Field Site: The Children’s Hospital of Philadelphia

We participated in CHOP’s Academic Associates Program, where we screened and enrolled emergency room patients into 14 different clinical studies. Study recruitment included specimen collection, surveys, and brochure talks. We also worked as part of the study team to collect and organize data into RedCap (a secure application used to collect survey information), conducted patient chart review, video review, and follow-up phone-calls. We worked specifically with the Medical Resuscitation Quality Improvement study, a study that evaluates patient care for patients that come through the Trauma Bay (Zauraiz), Ankle Fractures and Injuries, a study that evaluated the use of ultrasound to determine ankle fractures, Novel Diagnostics for Lyme, a study that uses biological specimen to find new diagnostic techniques for Lyme, and Dexamethasone study, a study that evaluates the use of antibiotics for asthmatic children (Nithya).

Learning Objectives:

We aimed to learn to identify relevant ethical considerations in pediatric clinical research pertaining to specific studies and patient populations, specifically answering questions about informed consent, child assent, and demographic considerations. By studying this, we hope to be more aware of the various factors that could encourage or discourage patient participation in clinical studies and be conscious about informing patients about their rights regarding care and research.

We also wanted to learn about the current clinical studies at CHOP, and develop the skills to screen and enroll eligible patients, interview families, and obtain informed consent.

Pediatric Clinical Research and Informed Consent

Clinical research is the study of preventing, diagnosing, and treating illnesses. It involves human participation to help translate lab research into information that benefits patients.

A researcher must obtain informed consent from patients for them to participate in clinical research. Informed Consent includes:

- Full knowledge and understanding of the study
- Voluntary decision to participate
- Comprehension and ability to make decisions

When performing pediatric research, in addition to parental consent, children above the age of 7 must also give assent, their affirmative agreement to participate in the research study.

Pediatric Clinical Research: Ethical Challenges

Challenges to Informed Consent:

- **Gender/Age and Education**: The gender and perceived age of the researcher as well as the gender and age of the patient/family providing consent may have some impact in enrollment. Generally, the more familiar with clinical studies a family is, the more likely they are to enroll in a research trial.

- **Race/Ethnicity**: Depending on cultural trust or mistrust of the healthcare system, race and ethnicity can play an integral role in our ability to enroll patients into studies.

- **Child Assent**: Children without any developmental delays and above the age of 7 must provide assent to participate in any clinical research. Depending on how that child is feeling during their stay in the ED, their assent cannot be assured.

- **Coercion**: Some of our longer studies have some monetary compensation, but under no circumstances can we coerce patients into studies.

Conclusions:

It’s difficult to be conscious about every aspect in clinical research, and its even more difficult to make sure that every patient receives an adequate understanding of the study before enrolling them into the study. We’ve learned much more about the ethics behind standard policies in Clinical Research, as well as the grey areas researchers still must navigate.

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