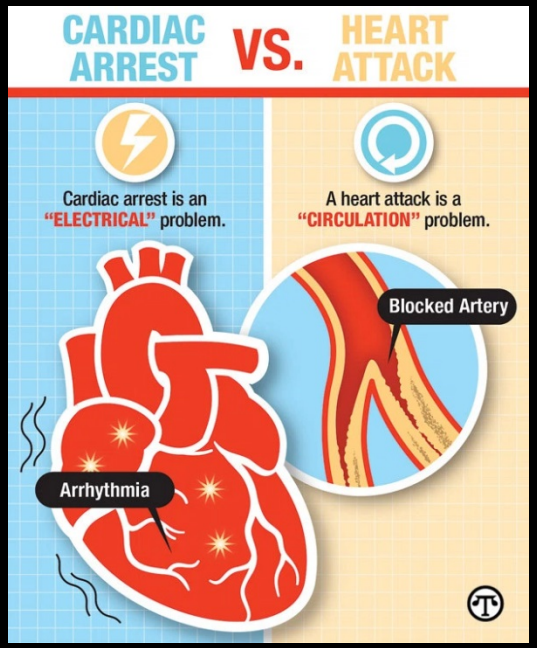
PRAGMATIC AIRWAY RESUSCITATION TRIAL

Milwaukee Community Consultation and Public Notification

10-1-15

Out-of-hospital Cardiac Arrest

- Out-of-hospital cardiac arrest (OHCA) is a major public health problem
  - 300,000 cases/year in US
  - 10% survival



Treatment for cardiac arrest

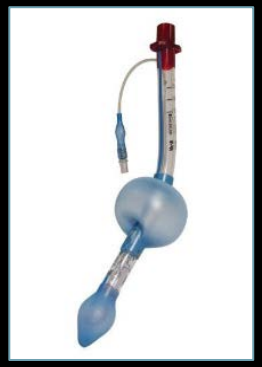
- CPR (Cardiopulmonary Resuscitation)
  1. Chest Compressions
  2. Open airway to give oxygen
     - » Laypersons use “head-tilt/chin lift”
     - » EMS providers use an “Advanced airway”

Types of advanced airways

- “Endotracheal Intubation”
  - Steps:
    1. EMS use a laryngoscope to view vocal cords
    2. Once vocal cords are seen, EMS inserts a plastic breathing tube between the vocal cords
  - Preferred method because it provides a direct path to lungs
  - However- this method is difficult, requires more training, and there may be a higher-than-desired failure rate

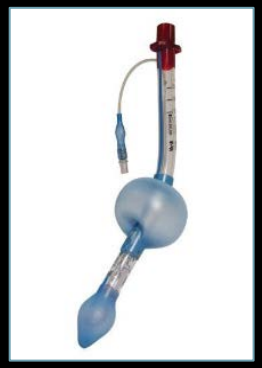
Types of advanced airways

- “Laryngeal mask airway”
  - Steps:
    1. EMS inserts this tube without having to use a laryngoscope to view vocal cords
    2. This tube is inserted into the esophagus and allows air to only go into the lungs
  - This method is less difficult and does not require as much training



Which Airway Method is better?

- Both methods are approved by the US Food and Drug Administration (FDA) and are commonly used by EMS providers
- There have been no studies which have shown whether one airway is better than the other when used by EMS providers outside the hospital



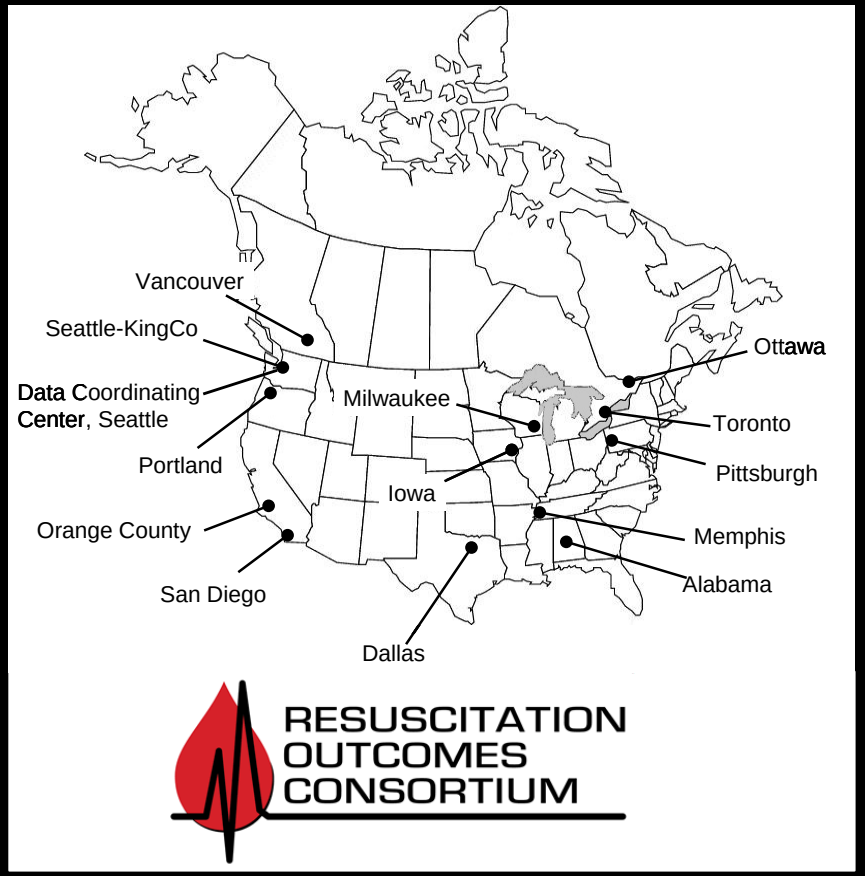
PART study

- Purpose: To compare the endotracheal tube to the laryngeal tube to see which is better for patient survival

- Milwaukee County EMS is participating in this national study
  - Currently use both types of airway methods
  - Each agency will use one airway for a period of time and then switch to using the other tube

Who is conducting this study?

- Resuscitation Outcomes Consortium
- Approximately 30 EMS agencies from:
  - Birmingham
  - Dallas
  - Milwaukee
  - Pittsburgh
  - Portland



ROC

How are patients selected for this study?

- Milwaukee County EMS providers will look at whether any cardiac arrest patient they treat is eligible for the study
  - No known prisoners, pregnant women, or children (< 18 yrs)
  - No cardiac arrests due to inability to breathe (choking)
  - No patients with DNR orders
  - No patients wearing an “Opt-out” bracelet/necklace

What about other treatments and care?

- People enrolled in this study will continue to receive all other treatments and care they would have received anyway, including:
  - Chest compressions
  - Defibrillation (shocks to stop irregular heart beats) if needed
  - Medication
- If EMS providers are not successful with one airway method, they will use a different method as backup

Are there any risks?

- Using both the endotracheal tube and the laryngeal tube have risks, including:
  - unsuccessful airway insertion, multiple airway attempts, airway tube misplacement (tube is inserted incorrectly), inadequate ventilation (tube does not allow enough air passing into the lungs), vomiting after airway insertion, injury to the throat/mouth area, and a collapsed lung.

- These risks have been thoroughly examined and found to be small and reasonable given the possible benefits to patients including saving their life and decreasing their disabilities.

What is the informed consent process for this study?

- The consent process is when we ask a person's permission and invite them to be in a study, explaining the risks and benefits, as well as answering any questions
- For this study, we will be unable to consent because they are unconscious and need emergency treatment
- This Emergency Research study is approved by the US Food and Drug Administration and Department of Human Health Services to enroll patients without consent because:
  - It is not known which airway method is better
  - Survival from cardiac arrest is very low and we need to research better treatments
  - It is impossible to obtain consent from the patient because they are unconscious

What is the informed consent process for this study?

- If possible, a script will be read by EMS providers to the patient's family/legal representative to offer an opportunity to decline participation

- Enrolled patients or their family/legal representative will be informed of study as soon as possible and will be allowed to withdraw from continued participation in the study

How to “Opt-out” of the study

- Give your name and address to the research staff
  - Email: rrc@mcw.edu
  - Phone: 414-805-6493
  - Website: www.mcw.edu/rrc
- We will mail a necklace/bracelet to the address provided

How is this study approved?

- This study has been approved under the FDA's "Exception from Informed Consent" Guidelines for emergency research because it meets all requirements.

  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=50.24

- In order to obtain approval from the Medical College of Wisconsin's ethics committee (IRB – Institutional Review Board), the researchers must consult with and notify the Milwaukee community about this study

Information you should know

- Patients and/or their family members/legal representatives can withdraw from continued participation in the study
- Patients who have been enrolled will still receive all other standard treatment
- There is no extra cost for being in the study; the patient will not receive compensation for being in the study
- All data reviewed for the purposes of this study will be de-identified - personal identification such as name, medical record number will be removed

Information you should know

- Every effort will be made to ensure patient privacy. All data reviewed for the purposes of this study will be de-identified - personal identification such as name, medical record number will be removed
- The FDA may inspect study records at any time
- Members of the community may “opt-out” if they do not wish to be in the study. Opt-out bracelets are available for those who DO NOT want to be considered for this study. If the patient has the opt-out bracelet on, they will not be screened or enrolled in this study

Questions?

- For questions pertaining to this study or if you would like to “opt out” of the study:

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- For questions pertaining to informed consent:
MCW Human Research Protection Program

414-456-8844

THANK YOU