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Recognizing and Responding to Medical Emergencies in Clinical Research

North Carolina Translational and
Clinical Sciences (NC TraCS) Institute

Janette Goins, RN - NC TraCS

Marie Rape, RN, CCRC – NC TraCS

Chayla Hart – Department of Pediatrics

Laura Tuttle, MA, CCRP – NC TraCS

Today's Session

- Background and Case Review
- Common Medical Emergencies
- The Importance of a Plan
- Resources
- Your study population and protocol logistics
- Discussion



Background

Why is this important?

- Unexpected
- Events can be life-threatening
- Consider the level of preparedness for yourself and your team regarding an Adverse Event or emergency



Case Review

- Ordinary scheduled visit for my pediatric participant
- Parent presented with initial complaint of generally not feeling well
- Parent appeared to be experiencing increased symptoms of pain and discomfort
- I probed a bit further for clarification and...
- SOUGHT HELP!
- Outcome: this event was ultimately life-threatening



Case Learning Points

- The event happened with an individual who accompanied the participant to the visit. It was not the participant.
- Prior knowledge of symptoms associated with medical emergencies and seeking professional assistance were especially important.
- Other things to consider



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Unique Position of Research Coordinators



- Often spend significant time with research participants and build relationships/trust
- Duty to ensure protection of research participants
- Focus on research protocol, administration, data collection, but in a clinical environment
- Monitoring for adverse events, unexpected problems



Common Medical Conditions & Emergencies

- Heart Attack and Angina
- Sudden Cardiac Arrest
- Stroke
- Anaphylaxis
- Hypoglycemia
- Fainting
- Seizure



Heart Attack

One emergency that you may come across is a person experiencing chest pain. A stroke, an acute anxiety attack, indigestion and angina can **all have similar symptoms as a heart attack.**

- **Almost half of sudden cardiac deaths happen outside a hospital.**
- Some heart attacks are sudden and intense but **most start slowly, with mild pain or discomfort.**
- A heart attack strikes someone about every 43 seconds.
- Don't wait to get help if someone is experiencing any of the following heart attack warning signs.



Heart Attack

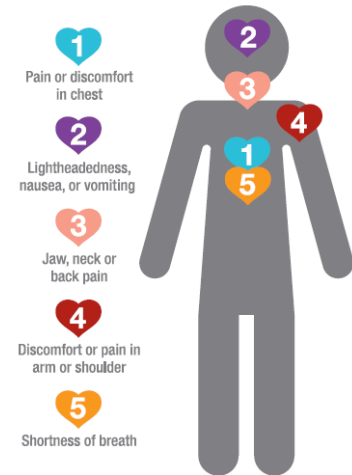


The National Heart Attack Alert Program notes these major signs of a heart attack:

- **Chest pain or discomfort.** Most heart attacks involve discomfort in the center or left side of the chest that lasts for more than a few minutes, or that goes away and comes back. The discomfort can feel like uncomfortable pressure, squeezing, fullness, or pain.
- **Discomfort in other areas of the upper body.** Can include pain or discomfort in one or both arms, the back, neck, jaw, or stomach.
- **Shortness of breath.** Often comes along with chest discomfort. But also can occur before chest discomfort.
- **Other symptoms.** May include breaking out in a cold sweat, nausea, or light-headedness.



Common Heart Attack Warning Signs



Learn more at [Heart.org/HeartAttack](https://www.heart.org/HeartAttack).



Heart Attack

- Symptoms vary between men and women. As with men, women's most common heart attack symptom is chest pain or discomfort. **Women are somewhat more likely than men to experience some of the other common symptoms, particularly shortness of breath, nausea/vomiting, and back or jaw pain.**
- Many people having a heart attack wait more than two hours before getting help. **Some people feel it would be embarrassing to have a “false alarm.”** Others are so afraid of having a heart attack that they tell themselves they aren't having one. These feelings are easy to understand, but they're also very dangerous.
- If you think that you or someone you know is having a heart attack, you should **call 911 or emergency medical services immediately.**

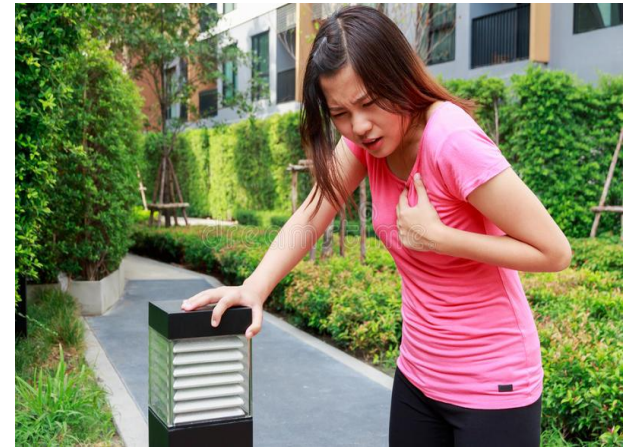


Heart Attack or Angina?

Angina is a form of chest pain caused by lack of oxygen to the heart muscle that usually only lasts a few minutes. It is usually brought on by exertion and is relieved by rest or the use of nitroglycerin tablets.

WHICH
ONE?

A heart attack may look like angina, or angina can progress to a heart attack. Never wait to summon help until you're sure it is a heart attack. **Call 911 or emergency medical services promptly.** The person will need medical attention to rule out if it is a real heart attack or not.



Sudden Cardiac Arrest

Sudden Cardiac Arrest (SCA) is **when the heart malfunctions and suddenly stops beating unexpectedly**. While a heart attack is a “circulation” problem, cardiac arrest is an “electrical” problem. Death can result quickly if proper steps aren’t taken immediately.

- Signs include a **sudden loss of consciousness, no heartbeat or normal breathing** (i.e. isn’t breathing or only gasping for air).
- Some people may have a racing heartbeat or feel dizzy or light-headed just before they lose consciousness. Within an hour before SCA, some people have chest pain, shortness of breath, nausea (feeling sick to the stomach), or vomiting.
- Cardiac arrest is reversible in most victims if it’s treated within a few minutes.

Call 9-1-1 or emergency medical services immediately.



Stroke

Use the letters in “**FAST**” to spot stroke signs and know when to call 9-1-1.



Face Drooping – Does one side of the face drop or is it numb? Ask the person to smile. Is the smile uneven or lopsided?

Arm Weakness – Is one arm weak or numb? Ask the person to raise both arms. Does one arm drift downward?

Speech Difficulty – Is speech slurred? Is the person unable to speak or hard to understand? Ask the person to repeat a simple sentence, like “The sky is blue.” Is the person able to correctly repeat the words?

Time To Call 911 – If someone shows any of these symptoms, even if the symptoms go away, call 9-1-1 or seek emergency medical services and say, “I think this is a stroke” to help get the person to the hospital immediately. Time is important! Don’t delay, and also note the time when the first symptoms appeared. Emergency responders will want to know.



Anaphylaxis

A life-threatening allergic reaction (anaphylaxis) can cause shock, a sudden drop in blood pressure and trouble breathing. **Anaphylaxis can occur minutes after exposure** to a specific allergy-causing substance (allergen) and **can progress quickly**. In some cases, there may be a delayed reaction or anaphylaxis may occur without an apparent trigger.

Signs and Symptoms include:

- A feeling of impending doom, may report they think they are “going to die” and often say “I don’t feel right”
- A weak and rapid pulse
- Nausea, vomiting or diarrhea
- Dizziness, fainting or unconsciousness
- Swelling of the face, eyes, lips or throat; hoarse voice
- Skin reactions, including hives, itching, and flushed or pale skin
- Constriction of the airways, leading to wheezing and trouble breathing

Signs and Symptoms of Anaphylaxis



If you're with someone having signs and symptoms of anaphylaxis, don't wait to see whether symptoms get better. **Call 9-1-1 or SEEK EMERGENCY MEDICAL TREATMENT RIGHT AWAY.**



Anaphylaxis

Some common anaphylaxis triggers include:

- **Medications**
- Foods such as peanuts, tree nuts, fish and shellfish
- Insect stings from bees, yellow jackets, wasps, hornets and fire ants



If you are with someone having an allergic reaction with signs of anaphylaxis:

- Don't wait to see whether or not symptoms get better. **SEEK EMERGENCY MEDICAL TREATMENT RIGHT AWAY.** In severe cases, untreated anaphylaxis can lead to death within half an hour.
- Ask the person if they are carrying an epinephrine auto injector (i.e. EpiPen) to treat the allergic attack.
- Loosen tight clothing and cover the person with a blanket if available.



- If there is vomiting, turn the person on their side to prevent choking.
- Get emergency treatment even if symptoms start to improve. It is possible for symptoms to recur.



Hypoglycemia

Hypoglycemia, also called low blood sugar, occurs when the level of glucose in the blood drops below normal (generally below 70 mg/dL). Symptoms develop **QUICKLY**.

Causes

- Medication side effects
- Too much diabetes medication
- Diabetes medication taken too often
- More physical activity than usual
- Drinking alcohol
- Skipped or delayed meals (**fasting**)



Symptoms

- Shaky or jittery
- Irritable or nervous
- Hungry
- Headache
- Blurred vision
- Tired or weak
- Fast heartbeat
- Sweating, chills and clamminess
- Dizzy or lightheaded
- Confused or disoriented



Hypoglycemia - Management

If conscious,

- Ask them to check their blood sugar level if they have a glucometer.
- Have the person (adult) **eat something containing sugar (15 grams of carbohydrates)** right away to raise the blood sugar level (examples listed below). **Repeat in 15 minutes if needed.** Most people will gradually improve, but if they don't or you are in doubt, call 911.
 - fruit juice or regular (not diet) soft drink
 - milk
 - pieces of candy (chewable, hard)
 - sugar (not artificial sweeteners) or honey



If unconscious,

- Severe hypoglycemia is extremely dangerous and may require a glucagon injection. If the person is unable to eat or drink, has seizures or convulsions, or is unconscious, **SEEK IMMEDIATE MEDICAL HELP.**



Hypoglycemia or Hyperglycemia?

BLOOD SUGAR MNEMONIC

HOT & DRY = SUGAR HIGH



COLD & CLAMMY =
NEED SOME CANDY

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Feeling Faint or Fainting



Fainting does sometimes occur as a result of venipuncture and can occur anytime during the procedure. A subject may experience symptoms of **facial pallor, perspiration, dizziness, hyperventilation, nausea, and confusion**. These symptoms often proceed fainting or loss of consciousness.

Before the procedure:

- Ask if they have been fasting.
- Ask if they had any previous problems with having blood drawn.
- If any past issues, draw the patient lying down to decrease the risk of fainting or use a chair with arm guard or a table when possible to help eliminate the possibility of injury due to falling or sliding out of the chair.



Feeling Faint or Fainting

During the procedure:

- **Observe the patient during the draw for any signs that they may be feeling faint.**
- If a subject faints during the venipuncture, stop the draw by removing the tourniquet and needle from their arm, apply gauze and pressure to the site.
- If the subject is seated, instruct them to place their head between their knees or place their head on the table; ensure they don't slide out of the chair.
- If in a supine position, elevate feet above the body.
- Apply a cold compress to the back of the neck or forehead (use cold tap water/paper towels if that is all that is available) – this may help revive them more quickly.
- When awake, instruct the person to take slow, deep breathes.
- Fainting spells are usually self limited and usually the subject comes around fairly quickly, however stay with the subject for at least 15 – 30 minutes to ensure they have recovered completely.



Feeling Faint or Fainting

After the procedure:

- **Never turn your back on the subject immediately** after completing the draw.
- If the subject states feeling dizzy after the procedure is completed:
 - instruct to place his/her head between their knees if in sitting position
 - elevate feet above the body if in supine position
 - apply cold compress
- Offer water, juice or snacks when you feel subject can tolerate food or drink as symptoms may be **related to low blood sugar from fasting**.
- Remain with the subject to **ensure they have recovered completely before they are allowed to leave**. Have subject stay in sitting/supine position for several minutes then in a standing position for several minutes to ensure there is no recurrence of fainting before being released.
- **Remind subject to notify future phlebotomists of past experience with fainting during blood draws.**



Seizure

Per the CDC, **about 1 out of 10 people has had a seizure.** That means seizures are common, and one day you might need to help someone during or after a seizure.

Here are **some things you can do to help** someone who is having a seizure (grand mal or generalized tonic-clonic)

- Ease the person to the floor
- Place in the recovery position, turn the person gently onto one side to help them breathe
- Clear the area around the person of anything hard or sharp to help prevent injury
- Put something soft and flat next to their head to protect from injury
- Remove eyeglasses
- Loosen ties or anything around the neck that may make it hard to breathe
- **Time the seizure.** Call 911 or contact emergency medical services if the seizure lasts longer than 5 minutes or if there is no history of seizures.



Seizure

Knowing what **NOT** to do is important for keeping a person safe during or after a seizure. Never do any of the following things:

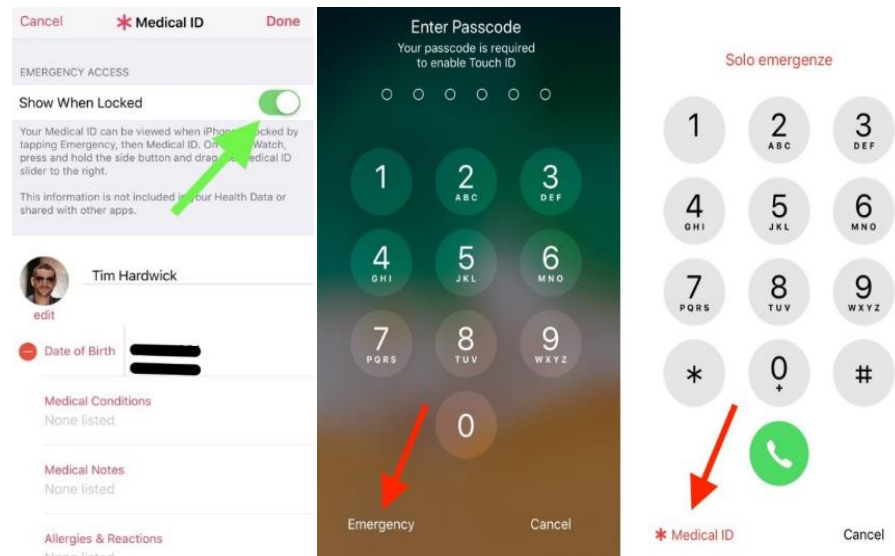
- Do **not** hold the person down or try to stop his or her movements.
- Do **not** put anything in the person's mouth. This can injure teeth or the jaw.
- Do **not** try to give mouth-to-mouth breaths (like CPR). People usually start breathing again on their own after a seizure.
- Do **not** offer the person water or food until fully alert.



Seizure

Key things to remember to help someone who is having a seizure.

- Stay with the person until the seizure ends and they are fully awake. After it ends, help the person sit in a safe place. Once they are alert and able to communicate, tell them what happened in very simple terms.
- Comfort the person and speak calmly.
- Check to see if the person is **wearing a medical bracelet or other emergency information** (such as Medical ID info on the iPhone).
- Keep yourself and other people in the area as calm as possible.



Automated External Defibrillator (AED)

An AED is used to urgently diagnose and treat ventricular fibrillation and is most successful when the first shock is delivered within 3 – 4 minutes of sudden cardiac arrest. If appropriate, the device will recommend that a shock be delivered to resume a safe rhythm for the victim's heart.

- AEDs are now found in major shopping centers, airports, universities, and are becoming more and more popular throughout the community.
- A person does not have to have any knowledge of how the heart works, or be able to read EKG monitors in order to use an AED.
- It is simple to use and can increase the chances of saving a life by as much as 50% when used early in sudden cardiac arrest.
- While untrained bystanders have successfully used an AED, they are **intended for use by trained personnel**. Take a class in AED training, and be one step ahead in being prepared on how to use one.
- Review UNC's AED policy at <https://ehs.unc.edu/manuals/ehsmanual/chapter-4/automated-external-defibrillator-policy/> for more information.



Recap: Common Warning Signs & Symptoms

Per the ACEP, emergency physicians believe it is everyone's responsibility to learn to recognize the warning signs of a medical emergency. The **below signs and symptoms are not intended to represent every kind of medical emergency or substitute for medical advice from a physician**, but rather provides examples of common issues:

- Difficulty breathing, shortness of breath
- Chest or upper abdominal pain, or pressure lasting two minutes or more
- Fainting, sudden dizziness, weakness
- Difficulty speaking
- Confusion or change in mental status, unusual behavior, difficulty walking
- Change in vision
- Any sudden or severe pain
- Uncontrolled bleeding
- Severe or persistent vomiting or diarrhea
- Coughing or vomiting blood
- Suicidal or homicidal feelings
- Unusual abdominal pain

You also can learn to recognize—and act on—emergency warning signs by taking a first aid class and learning CPR (cardiopulmonary resuscitation).



Key Points

- **Don't hesitate to call 9-1-1 or seek medical help right away if you think someone is having symptoms of a medical emergency.**
- Discuss the symptoms with the Principal Investigator or Study Physician.
- If you are in a clinic setting, discuss the symptoms or your concerns with a nurse or other licensed medical provider.
- Remain calm, be prepared and know your surroundings:
 - Where is the nearest phone?
 - Is there an AED in the building?
 - Is there a code response team available in your location (9-1-1 versus Code Team)? Know how to activate the code team if it is available.
 - Is there anyone else in the area? How would you respond if you are alone?
- Remember that not everyone will exhibit the same symptoms or have all the symptoms listed.
- It is always better to err on the side of caution when it involves someone's health, even your own. **Every minute matters!**



Takeaway

This presentation is not intended to take the place of first aid training, but may be helpful to alert you on some of the most common medical emergencies that can become life threatening.

Knowing how to recognize warning signs is the first step in acting fast and responding well in an emergency situation. ***One never knows when an emergency will happen***...seek out a training course to learn more.



Training Resources



- Resident of Orange County? The South Orange Rescue Squad offers free CPR classes. Visit <http://sors.us/cpr/> for more information.
- CPR Consultants in Raleigh. Visit <https://www.cprconsultants.com/> for more information.
- Triangle CPR in Raleigh. Visit <https://www.trianglecpr.com/> for more information.

- American Heart Association CPR and First Aid Courses at Durham Tech. Visit <https://www.durhamtech.edu/publicsafety/ems/aha.htm> for more information.



Why is CPR Training Important?



American Red Cross First Aid App

Download the free Red Cross app in the Apple App Store or Google Play for instant access to step-by-step first aid advice, including advice about seizures and epilepsy.



Emergency Allergies / Anaphylaxis

- 1 A person who is having a severe, life-threatening allergic reaction (called anaphylaxis) may develop one or more of the following signs and symptoms within seconds or minutes of coming into contact with the allergen:
 - Trouble breathing
 - Swelling of the face, neck, tongue or lips
 - A feeling of tightness in the chest or throat
 - Skin reactions (such as hives, itchiness or flushing)
 - Stomach cramps, nausea, vomiting or diarrhea
 - Dizziness
 - Loss of consciousness
 - Signs and symptoms of shock
- 2 When you observe these symptoms, call 911.

[Call 911](#)

- 3 If the person has a known allergy and has an auto-injector/Epi-pen, you can help them to use it. Give them constant reassurance while waiting for the ambulance.



Other Scenarios to Consider

- Adult participant with medical emergency who brings minors to study visit
- Minor participant whose sole caregiver experiences an emergency during a visit
- Remember to create a plan with your team of investigators, coordinators, providers, educators, etc.

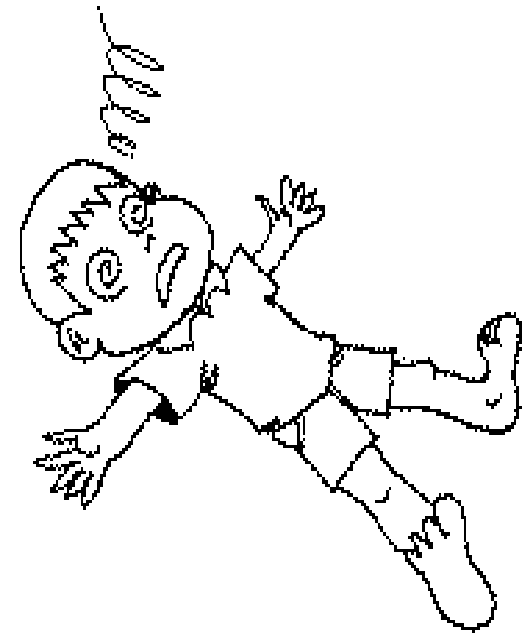


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Is the event reportable?

- Was event unexpected, possibly related, placed subjects or others at increased risk?
 - UNC IRB SOP 1401, reporting of new safety information, <http://ohresop.web.unc.edu/>
- Who experienced event?
 - Research subject:
 - Report to IRB, FDA, funding agency
 - Visitor or family member:
 - Report to clinic, facility administrator
 - Risk management
 - PI, supervisor
 - Others?



Develop a plan for managing emergencies

To develop plan for managing potential emergencies, look at protocol, think about areas that may have risk:

- Location where subjects seen
- Study Population
- Risks of Intervention
- Other considerations



“When you prepare for an emergency, the emergency ceases to exist.”



Location where subjects seen

- Consider location
 - CTRC or UNC Hospital Clinic
 - Unfamiliar (new to you) clinical environment
 - Isolated location (library, office, subject home, after hours clinic)
- Where can you get help in emergency?
 - Search out environment ahead of time
 - Can you call on medical professionals in clinic
 - Learn clinic set up, emergency resources available, how to call code
 - Will other people be nearby if off site?
 - To call 911: phone available, directions to location, ease of access, doors locked at certain hours?



Study Population

- Study Population
 - Healthy volunteers
 - Sicker individuals, medical condition
 - Children
 - Elderly or disabled
- Understand medical condition, prepare for potential events common in population
 - DM → low blood sugar → snacks available
 - Cardiac patients → possible emergency scenarios
 - Review with PI signs/symptoms to watch for
- Safety of environment for young, old, disabled, sick
 - Request clinic room closer to nurses station, phlebotomy
 - Room with no equipment to cause safety issue to child



Risk of Study Interventions

- Risks, measures to minimize risk described in IRB, Protocol
- Is plan outlined in IRB / Protocol sufficient?
- Have there been changes (location of visits) that might affect how you monitor subjects?
- Consider risk of procedures
- Understand process to unblind study medication if needed in emergency
- Who to call for AEs or problems experienced - PI, study physician, on-call MD
- Add details to emergency plan, update IRB application if needed



Other considerations

- Will family member or child accompany subject?
- Phlebotomy –
 - Space for subject to lie down if faint?
 - Safe environment to draw blood?
 - Is subject nervous, anxious about blood drawing—allowing to lie down during procedure can help
 - Will subjects arrive fasting for labs? Snacks?
- If need to call 911, be prepared to provide emergency personnel with medical history of subject, investigational drug info



After a medical emergency happens...

Discuss with others, talk it out, share, decompress!

Self-reflection after a medical event

- Allows for review of what happened, how it was handled
- Discuss what went right or went wrong
- What could be done differently, better



What changes are needed in environment, process, emergency plan, Learn from the experience!



Questions/Discussion

Thank you!



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