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Date: July 18th, 2006

To: Dr. Michael Caligiuri
Director HRPP

Project: #060184

Name: Hypertonic Resuscitation Following Traumatic Injury

Dr. Caligiuri,

This letter is to report the activities and findings of the community consultation and public notification process for the above mentioned protocol as required for the exception to informed consent.

The process of reaching out to the various communities in San Diego County began with sharing the protocol concepts with the physicians who are the trauma directors for the major trauma hospitals in the county at the Medical Advisory Committee (MAC). This committee includes all the trauma directors, their trauma coordinators and the San Diego County EMS Medical Director and Interim EMS Director. The communication was initiated in the summer of 2004 when San Diego was anticipated to be accepted by the Resuscitation Outcomes Consortium (ROC) Executive Committee as being a site and active contributor to ROC. Once a trauma protocol was selected, it was essential that the trauma directors agree upon its feasibility and express their support. This support was garnered by Dr. David Hoyt, who at the time was the principal investigator for the San Diego ROC grant, a very influential member of ROC, and Co-chair of MAC. He was also Trauma Director and Interim Chair of Surgery for UCSD at that time. Within the past three months, Dr. Hoyt has relocated to Irvine after accepting the position of Chair of Surgery at UC Irvine. He remains active within ROC as a co-investigator at the San Diego ROC site and as ROC Steering Committee Trauma Co-Chair. Dr Hoyt initiated the process of community consultation and public notification while still at UCSD.

As of July 2006 I have accepted the role of PI at the San Diego ROC site and have completed the process initiated by Dr. Hoyt. This transition has been relatively seamless, as I was previously involved in the San Diego ROC site as co-PI, and am well versed in the requirements of

this protocol and the responsibilities as the San Diego ROC site PI. I too am very active within ROC as Chair the EMS Operations Committee and a member of multiple other ROC committees.

One of the first activities related to informing the community about ROC and the potential protocols came from the National Institute of Health (NIH) with their March 24, 2006 press release. The intent of this press release was to let the national public know about ROC, the support from the National Heart Lung and Blood Institute (NHLBI), the participating sites, and how this research is anticipated to help major trauma and cardiac arrest victims. That press release is included in this packet.

The UCSD Public Relations department has become quite familiar with ROC and has been actively involved in the community notification process. They authored the local press release and distributed it to the San Diego news media on July 27th 2006. On August 13, 2006 the North County Times interviewed myself and wrote an article about ROC and how it will integrate with other local hospital initiatives to improve patient care in trauma and cardiac arrest. In addition, Cheryl Clark from the Union Tribune is conducting a series of interviews with myself to run later this month.

The UCSD Public Relations Department also contacted a local television station, which sent a crew to UCSD to film an interview with myself and reporter Carol LeBeau. This was aired on July 28, 2006 at 5:00 p.m. on the Channel 10 news as a "Staying Healthy" feature. Channel 10 also posted the information on their website. A copy of that information is included in this packet.

Community meetings were arranged in various parts of the county including, Chula Vista Library (Wednesday, August 16, 2006), Carlsbad Library (Thursday, August 17, 2006), San Diego Library, Poway Branch (Thursday, August 17, 2006), and El Cajon Library (Friday, August 18, 2006). These meetings varied in time of day and day of week and were located at libraries for easily access and parking. The meeting rooms were arranged so that handouts and sign in sheets were readily available at the door, and a ROC staff member was present to greet each person as they arrived. Space was allotted for large audiences with plenty of seating. The presentation was provided by PowerPoint and the handout matched the presentation. The same survey that was performed by the Hebert Research group for the telephone survey was also given out to all participants at the community meetings. All participants completed the surveys after having seen the presentation.

Newspaper advertisements were purchased to promote ROC and the community meetings two weeks in advance of the meeting dates. The larger newspapers (Union Tribune – July 30th and August 1st and North County Times on August 8th and August 6th) have a combined circulation of approximately 500,000 per day and are read widely across the county. In addition, the advertisement was translated into Spanish and placed in two newspapers (La Prensa – August 4th and El Latino – August 4th) with a combined circulation of 130,000. An advertisement was also placed in a well known Filipino newspaper (The Filipino Press – August 5th) with a circulation of 25,000 per issue, and the Voice and Viewpoint (August 3rd), with a circulation of 25,000 per issue. Despite these efforts, there was a relatively low turn-out to these meetings. Surveys were provided to all participants and collected after the meetings, with none of the participants declining to participate in the trials.

In the interim there were ongoing discussions with various levels of the EMS community. Both the Medical Advisory Committee, involving the trauma directors, and the Base Hospital Physician Committee, involving the San Diego County EMS, base hospital physicians, and EMS nurse coordinators, were updated monthly. Presentations were given at both these meetings so that

everyone involved was kept informed and understood what progress had been made. Special meetings were requested by some of the hospitals so that persons and physicians not routinely attending these meetings were also informed about ROC the pending trials. Additional detail can be found in the enclosed table.

The Emergency Medicine Services (EMS) paramedics and EMT's have been visited by myself throughout 2005 and early 2006. This provided a face-to-face opportunity with the medics and was also used to discuss the idea of research at the EMT level and its importance. The medics have consistently demonstrated strong enthusiasm to participate in the ROC initiatives, which promise to have a substantial impact on patient outcomes. All county EMS agencies have been contacted by ROC staff and have voiced strong enthusiasm for this research, with no agencies declining to participate. This includes the private agency, American Medical Response (AMR), with a letter of support provided by their Medical Director, Dr. Brad Swartz.

The elected officials of San Diego County have also been informed about ROC and the initial trial. Dr. Bruce Haynes, San Diego County EMS Medical Director and Carmel Angelo, San Diego County EMS Interim Director regularly attend the MAC and BHPC meetings and have shared this information with the San Diego County Board of Supervisors and San Diego County Public Health Officials. Dr Haynes has provided a letter of support for ROC on behalf of San Diego County EMS.

UCSD Public Relations Department invited Assemblymember Lori Saldana (District 76) to UCSD for a tour of the trauma and emergency department facilities. This was followed by a meeting at her office on August 11, 2006 to discuss ROC and the trial in more detail. She did not voice major concerns about the trial or how it was conducted but wanted to assure that her constituents were fairly represented and informed about this trial on an ongoing basis. She expressed that this type of research should be encouraged and helped to brainstorm strategies to improve community engagement.

UCSD Public Relations also shared the press release with City Councilmember, Donna Frye, with no specific comments received in response.

Dr. James Dunford, ROC co-investigator and Medical Director for the City of San Diego, has been part of the San Diego ROC site since the beginning. He has kept the San Diego City Council and Mayor's office informed about ROC and how the trial will be conducted in the city. There was an initial meeting on December 12, 2005 to introduce the ROC study group to the City of San Diego attorney, Joey Sanchez, the city ALS/EMS coordinator, Donna Goldsmith, and several of the EMT educators and San Diego Fire Department chiefs. This included a total of approximately 35 participants, with the overall consensus at that time to proceed with plans to include the San Diego City Fire Department in the research plan for the County. Ongoing discussions between ROC and the city council and mayor's office are continuing and should be completed soon.

The trauma hospital administrations were informed through the various individual IRB processes at Scripps Mercy Healthcare, Scripps La Jolla Healthcare, Sharp Health Care, and Palomar Pomerado Health Care. All the above mentioned IRB's have fully reviewed this trial on behalf of each of their facilities, with no major objections put forth and only minor clarifications requested. Each of these IRB approvals are pending full approval from the UCSD IRB. One week prior to the community meetings, emails were sent to all IRB Administrative Directors and their associated Trauma Directors inviting them and anyone they thought might have interest to attend one of the community meetings.

If you would like additional information on any of these matters, please contact me or my research coordinator, Donna Kelly at 619-471-0616.

Sincerely,

Daniel Davis, MD
Principal Investigator

San Diego County Community Consultation and Public Notification
ROC Hypertonic Saline Resuscitation following Traumatic Injury Table Report

ROC Participant **Type of Event** **Event Date** **Response and Comment**
General Public Notification

Hebert Research Inc.	Telephone survey	Week of June 6 th to 14 th 2006	A telephone survey was done by the Hebert Research from Bellevue, Washington to assess what San Diegans felt about this type of research being done in their community. The company surveyed 502 persons in English and Spanish through out the county. This company is familiar with ROC and have done similar surveys for the Seattle ROC site, the Portland ROC site, Milwaukee ROC site and the Dallas ROC site. Survey results for San Diego were that the overall response to doing this type of research is well accepted with 80% respondents would not object to being included in this HSD trial. There were no trends in potential issues raised by the public. Full report enclosed.
UCSD Public Relations	UCSD Press Release	July 27 th 2006	Press release from UCSD with general information on ROC and the research intended. This was distributed to local newspaper reporters. As a result the North County Times Newspaper interviewed Dr. Daniel Davis and printed a story about UCSD's participation in ROC on August 13 th 2006. The article was favorable and explained how the county will work together in this venture with UCSD leading the program. Copy enclosed. The press release was also posted to the public UCSD website and highlighted on the main web page as well as being posted to the UCSD Healthcare webpage. Copies of both enclosed.
Dr. Daniel Davis /UCSD Public Relations	Interview with Carol LeBeau Channel 10 local news coverage	July 28 th 2006	Aired on "Staying Healthy" Saturday July 28 th 2006 at 5:00 pm on evening news program and posted to their web site.
UCSD ROC Staff	Newspaper advertisement	Union Tribune, North County Times, La Prensa, Voice	Advertisements were taken out in five different local newspapers including two with a Hispanic circulation, one with a Filipino circulation, two with general county wide circulation. Stated what ROC

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Dr. Daniel Davis	Chula Vista Library Community Meeting	and Viewpoint, El Latino, Filipino Press July 30 th to August 5 th 2006 (See attached Grid) August 16 th 2006 6:30 pm to 7:30 pm	is and what types of clinical trials would be conducted. Invitation to community meetings with dates times and addresses included. Union Tribune also placed the advertisement on their website "SignOnSanDiego.com " for one week. Copy of newspapers and print dates enclosed. Attended by ROC staff of Dr. Davis, Dr. Dunford, Lana McCallum Brown and Donna Kelly. Single participant attended and the program was discussed with him. Reviewed hand out and he completed the questionnaire with being in favor of doing this type of research in San Diego. Since the presentation was informal questions related to trials were answered as they came up. Handouts and brochures available for any participant at the door. Copies enclosed.
Dr. Daniel Davis	Carlsbad Library Community Meeting	August 17 th 2006 10:30 am to 11:30 am	Attended by ROC staff of Dr. Davis, Lana McCallum Brown and Donna Kelly. Two participants attended and formal presentation presented by Dr. Davis. Open questions related to trials answered through out presentation and surveys from both participants were obtained, both in favor of doing this type of research in San Diego. Handouts and brochures available for any participant at the door.
Dr. Daniel Davis	Poway Library Community Meeting	August 17 th 2006 2:30 pm to 3:30 pm	Attended by ROC staff of Dr. Davis, Dr. Raul Coimbra, Lana McCallum Brown and Donna Kelly. Participation was limited to two persons. One from the San Diego County EMS office and one from California Assemblywoman Lori Saldana's office. Both these individuals were already very familiar with ROC and the upcoming trials so the discussion was left informal and general questions about this type of research were discussed. There were no surveys completed. Handouts and brochures available for any participant at the door.
Dr. Daniel Davis	El Cajon Library Community Meeting	August 18 th 2006 2:30 pm to 3:30	Attended by ROC staff of Dr. Davis, Lana McCallum Brown and Donna Kelly. There were three

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<u>ROC Participant</u>	<u>Type of Event</u>	<u>Event Date</u>	<u>Response and Comment</u>
Dr. Daniel Davis	Interview with Union Tribune Reporter Cheryl Clarke	August 30 th 2006 pm	participants attending. Formal presentation given and questions during and after answered. All 3 participants completed surveys and there were no objections to doing this type of research in San Diego. Handouts and brochures available for any participant at the door. Article to be printed in the Union Tribune on what ROC is and how it will help the future of Trauma and Cardiac Arrest survival. To go to print in September.
Medical Community			
Dr. David Hoyt and Dr Raul Coimbra, both ROC Co investigators	Medical Advisory Committee (MAC)	Monthly updates to the San Diego County trauma directors and County EMS (third Monday of the month)	The group includes the Trauma Directors for all the major trauma centers in the San Diego County area. Dr. Hoyt was the previous P.I to the HSD trail and is now a co investigator since having accepted a position of Chair of Surgery, UC Irvine. Dr. Coimbra is also a co investigator to the HSD trial and now the UCSD Medical Center. Over the past year various discussions occurred at these meetings related to ROC and the feasibility of doing the research and following the care guidelines within the protocol. All Trauma Directors have agreed to participate.

San Diego County Community Consultation and Public Notification
ROC Hypertonic Saline Resuscitation following Traumatic Injury Table Report

<u>ROC Participant</u>	<u>Type of Event</u>	<u>Event Date</u>	<u>Response and Comment</u>
Dr. Daniel Davis	San Diego County Base Hospital Physician Committee (BHPC)	Monthly meetings to advise and set policy for San Diego County Medical Director. (third Tues of the month)	This group includes the base hospital physicians and nurses, county and city EMT educators, and San Diego County EMS office. Over the past year there have been updates to this group By Dr. Davis who is a regular member as he is the Mercy Air Medical Director as well as the P.I. for ROC. Input from this group has help determine the ability of the research to be done across the county. Questions have been answered as they updates have been provided. There have been no major objections from this group to do this research in San Diego County.
Donna Kelly and Lana McCallum Brown, ROC Research Coordinators	Personal contact with each fire department and first responder agency in San Diego County	Ongoing since October 2004	Contacts have been made with all 39 first responding agencies in San Diego County by the ROC coordinators to explain personally what ROC is and how they can participate in the trial. All agencies have provided what ever information was requested of them related to location, personnel, types of responders available at their locations, types of equipment available to them and so on. There have been no objections voiced by any of the agencies and all are anxious to participate in the trial.
Dr. Daniel Davis and Lana Brown, ROC coordinator	Special Meeting to explain ROC to Scripps Mercy physicians and staff	July 5 th 2006	Drs. Daniel Davis and Michael Sise met with Cardiology Research Nurse Nancy Grey RN, Chief of Staff for Scripps Mercy Hospital Davis Cracoft Chief of Staff for Scripps Mercy Hospital, Administrative Director Patricia Untied, Emergency Department Nurse Manager Jackie Saucier, Physician Educator Beth Sise and ROC Coordinator Lana Brown.

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<u>ROC Participant</u>	<u>Type of Event</u>	<u>Event Date</u>	<u>Response and Comment</u>
Dr. Gary Vilke, ROC Co investigator	Scripps Mercy Medical Staff Grand Rounds	July 25 th 2006	The trails and ROC were presented at the medical staff grand rounds. There were twenty participants including Trauma physicians and nurses, Orthopedic surgeons, Anesthesiologists, Plastic surgeons and Emergency Medicine physicians who attended. There was strong support voiced from the group.
San Diego ROC Staff	All Trauma Directors and IRB Administrators personal email	July 31 st 2006	Email invitations were sent to all the directors of the five trauma facilities and all the IRB Administrative Directors informing them of the schedule of community meetings to take place over the following week. An open invitation was extended to them and anyone they thought might have interest in attending any of the meetings including all the IRB members. There were no participants relating any connection to this group attend any of the community meetings.
Dr. Daniel Davis	Scripps La Jolla Medical Grand Rounds.	August 24 th 2006	Scripps La Jolla Medical Grand Rounds featured Dr. Daniel Davis' talk on what ROC is and what the upcoming HSD trial is about. Approximately twenty participants attended including Trauma physicians and nurses, Anesthesiologists and Neurosurgeons. There was 100% approval voiced from the participants to do this type of research and to support the HSD trial.
Dr. Daniel Davis	San Diego County EMT-P and EMT-D contact including EMS agency medical oversight personnel	Summer of 2005 to current	Dr. Davis has been training and conversing with the San Diego County EMT-P (paramedics) and EMT-D in a one on one environment for the past year. The discussions relate to the importance of doing research to improve their patient's outcomes and the science behind why this is beneficial to participate in and perform the trials correctly. The medics have voiced being excited about participating with this protocol and feel that what is being asked of them is not over burdensome.

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<u>ROC Participant</u>	<u>Type of Event</u>	<u>Event Date</u>	<u>Response and Comment</u>
<u>Elected Officials</u>			
Dr. James Dunford, ROC Co Investigator and San Diego Fire Department EMS Medical Director, Dr David Hoyt and Dr Daniel Davis	San Diego City Structures meeting	December 12 th 2005	Initial meeting set up by Dr. Dunford to introduce the concept of ROC and introduce the ROC staff to some of the city officials that will be involved with ROC. Attending was Joey Sanchez, City Attorney, Donna Goldsmith City ALS/EMS Coordinator, Criss Brainard San Diego Fire Chief, Several of the EMT instructors and the ROC staff. The meeting was well attended with approximately 35 persons attending, mostly from San Diego Fire Department. The concept of research at the field level was discussed and overall agreed that it was something that could be perused.
UCSD Public Relations Sarah Steinhoffer	Council member Donna Frye forward the press release from UCSD	July 27 th 2006	No comment returned from this council member.
Dr. James Dunford, ROC Co Investigator and San Diego Fire Department EMS Medical Director		April 2006 to present	Dr Dunford has been meeting with representatives of the Mayor's office updating the office with the progress of what will be required on behalf of the city and the San Diego Fire Department.
Dr. Bruce Haynes, San Diego County Emergency Medical Services (EMS) Medical Director and Carmel Angelo RN, San Diego County EMS Interim Director	Meetings with San Diego County Board of Supervisors and Public Health Officials	Ongoing meetings over past 9 plus months	Dr. Haynes is the San Diego County EMS Medical Director and has been involved with ROC since he took office at the beginning of this year. He has attended multiple meetings with the County Board of Supervisors and between he and Carmel Angelo the information they receive. Dr. Haynes and Ms. Angelo both regularly attend the Medical Advisory Committee (MAC) and the Base Hospital Physician Committee (BHPC) as well as having frequent direct contact with Dr. Daniel Davis, ROC P.I. They have shared the information from these meetings with the board so that the board can remain informed of the trials being presented, the exception to informed consent issues and the potential impact on the community. There have

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UCSD Public Relations, Sarah Steinhoffer and Dr. Daniel Davis	Meeting with Lori Saldana, Assemblymember, 76 th District	August 11 th 2006	<p>been no reports back that issue exist. Dr Haynes has provided a letter of support for this project to UCSD HRPP.</p> <p>Meeting with Assemblymember Saldana was held in her office with herself, Melanie Cohn, her Field Representatives, Dr. Davis, ROC PI., Donna Kelly RN, ROC coordinator, Dr. Michael Caligiuri, UCSD HRPP Director, Leslie Franz, UCSD Public Relations. This was a follow up meeting as there had been a tour of UCSD trauma facility and emergency department the week prior with Drs. Raul Coimbra, James Dunford and Daniel Davis with Assemblymember Saldana. There was no objection to this kind of research on behalf of Ms. Saldana. Issues raised were more related to how do we let the public be aware of this.</p>

Resuscitation Outcomes Consortium

Community Consultation

San Diego Resuscitation Research Center
Summer 2006

Principal Investigator

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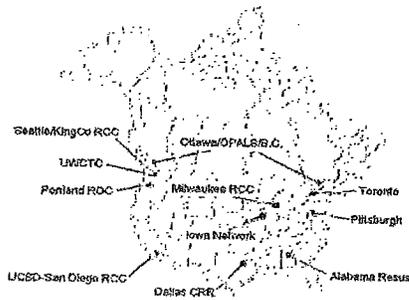
ROC Overview

- ROC was created to conduct clinical research on cardiac arrest & severe trauma
- Trials may evaluate existing or new therapies
 - New drugs, fluids, techniques, etc...
- Focus on prehospital environment

ROC Partners

- National Institutes of Health
- U.S. Department of Defense
- Canadian Institute of Health Research
- Canadian Department of Defense
- American Heart Association

Resuscitation Outcomes Consortium



ROC Hypertonic Saline Trial

Study purpose

To evaluate the life-saving potential of hypertonic saline, with and without Dextran, for the treatment of traumatic shock and severe brain injury.

Definitions

Hemorrhagic shock

- Dangerously low blood pressure from massive blood loss.
- Internal organs don't receive enough blood.

Traumatic brain injury

- Primary injury occurs at the time of trauma.
- Problems with blood flow, breathing, brain swelling, & inflammation dramatically expand the area of injury.

Many patients die because the "standard of care" cannot reverse the damaging effects of hemorrhagic shock and may actually worsen brain injury.

Standard of Care

Current standards

- Prehospital = normal saline
- Hospital = normal saline + blood

Problems

- Very little fluid stays in the blood stream
 - Cerebral edema (brain swelling)
 - Pulmonary edema (lung swelling)
- Normal saline & blood result in harmful activation of the immune system
 - Multi-organ dysfunction syndrome (vital organ failure)

Hypertonic Saline

- Hypertonic saline has a higher salt concentration than normal saline
 - 7.5% NaCl vs. 0.9% NaCl
 - Pulls fluid into the blood stream
 - Decreases brain swelling
 - Diminishes the harmful immune response from traumatic shock or brain injury

Hypertonic Saline Experience

- Hypertonic saline has been studied several times for prehospital use
 - Studies too small to convince FDA
 - Already used in Europe and South America
- Currently used in several San Diego ICUs
- Lower concentration (3%) used in Iraq
- Appears to be safe and effective

Dextran

- Type of sugar molecule
- Pulls fluid into the blood stream
- Extends the blood pressure effects of hypertonic saline from 1 to 4 hours

Potential risks

Too much sodium?

- The brain can be injured by high sodium levels
 - Has not been seen with small volumes
 - Will be monitored
 - Risk of death and disability due to shock or brain injury felt to be much greater

Potential risks

Allergic reaction?

- Occurs rarely with Dextran
 - Not seen in previous trauma patient trials
 - Will be monitored
 - Infusion stopped if allergic reaction seen
 - Risk of death and disability with shock or brain injury felt to be much greater

Potential risks

Bleeding?

- Reported with higher doses of Dextran
- Related to rapid rise in blood pressure & interference with clotting
 - Not clinically important in small doses
 - Will be monitored

ROC HS Trial

- Randomized, blinded trial comparing:
 - Hypertonic saline (7.5% saline) - HS
 - Hypertonic saline/Dextran - HSD
 - Normal saline (0.9% saline) - NS... as the *initial* prehospital resuscitation fluid

ROC HS Trial

Study candidates

- Trauma patients in shock
 - Trauma patients with severe brain injury
- ...randomized to receive 250cc of "study fluid"

Sample size

- Shock study
 - 3700 patients over 3.5 years (~500 from SD)
- Traumatic brain injury study
 - 2100 patients over 1.5 years (~350 from SD)

Who Would Be Excluded?

- Patients who are obviously pregnant
- Prisoners
- Patients who have “unsurvivable” injuries
 - Penetrating brain injuries
 - CPR

Randomization and Blinding

- Randomization is similar to “flipping a coin”
 - In this study, it’s done in advance
- This assures the validity of results
 - Reduces chance of bias
 - Can’t let medics choose which to give



What is Informed Consent?

Informed consent

- A process by which patients make informed decisions about participating in studies
 - Patients are informed of the potential risks and benefits associated with each treatment
 - Patients choose whether to participate

Exception from informed consent

- Patients are enrolled in a research study without giving their informed consent

How Can That Be?

A 1996 federal regulation allows certain studies that meet the following criteria to use this exception:

- *Patients' lives must be at risk.*
- Available treatments are not satisfactory.
- Patients are unable to give consent.
- Potential risks are reasonable.
- Participation in the research could provide a direct benefit to the patient.
- The research could not be practicably carried out without an exemption.

Consent Safeguards

- Medics will ask the patient or a family member present at scene if they object to being enrolled.
- After enrollment, the patient or a family member will be informed & consented for further data collection.
- Participation can be withdrawn at any time.

Patient Protection

The study has been reviewed by:

- ROC Steering Committee (including Ethicist)
- FDA
- NIH peer review committee
- Data Safety Monitoring Board
- State EMS Commission
- Local IRBs
- Local EMS agencies

ROC Hypertonic Saline Trial Community Meeting

Location- Carlsbad Date 8/17/06

Please take a minute to sign in so that we know that you were here, Thank You.

Name	Zip Code
LESTER ROTTSOLK	92054
JOANNA RAUBIER	92084 92084

Community Survey for Hypertonic Saline Trial
University of California, San Diego

Thank you for attending our meeting. Now that you have had a chance to listen to our presentation please take some time to complete the following survey so that we know how you feel about this.

1. If you were severely injured and had a one in three chance of dying with standard treatment, would you want to be entered into the study and possibly receive this experimental treatment, even though you couldn't give 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 dying with standard treatment, would you want them to be entered into the study and possibly receive this experimental treatment, even if they or you couldn't give consent?
 1. Yes
 2. No
 3. Don't know
 4. Question refused

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. 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
 2. No
 3. Don't know
 4. Question refused

5. If you suffered a cardiac arrest and had less than a 10% chance of surviving with standard treatment, would you want to be entered into the study and possibly receive the experimental treatments, even though you couldn't give consent?
 1. Yes
 2. No
 3. Don't know
 4. Question refused

6. If one of your family members suffered a cardiac arrest and had less than a 10% chance of surviving with standard treatment, would you want them to be entered into the study and possibly receive the experimental treatments, even if they or you couldn't give consent?

1. Yes

2. No

3. Don't know

4. Question refused

7. If you were in a severe accident or suffered a cardiac arrest and later learned that you were in this study, would you be upset?

1. Yes

2. No

3. Don't know

4. Question refused

8. We will tell the community about this study before it begins. Please answer "Yes" or "No" whether you use the following sources to get information?

1. Newspaper *YES*

2. Internet *YES*

3. Neighborhood Associations

4. Newsletters

5. Churches

6. Schools

7. Radio *YES*

8. Television *YES*

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

*NEW Treatment Protocols need to be developed
to increase the chances for survival from major
trauma & cardiac arrest. In these instances informed
consent is not practical or possible! Research is the
only way to learn more about possible enhancements.*

Age 64

Ethnic background White

Gender (circle one) - Male Female

Zip Code 92124

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 Daniel Davis or Donna Kelly RN at 619-543-3829

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

www.uwctc.org and click on ROC

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University of California, San Diego

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- 3. Don't know
- 4. Question refused

8. We will tell the community about this study before it begins. Please answer "Yes" or "No" whether you use the following sources to get information?

- 1. Newspaper
- 2. Internet
- 3. Neighborhood Associations
- 4. Newsletters
- 5. Churches
- 6. Schools
- 7. Radio
- 8. Television

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

go for it

Optional Information

Age 59 Ethnic background Cauc

Gender (circle one)- Male Female Zip Code 92084

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 Daniel Davis or Donna Kelly RN at 619-543-3829

There is also a website you can visit. Would you like that internet address?
www.uwctc.org and click on ROC

Community Survey for Hypertonic Saline Trial

University of California, San Diego

Thank you for attending our meeting. Now that you have had a chance to listen to our presentation please take some time to complete the following survey so that we know how you feel about this.

1. If you were severely injured and had a one in three chance of dying with standard treatment, would you want to be entered into the study and possibly receive this experimental treatment, even though you couldn't give 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 dying with standard treatment, would you want them to be entered into the study and possibly receive this experimental treatment, even if they or you couldn't give consent?
 1. Yes
 2. No
 3. Don't know
 4. Question refused

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. 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
 2. No
 3. Don't know
 4. Question refused

5. If you suffered a cardiac arrest and had less than a 10% chance of surviving with standard treatment, would you want to be entered into the study and possibly receive the experimental treatments, even though you couldn't give consent?
 1. Yes
 2. No
 3. Don't know
 4. Question refused

6. If one of your family members suffered a cardiac arrest and had less than a 10% chance of surviving with standard treatment, would you want them to be entered into the study and possibly receive the experimental treatments, even if they or you couldn't give consent?

- 1. Yes
- 2. No
- 3. Don't know
- 4. Question refused

7. If you were in a severe accident or suffered a cardiac arrest and later learned that you were in this study, would you be upset?

- 1. Yes
- 2. No
- 3. Don't know
- 4. Question refused

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- 4. Newsletters
- 5. Churches
- 6. Schools
- 7. Radio
- 8. Television

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Optional Information

Age 57

Ethnic background WHITE

Gender (circle one)- Male Female

Zip Code 92054

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 3. Don't know
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- 3. Don't know
- 4. Question refused

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- 3. Don't know
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8. We will tell the community about this study before it begins. Please answer "Yes" or "No" whether you use the following sources to get information?

- 1. Newspaper
- 2. Internet *no computer*
- 3. Neighborhood Associations
- 4. Newsletters
- 5. Churches
- 6. Schools
- 7. Radio
- 8. Television

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

Optional Information

Age 76

Ethnic background CAD.

Gender (circle one) - Male Female

Zip Code 92020

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www.uwctc.org and click on ROC

Community Survey for Hypertonic Saline Trial
University of California, San Diego

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1. Yes

2. No

3. Don't know

4. Question refused

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2. Internet No

3. Neighborhood Associations No

4. Newsletters Yes

5. Churches Yes

6. Schools No

7. Radio Yes

8. Television Yes

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

If I were in need of emergency medical care I would be grateful for any help I could get.

Optional Information

Age 77

Ethnic background Caucasian

Gender (circle one)- Male Female

Zip Code 92020

THAT CONCLUDES OUR SURVEY.

THANK YOU VERY MUCH FOR YOUR TIME AND COOPERATION.

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- 4. Newsletters
- 5. Churches
- 6. Schools
- 7. Radio
- 8. Television

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

Optional Information

Age _____ Ethnic background White

Gender (circle one)- Male Female Zip Code 92019

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There is also a website you can visit. Would you like that internet address?
www.uwctc.org and click on ROC

X 37880
 33829
 33829

San Diego ROC Coordinating Center

Log of calls from the public received and response provided

Date of call	Name of caller	Zip Code of caller	Issue from caller	Return call date	Return call person	Response to caller
8/1/06	FRANK KUBBER 858/580-1744	92174	wanted more info Re: ROC	8/1/06	LANA	THANKED ME FOR RETURNING HIS CALL
8/3/06	CAROL SIMONSON 858/922-5801	92109	THOUGHT SHE WANTED TO PARTICIPATE - HAS HAND AT TGA	8/1/06 LA	LANA 9/1/06	THOUGHT SHE WANTED TO PARTICIPATE - MISHANDLED THANKS FOR RESPONSE GIVE
8/3/06	DEBORAH TERAY 858/488-8272			8/1/06 LA	DID NOT RETURN CALL	

Questions asked by participants during community meetings

“Who makes the decision at the time of the emergency?”

“Are you talking about mass enrollment?”

“How about a diabetic person? Does this affect them?”

“Why do you want to use this drug?”

“Is it about the cost of the drug?”

“What about the defibrillator on my pacemaker? Does that matter?”

“Who uses this (hypertonic saline) now?”



UNIVERSITY of CALIFORNIA, SAN DIEGO
MEDICAL CENTER

Newsroom

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News Release

Date: July 27, 2006

SAN DIEGO TO PARTICIPATE IN NIH PROJECT AIMED AT IMPROVING SURVIVAL FROM CARDIAC ARREST AND SEVERE TRAUMA

The University of California, San Diego (UCSD) will lead a five-year countywide research project as part of a major bi-national initiative to improve survival from cardiac arrest and severe trauma.

The effort is spearheaded by the National Institutes of Health (NIH) and the Canadian Institutes of Health Research (CIHR) through a new partnership called the "Resuscitation Outcomes Consortium," or ROC. The initial funding commitment is \$50 million to support research in 11 regions throughout the U.S. and Canada, including San Diego. The University of Washington in Seattle will serve as the coordinating center.

UCSD has been awarded a \$2.3 million grant to participate in ROC and lead the San Diego component, which will be named the San Diego Resuscitation Research Center (SDRRC). The SDRRC will integrate pre-hospital care providers, trauma centers, and cardiac arrest-receiving hospitals into an organized network to conduct ROC-sponsored studies. The SDRRC will also train paramedics in protocol implementation and support a data system to track patient outcomes.

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

The U.S./Canadian consortium will support clinical trials and create an extensive and unique database of trauma resuscitation and cardiac arrest information that is expected to expand the understanding of resuscitation and speed the development of new treatments. By studying new and promising drugs, technologies and techniques, researchers hope to identify treatments most likely to benefit the public and improve outcomes for patients who experience cardiac arrest or a traumatic injury. The goal is to decrease mortality, improve cognitive outcomes, and return patients to their prior functional capacity.

Daniel Davis, M.D., from the UCSD Department of Emergency Medicine, is the Principal Investigator for the San Diego ROC site.

"This grant allows a diverse group of researchers across North America to develop new methods to treat cardiac arrest and trauma patients. We have widespread support throughout the County to perform this vital research and identify better ways of addressing these frequently lethal diseases," said Davis. "This will be a wonderful, collaborative effort involving our region's emergency medical services (EMS) system, hospitals, and EMS agencies. It is an honor to have been selected by the NIH. This project will significantly enhance our ability to deliver cutting-edge care to our citizens and move us closer to our goal of making San Diego America's safest community."

The first ROC study will assess the effectiveness of initial resuscitation of trauma patients with hypertonic fluid, which is a highly concentrated form of saline solution. In the crucial minutes before blood transfusions can be safely administered in a hospital, paramedics currently give trauma patients intravenous normal saline solution to compensate for

blood loss. In this study, trauma patients with signs of shock or severe brain injury will receive one of three saline solutions – normal saline, high concentration (hypertonic) saline alone, or hypertonic saline with dextran, a circulation-enhancing substance.

Hypertonic saline solutions have been used in Europe for several years but are not yet approved by the U.S. Food and Drug Administration (FDA). Hypertonic saline solutions are designed to compensate for blood loss more effectively, decrease the harmful inflammatory response to injury, and prevent brain swelling. Encouraging prior research indicates that these beneficial effects should lead to a reduction in organ failure for patients with major blood loss and improve neurological function for patients with brain injury.

The five trauma centers in the San Diego Trauma System will all participate in this study. The second ROC trial, also in the review stages in San Diego, will evaluate the effectiveness of new treatments for cardiopulmonary resuscitation (CPR). In cardiac arrest the heart typically fibrillates and stops beating, blood no longer circulates, and the victim collapses into unconsciousness. The trial will study the best time to deliver an electrical shock following CPR as well as the use of an airway valve to enhance the effectiveness of chest compressions. This project would involve all 20 San Diego County hospitals that receive paramedic ambulances.

Every ROC study undergoes rigorous review and approval. The initial review is done by an independent group of scientists and ethicists at the NHLBI. Subsequent review occurs by the FDA as well as a state and regional EMS authorities. ROC studies must also be reviewed and approved by the Institutional Review Boards (IRBs) of each of the participating hospitals. Since these trials will address patients in life-threatening situations who are often unconscious, the federal government employs stringent FDA guidelines to govern their safe conduct. Individuals wishing to exempt themselves from enrollment have the option of wearing or carrying a wristband indicating the choice. Wristbands will be provided through the SDRRC and can be obtained by calling 619-543-3829.

The San Diego hypertonic saline study is expected to begin in late summer or early fall. Community forums and other media outreach are being planned throughout the County to invite public discussion. The community's feedback will be assessed by the UCSD Institutional Review Board in determining whether to move forward with the trials.

UCSD and other San Diego hospitals have partnered with San Diego County in several prior important research activities. The San Diego Paramedic Rapid Sequence Intubation Trial (1998-2002) is widely regarded as one of the most important prehospital studies ever performed to determine the optimal management of critical head injury victims.

For additional information and the NIH press release visit the ROC website at roc.uwctc.org or contact Donna Kelly, SDRCC Study Coordinator, at 619-543-3829.

###

To learn more about ROC studies a series of community meetings will be held:

Wednesday, Aug. 16, 6:30 to 7:30 p.m.
Chula Vista Library, Civic Center Branch
365 F Street
Chula Vista, CA 91910

Thursday, Aug. 17, 10:30 to 11:30 a.m.
Carlsbad Library, Dove Branch
1775 Dove Lane
Carlsbad, CA 92011

Thursday, Aug. 17, 2:30 to 3:30 p.m.
San Diego Library, Poway Branch
13137 Poway Road
Poway, CA 92064

Friday, Aug. 18, 2:30 to 3:30 p.m.
El Cajon Library Main Library
201 E. Douglas
El Cajon, CA 92020

Media Contact: Eileen Callahan, 619-543-6163, ecallahan@ucsd.edu



UNIVERSITY of CALIFORNIA, SAN DIEGO
MEDICAL CENTER

Specialties & Programs

[Home](#) > [Specialties & Programs](#) > [Trauma Center](#) > [Resuscitation Outcomes Consortium](#)

Resuscitation Outcomes Consortium

NEW RESEARCH PROGRAM AIMS TO IMPROVE SURVIVAL FROM CARDIAC ARREST, SEVERE TRAUMA

Each year, thousands of Americans die from sudden cardiac arrest and traumatic injuries. However, recent studies suggest many of these people can be saved with new approaches to treatment. San Diego is one of 10 sites in the United States and Canada chosen to participate in a massive research program known as the Resuscitation Outcomes Consortium (ROC).

ROC is funded by the National Institutes of Health and other federal and Canadian agencies. In San Diego, ROC will be coordinated through the UCSD and will involve Emergency Medical Services (EMS) agencies and hospitals throughout the county. The study could potentially affect anyone in San Diego County who is involved in a serious injury or experiencing cardiac arrest.

FOR MORE INFORMATION

- * Read more about the [Resuscitation Outcomes Consortium](#)
- * Call the Principal Investigator, [Daniel Davis, M.D.](#), at (619) 543-3829

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>>> "Cohn, Melanie" <Melanie.Cohn@asm.ca.gov> 9/27/2006 4:56:57 PM >>>

STATE CAPITOL
P.O. BOX 942889
SACRAMENTO, CA 94290
(916) 319-2076
FAX: (916) 319-2176

DISTRICT OFFICE
1557 COLUMBIA STREET
SAN DIEGO, CA 92104
(619) 645-3090
FAX: (619) 645-3094

Assembly
California Legislature



LORI SALDANA
Assistant Majority Whip
ASSEMBLY MEMORIAL SEVENTH-DISTRICT

COMMITTEES:
AGRICULTURE
NATURAL RESOURCES
VETERANS AFFAIRS
WATER PARKS AND WILDLIFE

SUBCOMMITTEES:
CLARK, BARR, CLOSURE AND
RECYCLING

SELECT COMMITTEES:
CLARK, BIOETHICS, MEDICINE AND
TECHNOLOGY

AN INFORMATIONAL HEARING
California State Assembly
Select Committee on Bioethics, Medicine and Technology

Tuesday, October 3, 2006
11:00am – 1:00pm

University of California, San Diego
Meridian Room
9500 Gilman Drive
San Diego, CA 92093

Directions and Parking

- Take Interstate 5
- Exit Genesee Avenue and head west
- Turn left on North Torrey Pines Road (3rd traffic light)
- Make the 1st left on North Point Drive
- Make right on North Scholars Drive
- Turn right into parking lot P355 or left into the parking lot P351. A, B, and S permit spaces require that you purchase a permit. A limited amount of coin operated meters are available in lot 351.
- Café Ventanas can be seen south of the parking lot. It is the large building with a wooden sail shaped roof and floor-to-ceiling windows. The Meridian Room is in the same building, adjacent to Café Ventanas, on the second floor.

Visit <http://hds.ucsd.edu/images/ucsdcampusmap.pdf> for UCSD campus map

Note three UCSD witnesses now, and the wild card of Sgt. Brainard from the City Fire Dept. Dan/Jim, please let us know what you learn from Chris about his intended comments.

Sara

Select Committee on Bioethics, Medicine and Technology
Informational Hearing on Informed Consent and Clinical Trials
October 3, 2006 • 11:00 a.m.

I – Informed Consent: Definition and Scope

- **Assembly Member Saldaña** – Convene Hearing/Opening remarks
- **Representative**, California Council on Science and Technology – *History of Informed Consent and Exemption (confirmed)*
- **Michael Kalichman, Ph.D.**, Director, Research Ethics Program, University of California, San Diego – *Ethics of Informed Consent (confirmed)*
- **Michael Caligiuri, Ph.D.**, Chair, University of California, San Diego Institutional Review Board – *Institutional Review Boards (confirmed)*

II – Phase III Clinical Trials in San Diego County

- **Dr. Daniel Davis**, University of California, San Diego Emergency Medicine – *PolyHeme and ROC (confirmed)*
- **David B. Millard**, Associate Director, Clinical Study Data Management, Pfizer, Incorporated – *Medicinal Outcomes (pending)*
- **Sgt. Brainard**, Office of San Diego Fire Chief Tracy Jarman – *Local Impacts (confirmed)*

III – Public Comment Period – (hold comments to 2-minutes each)

IV – Assembly Member Saldaña - Closing Remarks/Adjournment

Exception from Consent Trials in San Diego County

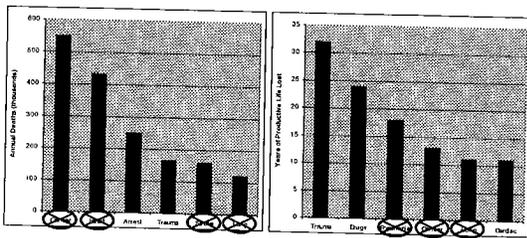
Daniel P. Davis, M.D.

UCSD Resuscitation Science & Training Institute
UCSD Emergency Medicine

Objectives

- Background
- Current limitations
- PolyHeme trial
- Resuscitation Outcomes Consortium
- Future issues

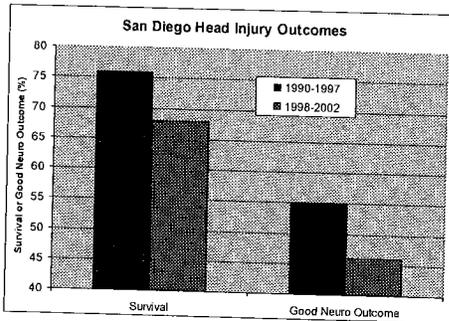
Burden of Disease



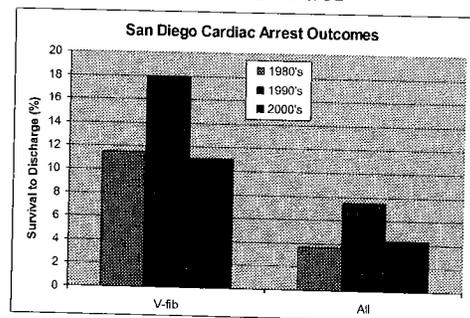
Resuscitation Standards

- Consensus Opinion
 - Advanced Cardiac Life Support (ACLS)
 - American Heart Association
 - Advanced Trauma Life Support (ATLS)
 - American College of Surgeons
- Animal studies, uncontrolled clinical trials
- Inconsistent!

Current Model



Current Model



Consent Issues

Informed consent

- A process by which patients make informed decisions about participating in studies
 - Patients are informed of the potential risks and benefits associated with each treatment
 - Patients choose whether to participate

Exception from informed consent

- Patients are enrolled in a research study without giving their informed consent

Exception from Consent?

A 1996 federal regulation allows certain studies that meet the following criteria to use this exception:

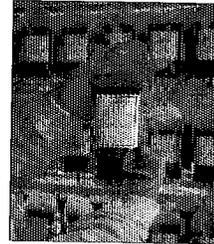
- *Patients' lives must be at risk.*
- Available treatments are not satisfactory.
- Patients are unable to give consent.
- Potential risks are reasonable.
- Participation in the research could provide a direct benefit to the patient.
- The research could not be practicably carried out without an exception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

Consent Safeguards

- At the scene
 - Paramedics ask the patient or a family member present if they object to being enrolled.
- After enrollment
 - The patient or a family member is informed & consented for further data collection.

PolyHeme Study

- PolyHeme
 - Reprocessed human blood
 - Better storage profile
 - No matching required
 - Less inflammatory
- Previous studies
 - Trauma resuscitation
 - Emergency surgery



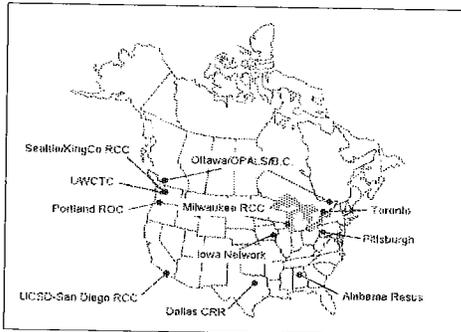
PolyHeme Study

- National, randomized, multi-center trial
- Experimental Group
 - PolyHeme in field & first 12 hours in hospital
- Control Group
 - Saline in field, blood in hospital
- Outcome measures
 - Survival (1 day, 30 days, hospital discharge)
 - Multi-organ failure, hemodynamics, transfusion

PolyHeme Community Consultation

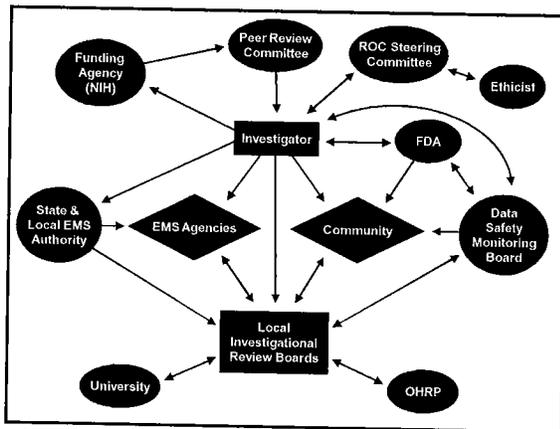
- Television and newspaper
- Public forums
- Focus groups
- Investigational Review Boards

Resuscitation Outcomes Consortium



Resuscitation Outcomes Consortium

- National Institutes of Health
- U.S. Department of Defense
- Canadian Institute of Health Research
- Canadian Department of Defense
- American Heart Association



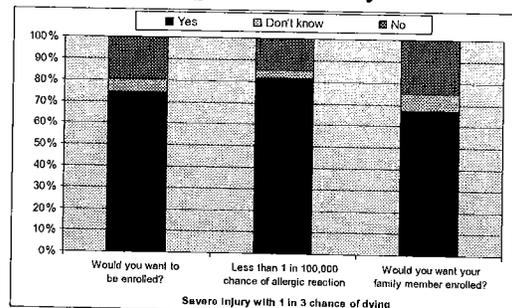
ROC Community Consultation

- Medical community
- Politicians and public health officials
- Television and newspaper
- Online
- Public forums
- Telephone survey
- Investigational Review Boards
- Ongoing education and updates

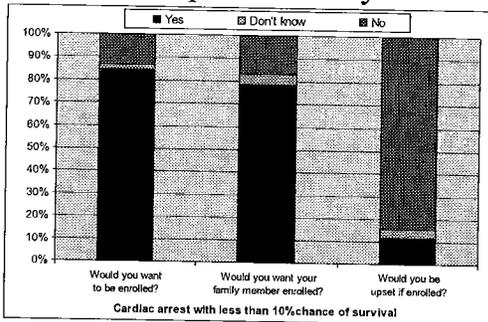
Community Survey

- Independent research firm
- Random digit dialing throughout SD County
- Total of 502 respondents
 - 12% in Spanish
- Survey
 - Brief explanation of research
 - Chances of survival with trauma and cardiac arrest
 - Questions regarding anticipated ROC research

Telephone Survey



Telephone Survey



Future Issues

- Community Consent
 - Define & refine the process
- Individual Consent
 - When to approach
 - Earliest convenient time?
 - After discharge?
 - What to ask
 - Use of all data (until what point)?
 - Contact for post-discharge data?

UCSD Resuscitation Science & Training Institute

- Research
 - Animal
 - Clinical (prehospital, inpatient)
- Training
 - Prehospital, inpatient
 - Fellowship, graduate, resident, medical student
- Administration
 - EMS agency oversight
 - Hospital resuscitation teams

“People should not die before they are done living.”

?



Copy to
replaced original
letter. 7/19/06

County of San Diego

JEAN M. SHEPARD
DIRECTOR

HEALTH AND HUMAN SERVICES AGENCY

NANCY L. BOWEN, M.D., M.P.H.
PUBLIC HEALTH OFFICER

PUBLIC HEALTH SERVICES
1700 PACIFIC HIGHWAY, SAN DIEGO, CALIFORNIA 92101-2417
(619) 531-5800 FAX (619) 515-6707

EMERGENCY MEDICAL SERVICES
6255 Mission Gorge Road
San Diego, CA 92120-3599
(619) 285-6429 Fax: (619) 285-6531

Community Epidemiology
Emergency & Disaster Medical Services
HIV/STD Hepatitis
Immunization
Maternal, Child and Family Health Services
Public Health Laboratory
PH Nursing/Border Health
TB Control & Refugee Health
Vital Records

May 23, 2006

Michael Caligiuri, MD, Director
UCSD Human Research Protection Program
8950 Villa La Jolla, Suite A208
La Jolla, CA 92037

Dear Dr. Caligiuri:

RESUSCITATION OUTCOMES CONSORTIUM

The San Diego County Health and Human Services Agency, Emergency Medical Services, supports the participation of San Diego prehospital providers and the EMS Agency in the Resuscitation Outcomes Consortium (ROC). This recognizes San Diego's excellent EMS system and is an opportunity for us to contribute to the future of resuscitation medicine. There are two specific ways in which we will contribute and support this effort.

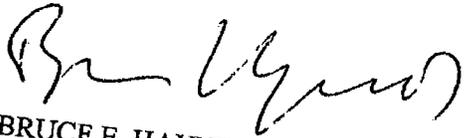
San Diego County EMS serves as the data repository for all prehospital encounters. The most effective strategy to populate the ROC Epistry and the individual protocols with necessary prehospital data is to coordinate this effort at the level of County EMS. We support the concept of establishing a contract between San Diego County EMS and the University of California at San Diego (UCSD) to provide data guardianship. This allows consolidation of data from all San Diego County EMS agencies into a single database.

We recognize this project will require ongoing cooperation between the investigators and the EMS Agency. We will be in close coordination with the principal investigator and work together to resolve any issues that might arise. The San Diego ROC Principal Investigator, Dr. Daniel Davis, will be responsible for training and implementation of the protocol. We will assure that he is able to perform effective system monitoring to conduct the ROC interventional trials.

Michael Caligiuri, MD
May 23, 2006
Page 2

We look forward to a successful project. Please contact me with any questions or comments.

Sincerely,



BRUCE E. HAYNES, MD
Interim EMS Medical Director

BEH:bb

Resuscitation Outcomes Consortium

Newspapers and dates when advertisement went to press for community meetings for hypertonic saline trial. Translated to Spanish for Hispanic papers.

Publications	Circulation	Issue Date
Union Tribune CTAS (5.67 x 5 BW)	400,000	7/30/2006 8/1/2006
Sign on San Diego (on line ad)	Website	One week after published in Union Tribune paper
North County Times (5.708 x 4 BW) (Both inland + coastal editions)	95,000	8/3/2006 8/6/2006 (Sunday Health edition)
Voice & Viewpoint (6 7/16 x 4 1/4 BW)	25,000	8/3/2006
La Prensa (5.7 x 4 BW)	40,000	8/4/2006
El Latino (5.125 x 6.1 BW)	90,000	8/4/2006
Filipino Press (6 7/16 x 5 1/4 BW)	25,000	8/5/2006

Nuevo Estudio Busca Incrementar la Probabilidad de Sobrevivir a Heridas Graves o a un Paro Cardíaco

Cada año, miles de americanos mueren debido a graves heridas o a un paro cardíaco. Sin embargo, estudios recientes sugieren que es posible salvar muchas de estas vidas con un nuevo tratamiento. San Diego es una de diez localidades dentro de Estados Unidos y Canadá, que se han seleccionado para participar en un estudio masivo titulado *Resuscitation Outcomes Consortium* (**Consortio de Resultados de Resucitación**, ROC por sus siglas en inglés).

ROC es financiado por el *Nacional Institute of Health* (Instituto Nacional de Salud) y otras agencias federales y canadienses. En San Diego, la universidad *University of California, San Diego* coordinará el proyecto, involucrando a agencias de servicios de emergencias y hospitales del condado. El estudio podría impactar a cualquier persona en el condado de San Diego que sufra heridas graves o de un paro cardíaco.

Para informar a la comunidad acerca de los estudios de ROC y detalles sobre su implementación, se realizarán juntas abiertas al público. Asimismo, el principal investigador, Dr. Daniel Davis está disponible por teléfono al (619) 543-3829.

JUNTAS COMUNITARIAS

Miércoles, 16 de agosto

6:30 p.m. – 7:30 p.m.

Biblioteca de Chula Vista

Sucursal Civic Center

365 F Street

Chula Vista 91910

Jueves, 17 de agosto

1:30 p.m. – 2:30 p.m.

Biblioteca de San Diego

Sucursal Poway

13137 Poway Rd.

Poway 92064

Jueves, 17 de agosto

6:30 p.m. – 7:30 p.m.

Biblioteca de Carlsbad

Sucursal Dove

1775 Dove Lane

Carlsbad 92011

Viernes, 18 de agosto

2:30 p.m. – 3:20 p.m.

Biblioteca Principal

de El Cajon

201 E. Douglas

El Cajon 92020



UNIVERSITY of CALIFORNIA
SAN DIEGO

MEDICAL CENTER

University of California, San Diego Extension

This is to certify that

Edith Fuentes

has satisfactorily completed the requirements for the
Professional Certificate in

Translation and Interpretation

210

hours of instruction

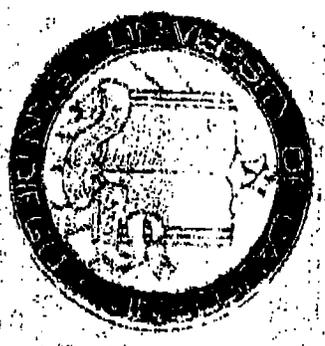
Winter 2003

Mary L. Walshok

MARY L. WALSHOK
ASSOCIATE VICE CHANCELLOR
EXTENDED STUDIES AND PUBLIC PROGRAMS
AND DEAN, UCSD EXTENSION

Bruce Dunn

BRUCE DUNN
ASSOCIATE DEAN
EXECUTIVE AND DEGREE-RELATED PROGRAMS



Debra Conolly

DEBRA CONOLLY
ASSOCIATE DEAN
OF CONTINUING EDUCATION

Edward Nabetta

EDWARD NABETTA
REGISTRAR

3 Aviso de Exención (NOE por sus siglas en inglés) para el plan propuesto en el Plan de Trabajo de la Agencia de Protección Ambiental de California (CEQA). Los documentos de la NOE establecen que la acción significativamente negativa al ambiente por el término de limpieza relativamente pequeña de volúmenes relativamente pequeñas de tierras contaminadas de plomo y arsénico en las parcelas residenciales (Área 3 y 4) en el material de relleno.

Significativas:

de Diferencias Significativas documentando los cambios en el Plan de Trabajo de la implementación del RAW (Noviembre de 2003 y Mayo de 2005), (2,745 yardas cúbicas) de tierra contaminada con plomo y arsénico fueron extraídas originalmente de 544 toneladas (363 yardas cúbicas) se excedió debido al descubrimiento o y arsénico en las parcelas residenciales (Área 3 y 4) en el material de relleno.

nar a los interesados de la comunidad la oportunidad de enterarse más sobre el Plan de Trabajo de la limpieza propuesta durante el período de comentarios comenzando el 7 de Agosto de 2006 y termina el 6 de Septiembre de 2006. Los comentarios del Trabajo en borrador pueden enviarse por escrito a la Srita. Stephanie SC, 1101 N. Grandview Ave., Glendale, CA 91201 o email: SLEwis1@dtsc.ca.gov. Información con la comunidad el Martes, 15 de Agosto de 2006, a las 6:30 p.m. en la sala de Trabajo en borrador. Los invitamos a esta reunión a compartir sus preguntas y comentarios en español. Los invitamos a esta reunión a compartir sus preguntas y comentarios en español.

FORMACIÓN?

a tentativa de RAW y otros documentos del proyecto en (1) la Biblioteca de Logan, 192113, (2) Biblioteca Central, 820 E Street, San Diego, CA 92101 y (3) Centro de DUSD, 4880 Rufiner Street, San Diego, CA 92111. También, todos los documentos administrativos completos relativos a este proyecto están disponibles para su revisión en la Oficina Regional de Archivos de DTSC, 1011 N. Grandview Avenue, Glendale, CA 91201 551-2886 para citas.

comunicación a fondo este proyecto, por favor comuníquese con la Srita. Maya Publica DTSC al (818) 551-2917 o comuníquese por email: Maktalia@dtsc.ca.gov. Para más información del Proyecto DTSC al (818) 551-2847 o email: SLEwis1@dtsc.ca.gov.

español, comuníquese con: Javier Hinojosa DTSC al (818) 551-2172.

dependiendo del grado de la enfermedad. con pacientes de menos riesgo de la piel con su doctor. Su propia vigilancia podría salvar su vida.

New Research Program Aiming to Improve Survival from Cardiac Arrest and Severe Trauma

Each year, tens of thousands of Americans die from sudden cardiac arrest and traumatic injuries. However, recent studies suggest that many of these people can be saved with new approaches to treatment. San Diego is one of ten sites within the United States and Canada chosen to participate in a massive research program known as the **Resuscitation Outcomes Consortium (ROC)**.

ROC is funded by the National Institutes of Health (NIH) and other federal and Canadian agencies. In San Diego, ROC will be coordinated through the University of California, San Diego and will involve Emergency Medical Services (EMS) agencies and hospitals throughout the county. The study could potentially affect anyone in San Diego County who is involved in a serious injury or experiencing cardiac arrest.

To learn more about ROC studies or how the program works, a series of community meetings are available and open to the public. The Principal Investigator, Daniel Davis, M.D., may also be reached at (619) 543-3829.

COMMUNITY MEETINGS

Wednesday, August 16 - 6:30 p.m. - 7:30 p.m.
Chula Vista Library - Civic Center Branch
365 F Street - Chula Vista 91910

Thursday, August 17 - 10:30 a.m. - 1:30 p.m.
Carlsbad Library - Dove Branch
1775 Dove Lane - Carlsbad 92015

Thursday, August 17 - 2:30 p.m. - 3:30 p.m.
San Diego Library - Poway Branch
13137 Poway Road - Poway 92064

Friday, August 18 - 2:30 p.m. - 3:30 p.m.
El Cajon Library - Main Library
2011 E. Douglas - El Cajon 92021



UNIVERSITY OF CALIFORNIA
SAN DIEGO
MEDICAL CENTER

present dispensation, human rights advocates themselves have become victims of human rights violations.

near Chula Vista Trolley Station.

Nagsasalita kami ng Tagalog.

present dispensation, human rights advocates themselves have become victims of human rights violations.

Cosmopolitan Lions Club again signed up at the Qualcomm Concession Stand Fundraising Program, committing to 14

New Research Program Aiming to Improve Survival from Cardiac Arrest and Severe Trauma

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COMMUNITY MEETINGS

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 El Cajon Library
 Main Library
 201 E. Douglas • El Cajon 92020



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per Opportunities

quitado Insurance Agency
 0D38287

R M E R S

1 E. 8th St., Ste. 110
 anal City, CA 91950
 (619) 274-6321
 re: (619) 479-7642
 uitado@farmersagent.com
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precious possessions. to you most. That's why we ne, and auto insurance policies all now to learn about special ance coverage is with Farmers.

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FARMERS

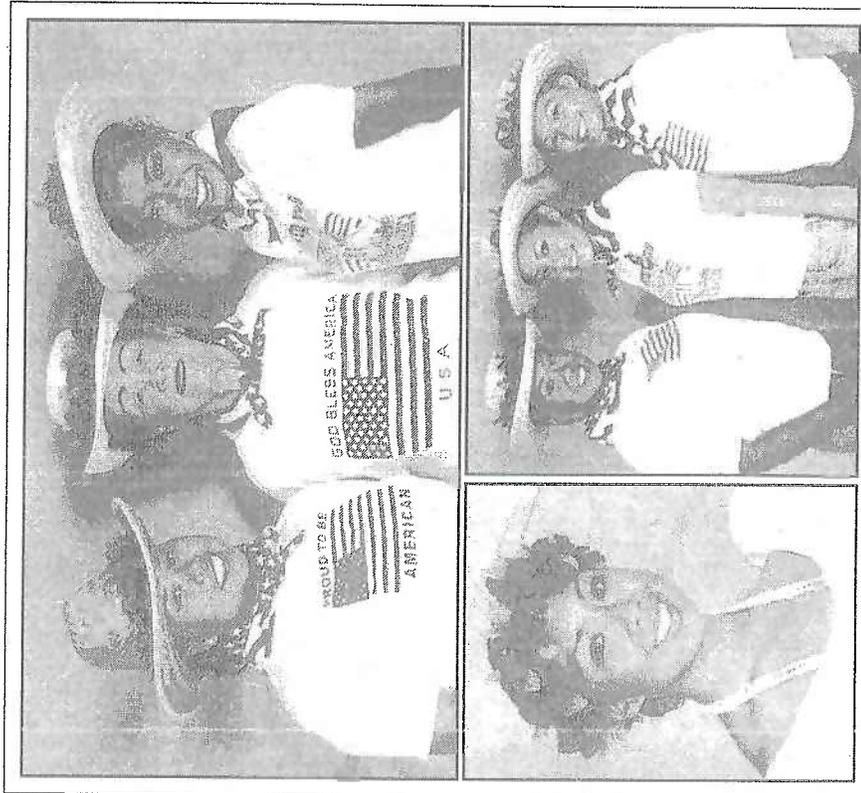
Maria Clara de Pipinas Sorority annual event slated

SAN DIEGO, Calif. — The Maria Clara de Pipinas Sorority (MCPS) has been successful in documenting and recording the pioneering history of Filipino Americans in San Diego. In pursuing this mission, the MCPS shall hold its 38th annual social event with the theme "Our Navy Connection: Past, Present and Future" on September 3rd at the San Diego Sheraton Hotel. The program starts at 5:00 pm. Pre-paid invitations only. Formal attire.

The family of Agnes Ella, event chair, is the inspiring Living Legacy Star whose continuous dedication, loyalty and service for 30 years brought together the different generations that are now enjoying their golden years.

During the event, the following debutantes will be recognized by MCPS Founder Lucy del Rosario-Gonzales.

Two Lorenzo del Rosario (1901-1953) grand daughters — Lindsey Achong Dias from Las Vegas, Nevada who is the daughter of Brian and Liane Dias; Lydia Achong Veniegas, grand daughter of Laura and Stephen Achong of Honolulu Hawaii; Trisha Montoya Diaz from



From top: MCPS officer Ella Lozano, founder Lucy del Rosario Gonzales, and 2006 Debutante Breanna Discar Espe. President Jessica Sta. Agueda Galdiano will call to order the MCPS Annual 38th Debutante Ball and Awards Night titled "Our Navy Connection: Past, Present and Future" on September 3. MCPS officer Tara Bediamol welcomes 2006 Debutantes Trisha Montoya Diaz of Easthampton in Massachusetts and Ma. Theresa Pesito Celis of Murrieta, California.

Rivero, Alice Legaspi, Toto events. All donations will be Legaspi, Beth Dalindin, Jimmy used for their forthcoming med-

Josie Isibido, coordinator for the event say "It's our turn to display the white, and blue to express patriotism." Those who wish to volunteer for September 3rd contact the coordinator. Zanaida Bersamira, the MCPS coordinator remarks that, "we're almost done with preparations and we're working on guests' seat arrangements."

MCPS President Jessic

LAW OFFICES OF

- Member, California State Bar Licensed to practice before the U.S. Federal District Court, Southern California and California Supreme Court
- Author, "How to Apply for the U.S. Tourist Visa" as listed by worldwide bookseller Amazon.com Bookstores
- Former San Diego Regional Coordinator for U.S. Immigration Amnesty for Catholic Community Services, Catholic Diocese of San Diego
- Legal Adviser, Los Chabacanos of Cavite City Association Inc., San Diego, California
- Juris Doctor law degree, University of

10News.com

San Diego Participates In New Cardiac Arrest, Trauma Treatments Study

UCSD Hospital To Coordinate Clinical Trials

POSTED: 3:35 pm PDT July 28, 2006

UPDATED: 3:45 pm PDT July 28, 2006

SAN DIEGO -- Saving more lives when someone suffers cardiac arrest or severe trauma is the goal of an international research project conducted by the National Institutes of Health.

San Diego is one of 10 cities in the country selected to test new interventions that may save more lives.

Whether you are a victim of a car accident or some other kind of severe trauma, your chances of surviving the life-threatening injury and cardiac arrest are dismally low.

"Outcomes have actually decreased in the last 10 to 20 years. You have a worse chance of survival from cardiac arrest today than you did 10 or even 20 years ago," said Dr. Daniel Davis of University California, San Diego emergency medicine.

UCSD is among 300 hospitals in the U.S. and Canada that will coordinate clinical trials of promising new treatments for cardiac arrest and traumatic injury.

Davis said, "These studies will be carried out by the paramedics at this point. We will be conducting studies both in cardiac arrest and trauma, often simultaneously, and will be conducting one study after another to continually build on what we learned in the previous study."

This is the first time scientists have used large-scale clinical trials to improve the treatment of patients with traumatic injury and cardiac arrest.

Davis added, "For cardiac arrest right now in San Diego, you have about a 4 percent chance of survival."

One of the first treatments to be tested will be highly concentrated forms of saline solution similar to the body's own fluids. It will help with severe blood loss.

Davis said, "They will receive a bag of fluid, which could be normal saline, which is used everyday in the field by paramedic, or they could get hypertonic saline."

Another study will test a device to enhance blood flow during CPR. It creates a small vacuum inside the patient's chest.

Another aspect of the study is looking at the use of defibrillators. Doctors are questioning whether the way they are used now actually results in the best outcome for patients.

"We now believe once a patient has been down for four minutes, the best thing is to actually do CPR before the shock, to prime the heart to receive the shock," said Davis.

All of these interventions have proved to be safe in smaller studies. Now doctors want to see if they have real impact on saving lives.

These clinical trials will be conducted on patients who will not be able to consent to the procedure because of their injuries.

The study has strict guidelines and all of the devices and procedures being looked at are known to be as good as or better than the current standard of care.

A series of community forums are planned for August. For more information, call 619-543-3829.

Wednesday, Aug. 16

6:30 to 7:30 p.m.

Chula Vista Library, Civic Center Branch

365 F Street

Chula Vista, CA 91910

Thursday, Aug. 17

10:30 to 11:30 a.m.

Carlsbad Library, Dove Branch

1775 Dove Lane

Carlsbad, CA 92011

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2:30 to 3:30 p.m.

San Diego Library, Poway Branch

13137 Poway Road

Poway, CA 92064

Friday, Aug. 18

2:30 to 3:30 p.m.

El Cajon Library Main Library

201 E. Douglas

El Cajon, CA 92020

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Kelly, Donna

From: Kelly, Donna
Sent: Monday, July 17, 2006 4:54 PM
To: McCallum-Brown, Lana; Davis, Daniel
Subject: Community Meeting dates distribution

Dan, Lana,
OK, I have sent the attachment out to

PPH IRB and Velky
Scripps IRB and Sise, Tominaga
Sharp IRB and Kennedy
UCSD IRB and, Hoyt, Vilke, Dunford, Coimbra
Eileen Callihan

That is all the IRB's except CHHC and I need the PI name (Lana finding it) and we can send it on to them.

Who at the county would like this? Could you please send it to them and let me know you did or just attach me. Bruce?
Leslie?
What about SDFD? Who has to know?
How about City Hall?
Donna

5/1/2007

Kelly, Donna

From: Kelly, Donna
Sent: Monday, July 17, 2006 4:17 PM
To: Michael Caligiuri (mcaligiuri@ucsd.edu)
Cc: Davis, Daniel; Hoyt, David; Dunford, James; Vilke, Gary; Coimbra, Raul
Subject: ROC HSD San Diego locations and times Community Meetings

Mike,
Please find attached the list of times, dates and locations of the 5 community meetings for the HSD ROC trial in San Diego County.
Would you be so kind as to forward this to the members of the IRB as they are all welcome to attend any of the meetings. I will be sending this to all the Trauma Directors and IRB's who are involved in the HSD trial so that they too can attend if desired.
The public notice will be going out in the next week or so to 6 newspapers of various populations and will be in Spanish and English. The public notice includes all the dates and times for all the meetings. I will forward you the notice before it is published.
Thank you,
Donna



Resuscitation Outcomes Consortium
COMMUNITY MEETINGS
for
Hypertonic Resuscitation Following Traumatic Injury

Revised for August 2006

Wednesday, August 16th • 6:30 p.m. – 7:30 p.m.
Chula Vista Library • Civic Center Branch
365 F Street • Chula Vista 91910

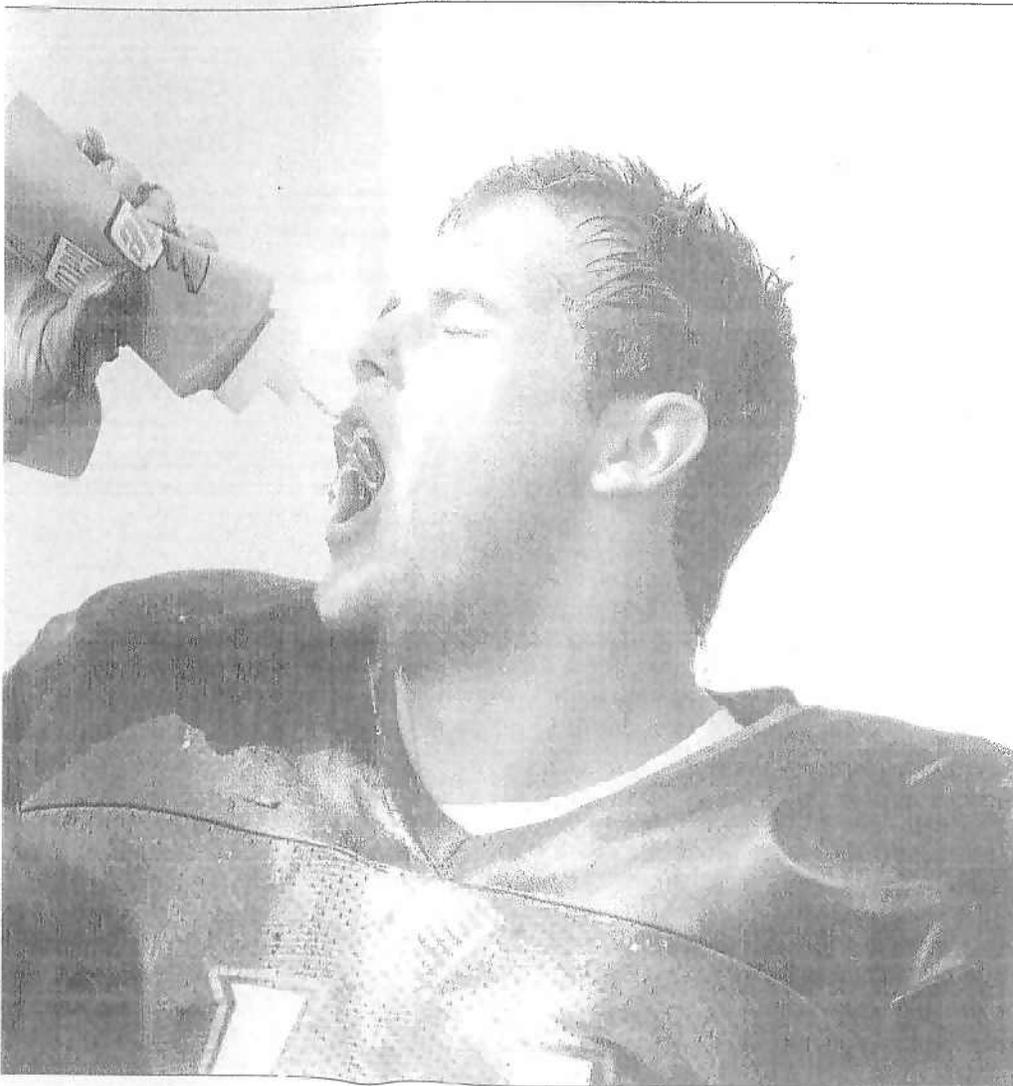
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Heat Secret:

hydration, hydration, hydration



STAN LIU / FOR THE NORTH COUNTY TIMES

ony DiMartinis drinks water during practice. Staying hydrated is key to avoiding heat-related problems.

r is far from over, so here's how

UCSD to lead trauma program

■ Plan aims to implement new treatments for cardiac patients

BRADLEY J. FIKES
STAFF WRITER

Heart attack and trauma patients will get more help from trained paramedics and better access to new treatments under a program led locally by UC San Diego.

The program adds to existing efforts to improve cardiac care already under way by Palomar Pomerado Health, Scripps Health and other local hospitals.

Called the "Resuscitation Outcomes Consortium," it is a joint United States and Canadian program to improve survival and recovery from cardiac arrest and traumatic injuries. It's funded by the National Institutes of Health and the Canadian Institutes of Health Research.

UCSD is getting \$2.3 million to coordinate the program in San Diego County, the university announced on July 27.

UCSD will work with paramedics and hospitals to run ROC-sponsored studies on how to improve care, said Daniel Davis, who is overseeing the program here. Davis is an associate professor of medicine in UCSD's depart-



STAN LIU / FOR THE NORTH COUNTY TIMES

ny DiMartinis drinks water during practice. Staying hydrated is key to avoiding heat-related problems.

It is far from over, so here's how to cope with scorching temperatures

HEAT STROKE SIGNS

- Extreme fatigue
- Confusion
- Rapid pulse or breathing
- Skin is hot, dry and red
- Seizures
- Loss of consciousness

killed more than 100 people and injured thousands of others. Heat-related deaths were also included in a woman's death. More were exhausted. Southern California from over. Endure the

heat, the North County Times turned to three people with expertise, a sports doctor, an emergency room physician — and Ted Giannoulas, better known as the Famous Chicken.

Coping with heat is part of life for San Diego's legendary mascot, who has performed his feathered gymnastics for 32 years. He doesn't use technological tricks such as ice packs or fans under that plumed pseudoepidermis. He estimates the temperature regularly gets up to 125 degrees underneath the costume.

This is one chicken that refuses to broil.

"It's like a rainforest inside that outfit ... a really good sweat like a sauna," Giannoulas said in a telephone interview from Salt Lake City

► HEAT, H-2

joint United States and Canadian program to improve survival and recovery from cardiac arrest and traumatic injuries. It's funded by the National Institutes of Health and the Canadian Institutes of Health Research.

UCSD is getting \$2.3 million to coordinate the program in San Diego County, the university announced on July 27.

UCSD will work with paramedics and hospitals to run ROC-sponsored studies on how to improve care, said Daniel Davis, who is overseeing the program here. Davis is an associate professor of medicine in UCSD's department of emergency medicine. Patients with heart attacks, trauma or brain injuries are the main targets of the studies.

The program will collect information about the patients from first contact until admission, Davis said. With the consent of the patients, they'll also be tracked after leaving the hospital to determine their long-term survival and condition. This information will then be used as part of a database to determine which treatments work best under what conditions, and also to determine the effec-

► PROGRAM, H-7

her it and

'They're trying to figure out if (Morgellons) is an epidemic. I hate to tell them, but it already is.'

— PAT BODDIE, A self-diagnosed Morgellons sufferer

Real or Imagined? CDC investigates skin condition

MIKE STOBBE
ASSOCIATED PRESS

ATLANTA — Imagine your body pocked by erupting sores. The sensation of little bugs crawling all over you. And worst of all, mysterious red and blue fibers sprouting from your skin.

It may sound like a macabre science fiction movie, but a growing legion of Americans say they suffer from this condition. And now the U.S. Centers for Disease Control



Left, Verna Gallagher, at home in Roseville, says she is suffering from a skin crawling condition called Morgellons. Above, she uses a pen to point to what she believes are the bugs connected to



Carolyn anticipates shock. Her second year Denver when some office her share 1,000, since her type

she had ge, raised

ance of small or microscopic fibers on or under the skin.

Some say they've suffered for decades, but the syndrome did not get a name until 2002, when the name "Morgellons" (pronounced mor-GELL-uns) was chosen by Mary Leitao. The South Carolina woman, who said her son suffers from the condition, founded the Morgellons Research Foundation.

She found the name in a 1974 medical paper that described a condition called Morgellons, with symptoms somewhat like her son's. So she began using the name. "I never expected it to stick," she said.

Leitao's organization has become a leading source of information and research advocacy, but it too has become controversial.

Last week, at least three of the eight members of the organization resigned over disagreements with Leitao, the executive director, about how she's been running the foundation. One member — the board's chairman — sent a letter to the U.S. Internal Rev-

of pharmacology. He was the organization's director of research.

Wymore had initiated the relationship last year. But because of the in-fighting he said he decided to distance himself. "The research I'm doing is not affected by this," Wymore added.

Until the CDC task force, Wymore was seen as the most reputable scientist to research Morgellons, although he was trained in molecular biology, not clinical disease or fibrous materials.

He recruited two Oklahoma State faculty physicians. They tweezed fibers from beneath the skin of some Morgellons patients who visited the Oklahoma State Center for Health Sciences in Tulsa in February, Wymore said, and sent those samples to the Tulsa Police Department's forensic laboratory.

The police checked the samples against carpet and clothing fibers and other materials, and conducted chemical analyses and other tests. Nothing matched, said Mark Boese, the police lab's direc-

but then imagine they are continuing to plague them, Matthews said.

Asked about reports of multiple Morgellons cases within a family, Matthews said delusions are transmissible — the psychiatric term is 'folie a deux,' for instances in which people come to share a delusion.

Some people will biopsy themselves, or seek large quantities of antibiotics, herbal remedies, industrial bug killers and other expensive and potentially harmful treatments, she said.

The CDC's Rutz said there may be several subgroups among the people who identify themselves as Morgellons sufferers. One group may have delusional parasitosis, but another may have something else.

The 12-person CDC task force includes two pathologists, a toxicologist, an ethi-

slid across his eye then burrowed in.

Verna Gallagher she's been seeing a ologist for nearly a y he doesn't believe lons. He said 'That' thing,' " said Gallaq seville, near Sacran

But while her misses the fibers a lagger says he is that she may becor "I cry, and he say live my life" and write down thing likes to do.

Meanwhile, she plagued by tiny d and fibers that house. She's paid t nators, taken antic bathed in Borax hundreds on vitar pills and other remedies.

"Nothing's he said.

PROGRAM

Continued from H-1

tiveness of experimental treatments.

In a separate but related project, UCSD is talking with other major hospitals in the county about establishing a common program to train paramedics. To be named the "Resuscitation Science and Training Institute," the program will "serve as a nucleus for training in cardiac arrest in San Diego County," Davis said.

This program is "in its infancy," Davis said, and still in the discussion stage. One thing the discussion will include is what expertise other hospitals can bring, he said.

Palomar Pomerado Health's Cardiac Alert program identifies high-risk patients on site and brings them into Palomar Medical Center's emergency department.

Paramedics from the Escondido, Ramona, Poway, Julian, San Marcos and Valley Center fire departments screen the patients with an EKG machine and transport those showing high risk.

Scripps Health announced in June it is building a cardiovascular institute that will combine the existing programs of the Green Hospital at Scripps Clinic and Scripps La Jolla. The Scripps Cardiovascular Institute is the first part of a three-phase relocation of the entire Scripps La Jolla hospital. The goal in combining the cardiovascular programs at one location is to increase the number of patients treated. High patient volume is associated with good outcomes, because doctors and staff benefit from the experience.

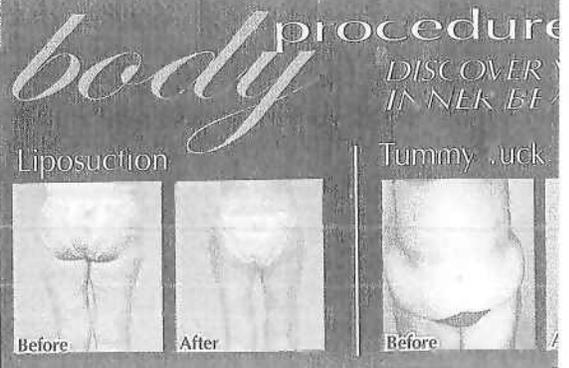
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AUG 30 2006

New Set Of CPR Parameters Aims To Save Lives

by Jared Cohen

In July, a new set of guidelines for administering Cardiopulmonary Resuscitation (CPR) went into use by local firefighters. The American Heart Association (AHA) released updated guidelines for CPR and emergency cardiovascular care late last year.

"There have been big changes since January," said Darren Young. "We need to be doing CPR longer and faster," he said. Young is a firefighter with the Coronado Fire Department.

Emergency response personnel perform CPR to "build up cardiac arterial pressure." The AHA Web site describes CPR as a method for supplying temporary blood flow to the heart and brain so that damage from lack of blood can be minimized until the patient reaches the hospital.

According to *Circulation*, a peer-reviewed journal of cardiovascular medicine, the most significant change in existing CPR procedures is the increase in the number and frequency of chest

compressions.

The proper ratio is now 30 compressions for every two rescue breaths.

"Once you start CPR, you rarely stop anymore," Young said. He described several recent situations where he felt that the new procedures saved lives. Despite a grim outlook, several calls turned out surprisingly well, with patients responding to successful CPR. After they recovered, the patients were talking, walking and seeing

CPR, Continued on Page 26.

CPR, Continued from Page 1.

their families again. "This is huge," said Young.

The Coronado Fire Department holds CPR classes that are open to the public in the Emergency Operations Center room twice a month.

According to the AHA, the survival rate of victims of out-of-hospital cardiac arrest is about 6 percent in the United States, but it jumps up to 50 when proper CPR is administered along with use of an Automated External Defibrillator.

Dr. Daniel Davis is an Associate Clinical Professor in the Department of Emergency Medicine at the UCSD School of Medicine. He is involved with the Resuscitation Outcomes Consortium (ROC), a research project that seeks to improve current methods of CPR and traumatic injury care

by collecting data from hospitals and emergency treatment systems. "There are ten systems in north America," he said. The study will draw data from two Canadian locations and eight in the U.S., one of which being San Diego County.

Davis hopes that the research will supplement the new guidelines released by the AHA. "The city of San Diego is the first agency to go fully forward toward the new guidelines," he said.

Davis mentioned that the study will also evaluate how effective new methods and equipment are. He mentioned a new mask with an adjustable valve to manipulate the flow of air. "It could improve blood pressure during chest compressions," he said. Information from the study will be used to enhance emergency medical care training.

been denied, and more than 32,600 qualified applicants have been turned away from entry-level nursing programs.

CDC stats suggest tuberculosis gaining ground worldwide

The good news is that in 2005, the number of tuberculosis cases in the U.S. fell to 14,093 — the lowest since records on TB began being kept in 1953. The bad news is that the 3.8% year-to-year decline was the smallest in more than a decade. Uglier yet, multidrug-resistant TB cases — those in which two first-line therapies, isoniazid and rifampin, are ineffective — increased 13.3% from 2003 to 2004, according to the Centers for Disease Control and Prevention.

Multidrug-resistant, or MDR, tuberculosis now accounts for 1.2% of cases for which drug susceptibility data is available, the CDC said.

The agency also for the first time reported on the worldwide emergence of XDR, or extremely drug-resistant, TB — meaning tuberculosis that's also resistant to three or more of six classes of second-line therapies, making patients virtually untreatable with current drugs.

Of MDR cases worldwide, 3% were classified as XDR in 2003; that surged to 11% in 2004, the agency said.

The CDC said it's working with partners around the world to keep XDR TB from becoming the pandemic that the MDR form was 15 years ago. Steps include strengthening national TB programs, improving diagnosis of the disease and

ensuring completion of treatment programs, designing new treatment regimens, and improving standards for second-line drug testing.

U.S.-Canada clinical trials to focus on treating cardiac arrest

The first large-scale clinical trials to improve treatment of cardiac arrest will investigate the use of highly concentrated saline solution in trauma patients to compensate for blood loss before a transfusion, plus a one-way valve to enhance blood flow during CPR.

"Most cardiac arrest victims die before they reach the hospital, and traumatic injury is a top killer in North America," according to a March 24, 2006, news release from the National Institutes of Health. The NIH is sponsoring the Resuscitation Outcomes Consortium, which over a three-year period will involve up to 15,000 patients, plus hospitals and public safety agencies, across the U.S. and Canada.

"This is the first time we have used large-scale clinical trials to improve the treatment of patients with traumatic injury and cardiac arrest," much as similar studies have tackled questions about best treatment for heart attack and heart failure, said Myron Weisfeldt, MD, professor and chair of internal medicine at Johns Hopkins University, Baltimore. Weisfeldt heads up the steering committee for the U.S.-Canadian research effort.

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Program

Continued from page 8

It was just around the corner that I wanted to study. I met physicians, leaders, and people who continue to be in contact with me. There is so much more to be learned by the public. Doctors give big shots and high hopes, honestly choose to live.

Live autopsies and procedures were almost once in a while. It was great in the sense that it varied; we did everything from visiting a fire station to

When I looked at the medical field, I saw the opportunity to bring the door to the medical

Program has been exciting for me. Two things that I am proud of in medicine. However, the most such about what it is to be a psychiatrist become one. That's why I joined the Program. It has really been because of the opportunity and also because of

I wasn't able to see the full picture. After hours talking to my psychiatrist, and a chance for me to throw in the towel. I met the psychiatrists and I know what I needed to do at medical school. The program at his job because I met and soul to him. I included the panel discussion with the physician and I have a passion for film that connects what and medicine and

Dr. Jackson was very helpful throughout my senior year application process. I was able to explore the field with my peers.

My graders at Preuss were very helpful in my love working with the medical field. I met a pediatrician. I met shadow Dr. [Name] at the Perlman Center. There, I saw her perform a circumci-

ROC Partnership Aims to Improve Survival from Cardiac Arrest and Severe Trauma

UCSD will lead a five-year countywide research project as part of a major bi-national initiative to improve survival from cardiac arrest and severe trauma.

The effort is spearheaded by the National Institutes of Health (NIH) and the Canadian Institutes of Health Research (CIHR) through a new partnership called the "Resuscitation Outcomes Consortium," or ROC. The initial funding commitment is \$50 million to support research in eleven regions throughout the U.S. and Canada, including San Diego. The University of Washington in Seattle will serve as the coordinating center.

UCSD has been awarded a \$2.3 million grant to participate in ROC and lead the San Diego component, which will be named the San Diego Resuscitation Research Center (SDRRC). The SDRRC will integrate pre-hospital care providers, trauma centers, and cardiac arrest-receiving hospitals into an organized network to conduct ROC-sponsored studies. The SDRRC will also train paramedics in protocol implementation and support a data system to track patient outcomes.

The U.S./Canadian consortium will support clinical trials and create an extensive and unique database of trauma resuscitation and cardiac arrest information that is expected to expand the understanding of resuscitation and speed the development of new treatments. By studying new and promising drugs, technologies and techniques, researchers hope to identify treatments most likely to benefit the public and improve outcomes for patients who experience cardiac arrest or a traumatic injury. The goal is to decrease mortality, improve cognitive outcomes, and return patients to their prior functional capacity.

Daniel Davis, M.D., from the UCSD Department of Emergency Medicine, is the Principal Investigator for the San Diego ROC site.

"This grant allows a diverse group of researchers across North America to develop new methods to treat cardiac arrest and trauma patients. We have widespread support throughout the county to perform this vital research and identify better ways of addressing these frequently lethal diseases," said Davis.

"This will be a wonderful, collaborative effort involving our region's emergency medical services (EMS) system, hospitals, and EMS agencies. It is an honor to have been selected by the NIH. This project will significantly enhance our ability to deliver cutting-edge care to our citizens and move us closer to our goal of making San Diego America's safest community."

The first ROC study will assess the effectiveness of initial resuscitation of trauma patients with hypertonic

fluid, which is a highly concentrated form of saline solution. In the crucial minutes before blood transfusions can be safely administered in a hospital, paramedics currently give trauma patients intravenous normal saline solution to compensate for blood loss. In this study, trauma patients with signs of shock or severe brain injury will receive one of three saline solutions – normal saline, high concentration (hypertonic) saline alone, or hypertonic saline with dextran, a circulation-enhancing substance.

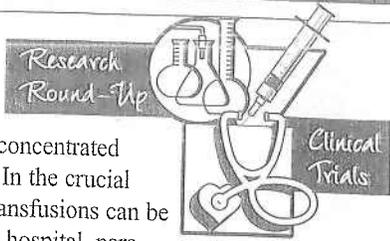
Hypertonic saline solutions have been used in Europe for several years but are not yet approved by the U.S. Food and Drug Administration (FDA). Hypertonic saline solutions are designed to compensate for blood loss more effectively, decrease the harmful inflammatory response to injury, and prevent brain swelling. Encouraging prior research indicates that these beneficial effects should lead to a reduction in organ failure for patients with major blood loss and improve neurological function for patients with brain injury.

The five trauma centers in the San Diego Trauma System will all participate in this study.

The second ROC trial, also in the review stages in San Diego, will evaluate the effectiveness of new treatments for cardiopulmonary resuscitation (CPR). In cardiac arrest the heart typically fibrillates and stops beating, blood no longer circulates, and the victim collapses into unconsciousness. The trial will study the best time to deliver an electrical shock following CPR as well as the use of an airway valve to enhance the effectiveness of chest compressions. This project would involve all twenty San Diego County hospitals that receive paramedic ambulances.

Every ROC study undergoes rigorous review and approval. The initial review is done by an independent group of scientists and ethicists at the NHLBI. Subsequent review occurs by the FDA as well as state and regional EMS authorities. ROC studies must also be reviewed and approved by the Institutional Review Boards (IRBs) of each of the participating hospitals. Since these trials will address patients in life-threatening situations who are often unconscious, the federal government employs stringent FDA guidelines to govern their safe conduct. Individuals wishing to exempt themselves from enrollment have the option of wearing or carrying a wristband indicating this choice. Wristbands will be provided through the SDRRC and can be obtained by calling 619-543-3829.

For additional information and the NIH press release, visit the ROC website at roc.uwctc.org or contact Donna Kelly, SDRCC Study Coordinator, at 619-543-3829.



Irradiation Preserves T-Cell Responses in Bacterial Vaccine

Using gamma radiation to inactivate bacteria for the preparation of vaccines, instead of traditional heat or chemical methods of inactivation, appears to create a vaccine that is more effective than so-called "killed" vaccines against disease, and has the added advantage of preserving the life of the bacteria.

To test the irradiated LM, mice were vaccinated with either heat-killed or irradiated vaccine, and then given lethal doses of LM bacteria. All of the unvaccinated or heat-killed vaccinated mice died, but 80 percent of those vaccinated with the irradiated vaccine survived. Protection against



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HEALTH SCIENCES

NEWS

Covering the School of Medicine, the Skaggs School of Pharmacy and Pharmaceutical Sciences, and UCSD Medical Center.

Fourth HIP Summer Program Immerses UCSD Preuss Students in the World of Medicine

What is a career in medicine really like? The best way to find out is to shadow a group of outstanding doctors as they perform their jobs—from surgery to diagnostic imaging to well-baby checkups. Ten students from the UCSD Preuss School had an opportunity to do just that. For the fourth year, UCSD Medical Center and the UCSD Preuss School have partnered to introduce high school juniors to various health care professions through the Health Information Partners (HIP) summer program. The goal of the program is to encourage the students to continue their education and to familiarize them with the roles of health care professionals.

The students entered the program with an interest in health care and the desire to meet professionals in the field and get a firsthand view of the world of medicine. Through the program, they gained knowledge and perspective about the health care field and its wide variety of disciplines.

For four weeks, the students were immersed in the health care environment. They lived in dorms on the UCSD campus and performed rotations in various departments at UCSD.

They also met for panel discussions with medical students, doctors, nurses, and other professionals, including **Richard Lickweg**, Chief Executive Officer of UCSD Medical Center, **Tom McAfee, M.D.**, Physician-in-Chief, who leads the HIP initiative, and **Edward W. Holmes**, Vice Chancellor of Health Sciences and Dean of the School of Medicine.

we were able to experience the work environment and meet the experts who perform a multitude of jobs.

UCSD Hospitalist **Leslie Martin, M.D.**, said "It was a true pleasure to introduce these students to a possible career in medicine. They were all so bright, enthusiastic, savvy and fun. I remember being in high school but I don't remember being that mature and together!"

"HIP is a unique opportunity for our Preuss students to meet and hear the stories of very accomplished members of our UCSD faculty," said **Felicia Beasley**, Director, Volunteer Services and HIP Program Director. "The UCSD partners who met and explained the science of medicine also shared their career paths, which were often unplanned. They shared their passion and expertise and encouraged students to find their own success by pursuing their passions. Regardless of which career in health care they pursue, they have a better understanding of the art and science of medicine, and will be responsible contributing members of their community."

Since its inception, HIP has offered a glimpse of what is possible. One hundred percent of the students who have participated in the HIP program are pursuing their possibilities in four-year colleges and universities.



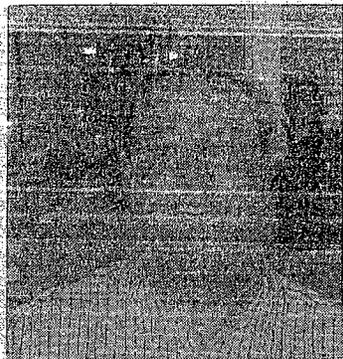
The 2006 HIP program students (L-R): **Kane Diep**, **Diana Nguyen**, **Iris Do**, **Paul Nguyen**, **Amita Noeay**, **Hieu Tran**, **Doantrang Dinh**, **Moises Esparza**, **Ludwan Kidane** and **Tomy Nguyen**.

- Paul Trinh, University of California, Berkeley
- Muneeb Malik, University of California, Berkeley
- Nancy Le, University of California, Riverside
- Gustavo Flores, University of California, Riverside
- Martina Wilson, California State University, Northridge
- Daniella Morales, Colgate University
- Bach Hue Le, Harvard University
- Britany Taylor, Howard University

HIP-ites 2005—Getting Ready

- TeKeyia Armstrong, University of California, Irvine
- Christopher Khavarian, Stanford University
- Anh Thi Nguyen, University of California, San Diego

FEB - 9 2007



Daniel Davis, a specialist in emergency medicine at the UCSD

UCSD physician to describe clinical trial for heart attack victims

SAN DIEGO - "Improving Survival from Cardiac Arrest and Severe Trauma" will be the topic of a series of community meetings being held around the county in February.

Daniel Davis, M.D., a specialist in emergency medicine at the University of California San Diego Medical Center, will describe a five-year countywide research project that is part of a major U.S.-Canadian initiative to improve survival from cardiac arrest and severe trauma. Davis is the principal investigator of the San Diego area component of the bi-national study, the Resuscitation Outcomes Consortium (ROC).

Times and locations of the San Diego County community meetings will be:

- Poway - February 9, 9:30 a.m. to 10:30 a.m., at the San Diego Library Poway Branch, 13137 Poway Road, Poway

- Carlsbad - February 9, 1:30 p.m. to 2:30 p.m., at the Carlsbad Library, Dove Branch, 1775 Dove Lane, Carlsbad

- El Cajon - February 12, 3:30 p.m. to 4:30 p.m., at the El Cajon Main Library, 201 E. Douglas, El Cajon

He will discuss a part of the study set to begin this spring. Its purpose is to evaluate the efficacy of a new method and device used for cardiopulmonary resuscitation (CPR) in treating victims of cardiac arrest and trauma and will involve San Diego County Emergency Medical Services (EMS), including many fire departments and hospitals. Many people in the county who suffer a serious injury or cardiac arrest and require San Diego's 911 services will be included in the clinical trial, unless they decline to participate.

In his talk, Davis will describe the upcoming CPR study, named ROC PRIMED (Pre-hospital Resuscitation using an Impedance valve and Early vs. Delayed analysis).

One part of the study will be a double-blind trial to test the effectiveness of an Impedance Threshold Device (ITD) to enhance blood flow within the chest during chest compressions. The device, which resembles a lemon in shape, size and color, attaches easily to regular CPR airway equipment. Its purpose is to promote a change in the pressure within the chest, resulting in increased blood flow to the heart and lungs.

The second part of the ROC study will compare two methods of CPR by varying the length of

SEE **UCSD, 14**

CONTINUED FROM PAGE 12

UCSD...

time the first responder does chest compressions. One, the standard used today, involves chest compressions and ventilations for only 30 seconds while setting up the equipment needed to analyze and shock the heart. This will be compared with a newer method,

in which chest compressions and ventilations are performed for 3 minutes before analysis and shock.

The U.S./Canadian consortium that is sponsored by the National Institutes of Health (NIH) is creating an extensive and unique database of trauma resuscitation and cardiac arrest infor-

mation that is expected to expand the understanding of resuscitation and develop new, more effective treatments.

More information about the public meetings or the study is available at 619-471-0616. In addition, information is on the Internet at www.uwctc.org, then clicking on ROC.

New Research Program to Study Procedures for Improving Survival from Cardiac Arrest and Severe Trauma

Each year, tens of thousands of Americans die from sudden cardiac arrest and traumatic injuries. However, results from recent studies suggest that a significant number of these people can be saved if they could be sustained long enough to reach a hospital alive. As part of the effort to increase survival chances from cardiac arrest and severe trauma, the County of San Diego is one of ten chosen sites within the United States and Canada to participate in a massive research program. This collaborative effort is conducted by the **Resuscitation Outcomes Consortium (ROC)**.

The ROC is funded by the National Institutes of Health (NIH) and other federal and Canadian agencies. The ROC in the County of San Diego will be coordinated through the University of California, San Diego and will involve the entire county's Emergency Medical Services (EMS) agencies, including many fire departments and hospitals. The ROC hopes to start the first research protocol this spring. The protocol will affect anyone in San Diego County outside of the San Diego city limits who is involved in a serious injury or experiencing cardiac arrest and requiring San Diego's 911 services. To learn more about how this research program might affect you and how the program works, a series of community meetings are available and open to the public.

Contact phone numbers are ROC office at 619-471-0614 or Dr. Daniel Davis at 619-543-3829.

COMMUNITY MEETINGS

Tuesday, February 6
6:30 p.m. - 7:30 p.m.
Chula Vista Library
Civic Center Branch
365 F Street • Chula Vista 91910

Friday, February 9
9:30 a.m. - 10:30 a.m.
San Diego Library
Poway Branch
13137 Poway Road • Poway 92064

Friday, February 9
1:30 p.m. - 2:30 p.m.
Carlsbad Library • Dove Branch
1775 Dove Lane • Carlsbad 92011

Monday, February 12
3:30 p.m. - 4:30 p.m.
El Cajon Library
Main Library
201 E. Douglas • El Cajon 92020



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MAR - 9 2007

Medical study using new treatments

VVETTE URREA
STAFF WRITER

Paramedics countywide are trying new treatments on patients with severe trauma or cardiac problems as part of a study that aims to improve field medical care and survival rates.

All such patients are subject to the study, which started two weeks ago and continues for at least two years, unless they opt out of the treatment in advance by obtaining a special medical bracelet. A federal clause allows paramedics to treat patients during the study without getting their consent because the patient would likely be incapacitated, a trial coordinator said.

UC San Diego spokeswoman Leshe Franz said the government allows the exception only when a study treat-

ment is highly unlikely to cause harm and is more likely to benefit the patient.

However, people who wish to be excluded from the study can obtain a special bracelet by calling (619) 471-0616.

The study, called the Resuscitation Outcomes Consortium, is being coordinated in the San Diego area by the UCSD Medical Center. The county is one of 10 areas in the United States that is participating in the study, which will also be conducted in Canada, said UCSD Emergency Medicine Dr. Daniel Davis.

Davis said that so far no one has called to request a bracelet but paramedics, who have all received special training for the program, are trained to look for it.

Davis added that the study is being evaluated at every step by federal review boards in case a patient is adversely

affected. Paramedics have noted improved chances for survival in cardiac patients during training, he said.

"We just enrolled our third patient (Tuesday). It's the second week of the trial. We're just getting started," Davis said. "That last one (patient) was taken to Palomar (Medical Center) and was out of Ramona."

The study is being conducted in two parts, with the goal of increasing blood flow to the heart and lungs. During the first part, which lasts until May, doctors will evaluate the effects of a hypertonic saline administered to severe trauma patients, according to the National Institutes of Health's Web site.

Davis said paramedics do not know whether they are administering the regular saline solution normally given to patients, a more concen-

trated version, or a version that includes dextran, a circulation-enhancing solution.

The second part of the trial will begin in May, and will address cardiac patients. It involves a new valve that raises blood pressure while paramedics do cardiopulmonary resuscitation, and compares the results to a combination of cardiopulmonary resuscitation and a defibrillator, Davis said.

The UCSD Medical Center held a series of community meetings in February, including several in Carlsbad and Poway, to tell residents about the study and answer questions. Other meetings were held in Chula Vista and El Cajon.

Contact staff writer Vvette Urra at (760) 901-4076 or vurree@nctimes.com. To comment go to nctimes.com.



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UCSD to lead cardiac, trauma care program

By: BRADLEY J. FIKES - Staff Writer

Heart attack and trauma patients will get more help from trained paramedics and better access to new treatments under a program led locally by UC San Diego.

The program adds to existing efforts to improve cardiac care already under way by Palomar Pomerado Health, Scripps Health and other local hospitals.

Called the "Resuscitation Outcomes Consortium," it is a joint United States and Canadian program to improve survival and recovery from cardiac arrest and traumatic injuries. It's funded by the National Institutes of Health and the Canadian Institutes of Health Research.

UCSD is getting \$2.3 million to coordinate the program in San Diego County, the university announced on July 27.

UCSD will work with paramedics and hospitals to run ROC-sponsored studies on how to improve care, said Daniel Davis, who is overseeing the program here. Davis is an associate professor of medicine in UCSD's department of emergency medicine. Patients with heart attacks, trauma or brain injuries are the main targets of the studies.

The program will collect information about the patients from first contact until admission, Davis said. With the consent of the patients, they'll also be tracked after leaving the hospital to determine their long-term survival and condition. This information will then be used as part of a database to determine which treatments work best under what conditions, and also to determine the effectiveness of experimental treatments.

In a separate but related project, UCSD is talking with other major hospitals in the county



Hot Topics Readers reflect on the latest trends

The politics of illegal immigration

Finally someone from Washington is paying a little attention to the battle going on over illegal immigration on this side of the country. 88 Comment(s)

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about establishing a common program to train paramedics. To be named the "Resuscitation Science and Training Institute," the program will "serve as a nucleus for training in cardiac arrest in San Diego County," Davis said.

This program is "in its infancy," Davis said, and still in the discussion stage. One thing the discussion will include is what expertise other hospitals can bring, he said.

Palomar Pomerado Health's Cardiac Alert program identifies high-risk patients on site and brings them into Palomar Medical Center's emergency department. Paramedics from the Escondido, Ramona, Poway, Julian, San Marcos and Valley Center fire departments screen the patients with an EKG machine and transport those showing high risk.

Scripps Health announced in June it is building a cardiovascular institute that will combine the existing programs of the Green Hospital at Scripps Clinic and Scripps La Jolla. The Scripps Cardiovascular Institute is the first part of a three-phase relocation of the entire Scripps La Jolla hospital. The goal in combining the cardiovascular programs at one location is to increase the number of patients treated. High patient volume is associated with good outcomes, because doctors and staff benefit from the experience.

Contact staff writer Bradley J. Fikes at bfikes@nctimes.com or (760) 739-6641.



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Bill G wrote on August 16, 2006 7:02 PM: "Glad to see this is spreading beyond just Palomar Pomerado. They do great but the travel time to Palomar from people further south is too much. Everyone should have access to this technology."

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Media Contact:
Leslie Franz
619-543-6163
lfranz@ucsd.edu

February 1, 2007

**UCSD Emergency Physician to Describe Large Clinical Trial
For Heart Attack and Trauma Victims**

“Improving Survival from Cardiac Arrest and Severe Trauma” will be the topic of a series of community meetings being held around the county in February.

Daniel Davis, M.D., a specialist in emergency medicine at the University of California San Diego Medical Center, will describe a five-year countywide research project that is part of a major U.S.-Canadian initiative to improve survival from cardiac arrest and severe trauma. Davis is the principal investigator of the San Diego area component of the bi-national study, the Resuscitation Outcomes Consortium (ROC).

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One part of the study will be a double-blind trial to test the effectiveness of an Impedance Threshold Device (ITD) to enhance blood flow within the chest during chest compressions. The device, which resembles a lemon in shape, size and color, attaches

easily to regular CPR airway equipment. Its purpose is to promote a change in the pressure within the chest, resulting in increased blood flow to the heart and lungs.

The second part of the ROC study will compare two methods of CPR by varying the length of time the first responder does chest compressions. One, the standard used today, involves chest compressions and ventilations for only 30 seconds while setting up the equipment needed to analyze and shock the heart. This will be compared with a newer method, in which chest compressions and ventilations are performed for 3 minutes before analysis and shock.

The U.S./Canadian consortium that is sponsored by the National Institutes of Health (NIH) is creating an extensive and unique database of trauma resuscitation and cardiac arrest information that is expected to expand the understanding of resuscitation and develop new, more effective treatments. By studying new and promising drugs, technologies and techniques, researchers hope to identify treatments most likely to benefit the public and improve outcomes for patients who experience cardiac arrest or a traumatic injury. The goal is to decrease mortality, improve outcomes, and help return patients to their prior functional capacity. The initial funding commitment last year of \$50 million supports research in eight regions throughout the U.S. and two Canada. The University of Washington in Seattle is the coordinating center for the program and assists with the coordination with the NIH.

UCSD received a \$2.3 million grant last year to participate in ROC and lead the San Diego component, which is named the San Diego Resuscitation Research Center (SDRRC). The SDRRC integrates pre-hospital care providers, trauma centers, and cardiac arrest-receiving hospitals into an organized network to conduct ROC-sponsored studies. The SDRRC also trains paramedics in protocol implementation and supports a data system to track patient outcomes.

The initial ROC study, which is about to begin, is assessing the effectiveness of initial resuscitation of severe trauma patients using hypertonic saline fluid, a highly concentrated form of saline solution. This trial will compare the use of a high concentration salt solution to a high concentration salt solution with a type of sugar added to the regular saline solution currently being used with severe trauma patients.

Every ROC study undergoes rigorous review and approval. The initial review is done by an independent group of scientists and ethicists retained by the NIH. Subsequent review occurs by the FDA as well as state and regional EMS authorities. ROC studies must also be reviewed and approved by the Institutional Review Boards (IRBs) of each of the participating hospitals. Since these trials will address patients in life-threatening situations who are often unconscious, the federal government employs stringent FDA guidelines to govern their safe conduct. Individuals wishing to exempt themselves from participation have the option of wearing a wristband indicating their choice not to participate. Wristbands will be provided through the SDRRC and can be obtained by calling 619-471-0616.