

# Innovations & Brainstorming



**Established  
Status  
Epilepticus  
Treatment  
Trial**

Peer to Peer

# Innovations and Brainstorming

- Enrollment Best Practices, Amanda Lee, Children's Medical Center UTSW
- PK/PD Blood Samples, Kyle Pimenta, UC Davis Children's Hospital
- Simulator Training, Abbey Staugaitis, University of Minnesota Medical Center Hospital



# Innovations and Brainstorming

- Enrollment Best Practices, Amanda Lee, Children's Medical Center UTSW



ESETT – Best Practices  
Children’s Medical Center/UTSW – Dallas, TX  
Amanda Lee, MPH, BS – Clinical Research Coordinator



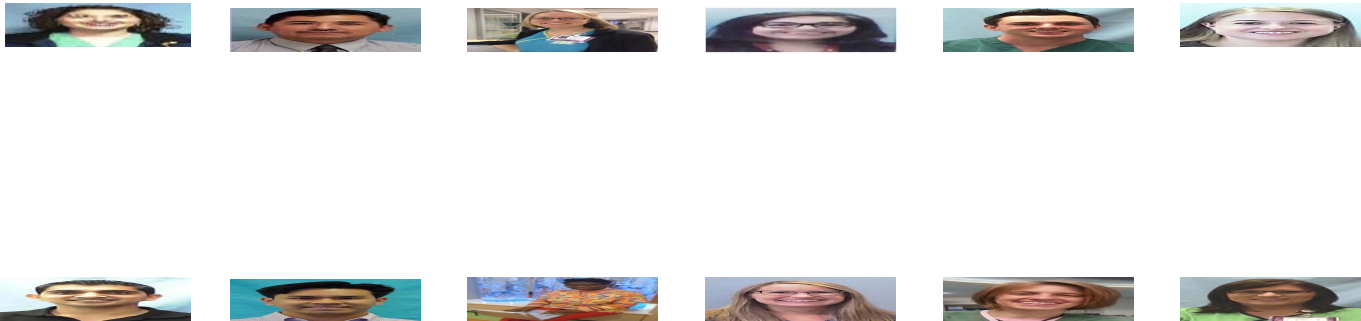
- Only Level 1 Trauma Center in North Texas
- Annual volume of ~125,000 pediatric patients
- ED staffed by:
  - PEM and Gen Peds faculty and rotating Adult EM physicians
  - 9 PEM Fellows
  - 12 ED Pharmacists
  - RAs, medical students and research volunteers

Source: [www.childrens.com](http://www.childrens.com)



# ED Pharmacists

- We utilize our ED Pharmacy team to help identify patients and begin enrollment procedures
- Small group that is easily accessible for training and updates
- Stays at the patient's bedside through enrollments



# Paging System

- All pagers are linked and when a page goes out, two different members of the research team receive the page
- There is always a primary and secondary on-call individual
- Most enrollments (95%) occur when a research team member is in the ED
- Puts clinical team and research team in direct contact to immediately address any issues



# Badge Buddies - Examples

ESETT Study – Pharmacy Badge	
<b>Inclusion Criteria</b>	
<ul style="list-style-type: none"><li>• Age <math>\geq 2</math> to <math>&lt; 18</math> years of age</li><li>• Seizing for <math>&gt; 5</math> minutes</li><li>• Continued/recurring despite adequate benzos</li><li>• Last dose of benzos given 5-30 minutes ago</li></ul>	
<b>Study Procedures</b>	
<ul style="list-style-type: none"><li>• Obtain “Use Next Box” from Omnicell</li><li>• Verify inclusion/exclusion criteria</li><li>• Prep study drug to be infused</li><li>• Fill out <b>drug administration card</b>-located in Use Next Box</li><li>• Page the research team:<ul style="list-style-type: none"><li>○ Call (972)-[ ] Enter Call Back #</li></ul></li></ul>	

ESETT Study- Exclusion Criteria	
Questions? Ask Pam Okada, MD (972)-[ ]	<ul style="list-style-type: none"><li>• Allergy or contraindication to Phenytoin (Dilantin), Fosphenytoin (Cerebyx), Levetiracetam (Keppra), or Valproic Acid (Depakote)</li><li>• Known pregnancy, metabolic/liver/renal disease</li><li>• Received IV 2<sup>nd</sup> line anticonvulsants or non-benzo sedatives (propofol, etomidate, ketamine, etc)</li><li>• Endotracheal intubation placed PTA in ED</li><li>• Status epilepticus thought to be caused by:<ul style="list-style-type: none"><li>○ Hypoglycemia <math>&lt; 50</math> mg/dL</li><li>○ Hyperglycemia <math>&gt; 400</math> mg/dL</li><li>○ Acute TBI: cardiac arrest; post anoxia</li></ul></li></ul>

Each provider group in the ED gets a role specific badge (Physician/Fellow, Research, Nursing, Pharmacy) that identifies their duties and includes tips for successful enrollments



# Other best practices

- Placing use-next box in easily accessible area near trauma hallway → no delays in care
- Sending out monthly newsletters to all staff
- Holding quarterly training parties
- Handing out goody bags for every individual involved in each enrollment
- Screening pharmacy log each month for potential misses → refresher for RAs and prompt alert of missed opportunities





# Innovations and Brainstorming

- PK/PD Blood Samples, Kyle Pimenta, UC Davis Children's Hospital



# PK/PD Enrollment #1

- 19yo subject, no LAR
- RC unavailable
- ED pharmacist called RC: 45-48 mins.
- Sample #1 (20-50 mins.): 58 mins.
- Sample #2 (60-120 mins.): 117 mins.
- Consent (mother/conservator): 5-6 hrs.
- Contacted PK/PD PIs re procedural deviation



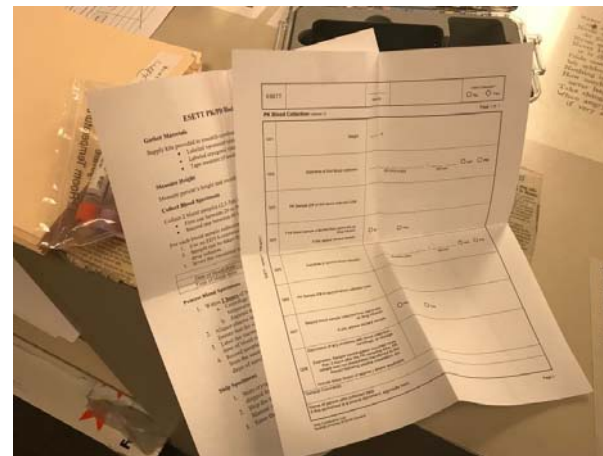
## PK/PD Enrollment #2

- 17yo subject, no LAR
- RC present
- Sample #1 (20-50 mins.): 23 mins.
- Parental permission (MOC): 69 mins.
- Sample #2 (60-120 mins.): 71 mins.
- Assent: 19 hrs. (next morning)



# Use-Next Box

- Biohazard bag contents:
  - 2x labeled 7mL lavender top vacutainer tubes
  - 2x labeled 5mL cryogenic vials
  - PK/PD sample collection procedures quick guide
  - PK/PD CRF
- IDS maintains supply



# Considerations

- Pediatric workflow
  - If no LAR available and subject not awake, proceed
  - If no LAR available and subject awake, do not collect samples
- Consent
  - Embed opt-out mechanism for sample collection



# Innovations and Brainstorming

- Simulator Training, Abbey Staugaitis, University of Minnesota Medical Center Hospital



# Seizure SIM (ESETT)

Abbey Staugaitis, MSN, CCRC



UNIVERSITY OF MINNESOTA  
**Driven to Discover**<sup>SM</sup>

# Seizure SIM incorporating ESETT

- What we did
- Lessons Learned



# What We Did

- Created a SIM scenario with ESETT enrollment goals (& training lessons) in mind
  - Actually used an ESETT screen failure as the case study
- Did a spontaneous (to the clinical team) Seizure (ESETT) SIM in the ED



# What We Did: Set-Up

- Worked with the Clinical Development Specialist in the ED and the Dept. of EM Clinical Instructor to create a ESETT eligible Seizure SIM scenario
- Morning of the planned (spontaneous) SIM: loaded a faux ESETT study bag (NS) into the ESETT box, set the PAD into “training” mode, put it back in it’s usual home



# What We Did

- Set up SIM man on a gurney
- Called in a seizure code (through real alert system)
- Ran a Seizure Code (based on the “ESETT” scenario) in the STAB room (ie. the same room the real seizure code would be treated)
  - Coordinator was present to help remind/ guide/answer questions
- Had a debrief with the clinical staff about the SIM and the study directly after the SIM



# Lessons Learned

- Reach out to the Clinical Educators & SIM lab (if applicable)
  - -they may already have a clinical scenario that could be slightly adapted to incorporate the study protocol
- Have 1-2 specific goals/“lessons” you want to convey (inclusion/exclusion)
  - Keep it simple!
- Create a complete scenario-with study in mind
  - labs, vitals, relevant H&P backstory



# Lessons Learned

- In Situ was very valuable (vs. SIM lab)
  - Assess: signage, equipment access/retrieval, previous training
- Work to be as “hands-on” as possible
  - Used actual PAD, ran drug (correct weight/rate?)
- Do a debrief/recap directly after the SIM
- Ideally, do 2 -one before and one after study is enrolling





**Established  
Status  
Epilepticus  
Treatment  
Trial**

[esett.org](http://esett.org)