

Resuscitation Outcomes Consortium: Overview and Update



OPALS PRG Ottawa November 2008

Resuscitation Outcomes Consortium: Overview

- **Mandate and Overview**
- **Partners**
- **Project Updates:**
 - ▶ **Epistry**
 - ▶ **HSD Trial**
 - ▶ **CPR Process**
 - ▶ **ROC PRIMED**
- **The Future**



1. *Mandate and Overview*

- ROC Consortium the first large-scale effort to conduct clinical trials in cardiac arrest and severe traumatic injury
- Focuses on very early delivery of interventions by Emergency Medical Services (EMS) teams in the field, when optimal potential for benefit



1. *Mandate and Overview*

In the first 4 years, ROC investigators have:

- Launched a large out-of-hospital cardiac arrest and trauma registry (**Epistry**)
- Started enrolling trauma patients in clinical trial of hypertonic IV fluid (**HSD Trial**)
- Rolled out the monitoring of **CPR Process** in all cardiac arrests
- Launched cardiac arrest trial (**ROC PRIMED**) that evaluates:
 - ▶ ITD valve - small CPR adjunct
 - ▶ Strategy of delayed defibrillation

Resuscitation Outcomes Consortium: Overview

- **Mandate and Overview**
- **Partners**
 - ▶ **Funding**
 - ▶ **Sites**
- **Project Updates:**
 - ▶ **Epistry**
 - ▶ **HSD Trial**
 - ▶ **CPR Process**
 - ▶ **ROC PRIMED**
- **The Future**



ROC Site Map



ROC Funding Partners



National Heart, Lung and Blood Institute



Canadian Institutes of Health Research



National Institute of Neurological Disorders and Stroke



Defence Research and Development Canada



United States Army



Heart and Stroke Foundation of Canada



American Heart Association



2. Partners: Sites and PIs

- **Alabama Resuscitation Center:** Jeff Kerby, MD
- **Dallas, TX:** Ahamed Idris, MD
- **Iowa City, IA:** Richard Kerber, MD
- **Milwaukee, WI:** Tom Aufderheide, MD
- **Pittsburgh, PA:** Clif Callaway, MD
- **Portland, OR:** Jerris Hedges, MD
- **Ottawa, ON:** Ian Stiell, MD
- **San Diego, CA:** Dan Davis, MD
- **Seattle / King County, WA:** Peter Kudenchuk, MD
- **Toronto, ON:** Art Slutsky, MD, Laurie Morrison, MD and Paul Dorian, MD, Co-PIs
- **Vancouver, BC:** Jim Christenson, MD

2. Partners: How Big are We?

- **268 EMS and fire services**
- **35,000 square miles**
- **24 million people**
- **3,500 EMS vehicles**
- **30,000 EMS personnel**
- **100 REBs (IRBs)**
- **287 hospitals**
 - ▶ **17% Level 1 trauma**

2. Partners: Data Coordinating Center (DCC)



U of Washington Clinical Trials Center:

- **Scott Emerson, MD, PhD - PI**
- **Graham Nichol, MD - Co-PI**
- **Eileen Bulger, MD - Co-PI**
- **Judy Powell, BSN - Project Director**
- **Art Kerr, MBA - Project Manager**
- **Berit Bardarson, RN - Consultant, Trauma**
- **Lois Van Ottingham, RN – Consultant, Cardiac**
- **Gena Sears, RN – Consultant, Epistery**

2. Partners: Study Chairs and NIH Project Officer



- **Myron L. Weisfeldt, MD** - Study Chair
 - Johns Hopkins Medical Institutions
 - Baltimore, MD

- **Joseph P. Ornato, MD** - Co-Chair-Cardiac
 - Virginia Commonwealth University Health
 - Richmond, VA

- **David Hoyt, MD** - Co-Chair-Trauma
 - University of California
 - San Diego, CA

- **George Sopko, MD** – Project Officer
 - NHLBI

Resuscitation Outcomes Consortium: Overview

- Mandate and Overview
- Partners
- Project Updates:
 - ▶ Epistry
 - ▶ HSD Trial
 - ▶ CPR Process
 - ▶ ROC PRIMED
 - ▶ CPR Feedback
 - ▶ Publications
- The Future



3. Project Updates: ROC Epistry




A prospective, population-based, epidemiologic **data registry** of patients seen by EMS providers:

- Life-threatening trauma
- Cardiac arrest

Complete this form:
- any episode where EMS performed CPR (any compressions)
- for any episode where the ITD was removed from its sealed packaged (even if not used).
Main data source: PCR
Other data resource: Dispatch

Patient Enrollment
Page 1 of 1


CARDIAC BLOOD-FLOW TRIAL

Episode Information:

Date: / /
(mm/dd/yyyy)

Time call received at dispatch (24hr clock): : : (hh:mm:ss)
Time is: estimated
 from dispatch

Incident Number(from EMS report):
Episode ID:
Always use this **Episode ID** when referring to this Episode

1) EMS response:

Arriving vehicle	Agency name	Agency #	Time of arrival 24 hours (hh:mm:ss)	ITD Opened		ITD Used		ITD #
				Yes	No	Yes	No*	
1st	<input type="text"/>	<input type="text"/>	<input type="text"/> : <input type="text"/> : <input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
2nd	<input type="text"/>	<input type="text"/>	<input type="text"/> : <input type="text"/> : <input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>

3. Project Updates:

- ROC Epistry



- Will become world's largest traumatic injury and cardiac resuscitation data sets:
 - ▶ 10,000/year major trauma
 - ▶ 17,500/year cardiac arrest
- Develop data collection and communication systems among EMS systems, sites, and DCC
- Will facilitate subsequent clinical trials
- Analyses will generate hypotheses

Epistry Update

- **47,000 cases enrolled overall**
- **13,715 trauma cases**
 - **88% treated**
- **33,480 cardiac arrest cases**
 - **59% treated**
- **8 abstracts** presented at American Heart Association in 2008
- **10 papers** published or in press

3. Project Updates: HSD Trial in Trauma



- **Hypertonic Saline Dextran Trial - hemorrhagic shock and severe traumatic brain injury (TBI)**
- **Data suggest potential benefits from pre-hospital resuscitation with hypertonic fluids**
- **Potential to improve outcome via:**
 - ▶ **Improved tissue perfusion**
 - ▶ **Reduced cerebral swelling in TBI**
 - ▶ **Modulation of inflammatory response**



3. Project Updates: HSD Trial in Trauma



The primary aims are to determine if pre-hospital hypertonic fluid resuscitation:

- Reduces **mortality** after hemorrhagic shock
- Improves **neurologic outcome** after severe TBI
- Reduces the rates of **inflammatory organ injury** (ARDS and MODS) after hemorrhagic shock
- Requires **dextran** as a component to impact outcome

3. Project Updates: HSD Trial in Trauma



- Randomized double-blind trials to evaluate same intervention in **2 patient cohorts**:
 - ▶ Severe TBI
 - ▶ Hemorrhagic shock
- **Compares** field IV administration of 250 ml:
 1. 7.5% saline alone
 2. 7.5% saline / 6% Dextran-70
 3. 0.9% saline
- **Primary outcomes**:
 - ▶ Neurologic outcome at 6 months - TBI cohort
 - ▶ 28-day survival - shock cohort

3. Project Updates: HSD Trial in Trauma



- **Sample size 5,848:**
 - ▶ 2,122 in TBI cohort
 - ▶ 3,726 in shock cohort

- **Timeline:**
 - ▶ 24 months for TBI
 - ▶ 42 months for shock

- **Importance:**
 - ▶ Definitively define the role of these therapies in the early resuscitation of trauma
 - ▶ Potential to change the standard for resuscitation that has not changed in 30 years

HSD Trial in Trauma Status – October 26th



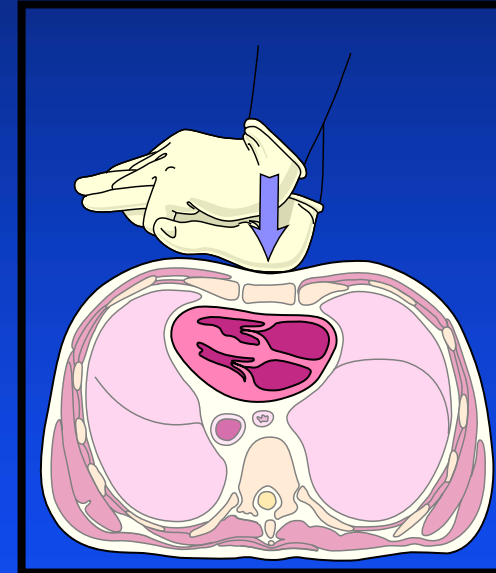
- **1st site commenced enrollment June 2006**
- **All ROC sites enrolling until voluntary suspension September 2008**
- **1,918 cases enrolled**
 - ▶ **1,082 TBI**
 - ▶ **836 Shock**

3. Project Updates: CPR Process Monitoring



Rationale:

- Recent studies have demonstrated that CPR is often not performed according to guidelines
- Greater rate of chest compressions associated with higher rate of ROSC
- Observation of deleterious hyperventilation in recent study confirms importance of monitoring CPR process



3. Project Updates: CPR Process Monitoring



Evolving Technologies offer the ability to monitor CPR process through AEDs:

- **Chest impedance** to monitor chest compression rate and ventilation rate
- **Chest acceleration** to monitor chest compression rate, depth, release, and duty cycle
- **Audio recording** to monitor audible events

3. Project Updates: CPR Process Monitoring



Devices

■ ALS:

- ▶ LP-12 – Medtronic ERS Inc
- ▶ MRX – Philips Inc and Laerdal Inc
- ▶ M- and E-Series – Zoll Inc

■ BLS:

- ▶ LifePak 500 – Medtronic ERS Inc
- ▶ Heartstart & MRX – Philips Inc and Laerdal
- ▶ AED Pro BLS – Zoll Inc

3. Project Updates: CPR Process Monitoring



Performance Standards

Parameter	Target	Min-Max
Ventilation / min	10-12	6 - 16
Chest Compression / min	100	80 -120
CPR Flow Fraction	0.85	0.5 –

1,583 cases enrolled so far

3. Project Updates: ROC PRIMED for Cardiac Arrest



A Factorial Design of “An Active Impedance Threshold Valve versus Sham Valve” and “Analyze Later versus Analyze Early”

- Incorporates 2 interventions to improve hemodynamics during CPR:
 1. Impedance threshold device (ITD)
 2. Chest compressions before rhythm analysis



3. Project Updates: ROC PRIMED for Cardiac Arrest



1. Impedance Threshold Device (ITD)

- Enhances venous return and cardiac output by increasing negative intrathoracic pressure during decompression phase of CPR
- Promising results in preliminary clinical trial [Aufderheide]
- Randomize real valve vs. sham valve
- **ResQPod** – Advanced Circulatory Systems



Impedance Threshold Device



**Endotracheal Tube
Set-up**

**Bag Valve Mask
Set-up**

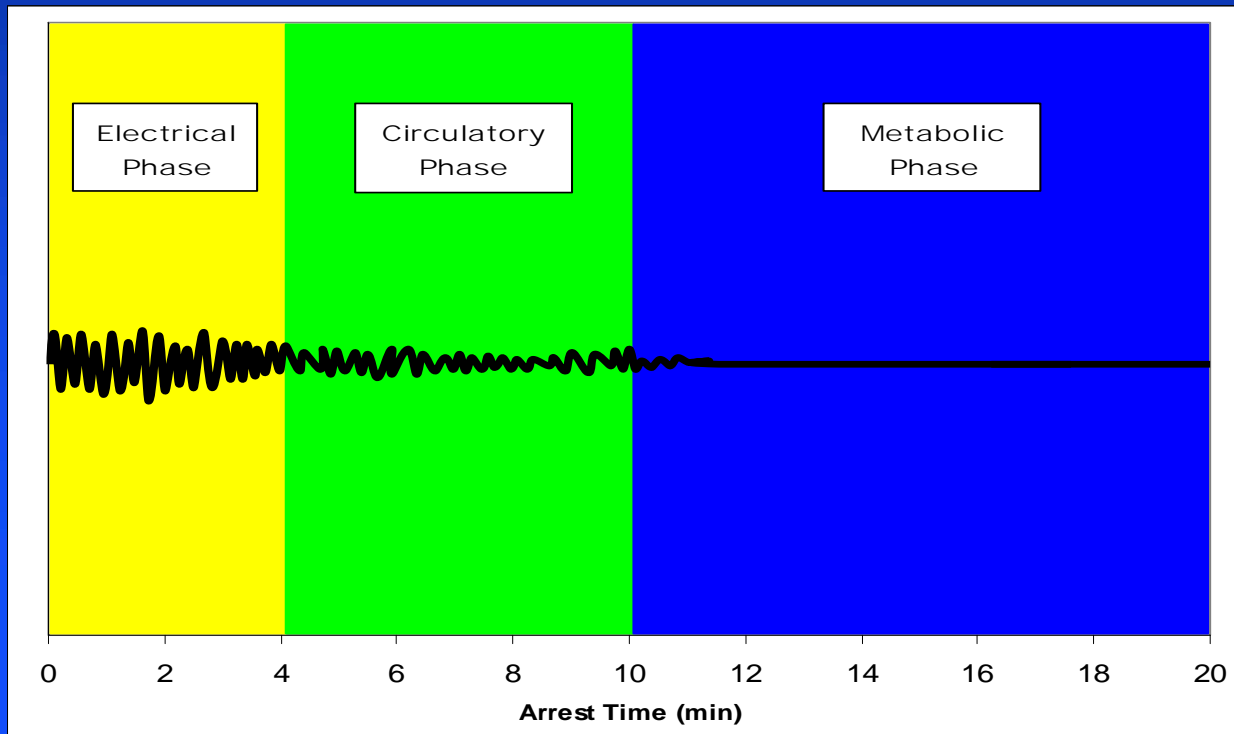


3. Project Updates: ROC PRIMED for Cardiac Arrest

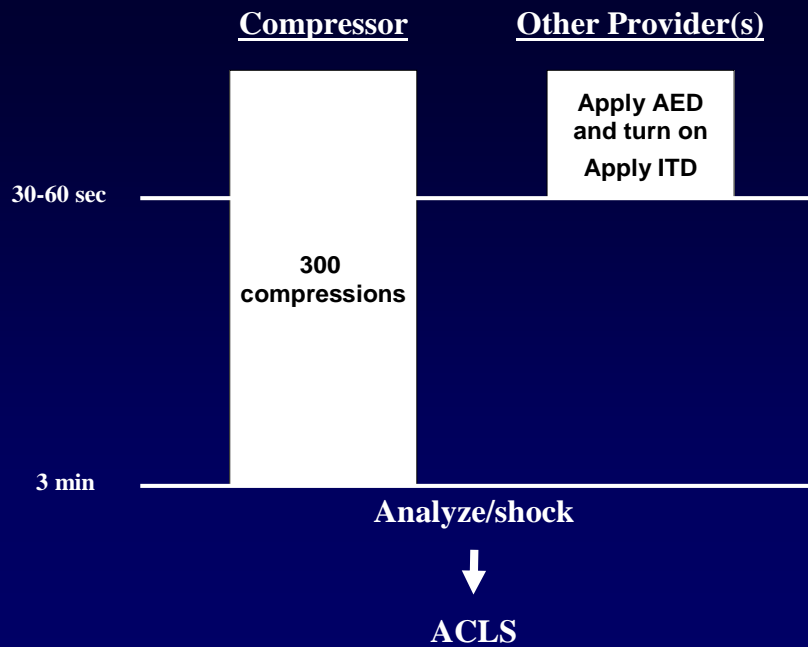


2. Analyze Later Vs. Analyze Early

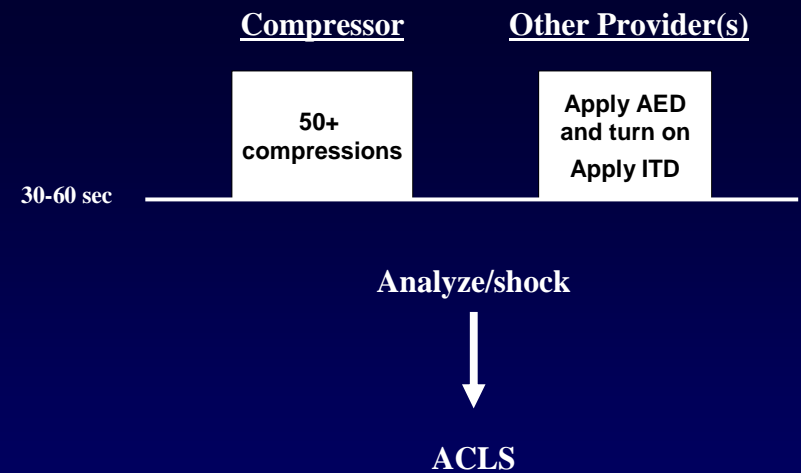
- Defibrillation may be more effective if CPR is given prior to shock for patients in circulatory phase of VF (prime the pump)



2. Analyse Later vs. Analyse Early Cluster Randomization; EMS & Fire



Analyse Later



Analyse Early

3. Project Updates:

ROC PRIMED for Cardiac Arrest

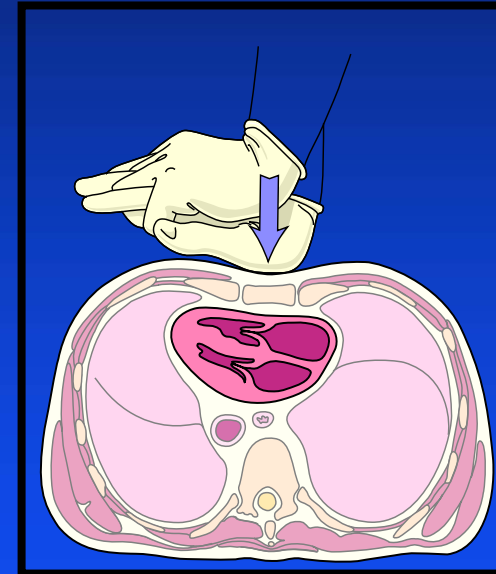


- **Primary outcome:** survival to hospital discharge with Modified Rankin Score ≤ 3
- **Sample size and timeline:** 15,000 patients over 16-18 months
- **Approvals:** ROC Protocol Review Committee, ROC DSMB, Health Canada, and FDA
- Detailed **training package** and **data entry** screens
- **Launch: June 2007** - all sites now enrolling
- **4,264 patients enrolled**

3. Project Updates: CPR Feedback Substudy



- Three ROC sites are actively enrolling in a cluster randomized substudy to evaluate real-time feedback to rescuers on multiple aspects of CPR
- Using Philips-Laerdal technology
- The effect on compliance with recommended techniques and on short term survival is likely to transform resuscitation and training practices



CPR Feedback Enrollment Report

Data as of 2008-10-20

	Ottawa	Pittsburgh	King County	Total
Enrolled	19	654	748	1421
Final Data Available	11 (58%)	620 (95%)	696 (93%)	1327 (93%)
Total Evaluable	4	538	651	1193
Male ¹	3 (75%)	337 (63%)	416 (64%)	756 (63%)
Female ¹	1 (25%)	200 (37%)	234 (36%)	435 (36%)
Final Vital Status Missing ¹	1 (25%)	15 (3%)	7 (1%)	23 (2%)
CPR Fraction Missing ¹	3 (75%)	136 (25%)	173 (27%)	312 (26%)
Compression Rate Missing ¹	3 (75%)	136 (25%)	173 (27%)	312 (26%)
Number of Ventilations Missing ¹	4 (100%)	258 (48%)	472 (73%)	734 (62%)
Compression Depth Missing ¹	3 (75%)	191 (36%)	257 (39%)	451 (38%)
Compression Release Missing ¹	3 (75%)	191 (36%)	257 (39%)	451 (38%)

¹Percentages are of total evaluable.

3. Project Updates: ROC Publications



OPALS authors on:

- ▶ 4 of 8 AHA abstracts 2008
- ▶ 1st author on Chest Compression Depth
- ▶ 6 of 7 AHA/AAST abstracts 2007
- ▶ 7 of 11 manuscripts
- ▶ 1st author on ROC PRIMED Methods II

Regional Variations in Out-of-Hospital Cardiac Arrest Incidence

Graham Nichol, MD, MPH

Elizabeth Thomas, MSc

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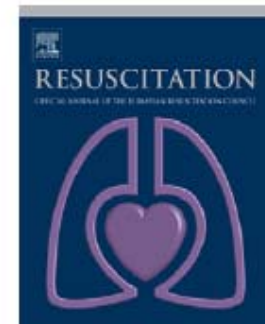
IT REMAINS TO BE DETERMINED HOW often out-of-hospital cardiac arrest (OHCA) occurs. Recent sources indicate that about 166 000 to 310 000 Americans per year experience an OHCA,¹ although resuscitation is not attempted in many of these



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journal homepage: www.elsevier.com/locate/resuscitation



CLINICAL PAPER

The Resuscitation Outcomes Consortium Epistry-Trauma: Design, development, and implementation of a North American Epidemiologic Prehospital Trauma Registry[☆]

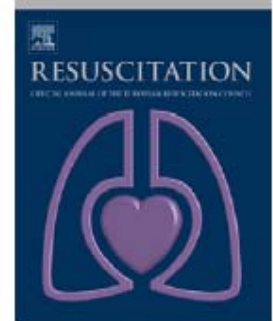
Craig D. Newgard^{a,*}, Gena K. Sears^b, Thomas D. Rea^c, Daniel P. Davis^d,
Ronald G. Pirrallo^e, Clifton W. Callaway^f, Dianne L. Atkins^g,
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CLINICAL PAPER

Resuscitation Outcomes Consortium (ROC) PRIMED cardiac arrest trial methods Part 1: Rationale and methodology for the impedance threshold device (ITD) protocol[☆]

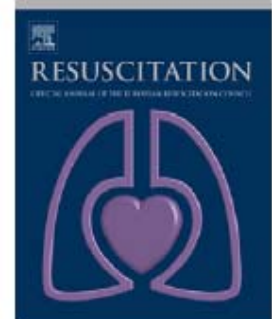
Tom P. Aufderheide^{a,*}, Peter J. Kudenchuk^b, Jerris R. Hedges^c,
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CLINICAL PAPER

Resuscitation Outcomes Consortium (ROC) PRIMED cardiac arrest trial methods Part 2: Rationale and methodology for “Analyze Later vs. Analyze Early” protocol[☆]

Ian G. Stiell^{a,*}, Clif Callaway^b, Dan Davis^c, Tom Terndrup^d, Judy Powell^e,
Andrea Cook^e, Peter J. Kudenchuk^e, Mohamud Daya^f, Richard Kerber^g,
Ahamed Idris^h, Laurie J. Morrisonⁱ, Tom Aufderheide^j,
for the ROC Investigators^{**}

Regional Variation in Out-of-Hospital Cardiac Arrest Incidence and Outcome

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IT REMAINS TO BE DETERMINED HOW often out-of-hospital cardiac arrest (OHCA) occurs. Recent sources indicate that about 166 000 to 310 000 Americans per year experience an OHCA,¹ although resuscitation is not attempted in many of these

Context The health and policy implications of regional variation in incidence and outcome of out-of-hospital cardiac arrest remain to be determined.

Objective To evaluate whether cardiac arrest incidence and outcome differ across geographic regions.

Design, Setting, and Patients Prospective observational study (the Resuscitation Outcomes Consortium) of all out-of-hospital cardiac arrests in 10 North American sites (8 US and 2 Canadian) from May 1, 2006, to April 30, 2007, followed up to hospital discharge, and including data available as of June 28, 2008. Cases (aged 0-108 years) were assessed by organized emergency medical services (EMS) personnel, did not have traumatic injury, and received attempts at external defibrillation or chest compressions or resuscitation was not attempted. Census data were used to determine rates adjusted for age and sex.

Main Outcome Measures Incidence rate, mortality rate, case-fatality rate, and survival to discharge for patients assessed or treated by EMS personnel or with an initial rhythm of ventricular fibrillation.

Results Among the 10 sites, the total catchment population was 21.4 million, and there were 20 520 cardiac arrests. A total of 11 898 (58.0%) had resuscitation attempted; 2729 (22.9% of treated) had initial rhythm of ventricular fibrillation or ventricular tachycardia or rhythms that were shockable by an automated external defibrillator; and 954 (4.6% of total) were discharged alive. The median incidence of EMS-treated cardiac arrest across sites was 52.1 (interquartile range [IQR], 48.0-70.1) per 100 000 population; survival ranged from 3.0% to 16.3%, with a median of 8.4% (IQR, 5.4%-10.4%). Median ventricular fibrillation incidence was 12.6 (IQR, 10.6-5.2) per 100 000 population; survival ranged from 7.7% to 39.9%, with a median of 22.0% (IQR, 15.0%-24.4%), with sig-

JAMA 2008;300(12):1423-1431

4. Future Projects

In Cardiac Arrest:

- Continuous chest compressions vs. standard CPR
- Hypothermia: immediate vs. delayed vs. no field cooling
- Immediate CPR feedback
- Amiodarone vs. Lidocaine
- Erythropoietin
- ECG waveform analysis
- Estrogen



4. Future Projects

In Traumatic Injury:

- Intubation
- Value of controlled ventilation
- Erythropoietin
- Estrogen
- Other IV solutions





RESUSCITATION OUTCOMES CONSORTIUM



National Heart, Lung and
Blood Institute



CIHR IRSC

Canadian Institutes of
Health Research



U.S. Department of
Defense



National Defence
Canada

