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
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• 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
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
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:
  o 2x labeled 7mL lavender top vacutainer tubes
  o 2x labeled 5mL cryogenic vials
  o PK/PD sample collection procedures quick guide
  o PK/PD CRF

• IDS maintains supply
Considerations

• Pediatric workflow
  o If no LAR available and subject not awake, proceed
  o If no LAR available and subject awake, do not collect samples

• Consent
  o 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
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