

RESUSCITATION OUTCOMES CONSORTIUM

WHAT IS ROC



THE RESUSCITATION OUTCOMES CONSORTIUM (ROC)

was created to study which treatments help people with cardiac arrest or severe injury. The ROC consists of regional sites across the US and Canada and study coordinating centers. The ROC investigators are physicians that work with fire rescue and Emergency Medical Service (EMS) systems and hospitals to do studies aimed at understanding what treatments are helpful when given during the early course of care. Treatments studied include promising resuscitation drugs, tools, techniques, and therapies.

The ROC investigators do studies in which people who qualify receive either the currently accepted treatment or an alternative treatment that scientific data suggests may be of equal or greater benefit. The treatment given is assigned by chance (like tossing a coin). ROC studies are designed to evaluate current practices and compare treatment options so that EMS, emergency department, and hospital providers can determine those treatments most likely to benefit the public.



Why was ROC formed?

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

- Little research has been done in emergency settings to guide practice.
- Medical experts believe the sooner these patients receive treatment, the better the outcomes.
- Accepted treatments can vary widely from place to place and ROC will help determine which work best.
- Improved patient outcomes may result from understanding, coordinating, and transitioning early care from EMS providers to the hospital emergency department staff.
- Research studies involving many sites take less time to complete, thus allowing trial results to more quickly guide future practice.
- Collecting information about the rate and outcome from severe injury and cardiac arrest will tell us how many patients with these conditions survive and return to live and work in their communities.

Why is ROC research vital?

Cardiac arrest and serious injury are important public health problems. Heart disease is the most common cause of death in North America. Over 180,000 treatable out-of-hospital cardiac arrests occur each year. Over half of these victims have no warning. Nearly 95% of patients who have an out-of-hospital cardiac arrest die before reaching the hospital. If survival could be raised from 5% to 20%, an additional 27,000 deaths would be prevented yearly.

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

What hope does ROC bring to the public?

People who live in ROC communities may benefit from having:

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

What are the ethical considerations with this kind of emergency research?

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

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

After the public has been notified and been able to give their input, an emergency care study can proceed without informed consent. Efforts are made following the emergency to notify the patient if they are capable, or their legally authorized representative if they are not, of their enrollment in a study. They may decide whether or not to continue participation in the study. In addition to the above, the ROC has several layers of research review in place to safeguard patients:

- An independent group of experts reviews the scientific value of each proposed study.
- A separate expert group authorized by the National Institutes of Health reviews the safety of the trial and monitors the safety of the patients throughout the study.
- An expert in medical ethics affiliated with ROC reviews the proposed research.
- If a device or drug is to be studied, the U.S. Food & Drug Administration (FDA) and Health Canada review and approve the study before it starts.
- At each site an independent review group evaluates and monitors the research locally. This final review and approval focuses on the local issues of how best to consult with the public regarding both the study treatment(s) and outcome(s) and notify them about the research.

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

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

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

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

Who will be doing the research?

The University of Washington Clinical Trial Center, Seattle, Washington, coordinates the ROC network and its satellites. The following regions are participating in ROC:

- **ALABAMA RESUSCITATION CENTER** is coordinated through the University of Alabama at Birmingham in Birmingham, Alabama, and includes fire and EMS agencies in Central Alabama.
- **BRITISH COLUMBIA SITE** is coordinated by the University of British Columbia, Department of Emergency Medicine and the St. Paul's Hospital Emergency Medicine Research Group. EMS agencies include the BC Ambulance Service and First Responding Fire Services in Greater Vancouver, Victoria, Southern Vancouver Island, the interior cities of Kelowna and Kamloops.
- **DALLAS-FORT WORTH CENTER FOR RESUSCITATION RESEARCH** is coordinated through the University of Texas Southwestern Medical Center in Dallas, Texas, and includes Dallas, Fort Worth, and some adjacent cities.
- **THE MILWAUKEE RESUSCITATION RESEARCH CENTER** is coordinated through the Medical College of Wisconsin in Milwaukee, Wisconsin, and includes 19 communities in Milwaukee County.
- **PITTSBURGH RESUSCITATION NETWORK** is coordinated through the University of Pittsburgh in Pittsburgh, Pennsylvania, and includes portions of Alleghany, Westmoreland, and Washington counties.
- **PORTLAND RESUSCITATION OUTCOMES CONSORTIUM** is coordinated through the Oregon Health & Science University in Portland, Oregon, and includes four counties in Oregon and Washington states.
- **RESCU AND THE TORONTO REGIONAL RESCUNET** includes EMS and Fire Fighters from Toronto and the surrounding regions and provides the platform for the University of Toronto's contribution to ROC.
- **SAN DIEGO RESUSCITATION RESEARCH CENTER** is coordinated through the University of California, San Diego, California, and includes all of San Diego County.
- **SEATTLE-KING COUNTY CENTER FOR RESUSCITATION RESEARCH** at the University of Washington is coordinated through the University of Washington, Seattle, Washington, and includes all of King County.
- **UNIVERSITY OF OTTAWA REGIONAL CENTER** is coordinated through the Ottawa Health Research Institute and is comprised of the City of Ottawa and the OPALS group of cities across the province of Ontario.

SATELLITES

- **HOUSTON CLINICAL COORDINATING CENTER (HCCC)** is coordinated through the Center for Translational Injury Research (CeTIR) at the University of Texas Health in Houston, Texas.
- **HOUSTON DATA COORDINATING CENTER (HDCC)** is coordinated through the School of Public Health at the University of Texas Health in Houston, Texas.
- **MEMPHIS RESUSCITATION RESEARCH CENTER** is coordinated through the University of Tennessee Health Science Center and the Regional Medical Center, Memphis, Tennessee. The Hospital Wing helicopter services a tri-state area, and the City of Memphis Fire Department services most of Shelby County, Tennessee.
- **UNIVERSITY OF TEXAS HEALTH** is located in Houston, Texas, and is a Level One trauma center that services the Houston metropolitan area and surrounding counties.
- **UNIVERSITY OF CALIFORNIA – SAN FRANCISCO** is located in San Francisco, California, and is a Level One trauma center that services the San Francisco metropolitan area.
- **UNIVERSITY OF CINCINNATI** is located in Cincinnati, Ohio, and is a Level One trauma center servicing the Cincinnati metropolitan area.
- **SUNNYBROOK HEALTH SCIENCES CENTER** is a Level One trauma center located in Toronto, Ontario. Sunnybrook Health Sciences Center services the Toronto metropolitan area.



Who is funding the project?

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

How can I learn more about ROC?

Visit the ROC website at www.uwctc.org and click on ROC.



www.uwctc.org

For more information

February 2011

