

Protected health information will be managed as per the guidelines as established by Sentara hospitals and the Health Insurance Portability Act (HIPPA). A review of the enrolled subjects hospital chart will be performed to determine patient outcome, hospital interventions and timing, as well as diagnostic results. At no time during the research, storage of data or reporting of study results, will subject identifiers be used.

Citizens of the City of Norfolk who would like to decline to participate can notify the investigators via phone or e-mail:

(757) 388-3397

or

Dr. Barry Knapp
knappbj@evms.edu

Dr. Donald Byars
don.byars@gmail.com

Those declining to participate will be provided a medical bracelet to indicate to emergency medical providers that they would not like to be enrolled in the study. They will also be included in a master exclusion list included in study enrollment packets.

This study is supported by a grant from the Sonosite corporation.

Summary of Enrollment Criteria

Ambulance Patients identified by EMS with:

1. Cardiac Arrest and/or
2. Major Trauma

Timeframe: Data collection would continue for one year after IRB approval and study initiation.

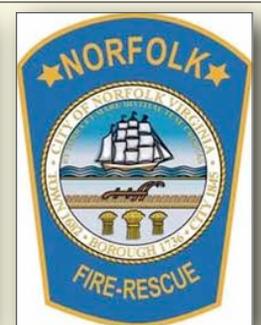
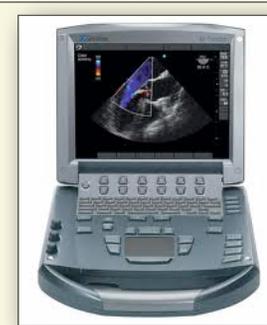
Anticipated Number of Subjects: 250

Benefits to Subjects: There are very real potential benefits to the subject, specifically the possibility of early identification for the need for operative intervention by the trauma team (e.g. internal bleeding) or elucidation of the cause of cardiac arrest (e.g. fluid around the heart) prior to arrival to the receiving facility thus potentially significantly facilitating definitive care.

Risks to Subjects: Bedside US is routine and common practice in both cardiac arrest patients and in critically injured trauma patients. Bedside US is painless and non-invasive, as such there are no anticipated physiologic risks. All data will be completely de-identified upon entry into the database.

EMS-FOCUS

A Prehospital Ultrasound Research Study



EVMS

Eastern Virginia Medical School

Investigators:

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The purpose of this study is to determine if the use of ultrasound technology in critically ill or injured people will improve the quality of care in the prehospital setting.

Ultrasound imaging enhances the acute care provider's ability to evaluate, diagnose, and treat patients requiring emergency care. Currently, such bedside ultrasound imaging is generally confined to the scope of practice of emergency physicians in hospitals or Emergency Departments.

Paramedics are severely hampered in their ability to determine severity of injury in the prehospital setting. The use of ultrasound would enhance that ability. A focused abdominal sonograph for trauma (FAST) examination would provide the paramedic with a powerful tool for more accurate patient assessment.

Along the same lines, when a person goes into "cardiac arrest", their heart stops beating normally. It is often very difficult, even with a trained provider, to determine if a pulse is present. The ability to "look" at the heart with an ultrasound machine to determine what the heart is doing greatly aids in medical decision making in the hospital. We would like to determine if this is the case on an ambulance as well.

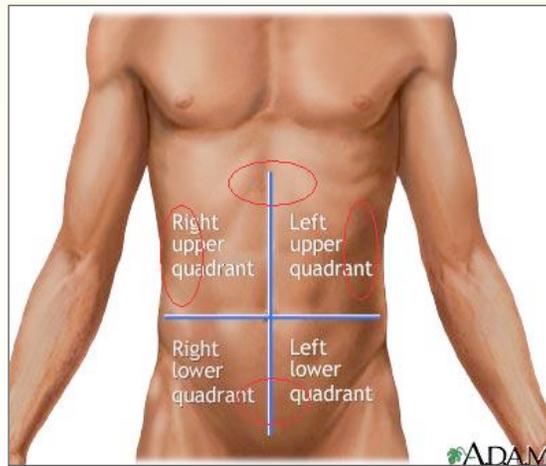
Eighty-nine EMS providers within the City of Norfolk have been trained by the investigators to perform and interpret ultrasound. Assessment of their accuracy using ultrasound is a major focus of this study.

Cardiac arrest and major trauma patients will be the focus of our research interest. Sonosite's newest ultrasound machines will be placed on twelve ambulances of Norfolk Fire Rescue in Norfolk, Virginia. Standard advanced life support (ALS) and advanced traumatic life support (ATLS) will be considered the standard of care and will not change once the study begins. The use of ultrasound in the prehospital setting will also not delay standard rapid transport practices.

Those subjects in the cardiac arrest will have an ultrasound probe placed on their chest or upper abdomen to determine if their heart is beating or surrounded with fluid.

Those subjects who have suffered significant trauma, will have an ultrasound probe placed on four areas of the abdomen to look for significant bleeding.

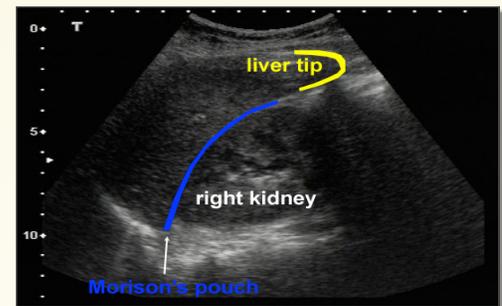
Below is an example of the areas (red ovals) that will be "looked" at with ultrasound.



An example below of an ultrasound being performed on a subject's abdomen:



An ultrasound image below of a normal liver and kidney:



Ultrasound machines simply use sound waves to "look" into a person's body. There is no radiation exposure and no known long-term risks associated with ultrasound use. As ultrasound is a widely accepted, noninvasive medical modality, this research involves minimal risk to participating subjects.

Subjects enrolled in our study are suffering from a critical medical or traumatic condition and could not practically be asked consent to be in the study. The researchers have been granted a "waiver of consent" to use protected health information.

This "waiver of consent" allows the researchers to perform the ultrasound and search their medical records without written permission. This will not affect the rights and welfare of subjects. Commonly accepted prehospital medical and trauma resuscitation practices will not change.