NOTICE OF EMERGENCY RESEARCH STUDY

Press Release
June 25, 2013

The Hennepin County Medical Center (HCMC) Department of Emergency Medicine will be conducting a medical research study starting in Summer 2013. The purpose of this press release is to educate and notify the public of the study. This study is different than most other research studies because it involves a process called Exception from Informed Consent.

Background
The process of placing a tube into a patient’s airway to help them breathe is called endotracheal intubation. Intubation is done to a patient because something has made it hard for them to breathe on their own, and it has to be done to make sure they keep breathing.

This type of procedure is performed in the Emergency Department at HCMC about 30 times each week. The process of endotracheal intubation is fast and usually only takes a few minutes.

Before a physician intubates a patient, medication is given to sedate the patient (make them sleepy) so that they are more comfortable. The two medications which are used most for this purpose are ketamine and etomidate. Both medications work very well and are used every day across the country. Research has shown no difference or additional risk with either medication. Allergic reactions to either medication are possible; however, these are rare for both ketamine and etomidate, and would be managed appropriately by the patient’s doctor. While it’s known that both medications work very well, it’s now known if one of these medications is better than the other.

This study will start in the summer of 2013 and will be done in the Emergency Department at HCMC. The Human Subjects Research Committee, the Institutional Review Board (IRB) at HCMC, has approved the Community Consultation Plan for this study. The full title of this study is Ketamine vs. Etomidate for Sedation of Emergency Department Patients during Rapid Sequence Intubation.

Purpose
This study will randomly assign (like flipping a coin) patients who are going to be intubated to receive either ketamine or etomidate. This will help researchers understand if one of these medications is better for sedating a patient before placing a tube in their airway to help them breathe.

Identifying Eligible Patients
When an adult (a patient 18 years of age or older) who requires endotracheal intubation is brought to the HCMC Emergency Department, standard medical care will be given. In addition, the Emergency Department physician will check the patient to see if he or she is eligible for this
research study. People who have are known to have had a bad reaction to either medication will be excluded.

STUDY PROCEDURES
If the physician decides that the patient is eligible for this research study, the patient will receive either ketamine or etomidate. Half of the patients in the study will receive ketamine and half will receive etomidate for sedation. All other medical care will be given at the discretion of the treating physician.

The research team will collect information about the patient’s vital signs, how long it took to complete the intubation, and whether there were any problems during the intubation. The patient’s chart will be checked after they leave the hospital to see which medications they were given, how long they were in the Intensive Care Unit (ICU), and other details about the hospital stay.

EXCEPTION FROM INFORMED CONSENT
Under normal circumstances, medical researchers are required to explain a research study and to obtain consent from a patient before starting a study. In some emergency situations, this cannot be done.

When a patient cannot breathe on their own, endotracheal intubation must be performed quickly, and the patient will be very confused and cannot make decisions about their medical care. There’s just not enough time to talk to the patient’s family member about the study before it can be done. For this reason, a patient who needs to be intubated will be enrolled in this study without obtaining written consent. Due to the emergent situations that prompt the need for intubation, informed consent cannot be obtained for most patients. If the physician determines the patient is eligible to be in this study, then the patient will be enrolled.

Once the patient is medically stable, a member of the research team will speak to the patient or one of their family members to inform them of the research study. They will be given written information about the study and an opportunity to ask questions. At this time, they will also be asked if they will consent to continue to participate or have their family member continue to participate in the study.

This situation is called Exception from Informed Consent. This study meets the guidelines for Exception from Informed Consent as outlined by the federal government and the IRB.

OPTING OUT OF THE STUDY
If you do not want to be enrolled in this research study, should you be brought into the HCMC Emergency Department, you must contact Dr. Brian Driver at Brian.Driver@hcmed.org or Dr. Johanna Moore at Johanna.Moore@hcmed.org or (612) 873-9366. A bracelet with the words “KvE declined” will be mailed to you to wear in order to inform Emergency Department personnel that you do not want to be enrolled in this study if intubation is required.

Details of the study can be obtained online at www.clinicaltrials.gov or by contacting one of the study physicians.