

Hillsborough County to Implement AutoPulse[®] Device on Ambulances

By: Carmel Delshad

TAMPA—Hillsborough County residents needing CPR might find a few changes in technique come late October.

Hillsborough County Fire Rescue is participating in a research trial that will test out automatic chest compressions on patients suffering from cardiac arrest.

The AutoPulse[®] machine simulates manual chest compressions and is FDA approved as a safe alternative to CPR.

Starting in October 2008, Hillsborough Fire Rescue will have about 11 out of 25 ambulances equipped with the device, according to Lt. Paul Costello, EMT paramedic and site coordinator for the trial.

"The FDA has cleared the AutoPulse[®] device as safe and effective for sale and use in the United States. This means that it is considered to be as safe and effective as manual chest compressions. What is not known is whether using the device would increase the survival rate," said Dr. Michael Lozano, medical director at Hillsborough Fire Rescue.

Patient anonymity will be ensured during the course of the trial, according to Hillsborough Fire Rescue. Pregnant women, children 17 and younger, prisoners, wards of the state, citizens with Do Not Resuscitate (DNR) orders, and those who succumbed to cardiac arrest because of exsanguinations, strangulation, smoke inhalation, drug overdose, electrocution, hanging and drowning are excluded from the study.

The study will test out the effectiveness in resuscitating patients who are in cardiac arrest, both manually and with the AutoPulse[®]. Patients will receive treatment provided they are of legal age and will fit the dimensions of the device.

The trial will be single-blinded, and participants will be chosen randomly following a pre-determined schedule. Half of the patients will receive manual compressions alone, while the other half will receive both manual and automatic chest compressions.

According to the CIRC trial website, patients cannot give consent for the use of the AutoPulse[®] due to the nature of cardiac arrests. A waiver of informed consent requirement is thus utilized, as framed by the FDA provisions for the trial.

"There have not been any reported malfunctions that have caused any substantial injuries with the product. We've had some malfunctions related to batteries, in which case the crews are trained to overcome that," said Lt. Costello.

Once brought to the hospital, a legal representative will be contacted to inform them that the patient has just been enrolled in the randomized trial. According to ZOLL, all personnel involved in the data collection from the experiment are required to sign confidentiality contracts.

Sites for the study include two other U.S. locations in Texas and Wisconsin, and overseas investigations in Austria and the Netherlands. Sites were chosen according to population size, variety of EMS services offered, history of patient care, and ability to comply with CIRC trial requirements. All studies have been approved by the Institutional Review Board.

One of the major benefits of the tool is its ability to offer chest compressions at a stable frequency over the girth of the entire chest—something that manual chest compressions cannot do. Transporting a patient from his or her home into an ambulance and subsequently into a hospital can occur without change and interruption in resuscitation techniques. User fatigue is no longer a factor, since the apparatus is battery-operated and has four computerized batteries that communicate with one-another should one battery fail.

“One of the problems [with chest compressions] is that pushing on the chest can be very tiring over time, and providers are not able to do it as well. This reduces the amount of blood that is moved through the body and reduces the likelihood that the person will survive. When chest compressions are done with an automated device, fatigue is not a factor. Therefore, it seems that the device will provide better blood supply to the body compared to manual chest compressions,” said Dr. Lozano.

Vacationer Marlene Wright, 60, says she sees nothing wrong with the device so long as it is effective.

“As long as the FDA approved it, I don’t see why it wouldn’t be a good idea to use in ambulances. I mean, in that situation, anything helps. I certainly wouldn’t mind having this used on me or a member of my family if I knew it worked and didn’t have any glitches,” Wright said.

According to the American Heart Association (AHA), roughly 310,000 people die of coronary heart disease before reaching the hospital. To put that into perspective, about 810 people are dying daily because of sudden cardiac arrest. The AHA states that with each minute that goes by without CPR or resuscitation, a person’s chance of survival decreases by 7 to 10 percent. ZOLL seeks to find out whether manual chest compressions teamed with the AutoPulse[®] will increase the survival rate of those suffering sudden cardiac arrest. CPR is still the most widely used method of resuscitating patients, but the ZOLL tool is expected to gain in popularity as trials prove its effectiveness.

The AutoPulse[®] device is about the size of a boogie board and weighs 22 pounds. Its intended use is for adults 18 and older who weigh no more than 300 pounds, but exceptions arise for those who might weigh more but can still fit under the band of the machine. As long as the inflatable band fits across the chest of the patient, the AutoPulse[®] can automatically adjust to the size of the person and begin compressions.

Each unit of the AutoPulse[®] costs approximately \$14,500. Under the agreement with ZOLL, Hillsborough County receives the equipment free of charge with every 10 patients enrolled in the program.

Senior biomedical studies student Yousif Salhab, 22, said that based on his family history of heart problems, he would not be against the machine being used on him or other family members.

“It’s considered a Class IIb device based on a recommendation from the American Heart Association Guidelines for Cardiopulmonary Resuscitation; this means it’s both acceptable and useful in everyday situations. The evidence provides support that it does work. Of course, complications can arise from any battery operated machinery. However, that’s no reason to doubt its reliability. Actually I would recommend it to my family given the history of heart problems,” said Salhab.

The AutoPulse[®] was subject of scientific scrutiny in 2005 after an article printed in the *Journal of the American Medical Association* cited that 10 participants of the trial in a specific city were perhaps not resuscitated because of their participation (by waiver of consent) in the CIRC trial, as noted in a June 2006 USA Today article by Robert Davis.

However, in a November 2005 ZOLL press release, Richard A. Packer, ZOLL's President and Chief

Executive Officer, stated, “We maintain our belief that automated chest-compression devices, such as the AutoPulse, possess great potential for improving CPR performance not only in the field, but also in hospitals. The favorable conclusions of two of the new studies presented at AHA, and five previous studies, add to a strong body of evidence favoring the AutoPulse®.”

With the study currently underway in Hillsborough County, residents can expect to hear non-profit advertisements and public service announcements in the near future, according to Lt. Costello.

For more information regarding the trial, call Hillsborough Fire Rescue at 813-272-6600 or visit <http://www.circtrial.com/>.