CARDIAC ARREST RESEARCH STUDIES

Frequently Asked Questions

Why are these studies being conducted in Milwaukee County?

For the past 20-30 years, Milwaukee County Emergency Medical Services (EMS) System in collaboration with the Medical College of Wisconsin has been dedicated to improving survival from cardiac arrest in our community through research. The citizens of Milwaukee County have directly benefited with new, innovative, and more effective treatments originated here in Milwaukee County from this research including Public Access Defibrillation (availability of automated external defibrillators in airports, airplanes, and public locations), high performance CPR (avoiding hyperventilation and incomplete chest recoil during CPR), electronic CPR feedback (providing high quality resuscitation practice), and the impedance threshold device (doubling the effectiveness of CPR). As a result, Milwaukee County has one of the highest survival rates from cardiac arrest in the country (12.5% survival rate for Milwaukee County versus 7.9% survival rate nationwide).

What are some of the misconceptions about cardiac arrest?

Myth: The survival rate from cardiac arrest is high.
Reality: The survival rate from cardiac arrest is dismal. The national average survival rate from cardiac arrest is 7.9%. This means that more than 9 out of 10 persons die from cardiac arrest with our current treatments.

Myth: The current treatments for cardiac arrest are well-established because of their proven effectiveness.
Reality: The standard treatments for cardiac arrest are, for the most part, untested. Because of this, survival rates are dismal. Further, it is unknown whether some standard treatments currently used are beneficial or harmful. Research needs to be conducted to evaluate promising interventions that hold significant potential to improve cardiac arrest survival rates in Milwaukee County and the nation.

Myth: A heart attack and cardiac arrest are the same thing.
Reality: A heart attack and cardiac arrest are completely different. A heart attack occurs when a blood clot blocks blood flow in an artery to the heart, causing a portion of the heart muscle to die. The heart continues to pump blood and survival is excellent if it can be treated within six hours. A cardiac arrest occurs when the heart suddenly and unexpectedly goes into a heart rhythm that does not pump blood, immediately causing no blood flow to the entire body, resulting in instant collapse and loss of consciousness. The survival rate is dismal. Treatment (calling 911, performing bystander CPR, defibrillation (shocking the heart), and delivery of advanced life support) must begin immediately if there is any hope for survival.

Myth: Cardiac arrest is not very common.
Reality: It is estimated there are approximately 450,000 cardiac arrests each year in the United States. To get an understanding of this number, it is similar to 2 full 747 airplanes crashing and killing everyone on board each day in the United States! It is the 3rd leading cause of death in this country.

Why are these studies on cardiac arrest being conducted?

It is unsatisfactory that approximately nine out of ten cardiac arrest victims will die before discharge from the hospital. Some current cardiac arrest treatments are suspected to be harmful (rather than beneficial) and alternative and promising new interventions have been developed that hold potential to improve survival above and beyond our current therapies. Research needs to be conducted to improve cardiac arrest survival rates.

Is Milwaukee County the only location this research is being performed?

No. Milwaukee County and the Medical College of Wisconsin are participating in national research studies funded by the National Institutes of Health to improve the survival of cardiac arrest victims. Because of its commitment to and success in improving survival from cardiac arrest, Milwaukee County was one of 11 sites in the United States and Canada chosen by the National Institutes of Health to participate in these studies. Milwaukee County's Emergency Medical Services system has been dedicated to improving survival of citizens who have cardiac arrest through partnership with the Medical College of Wisconsin. As a result, Milwaukee County has one of the highest survival rates in the nation. The cardiac arrest survival rate in Milwaukee County is 12.5%. Nationwide, the survival rate for cardiac arrest is 7.9%.

What do you hope to gain by conducting these studies?

By participating in cardiac arrest research, Milwaukee County Emergency Medical Service (EMS) providers have developed high-performance resuscitation protocols that improve survival in general practice outside of research. Further, by participating in cardiac arrest research, we also hope to identify current treatments that may be harmful or helpful as well as identify promising new interventions that are more effective than our current therapy. Rapid adoption of these proven findings in clinical practice will continue to improve survival rates from cardiac arrest for the citizens of Milwaukee County.

Do these studies do any good? Have previous studies on cardiac arrest improved the survival rates?

Absolutely! Milwaukee County participated in the Public Access Defibrillation Trial (automated external defibrillators [AEDs] placed in public locations that a layperson can use to shock the heart) demonstrating a doubling of survival rate from cardiac arrest. These devices are now located at airports, on airplanes, in community centers, fitness centers, workplaces, and other public locations throughout our community and throughout the country saving countless lives each year.

Through cardiac arrest research performed in Milwaukee County, it was discovered that the common practices of hyperventilating during CPR and leaning on the chest during CPR were harmful. Based on this new information, the American Heart Association changed their guidelines to avoid this universally common practice. Survival rates from cardiac arrest were significantly increased following implementation of those guidelines – not only in Milwaukee County but throughout the United States and the world.

Discovery of the importance of CPR quality on outcome from cardiac arrest in Milwaukee quickly led to development of biomedical devices that can electronically monitor CPR.

Milwaukee County EMS immediately adopted this technology, leading to the ability to provide high-performance CPR at every resuscitation and improve survival.

A new biomedical device, the impedance threshold device, was evaluated for the first time in a research study in Milwaukee County, demonstrating a doubling of blood pressure during CPR (and a doubling of the effectiveness of CPR) with its use. Survival rates from cardiac arrest were significantly improved as a result.

The overall improvement in resuscitation practice, immediate adoption of best clinical care, and implementation of new discoveries demonstrating better outcomes compared to current treatments has resulted in direct benefit to the citizens of Milwaukee County, who enjoy one of the highest survival rates from cardiac arrest in the country. By defining best resuscitation practice, Milwaukee County has shaped American Heart Association guidelines and improved survival not only in Milwaukee County but throughout the nation and the world.

Who is responsible for this research?

The two cardiac arrest research studies underway are funded by the National Institutes of Health and are regulated by the U.S. Food and Drug Administration. In Milwaukee, the principal investigator for the study is Tom P. Aufderheide, MD, MS, Professor of Emergency Medicine at the Medical College of Wisconsin. Milwaukee County Emergency Medical Services (EMS) System is a co-sponsor of the cardiac arrest research studies in Milwaukee County, directed by Riccardo Colella, DO, MPH.

Why are you informing the public about these studies?

The two cardiac arrest research studies are being conducted throughout Milwaukee County and may be employed when Milwaukee County Emergency Medical Services personnel are required to perform cardiac resuscitation on cardiac arrest victims. Because these victims are unconscious, they are unable to provide their consent to participate in a research study.

The U.S. Food and Drug Administration allows such research to occur under a process called Exception from Informed Consent under Emergency Circumstances. This means that cardiac arrest victims may be included in the research studies without their consent.

The federal government approves Exception from Informed Consent under Emergency Circumstances studies only if the current treatments are unsatisfactory, intervention must begin immediately if there is any hope for survival, and science demonstrates the potential for direct benefit to patients above and beyond current treatments. .

Citizens of Milwaukee County may choose in advance to opt out of these research studies. Individuals wishing to opt out of the studies are provided a bracelet or necklace noting their decision to not be included in research studies in the event of a sudden cardiac arrest.

How are you informing the public about these studies?

Before the two cardiac arrest research studies began, public notification was provided through communications in the newspaper, radio, television, and community newsletters.

Ongoing communication for the studies is being provided through media coverage, and outreach efforts to Milwaukee County Supervisors, mayors and health departments in each Milwaukee County city and village, major employers in Milwaukee County, and all churches and synagogues in the county.

What is Exception from Informed Consent under Emergency Circumstances, and how does it impact me and my family?

Because cardiac arrest victims are unconscious, they are unable to provide consent to participate in a research study. The U.S. Food and Drug Administration has authorized a process called Exception from Informed Consent under Emergency Circumstances to allow such research to occur. Such studies can only occur if the current treatments are unsatisfactory, intervention must begin immediately, and science demonstrates the potential for direct benefit to patients above and beyond current treatments. In this process, researchers first consult with the citizens of Milwaukee County to determine if there is willingness and consensus to implement the studies (which has been established for these research trials) and then notify the community through various media that the studies are beginning (also accomplished and ongoing). These studies are very tightly regulated and monitored by the Institutions Research Committee at the Medical College of Wisconsin locally, and the National Institutes of Health, an independent Data and Safety Monitoring Board, and the Food and Drug Administration nationally to assure patient safety.

This means that cardiac arrest victims may be included in the research studies without their consent. Citizens of Milwaukee County may choose in advance to opt out of these research studies. Individuals wishing to opt out of the studies are provided a bracelet or necklace noting their decision to not be included in research studies in the event of a sudden cardiac arrest.

Instead of involving the entire county, can't you just conduct the research on those people who wear bracelets indicating that they consent to participate in these clinical trials?

The research must be performed in compliance with federal regulations. The U.S. Food and Drug Administration regulations for Exception from Informed Consent under Emergency Circumstances do not provide for that option.

If I or one of my family members has a cardiac arrest, I want to be sure that we are getting the best treatment available. Is the quality of care impacted by participation in a research study?

All patients treated by the Milwaukee County Emergency Medical Services (EMS) System, whether entered in a study or not, will receive the best quality of care available. Further, the federal government approves Exception from Informed Consent under Emergency Circumstances only for those studies in which science demonstrates additional potential direct benefit to patients above and beyond current treatments.

What if I don't want to participate in these studies if I have a cardiac arrest?

For more information about these studies or to request an opt-out bracelet or necklace, please contact the following:

Call: 414-805-6493
E-mail: RRC@mcw.edu

I don't want to wear a bracelet or necklace all the time on the off-chance that I'll have cardiac arrest. Can't you just list my name on a computer database of people who do not want to participate in this clinical research study?

No. This option is not possible. In a cardiac arrest, treatment must begin immediately if there is any hope for survival. Time is precious. A delay by seconds or minutes could make the difference between life and death. The first and highest priority is patient treatment. The time required to check an online database could delay lifesaving care.

Can I just carry a card in my wallet indicating that I don't want to participate in a clinical trial?

No. This option is not possible. Milwaukee County Emergency Medical Services personnel never check a person's wallet for identification or other information.

What are you studying in the two cardiac arrest research studies?

Two different cardiac arrest studies are underway in Milwaukee County.

The **first study**, commonly called the **ALPS Trial**, stands for Amiodarone, Lidocaine or Neither for Out-Of-Hospital Cardiac Arrest Dues to Ventricular Fibrillation or Tachycardia. The purpose of the study is to determine if survival to hospital discharge is improved with early therapeutic administration of one of two medications, administered with defibrillation.

Patients in the study are randomized to three different groups:

- Amiodarone (administration of Amiodarone with defibrillation)
- Lidocaine (administration of Lidocaine with defibrillation)
- Placebo (administration of sugar water with defibrillation [no medication])

It is important to note that the standard treatments for cardiac arrest are, for the most part, untested. It is unknown if either Amiodarone or Lidocaine provides better outcomes than no medication. Despite being frequently used in cardiac arrest, Amiodarone and Lidocaine have never been shown to improve survival from cardiac arrest. Further, they are associated with potentially life-threatening side effects including very low blood pressure, conversion to a worse heart rhythm, or return of a pulse that is too slow to sustain life and cannot be sped up. For these reasons, there are concerns that either of the medications may cause more harm than good. Research is needed to identify which procedures will result in the best outcomes.

Patients entered in the ALPS Trial continue to receive all other treatments for cardiac arrest including high-performance CPR, defibrillation, and other intravenous medications such as epinephrine.

The **second study**, commonly called the **CCC Trial**, stands for Continuous Chest Compressions or Continuous Compressions versus Standard CPR in Patients with Out-Of-Hospital Cardiac Arrest. The purpose of the study is to determine the effectiveness of two different chest compression approaches for cardiopulmonary resuscitation (CPR), and if one approach is more effective.

Patients in the study are randomized to one of two different groups:

- Continuous chest compressions with intermittent breaths for the first six minutes

- Interrupted chest compressions in which 30 compressions are administered followed by two breaths

Both approaches are accepted treatments for cardiac arrest. It is unknown whether one chest compression approach provides better outcomes. Research is needed to identify which procedure will result in the best outcomes.

Is it possible that both cardiac arrest studies may be performed on the same person with a cardiac arrest?

If a cardiac arrest patient requires CPR and has a cardiac arrest rhythm that does not respond to a shock, it is possible they might be entered into both studies. These studies are integrated into the EMS providers' standard operating procedures and will not affect the quality of care they provide.

I've heard that some clinical trials provide participants with "placeboes" and some study participants are placed in "control groups" where they don't receive any treatment. Will that happen with these studies on cardiac arrest?

Cardiac arrest victims involved in the research studies will receive the best quality of care available.

It is important to note that the standard treatments for cardiac arrest are, for the most part, untested. For the ALPS Trial, it is unknown if either Amiodarone or Lidocaine provides better outcomes than no medication. Despite being frequently used in cardiac arrest, Amiodarone and Lidocaine have never been shown to improve survival from cardiac arrest. Further, they are associated with potentially life-threatening side effects including very low blood pressure, conversion to a worse heart rhythm, or return of a pulse that is too slow to sustain life and cannot be sped up. For these reasons, there are concerns that either of the medications may cause more harm than good. Research is needed to identify which procedures will result in the best outcomes.

Patients entered in the ALPS Trial continue to receive all other treatments for cardiac arrest including high-performance CPR, defibrillation, and other intravenous medications such as epinephrine.

There is no placebo in the CCC study. The two chest compression procedures being evaluated are both considered to be acceptable standards of care. The purpose of the study is to determine if one procedure provides the best outcomes.

How will you inform the people of Milwaukee County about any results from these studies?

The U.S. Food and Drug Administration requires that the results of research studies utilizing Exception from Informed Consent under Emergency Circumstances must be shared with the community.

Upon completion of these studies, the results will be shared with residents of Milwaukee County through communications in the media such as newspaper, television, radio, and community newsletters.

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