going on is very important. Do not keep any secrets from the public. It benefits the whole community.	1	1.16	73	84.88
It is acceptable because of the low risk of allergic reaction.	1	1.16	74	86.05
It is too risky; I think that if it was something that we knew about and we used it before it wouldn't be a problem. It should be used for consenting people only; I don't think anything experimental should be used without consent.	1	1.16	75	87.21
It should be done cautiously.	1	1.16	76	88.37
It would have to be something that the doctors would be comfortable with, I understand that it is a touchy subject but research needs to be done.	1	1.16	77	89.53
Most older people have someone to speak for them, even if it's the clergy. Someone should be responsible; there's always someone around to make those decisions. Someone should give permission to have this done.	1	1.16	78	90.70
	1	1.16	79	91.86

## The FREQ Procedure

Open ended response to Yes in Q7

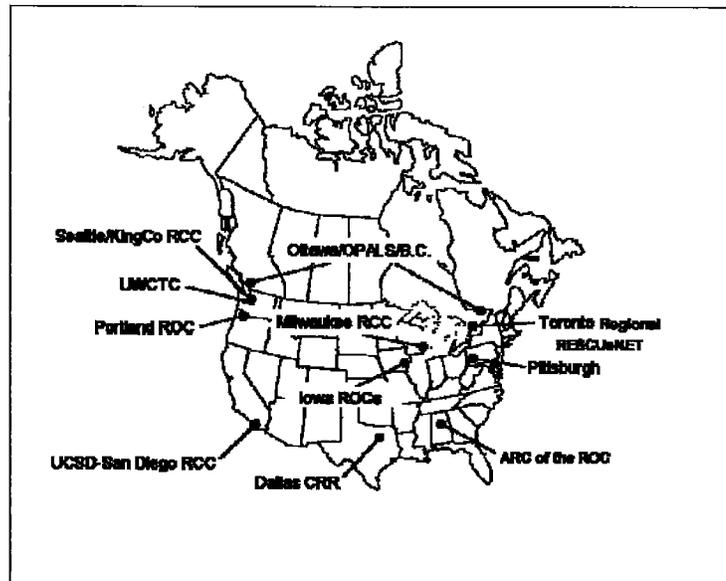
O_Q6YES	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Once you explained the study, it didn't seem as bad as it did at first.	1	1.16	80	93.02
Some people might want to know before, but I wouldn't.	1	1.16	81	94.19
The probability of it being effective has to be equal or better to the current treatment. It needs to be scientifically better, not just 1%, or something like that.	1	1.16	82	95.35
This is borderline unethical.	1	1.16	83	96.51
This would be wrong. It's just a way for a drug company to get research. It's a way of doing research without having to pay for it.	1	1.16	84	97.67
Written consent should be done first for people that can do that.	1	1.16	85	98.84
You would expect them to test it completely before they do it.	1	1.16	86	100.00



## What is ROC?

The Resuscitation Outcomes Consortium (ROC) was created to study which treatments help people with cardiac arrest or severe injury.

The ROC consists of 11 sites and a coordinating center. The ROC investigators work with Emergency Medical Services (EMS) systems to do these studies. Treatments studied include new or alternative resuscitation drugs, tools, and techniques. The ROC investigators do studies in which people who qualify receive either the currently used treatment or an alternative treatment (sometimes already in use in other communities) assigned by chance (like tossing a coin). The studies are designed to compare treatment options so that EMS providers can determine those treatments most likely to benefit the public. The ROC investigators will also describe the rate of severe injury and cardiac arrest in the ROC communities.



## Why was ROC formed?

The ROC is a group of investigators and EMS providers who study cardiac arrest and severe injury as these conditions cause many deaths. Experimental treatments for cardiac arrest and severe injury are being studied within the ROC because:

- Medical experts believe the sooner these patients receive either treatment, the better the outcomes.
- The ROC will help determine which treatment works best.
- Doing research in cities and in rural areas will help us learn what works best in different settings.
- Research studies involving many sites take less time to complete, thus allowing trial results to more quickly guide future practice.
- Collecting information about the rate and outcome from severe injury and cardiac arrest will tell us how many patients with these conditions survive and return to live and work in their community.

## Why is ROC research vital?

Cardiac arrest and serious injury are important public health problems. Heart disease is the most common cause of death in North America. Over 180,000 treatable out-of-hospital cardiac arrests occur each year. Over half of these victims have no warning. Nearly 95% of patients who have an out-of-hospital

cardiac arrest die before reaching the hospital. If survival could be raised from 5% to 20%, an additional 27,000 deaths would be prevented yearly.

Life-threatening severe injury is the leading cause of death in North America for persons between the ages of 1 and 44 years, and one of the leading causes of death in those over the age of 65 years. Approximately 175,000 injury-related deaths occur each year in North America. New drugs, tools, and techniques have the potential to significantly improve the outcomes of people with these medical conditions.

### **What hope does ROC bring to the public?**

People who live in ROC communities may benefit by having:

- Better training and support for EMS providers.
- Careful study of treatments for patients with cardiac arrest and serious injury.
- Close follow-up of patients who receive the treatments being investigated.

### **What are the ethical considerations with this kind of research?**

Clinical studies of treatments are only approved when the best available scientific evidence cannot determine whether one treatment is better than another (equipoise). In this case, there are scientists and physicians who advocate for the different treatments, but no agreement that one approach is better than the other.

People who may be part of a research study usually are told about the benefits and risks of the study (and their legal rights) before they receive any study intervention. Patients generally sign a consent form before they participate in the study. In an emergency, there is not enough time to get consent from the patient or their family. Thus EMS research must be done with an exception to informed consent. Before the exception can be granted, the public must be told about the research and be able to give their opinion about it.

After the public has been notified, a study can proceed without informed consent. Efforts are made following the emergency to obtain informed consent from the patient if they are capable of doing so, or from their legally authorized representative if they are not, for continued participation in the study.

In addition to demanding the above features be met, the ROC has several layers of research review in place to safeguard patients:

- An independent group of experts reviews the scientific value of the proposed trial.
- A separate expert group authorized by the National Institutes of Health reviews the safety of the trial and monitors the safety of patients through out the study.
- An expert in medical ethics affiliated with ROC reviews the proposed research.
- If a new device or drug is to be studied, the U.S. Food & Drug Administration (FDA) reviews and approves the study before it starts.

•At each site a review group evaluates and monitors the research locally. This final review and approval focuses on the local issues of how best to consult with the public regarding both the study treatment(s) and outcome(s) and notify them about the research.

**IF SOMEONE WERE UNCONSCIOUS DUE TO A CARDIAC ARREST OR SEVERE INJURY WOULD THEY BE ENROLLED IN A ROC RESEARCH STUDY?**

Yes, the goal of the ROC community-wide EMS resuscitation studies is to enroll all eligible patients at the earliest possible time, when treatment is most promising.

**IF SOMEONE WERE ENROLLED IN A ROC RESEARCH STUDY, HOW WOULD THE PERSON OR FAMILY BE MADE AWARE OF THIS?**

Participating EMS providers notify the ROC research staff when a patient is enrolled in a research protocol. A ROC research staff member will then approach the patient or their representative in person, by phone or via letter. The study will be described to them at that time.

**Who will be doing the research?**

- The University of Washington Clinical Trial Center, Seattle, WA, coordinates the network. The following regional sites are participating:
- The Alabama Resuscitation Center is coordinated through the University of Alabama at Birmingham in Birmingham, AL, USA and includes systems in Alabama.
- The Dallas Center for Resuscitation Research is coordinated through the University of Texas Southwestern Medical Center in Dallas, TX, USA and includes some surrounding cities.
- The University of Iowa Carver College of Medicine-Iowa Resuscitation Network is coordinated through the University of Iowa in Iowa City, IA, USA and includes 10 cities throughout Iowa.
- The Milwaukee Resuscitation Research Center is coordinated through the Medical College of Wisconsin in Milwaukee, WI, USA.
- The Pittsburgh Resuscitation Network is coordinated through the University of Pittsburgh in Pittsburgh, PA, USA and includes some suburbs of Pittsburgh.
- The Portland Resuscitation Outcomes Consortium is coordinated through the Oregon Health & Science University in Portland, OR, USA and includes 4 counties in Oregon and Washington states.
- 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, British Columbia in Canada and includes 20 other cities in the OPALS group.

- The UCSD-San Diego Resuscitation Research Center is coordinated through the University of California at San Diego in San Diego, CA, USA and includes the entire county.
- Seattle-King County Center for Resuscitation Research at the University of Washington is coordinated through the University of Washington WA, USA and includes all of King County.
- The Toronto Regional Resuscitation Research Out-of-hospital Network is coordinated through the University of Toronto in Toronto, Ontario, Canada and includes surrounding areas.

### **Who is Funding the Project?**

- The National Heart, Lung and Blood Institute (the lead Federal Government sponsor of this program)
- U.S. Army Medical Research & Materiel Command
- National Institute of Neurological Disorders and Stroke
- The Institute of Circulatory and Respiratory Health (ICRH) of the Canadian Institutes of Health Research
- Defense Research and Development Canada
- The Heart and Stroke Foundation of Canada
- The American Heart Association

### **How can I learn more about ROC?**

You can contact Denise Griffiths at 503-494-7015; 888-370-2888 or visit the ROC website at [www.ohsu.edu/emergency/roc](http://www.ohsu.edu/emergency/roc)



22-June-2006

## **Hypertonic Resuscitation Following Traumatic Injury Community Consultation Summation**

We have spent the past 3 months focusing much of our time on the community consultation process for the Hypertonic Saline (HS) study. During this time we have reached out to the community and learned much:

### **What we did to communicate with the community\*:**

- Regional media (newspapers, radio, and television) were provided a series of materials related to the study (e.g., NIH press release [nationally released]; OHSU community focused press release). These media contacts resulted in 2 news stories in the Oregonian, one in the Columbian, one in the Portland Chinese Times, a news calendar announcement in the Portland Tribune, and a story on KPAM radio.
- Newspaper ads were run in both the Oregonian and the Columbian to announce public forums for discussion of the study in each county (Clackamas, Multnomah, Washington, and Clark).
- Flyers (40+) announcing the open forums were posted in bus stops, grocery stores, public restrooms, elevators, etc. in the 4 counties.
- Information regarding the study and open forums was posted in newsletters around OHSU (one of the communities' largest employers).
- The open forums were held in each of the 4 counties providing direct community dialogue.
- A local website was developed that provides information about the study, answers to frequently asked questions, and offers contact information so that the public can get in touch with the research personnel. The website also permitted an opportunity for the community to complete the study survey (35) addressing personal willingness to participate as a subject in the study.
- In each of the 4 counties, letters providing background and offering the opportunity to discuss the study were sent to city officials, state representatives, senators, and neighborhood associations.
- Two random digit dial (RDD) phone surveys (including cell phone numbers) in the 4 counties were administered independently by Portland State University personal willingness to participate as a subject in the study. The first RDD produced 186 surveys and the second produced 86 surveys.
- Presentations regarding the study were provided to selected community groups to encourage dialogue with minority groups (e.g., the Asian Health & Service Center, the Vancouver Avenue First Baptist Church) and where requested in response to letters, presentations were given to interested neighborhood groups (e.g., West Linn Hidden Springs Neighborhood Association). Surveys (55) were completed at the end of these presentations. Efforts to present to other ethnic and community groups (e.g., Hispanic-Latino community groups) were repeatedly made, but did not succeed due to full agendas by those organizations.
- A cable-access broadcast of the material given in the open forums (and during community group meetings) was aired with a focus on the Multnomah Co. African-American viewer. This 1-hr video broadcast was aired 3 times (once live) with the Portland Community Media.
- Contacts were made with a number of other groups, such as, churches, unions, rotary clubs, Christian Scientist, Jehovah's Witnesses, special events, and community leaders.

*\*All materials that went out to the community have the ROC website and contact information on how to reach us.*

22-June-2006

**What we learned from the community:**

-The random digit phone survey represents perhaps the least biased method of approaching the community at-large, albeit it like all surveys, it is limited since it is voluntary and many people choose not to participate. Other limitations are that some citizens are away from their phone more than others or do not have a phone. Despite these limitations, the independent surveyors had a participation rate better than most political surveys. Further, the initial survey demonstrated a 77% positive response. This favorable response rate increased when the respondent was informed of the safety of the agents under study. The second phone survey demonstrated a 65% positive response. This survey took place amidst considerable negative publicity regarding a blood substitute study in the media. This other commercially-funded study (although not being performed in our community) also was being done under the exception to informed consent provision. The adverse media coverage may have influenced our respondents. The second survey also used slightly different wording, which conveyed patient "willingness" versus patient "want" given a severe injury with potential life-threat.

-The 4 open forums were poorly attended but few concerns were raised. Despite considerable effort to publicize these meetings through advertisements, letters and media releases, the limited attendance at these meetings suggests that the issue may be less controversial to the community at-large than self-selected respondents to our offer for further discussion. To that end, the majority of attendees at two minority-group focused meetings favored the study, although one neighborhood group that requested a presentation spoke against any study that did not use fully prospective informed consent. Similarly, we received 5 phone calls from members of the community after the announcement went out. Two were negative and 3 were positive.

In summary, the community generally accepted the scientific basis for the hypertonic saline study and its rigorous review process and safety features. Although, both investigators and community members agree that using the exception to informed consent is less desirable than a fully prospective informed consent process, the majority of community members responding through the various modes of contact supported moving forward with the study as a reasonable alternative. There remains a small, but vocal minority within the community that does not favor research of any nature without fully prospective informed consent. The investigators have reviewed the suggestions made by these individuals for the purpose of obtaining such consent from all at-risk individuals (including those passing through the community) in advance of a serious injury. We do not find any of these approaches to be feasible. Indeed, these approaches are prohibitively costly (in terms of resources and time) and even with unlimited resources would inadvertently exclude large numbers of potentially impacted subjects (who based upon community surveys and community forums) are more likely to desire participation than not. That said, we believe it is reasonable to provide an option for those individuals who are opposed to any such study participation to prospectively opt out of an EMS-based resuscitation study.

**What we will do to satisfy those who oppose the study:**

We will inform the community regarding the method to opt out of study participation via the wearing of an identifiable bracelet. We will do this by notices in the local newspapers, city and county newsletters, and on the local ROC website. We will let the public know how they can contact us to request such a bracelet. We will mail the bracelet or they can pick it up. These bracelets will be available to those requesting to opt out of the study in advance of the study initiation and while the study is ongoing. To allow those who opt out the opportunity to change their mind, the bracelets will be removable.