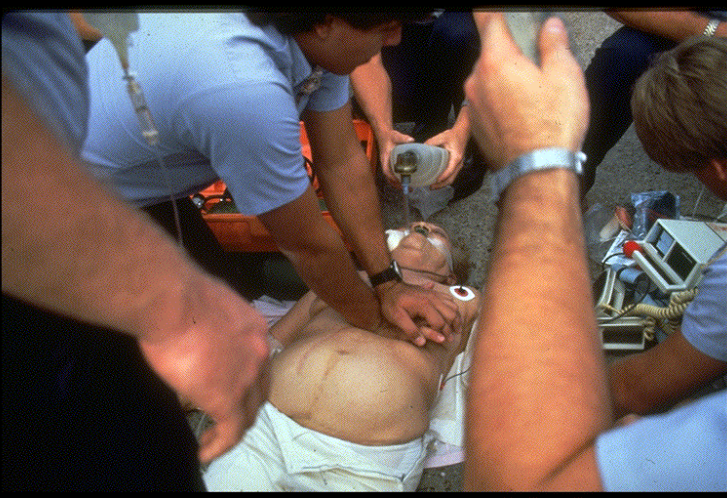
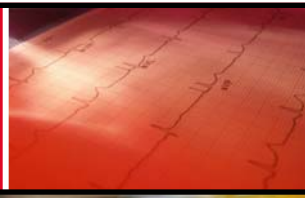


ROC PRIMED



Purpose of this Study

To determine outcomes in cardiac arrest when comparing...

1

Difference between *analyze early* and *analyze later* protocols.

2

Difference between *CPR with the ITD* and *CPR with a sham valve*.





Analyze Later versus Analyze Early

Analyze Later vs Analyze Early

This part of the study will involve EMS and Fire Services

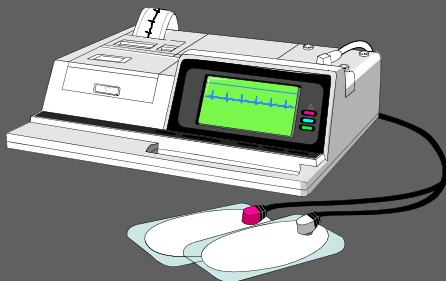


Randomization: Two Protocols

Analyze
EARLY



**30+ sec.
of CPR**

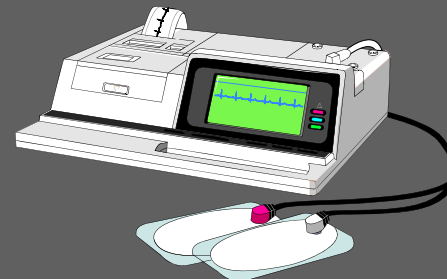


...then analyze
rhythm

Analyze
LATER



**3 minutes
of CPR**



...then analyze
rhythm

Randomization

- Patients will be randomized to either Analyse early or Analyse later
- Randomization will be either by community (city), by service or by defibrillator

Cluster Randomization Plan

| Base Hospital | EMS | Fire |
|----------------------|------------|-------------|
| Cambridge | Service | Service |
| Cornwall | Service | Service |
| Halton | Service | Service |
| Kingston | Community | |
| London | Defib | Service |
| Niagara | Service | Service |
| Ottawa | Defib | Service |
| Peterborough | Community | |
| Sarnia | Community | |
| Sudbury | Community | |
| Thunder Bay | Community | |
| Windsor | Service | Service |





Impedance Threshold Device



Impedance Threshold Device

Patients will only be enrolled in this part of the study by Paramedics but Fire Services will receive training on the ITDs because of their role in Airway Management on VSAs.



Impedance Threshold Device (ITD)

Ventilation Port

Ventilation Timing Lights

Flashes at 10 breaths per minute

Timing Lights On/Off Switch

Turns timing lights on & off

Atmospheric Pressure Sensor System

Provides selective impedance to inspiratory air flow

Safety Check Valve

Enables inspiration @ -16 cmH₂O with spontaneous respiration



Patient Port

Real ITD versus Sham ITD

Either an actual ITD or a “sham” device will be used. Rescuers will not know which one they are using.



Both devices **look** identical
“Sham” is just a hollow tube



Inclusion/Exclusion Criteria

Inclusion Criteria (both groups)

- **Patients 18 years or greater, or local age of consent.**
- **Non-traumatic cardiopulmonary arrest outside of hospital in study communities.**



Exclusion Criteria (both groups)

- Do not attempt resuscitation (DNAR) orders.
- Obvious non-cardiac:
 - Trauma, Burns, Drowning, Electrocution, Strangulation, Exsanguination, Obvious death...
- Known prisoners.
- Known pregnancy.
- Study specific exclusions



EXCLUSION Criteria *continued...*

- ITD cannot be used if:
 - Tracheostomy present
 - Mechanical CPR device being used
- Exclude from analyze early or analyze late, if:
 - EMS-witnessed arrest (shock immediately)
 - Rhythm analyzed by non-EMS provider (e.g., law enforcement, layperson, etc.)
 - If AED placed by non-ROC EMS personnel first.



Sample Size

- This study will enrol approximately 15,000 adult patients who have sustained a nontraumatic out-of-hospital cardiac arrest over 16-18 months.



Start-up Status

- The start of the ROC PRIMED study is dependant on:
 - **REB approvals**
 - **Training**
 - **CPR Process**

REB Status

- The protocol has been submitted to the REB's at 7 of our 12 sites
- We have approval at 3 of those 7 sites

Training

- **Most services have done the initial training on ROC PRIMED**
- **In June the EMS Ops Committee approved an expanded training document which included Psychomotor Skills Assessment (Scenarios)**
- **Sites must retrain their medics using the provided documents and scenarios before being able to start the study**

Training

- 4 sites have completed the new expanded training requirements
- 3 sites have a plan in place and training will be done in the near future
- 3 sites have not gotten back to me with their plans on scenario training

**Training plans are very flexible,
many options are available**

CPR Process

- **CPR process is a requirement for the ROC PRIMED Study**
- **Patients cannot be enrolled in the study if we are not getting your CPR data**

OPALS

ONTARIO PREHOSPITAL ADVANCED LIFE SUPPORT STUDY

