

Clinical Space Etiquette

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What are clinical spaces?

- **As UNC grows, clinical research is happening in many different places**
 - Hospital units (ICUs, inpatient rooms)
 - Outpatient clinics
 - Research units (CTRC, Eastowne)
 - Operating rooms, surgical suites

- **Researchers may need to navigate different spaces to reach more patients**



Feeling comfortable in the clinical environment

- **Different roles, same goals**
 - Keep patients safe
 - Conduct high quality research
 - Make UNC a place where patients feel welcome and want to return!
- **Communication bridges the gap between research and clinical care**
 - Integrating research into the clinical workflow – better for researchers, clinicians, and patients!
- **UNC is an academic research hospital – researchers are at the core of our mission!**



Finding your place in clinical spaces

- Think about the **power you hold in a clinical space** - the way we present ourselves really matters!
 - How do we enter the room?
 - How are we dressed?
 - How are we handling study specimens?
 - What impressions are we making on clinic staff? Will they allow other studies in this clinic in the future?
 - Do patients trust us?



It's never too late to build a solid foundation for your study.

- **Assume best intentions** – we are all here to keep patients safe and improve their health!
- **Starting a new study/implementing a major protocol change?** PI should initiate contact with nursing/clinical staff
- Provide **training for clinical staff** (if they will complete any study procedures)
- Have a **short (1-2 sentence) description** of the study's purpose and what you will need from clinical staff
- Create a '**cheat sheet**' or provide a quick 1 pager **protocol summary** of your study
 - For drug studies, provide a **safety and adverse event expectations sheet**
- Find a **“Study Champion”** that will support your research
- If something feels off, **ASK MORE QUESTIONS**



Communication, Communication, Communication

- Check in with **Charge Nurse or Nurse Manager** when arriving on a unit
- Check with **participant's assigned nurse** beforehand to get a sense of participant readiness
- **ALWAYS introduce yourself and purpose for being there** - clinics and hospital units are busy places!
- If attending a **clinical or surgical procedure**, ask where you should stand, what PPE you will need, etc.
- **Clinical Supplies** should generally not be used for research - if you need something, ask



Location, Location, Location

- **Clean Utility Room**
- **Dirty Utility Room**
- **Sterile Areas/ Sterile procedures** (such as Operating Rooms) require hair covering and face masks, shoe covering may be required but recommended!

Safety in Clinical Spaces



Universal Precautions with EVERY PATIENT, EVERY TIME

ALWAYS

“Clean In, Clean Out”
of a hospital or clinic room with
hand washing or hand sanitizer



If touching open skin, bodily fluids, or your own preference, wear nitrile gloves. Wash hands after removing.

Trust your gut! It's always okay to ask for a second opinion, get more information, or come back another time.

If your participant doesn't look their baseline - in pain or agitated, uncomfortable etc, call the patient's nurse as soon as possible- don't wait!



UNC
THE NORTH CAROLINA
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Recognizing and Responding to Medical Emergencies in Clinical Research

North Carolina Translational and
Clinical Sciences (NC TraCS) Institute

Objectives

- Identify signs and symptoms of common medical emergencies in clinical research and take appropriate action
- Consider how study population and protocol logistics may impact emergency management



Common Medical Conditions & Emergencies

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



Heart Attack



Blood flow to the arteries in the heart is severely reduced or blocked

Symptoms:

- Chest pain or discomfort
- Discomfort in other areas of the upper body
- Shortness of breath
- **Other symptoms:** may include breaking out in a cold sweat, nausea, vomiting, 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
- Many people having a heart attack wait before getting help
- If you think that you or someone you know is having a heart attack, you should **call 911 or activate the emergency response immediately!**



Sudden Cardiac Arrest

The heart malfunctions and stops beating unexpectedly

- Signs include:
 - sudden loss of consciousness
 - no heartbeat
 - no breathing, or only gasping for air
- Cardiac arrest can be reversed if CPR is performed and a defibrillator shocks the heart and restores a normal rhythm within a few minutes
- **Call 911 or activate the emergency response immediately!**
- ***Then, start chest compressions and obtain an AED***



Automated External Defibrillator (AED)

An AED is a device used to treat cardiac arrest

- Most successful if used within the first 3-4 minutes of cardiac arrest
- Found in major shopping centers, airports, universities, etc.
- No training required for use – uses audio and visual prompts
- Immediate CPR and AED use can double or even triple survival rates
- North Carolina General Statute Section 90-21.14



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 droop 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.



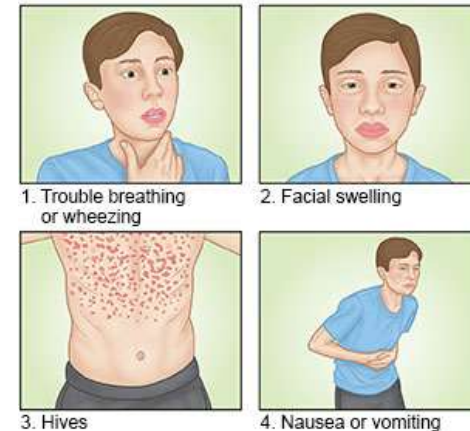
Anaphylaxis

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



Anaphylaxis

Some common anaphylaxis triggers include:

- **Medications**
- Foods: peanuts, tree nuts, fish and shellfish
- Insect stings: 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 unconscious or pregnant, turn the person on their left side.
- 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 **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
 - 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.**



Feeling Faint or Fainting



Venipuncture can cause a subject to faint

Symptoms that may precede fainting:

- facial pallor
- perspiration
- dizziness
- hyperventilation
- nausea/vomiting
- confusion

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 breaths.
- 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

Abnormal electrical activity in the brain causes uncontrolled jerking, loss of consciousness, blank stares, or other symptoms

If someone is having a seizure, you can take the following steps:

- 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.



Recap: Common Warning Signs & Symptoms

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
- It is always better to err on the side of caution when it involves someone's health, even your own. **Every minute matters!**





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.
- UNC Campus Recreation- First Aid/CPR/AED: <https://campusrec.unc.edu/program/first-aid-course/>
- NC TraCS CTRC hosts BLS Healthcare Provider course for research personnel (advertised on the NPR listserv)



Is the event reportable?

- Was event unexpected, possibly related, placed subjects or others at increased risk?
 - UNC IRB SOP 1401, Promptly Reportable Information
- 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
- Study Population
- Risks of Intervention
- Other considerations



Location

- Consider location
 - CTRC or UNC Hospital Clinic
 - Unfamiliar (new to you) clinical environment
 - Isolated location (library, office, subject's 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

- 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 –
 - Safe environment to draw blood?
 - Is there space for participant to lay down?
- 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

Learn from the experience!



Questions/Discussion

Thank you!



References

- Centers for Disease Control and Prevention “Diseases & Conditions.” Retrieved from <https://www.cdc.gov/diseasesconditions/index.html>
- American Heart Association “Heart Attack.” Retrieved from <https://www.heart.org/en/health-topics/heart-attack>
- American Heart Association “Angina (Chest Pain).” Retrieved from <http://www.heart.org/en/health-topics/heart-attack/angina-chest-pain>.
- National Institute of Health’s NHLBI “Sudden Cardiac Arrest.” Retrieved from <https://www.nhlbi.nih.gov/health-topics/sudden-cardiac-arrest> and “Sudden Cardiac Death: Epidemiology and Risk Factors. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5014372/>.
- American Heart Association “Stroke Warning Signs.” Retrieved from http://www.strokeassociation.org/STROKEORG/WarningSigns/Stroke-Warning-Signs-and-Symptoms_UCM_308528_SubHomePage.jsp.
- Mayo Clinic “First Aid: Anaphylaxis.” Retrieved from <https://www.mayoclinic.org/first-aid/first-aid-anaphylaxis/basics/art-20056608>
- American Diabetes Association “Hypoglycemia (Low Blood Glucose).” Retrieved from <http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/hypoglycemia-low-blood.html>
- Blood Sugar Mnemonic. Retrieved from <http://www.thehealthsite.com/diseases-conditions/first-aid-tips-for-diabetic-emergencies/>
- Abbott Nutrition “Adjusting to Life with Type 2 Diabetes or Prediabetes.” https://static.abbottnutrition.com/cms-prod/anh-2017.org/img/ANHI_Diabetes_Infographic_tcm1423-116921.pdf
- Mayo Clinic “First Aid: Fainting.” Retrieved from <https://www.mayoclinic.org/first-aid/first-aid-fainting/basics/art-20056606>
- WHO “Guidelines on Drawing Blood: Best Practices in Phlebotomy.” Retrieved from http://apps.who.int/iris/bitstream/handle/10665/44294/9789241599221_eng.pdf;jsessionid=8320144E3591C97E9B0C983BACFCE2B7?sequence=1
- Centers for Disease Control and Prevention “Get Seizure Smart!” Retrieved from <https://www.cdc.gov/features/getseizuresmart/index.html>
- Centers for Disease Control and Prevention “Seizure First Aid.” Retrieved from <https://www.cdc.gov/epilepsy/about/first-aid.htm>
- American College of Emergency Physicians “Is it an Emergency?” Retrieved from <http://www.emergencycareforyou.org/emergency-101/is-it-an-emergency/#sm.00001rzbnuytoffr9y68eoa8bekqa>
- American Heart Association “Emergency Treatment of Cardiac Arrest and “Every Second Counts: Rural and Community Access to Emergency Devices.” Retrieved from <http://www.heart.org/en/health-topics/cardiac-arrest/emergency-treatment-of-cardiac-arrest> and https://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_301646.pdf

