Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

December 2016 – Volume 5, Issue 1

2016: A Year in Review

2017: Focusing on a New Milestone 'SHINE on the Road to 1000'

IN THIS ISSUE

To recap the highlights of 2016, we'd first like to thank all of our SHINE sites for their continued dedication to enrolling and capturing high quality 6 week and 90 day outcomes data. Kudos to all sites for helping SHINE maintain an excellent 96.64% retention average, we are almost to our goal of 97%!

This past summer both **Emory University** and **NYP Columbia University Medical Center** enrolled their 100th SHINE subject! Also, the **UVA SHINE team** launched a Clinician Stroke Training Webinar for which nurses and physicians may earn up to 2.0 *AMA PRA Category 1 credit*™ (s) for completing the training.

Currently, 43 sites are actively enrolling in SHINE, including 30 NETT sites and 13 SHINE Ancillary Sites. This year we had 11 sites that have enrolled 7 or more subjects this year! In addition, the following sites beat their 2015 enrollment rate: **Baylor College, Wayne State University, Hennepin County Medical Center, UT Houston, UT Southwestern, University of Cincinnati Medical Center, University of Iowa,** and **University of Kentucky!** Thanks to all for your hard work.

Congratulations to our 2016 Bravo Zulu Flag holders: UT Houston, Wayne State University, SUNY Downstate University, and Mount Sinai Medical Center. It has been our pleasure to recognize your outstanding efforts each quarter by presenting each of you with the Bravo Zulu flag.

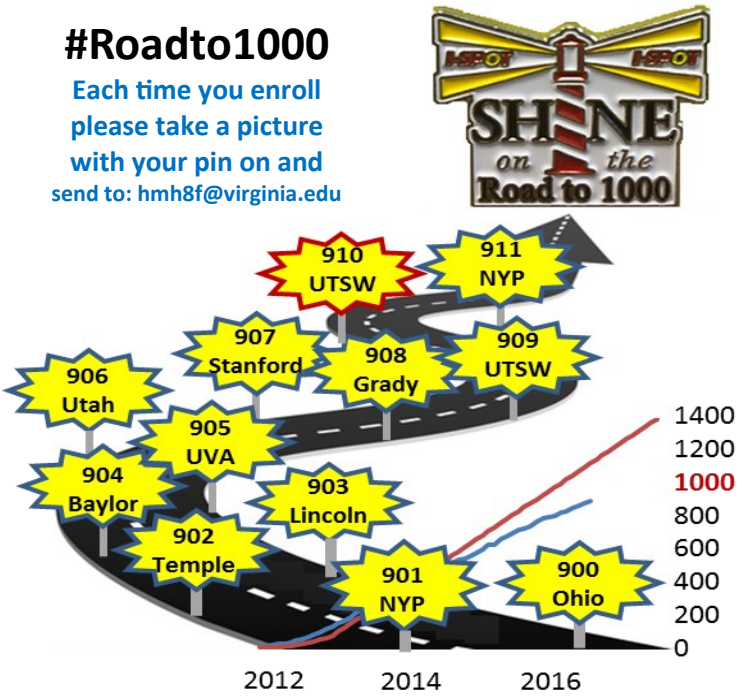
We are excited to reach our next Milestone, **#roadto1000**. We hope you all enjoy the SHINE/ISPOT pins! If you have not yet received your pins please let Heather hmh8f@virginia.edu know. Please share with us your ideas on how you award your pins at your site, so far we have heard that sites are choosing a name out of a hat after every 10th enrollment.

As always, we welcome your input on any issues or ideas related to SHINE. Thanks again for all your continuing efforts on SHINE.

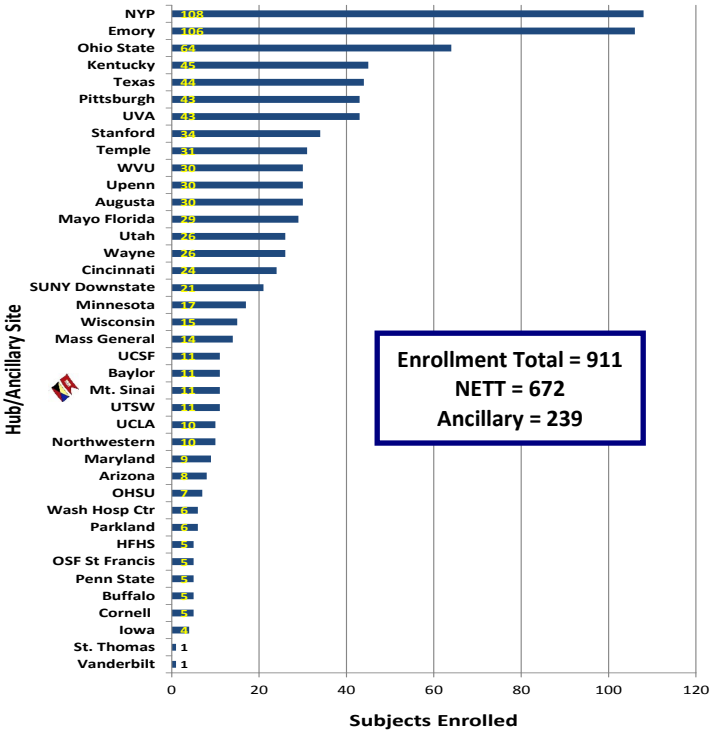
Karen C. Johnston, MD, MSc, SHINE Administrative PI

#Roadto1000

Each time you enroll please take a picture with your pin on and send to: hmh8f@virginia.edu



SHINE Enrollment by Site through DEC 19th 2016



SHINE Bravo Zulu Award

Our sincere congratulations to one of our *newest* SHINE study teams at **Mount Sinai**, this quarter's recipient of the SHINE Bravo Zulu flag. The Bravo Zulu flag is traditionally used by US naval forces to publically recognize a job especially well done.

The SHINE study team at **Mount Sinai** is one of our newest teams to join SHINE and hit the ground running, having enrolled their 1st subject in February 2016, and already have 11 enrollments and perfect retention! This team is also very responsive to data queries and always has a positive attitude. It is this kind of commitment to the SHINE trial that will continue to make SHINE a successful study!

Back: Javaad Ahmad, MD; Stephen Griffiths, Errol Gordon, MD, Stephan Mayer, MD; Danielle Wheelwright, RN, Front: Pavis Laengvejkal, MD; Neha Dangayach, MD, Ruth Levy, NP.

SHINE MOP Updates

- **Version 6 of the MOP is ready, changes include:**
  - Addition of some helpful FAQs
  - Glargine (Lantus) dose calculation clarification
  - Appendices 2, 6, 8, and 9 have been updated
  - Administrative updates throughout

WebDCU™ Reminders

- Form 12: Unblinding Questionnaire: If the subject says 'very sure' to treatment assignment assigned, please explain their reasoning in the general comment section on form 12.
- Pharmacy personnel must be added to the eDOA, and will not need an account activated in WebDCU.
- Please enter data in window for 6 week & 90 day outcomes

Updates from the CCC

SAE - Narrative Templates

Using a template to develop a narrative helps in guiding the level of detail to include, ensures adequate relevant information is included, and aids with a quick review by reducing the number of data clarification queries as well. To help sites, SAE narrative templates are available for the most commonly reported SAEs on the SHINE study. The templates are a valuable tool and this is a kind reminder to use the template to develop SAE narrative. Please don't hesitate to contact me if you have questions regarding completing the SAE CRF or drafting a narrative. Link to SHINE SAE Templates: https://nett.umich.edu/clinical-trials/shine/toolbox#SAE

New and Departed Team Members

Add all new team members to 'Study Team Member Request' table and also 'Request User Permissions' as appropriate to their role. In addition, the team members will need to be added to the eDOA log with start date along with study responsibilities. After the eDOA is accepted, required trainings will populate in the database. Following these steps helps everyone ensure regulatory compliance for trainings and certifications are reconciled and current in the database for the new team member.

If a team member has departed, steps are posted in the SHINE FAQs to make them inactive and remove their access and permissions to WebDCU™ SHINE. In addition, follow local IRB guidelines for team member changes, as applicable. Upload the acknowledgement from IRB as "IRB Modification Notification". Link to regulatory database FAQs: https://nett.umich.edu/clinical-trials/shine/faqs#RegDatabase

Arthi Ramakrishnan, SHINE Site Manager

Best Practices for Enrolling a transfer INR patient into SHINE from Mayo Jacksonville

Our recent SHINE enrollment on November 17th was a stellar example of teamwork. We received a Tier 2 Brain Attack page around 6 pm, which indicates a hospital-hospital transfer patient that could potentially go to interventional radiology, so I texted the Neurocritical care attending, Dr. W. David Freeman, and asked him to notify me when the patient was back in the unit. Dr. Freeman and his fellow, Dr. Michael Pizzi, were excellent about sending me updates on the patient's arrival, his medical history, the estimated arrival of the spouse, the status of the patient during the IR procedure, his follow up NIHSS, and when he was back in the unit. After 5 hours of screening and waiting, Dr. Rocio Vazquez do Campo, the neurology resident on call, texted me when the patient's wife arrived and introduced her to the study so when I arrived around 11 pm she was ready to review the consent form. Her previous experience participating in a research study was very helpful and she had a great understanding of the requirements. We talked about the 90 day follow up visit, which would be difficult to manage since they live 3 hours away, but I gave her plenty of options that we could look into, including traveling to another SHINE site, our team traveling to them, or paying for their transportation back to our hospital or another affiliated institution where we could complete the visit via Telemedicine. This enrollment wouldn't have been possible without the consistent text updates from the physicians, especially in regards to extubation after the IR procedure.

Emily Edwards, SHINE PSC

Stroke Mimics - Best Practices

SHINE has a stroke mimic rate of 5% and further reduction of this rate is possible. Below are best practices and neuroimaging options.

When to consider a stroke mimic:

Patients with a history of migraine headaches, particularly migraine with aura - If headache, complex visual disturbance, or marching/evolving symptoms are present at onset then consider a migrainous basis for stroke-like deficits.

General medical illness and history of prior stroke— Patients with prior strokes can have worsening/reactivation of prior deficits in the setting of acute infection (i.e. urinary tract infection, chest infection) or metabolic disturbance (i.e. acute renal failure). Knowledge of prior stroke symptoms and degree of recovery can inform current acute stroke symptoms are likely due to new or old cerebral ischemia.

Unwitnessed symptom onset - History of epilepsy, use of anti-epileptic drugs, or evidence of tongue biting/incontinence should prompt consideration of a post-ictal deficit (i.e. Todd's paralysis).

Younger than usual patient without significant stroke risk factors - Variable, inconsistent, and distractible deficits are uncommon in acute ischemic stroke and should raise the possibility of a functional disorder (conversion disorder).

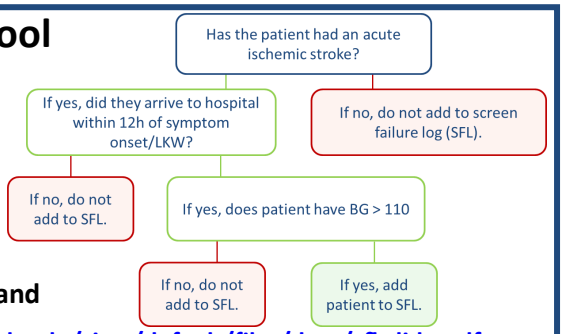
Utilization of neuroimaging to confirm ischemic stroke diagnosis:

Brain MRI – Diffusion weighted imaging (DWI) is sensitive to acute ischemia and can provide diagnostic confirmation of ischemic stroke *prior* to enrollment. It is important to note that false-negative DWI results may occur in up to 5% of ischemic stroke cases. DWI negative stroke is associated with brainstem and lacunar infarction likely due to the inherent difficulty in imaging the posterior fossa and the relatively smaller volume of infarction. As a consequence, a clinical diagnosis of stroke can be rendered with a negative DWI result in carefully selected patients.

CT angiography/CT perfusion – Advanced CT imaging can be used in conjunction with non-contrast head CT to confirm ischemia as the cause of stroke symptoms. Evidence of vascular occlusion or perfusion deficit in the clinically relevant territory can confirm ischemic stroke. We encourage sites to use their best clinical judgement when determining eligibility for SHINE. As a reminder, a SHINE PI is available 24/7 on the study hotline to help consider this and other inclusion and exclusion criteria.

Kevin Barrett, MD SHINE Recruitment PI

New SFL Tool



Found in MOP and
https://nett.umich.edu/sites/default/files/docs/sfl.slide.pdf

SHINE Study Hotline 800-915-7320

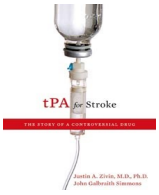
You must call when:

- Subject experiences BG < 70 mg/dL 3 times within 24 hours
- When BG < 40 mg/dL
- When BG ≥ 500 mg/dL

I-SPOT

Insights on Selected Procoagulation markers and Outcomes in stroke Trial

Total Enrollment:152
IV tPA subjects: 33



Remember that subjects who receive **IA** treatments are NOT eligible for I-SPOT but those who get **IV tPA** are eligible.

A big thank you to all teams who enrolled in I-SPOT!

Please come see us at ISC Hall E #CTP27!

Questions call the I-SPOT hotline: (774) 234-7768

Hannah Reimer, I-SPOT Project Manager

INTERNATIONAL STROKE CONFERENCE 2017

Please make plans to join the SHINE leadership team at the Ongoing Clinical Trials Poster Session on Thursday, February 23, from 6:15-6:45PM in Hall E #CTP9. Again this year, the poster will highlight the successes of many of our study teams. Hope to see you there.

WHO TO CONTACT

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SAE reporting & regulatory — Arthi Ramakrishnan — arthrama@med.umich.edu
Recruitment/retention — Katrina van de Bruinhorst — katrina.vandebruinhorst@utsouthwestern.edu
CRF completion/data management — Kavita Patel — pateka@musc.edu
Ancillary contracts/invoicing — Emily Gray— eaw8t@virginia.edu

24 hour Emergency Contacts:
SHINE Study Hotline — 800-915-7320
WebDCU Emergency Randomization Hotline — 1-866-450-2016
I-SPOT Study Hotline — 744-234-7768