

April 20, 2005

TO: John Szerlag, City Manager

FROM: Charles T. Craft, Chief of Police  
William S. Nelson, Fire Chief

SUBJECT: AGENDA ITEM- William Beaumont Hospital Research Study

Attached is a letter and PowerPoint handout from Dr. Robert Swor of William Beaumont Hospital describing a study to be conducted involving field evaluation of two devices used during CPR. Dr. Swor indicates that several communities will be participating in the study including Birmingham, Royal Oak, and Sterling Heights. Alliance Mobile Health has indicated interest in participating with the EMS units assigned to Troy.

A requirement of this field test is a period of "community consultation" designed to make community leaders aware of the study, provide an opportunity to ask questions, and receive input from the community. Beaumont will be holding several informational meetings in May. I support the field trial and recommend that this be provided to council as an informational item. If you have any questions, please contact me.

Prepared by: William Nelson

March 17, 2005

William Nelson  
Fire Chief  
City of Troy

Re:    Proposed Cardiac Arrest Study  
      ResQ Trial

The Emergency Departments of William Beaumont Hospitals in cooperation with area EMS agencies, are preparing to participate in a National Institute of Health (NIH) sponsored multi center trial. The study's purpose is evaluate the effectiveness of two biomedical devices (ResQPOD and ResQPump), used during the performance of cardiopulmonary resuscitation (CPR) on adult patients experiencing cardiac arrest (loss of pulse). The study is proposed to be initiated in 4 other states, and 5 Oakland and Macomb county communities (Birmingham, Ferndale, Royal Oak, Sterling Heights and Troy). Initial studies indicate the devices improve blood flow during CPR and may improve survival. Researchers at Beaumont will compare survival rates and brain recovery in cardiac arrest patients receiving the current standard of care- conventional CPR, compared to those receiving the ResQPOD with conventional CPR, and those receiving the ResQPOD and ResQPump.

This study meets the Food and Drug Administration (FDA) requirements for an exception from informed consent for emergency research because it is not possible to obtain informed consent from victims of sudden cardiac arrest. Prior to the initiation of this study the FDA requires approval of the Beaumont Human Investigation Committee, and a period of community consultation. Public meetings to receive more information on this study will be held at the following dates and times:

May 16th – Beaumont- Royal Oak, Classroom 1 ABW 7 to 9 pm.

May 31st – Beaumont- Troy, Classrooms 3 and 4 from 7 to 9 pm

The community consultation required by the FDA requires feedback from the affected communities and we would appreciate representation of interested parties from your community at this meeting.

If you would like further information, request a formal presentation, or have further questions or concerns regarding this study, please feel free to contact me.

Sincerely,

  
Robert Swor DO  
Principal Investigator-ResQ trial  
Department of Emergency Medicine  
William Beaumont Hospital  
raswor@beaumont.edu

## ResQ Trial Cardiac Arrest Research Community Consultation Presentation



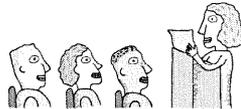
## Introductions

- Beaumont Human Investigator
  - Phillip Bendick PhD
- Robert Swor DO
- Brian O'Neil MD
  - William Beaumont Hospital
- Study Sponsor
  - Advanced Circulatory Systems, Inc.
  - Eden Prairie, MN



## Agenda

- Federal Regulations & Meeting Purpose
- Study Overview
- Videotape Presentation of CPR Methods
- Question, answer & discussion period (open)



## Informed Consent

- Study involves research
- Study purpose & length
- Risks or discomforts
- Benefits to subject or others
- Alternative treatments
- Compensation
- Treatment for injury
- Voluntary without penalty
- Discontinue at any time

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## Exception to Informed Consent for Emergency Research

- Emergency nature of the research
- Exception issued by FDA
  - (21 CFR 50.24)



## FDA Requirements for an Exception from Informed Consent Requirements

- Life threatening situation that requires immediate action from someone
- Obtaining informed consent is not possible or reasonable
- Participation has prospect of direct benefit because other studies have shown a possible benefit
- Risks are reasonable compared to the subject's condition

### FDA Requirements for an Exception from Informed Consent Requirements

- Research could not practicably be done without waiver
- Potential therapeutic window is short
- IRB approves a consent process that provides the opportunity for the subject (or legal representative) to object afterwards.

### FDA Requirements for an Exception from Informed Consent Requirements

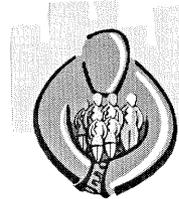
- Community consultation
- Public disclosure about the study
  - Before and after
- Independent Data Monitoring Committee
- Subject notification

### Meeting Purpose

- Meet the requirements for community consultation
- Describe the study that will be conducted
- Opportunity to get feedback and answer questions from interested parties

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### Invited Participants



- Community leaders from Study Communities
- Emergency medical services (EMS) regulatory agency
- Community hospitals & IRBs
- Interested members of the public and community agencies
  - Various ages
  - Various religions
  - Both sexes
  - Various races

### Cardiac Arrest

- Definition: heart suddenly stops beating
- Treatment: immediate CPR

CPR's effectiveness is poor  
Forward blood flow during CPR is less than 25% of normal.



### Extent of the Problem

Each year:

- United States:
  - 225,000 out-of-hospital
  - 1-2/1000 population/year
- 160/year transported to Beaumont Hospitals



### Cardiac Arrest

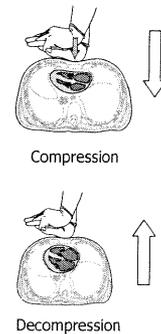
- Treatment of cardiac arrest:
  - Unsatisfactory
- Outcome from cardiac arrest:
  - 5-10% Survive to hospital discharge annually
- Survival rate transported to Beaumont Hospital: 7%



### Why CPR Works...

Blood flow during CPR is due to:

- ❶ Direct compression of the heart between the sternum and spine
- ❷ Pressure differences in the chest that result from chest compression and relaxation

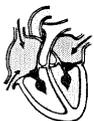


### Study Devices

**Active Compression  
 Decompression CPR (ACD-CPR)**

+

**Impedance Threshold Device  
 (ITD)**

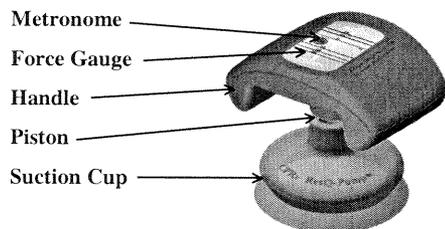


### ResQPump®

- Performs active compression decompression CPR (ACD-CPR)
  - Same as standard CPR (S-CPR):
    - Actively compresses the chest
  - Different from standard CPR (S-CPR):
    - Actively decompresses the chest, which assists in the creation of a vacuum within the chest



### ResQPump Components



### ResQPOD™

#### Impedance Threshold Device (ITD)

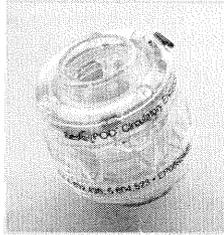
Prevents unnecessary air from rushing into the chest during chest decompression, thus assuring that a vacuum is created and maintained throughout the decompression cycle



### ResQPOD Components

- Timing assist lights
- Diaphragm
- Filter
- Safety check valve

Ventilation Port

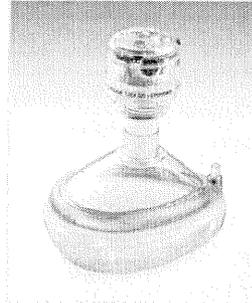


Patient Port

### ITD in Respiratory Circuit

#### Facemask Ventilation

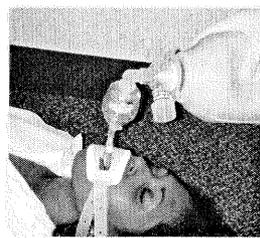
Basic life support  
airway management



### ITD in Respiratory Circuit

#### Ventilation with Endotracheal Tube

Advanced life support  
airway management



### ITD Ventilation

- Same compression to ventilation ratio and volume as S-CPR
- Rescuer can freely ventilate patient.
- Patient can freely exhale.
- Patient can inhale (with difficulty) if they begin to breathe on their own, so ITD must be removed if pulse returns

### Cardiac Arrest Research

- Preliminary information
  - Animal studies
    - Vital organ blood flow improved
    - Blood pressure increased
    - Coronary perfusion pressure significantly increased

### Cardiac Arrest Research

#### Human studies

- ACD-CPR improves survival
- Use of an ITD improves blood pressure and survival among victims who receive ACD-CPR

### Cardiac Arrest Research

#### Human studies

- Use of an ITD with S-CPR improves short-term survival
- Use of an ITD improves blood pressure among victims who receive S-CPR

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### Cardiac Arrest Research

Information to date is encouraging BUT...

Unknown if improved blood flow with ACD-CPR + ITD results in improved outcome for victims of cardiac arrest.

### Purpose of Study

Evaluate outcome in victims of cardiac arrest treated with:

- S-CPR
- S-CPR + ITD
- ACD-CPR + ITD



### Randomization

- Subjects will have:
  - 1/3 chance of receiving S-CPR
  - 1/3 chance of receiving S-CPR + ITD
  - 1/3 chance of receiving ACD-CPR + ITD



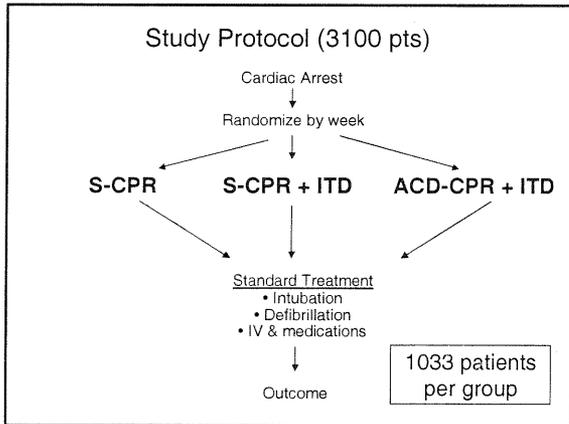
### Study Subject Inclusion

- Adult cardiac arrest patients
  - 18 years old or greater
  - Non-traumatic
  - Out-of-hospital
- Treated by EMS personnel with CPR



### Study Subject Exclusion

- Less than 18 years old
- Trauma as cause of arrest
- Known, pre-existing "do not resuscitate" orders
- Chest surgery in the previous 6 months
- CPR cannot be performed
- Cardiac arrests in the hospital
- Patients whose family members request discontinuation of experimental CPR method



### Study Procedures

- Results of resuscitation efforts and short and long-term outcomes will be compared
- Experimental:
  - Unknown if adding an ITD to S-CPR or ACD-CPR improves outcome
- Patients will remain anonymous

### Potential Risks Associated with Experimental CPR Methods (in general)

- Increased number of patients resuscitated who are neurologically impaired
- Unknown or unanticipated discomfort or risks

### Potential Risks Associated with an ITD

- Mechanical failure of the device
- Excessive fluid buildup in lungs
- If the resuscitation is successful, the device must be removed; if this doesn't happen:
  - Increased work of breathing
  - Fluid buildup in the lungs

### Potential Risks Associated with ACD-CPR

- Mechanical failure of the device
- Chest fractures
- Chest/abdominal organ damage
- Excessive fluid buildup in lungs
- Suction difficulties
- Superficial skin bruising

### Potential Study Benefits

- Improved outcome
- Improved effectiveness of CPR
- Helpful to others
- Useful scientifically
- Benefits not guaranteed



### Potential Study Risks

- Device failure
- Lack of benefit of the device
- Surviving cardiac arrest with brain damage
- Unknown or unanticipated discomfort or risks

### Safety Monitoring

- Data and Safety Monitoring Board:  
Monitor differences in
  - Adverse events
  - Survival rates
  - Neurologic outcome



### Study Protocol

- Financial benefits: none
- Alternative procedures: none
- Confidentiality
  - Information will remain confidential
  - Access to medical records
    - Food and Drug Administration (FDA)
    - Company sponsor
    - Research team

### Study Endpoints

- Return of pulse
- Survival to one hour
- Survival to hospital admission
- Survival to 24 hours
- Survival to hospital discharge
- Survival to 30, 90 & 365 days
- Neurologic recovery at hospital discharge, 30 days, 90 days & 1 year
- Quality of life at 1 year
- Complication rates

### Study Duration & Timeline

- Total Number: 3100 patients
  - 1033 each group
- 3 years
- Start date: [date]



### Study Approval

- Study will not proceed without final approval from:
- Local IRBs
  - FDA

## Community Consultation

- Feedback/Concerns
- Comments
- Discussion



For further questions, comments or  
information please contact:

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FAX: 248-898-2017  
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