**ESETT Tips**

**University of Michigan Hospital**

RC phone: 734.936.7715

Lead RC email: noellel@med.umich.edu

* **Clinical Team Training: Initial and Ongoing**
* **Nursing Staff**
	+ During study startup, we attended nursing shift change meetings as often as we could over a few week period of time to train on the study. We go over inclusion/exclusion, step-by-step poster, workflow of who is responsible for identifying an ESETT patient and how to contact RCs, drug infusion, and max dose drug infusion. We print materials on these topics to pass out during the meetings. *Refer to* *the Nursing Guide to ESETT for RC use.*
		- Max dose drug infusion needed more attention in nurse training. There were concerns about the patient receiving full dose when the line starts to run dry since the drug vials are only 100 mL and max dose is 90 mL. *Refer to the* *Drug Infusion Guide and Procedure Demonstration for Max Dose.*
		- If we attend a meeting where most nurses have heard our ESETT training spiel, we will then quiz them on the basics.
		- Once we feel most nurses understand the procedures, we plan to visit shift change meetings during the first week of each month to satisfy the ongoing training requirement mentioned in section 5 of the MOP.
	+ RCs and PI also attended prescheduled charge nurse monthly meetings.
* **Pharmacy**
	+ RCs and PI attended prescheduled pharmacy monthly meetings. Pharmacy is a useful contact for us because the staff is much smaller than the nursing staff and is involved in all medication dispensing. Therefore, they are usually our first go-to when a potential ESETT patient presents to the ED.
* **Social Work**
	+ RCs and PI attended prescheduled social work monthly meetings. Since this is an EFIC trial, an LAR may be involved, and parents often stay in the resus bay, we wanted to ensure social work was familiar with the study in case any questions or issues arise. Social work is prepared for these scenarios until an RC arrives. We have provided them with the Social Work Guide to ESETT and brochures. *Refer to the* *Social Work Guide to ESETT.*
* **Attending Physicians**
	+ Attending physician education was managed by our site PI through faculty meetings and emails.
* **Supplemental Materials**
	+ RC contact information is available at the charge nurse desks, on the step-by-step posters, use-next boxes, and pocket cards (explained below). This is for easy and quick accessibility when a patient comes in (we do 24/7 on-call).
		- We use Google voice, but other sites use paid services with a higher hit rate (Google Voice sometimes fails to deliver messages to some people on the forwarding list).
	+ Pocket cards were made for attending physicians, RCs, and nursing staff to keep in ID badges. These include the PI hotline and RC on-call contact numbers, and brief inclusion/exclusion criteria for easy reference. *Refer to the* *pocket cards for RCs/attending physicians and nursing staff.*
* **Screening**
* When a potential patient first presents to the ED, review of inclusion/exclusion with pharmacy and/or nursing staff is a good idea. This is beneficial for the following reasons: Clinical team would be ready if the patient becomes eligible during the ED visit and this serves as a recap of general education.
	+ Carrying the ESETT enrollment folder when a potential patient presents to the ED serves as a subtle reminder of the study as well.
* We have a BPA (automatic notification) set up to page us when a patient presents to the ED who is roomed in a resus bay with a chief complaint of seizures and is ≥ 2 yo. We do not depend on this for screening and it does not replace the current method of MD, RN, pharmacy being aware of the study, but this gives us real-time notification when an RC is in the office.
* **Enrollment**
* If sites do not have the PAD, be sure to set an alarm, such as on your phone, for the 20 and 60 minute assessments so as not to forget.
	+ Have clinical team conduct the 20 and 60 minute assessments and be sure patient’s status at these times is noted in the patient’s chart.
* If you are in the resus bay before drug infusion, be sure to note the exact time when study drug infusion starts, and confirm the time of benzo administration. With so much happening all at once, the administration times of one or both are sometimes charted a few minutes off.
	+ If you know *for a fact* when study drug infusion started and this does not correspond with what is noted in the chart, look into getting this timestamp corrected in the EMR.
* **Consenting**
* In the event of no LAR present, utilize social work to inquire into the status of an LAR and get their feedback to determine if the adult patient is cognitively able to understand the consent process.
* Since this is an EFIC trial, wording is important. Our Consent Introduction and Talking Points are included in our RC Enrollment Guide that we follow during an enrollment. *Refer to the* *RC Enrollment Guide.*
	+ Our site PIs usually try to do the Consent Introduction and then RCs will go through the consent form. We feel this is best for the patient, especially if we are talking to the parents of a child, to first learn about the enrollment and the study from the PI. If no PI available in person, be sure they are available by phone when needed, RCs then follow these tips:
		- Don’t be too ambiguous; make sure the parent or patient knows they were enrolled into the study – not that they *might* be in the future.
		- Stress that the patient would have received one of these three drugs anyway via doctor’s preference per standard care. There is no good scientific evidence to suggest one is better than the other and there is no universal agreement among doctors about which is best.
		- Avoid the verbiage “FDA approved” since levetiracetam and valproic acid have not yet been approved to stop long seizures and fosphenytoin has not been approved to stop seizures in children. We say “commonly used” medications that doctors use.
* Consenting should take place after things have calmed down. This varies among sites, some wait until after the 60 minute time point, we approach for consent as soon as it is appropriate.
* If no PI is present for the consenting process, we have found that dual RC consenting is helpful. One RC serves as the main consenter while the other can assist by observing how the parent or patient is reacting, offering additional information, etc.