Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

September 2016 – Volume 4, Issue 3

IN THIS ISSUE

As summer turns into fall, we write to provide updates on the SHINE trial and share information that we think may be useful to our study teams.

In this issue of the newsletter, we highlight **Best Practices** for; the SHINE Trial Portal, key retention strategies, and the newly available **CME Stroke Training Webinar**. We encourage all nurses/MDs to earn credit with us, and other members of your team to review if the like.

A friendly reminder, now that *new* fellows and residents have joined our national SHINE teams, to encourage all members to follow us on Twitter (@SHINE_TRIAL) and to download our *re-released* SHINE recruitment App to help screen potential SHINE subjects. This issue also features a **Special Announcement** highlighting *a novel web-based stroke clinical trials screening and enrolling survey tool* developed by our collaborators Drs. Ilana Spokoyny and Karen Hirsch at Stanford University. Thanks so much to them for sharing this tool with all of us.

Finally, we share with you the latest findings from our recent **SHINE Protocol Adherence Report** which is based on 847 subjects. Sites are continuing to collect high quality data, and are doing so with a *lower* overall rate of protocol deviations! Congratulations to all SHINE sites for your continuous efforts to capture all SHINE eligible patients and collect the best quality data possible. Your efforts do not go unnoticed! 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**

SHINE Bravo Zulu Award

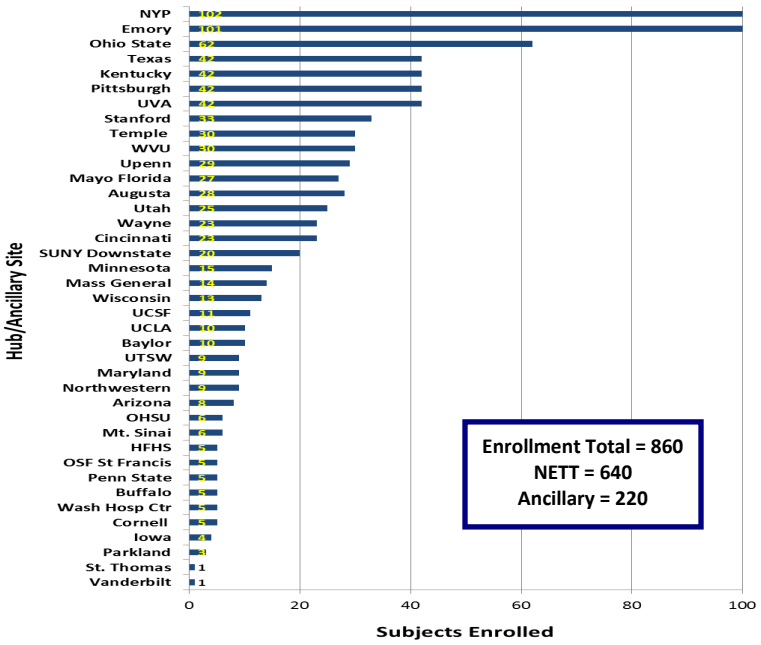
Our sincere congratulations to our SHINE study team at **SUNY Downstate**, this quarter's recipient of the SHINE Bravo Zulu flag. The Bravo Zulu flag is traditionally used by US naval forces to publically recognize a job especially well done.

The SHINE study teams at **SUNY Downstate** have been model teams for responsiveness to data queries, positive attitude and due diligence for retention with a rescue of a subject thought lost to follow-up. They always go above and beyond. On top of that, SUNY Downstate enrolled 4 subjects in June, totaling 20 subjects in the trial with a perfect rate of retention. Many thanks for all your efforts!

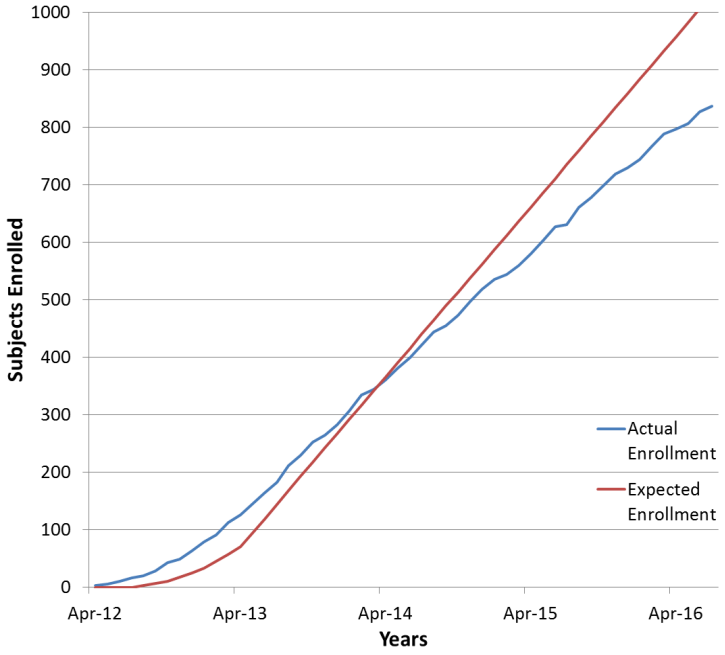
SUNY Downstate/Kings County team's from left to right are: Bryce Petty, Dr. Steven Levine, Motria Mishko, Sarah Weingast, Dr. Richard Sinert, Nadege Gilles, Dr. Yongwoo Kim.

Lincoln's team from left to right are: Dr. Shekar Murthy, Dr. Kennedy Omonuwa, Dr. Riyad Basir, Dr. Nicholas Caputo, Jessica Montalvo and Dr. Balavenkatesh. Missing members are: Drs. Martindale, Law, Zehtabchi, Valsamis, Marchidann, Paladino, and Sandor Vasvari.

SHINE Enrollment by Site through Aug 2016



SHINE Enrollment—Actual vs Expected—Apr 2012– Aug 2016



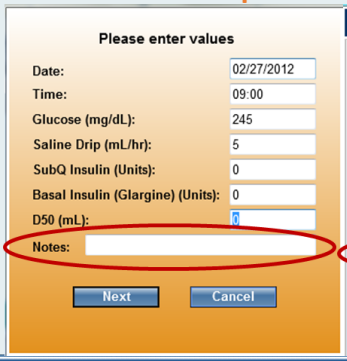
SHINE Trial Portal: Best Practices

All, **please** encourage your clinical nurses to enter any/ all useful comments in the *notes/comments* box in the SHINE Trial Portal on the SHINE laptop.

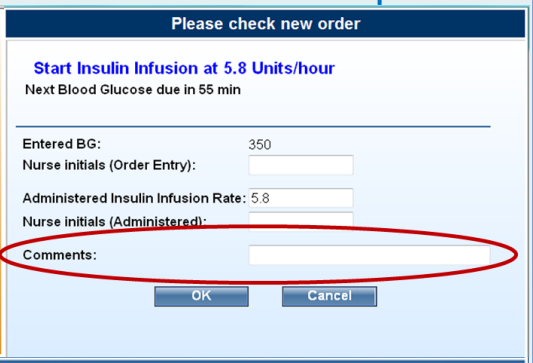
Although not required, when the clinical nurses enter the required glucose levels, it is extremely helpful to have comments in the notes/comments box for relevant activities such as; **drip on hold; subject off the unit for an MRI, new drip started, or stopping protocol treatment early for discharge**. This helps us tremendously with our monitoring of subjects. Many thanks in advance for your efforts.

Askiel Bruno, MD, MSc
SHINE Protocol Adherence PI

Control Group



Intervention Group



*** This version is for testing and demonstration only. Do not use on a real patient. ***

SHINE Subject ID: 123 | New Event | Remove | Hide Protocol | Logged In: shine | Unit: University of Virginia | Tools | Lock Program | Log Out

Date/Time	Glucose (mg/dL)	Saline Drip (mL/hour)	SubQ Insulin If Applicable (Units)	Basal Insulin (Glargine) (Units)	D50 (mL)	Notes
08/08/2013 09:04	177	4	0	0	0	
08/08/2013 05:47	182	5	4	8	0	Advanced to Level 3 at 05:45. Lantus +SQ reg dose
08/08/2013 02:57	189	5	0	0	0	
08/07/2013 23:54	198	5	4	0	0	
08/07/2013 20:58	206	5	0	0	0	
08/07/2013 18:02	196	4	4	0	0	
~~08/07/2013 15:05~~	~~188~~	~~5~~	~~8~~	~~8~~	~~8~~	
08/07/2013 15:04	186	5	0	0	0	
08/07/2013 11:46	211	5	6	0	0	
08/07/2013 09:07	231	5	0	0	0	
08/07/2013 06:02	201	5	6	0	0	Advanced to Level 2 at 05:45.
08/07/2013 03:05	180	5	0	0	0	
08/06/2013 23:51	184	5	2	0	0	

Retention Strategies: Best Practices

The primary endpoint in SHINE is the blinded, in-person 90 day assessment of the modified Rankin Scale. The importance of capturing this blinded outcome is a top priority for the SHINE trial. We share the following suggestions and best practices as potential opportunities to improve retention:

- ***Introduce and emphasize the importance of follow-up at the time of initial discussion regarding SHINE trial participation*** – consider placing equal importance on acute management of blood glucose in the first 72 hours post-stroke and need for follow-up neurological assessment as requisites of study participation.
- ***Provide specifics of follow-up at time of consent*** – 6 week telephone follow-up & 90 day in-person follow-up.
- ***Explore potential barriers to follow-up at the time of consent*** – where does the patient live? How does the patient prefer to communicate? Email, text, phone? Does the patient have independent transportation or rely on alternative sources.
- ***Develop rapport with patient and family/friends during the course of acute hospitalization*** – identify the most reliable person to serve as a point of communication following hospital discharge. Establishing rapport during hospitalization may improve the probability of successful follow-up after discharge.
- ***At discharge, remind patient/family of importance and timing of follow-up*** – confirm best contact numbers, back-up numbers, email contacts and contact preference (phone, text, email).

Kevin Barrett, MD SHINE Recruitment PI

Recognizing our SHINE Sites

- Congratulations to the Emory-Grady Memorial Hospital team on reaching your 100th enrollment on August 11th, 2016 and on your amazing enrollment surge of 8 enrollments this past quarter (Jun-Aug). Kudos to the entire Emory-Grady team!
- Congratulations to the WVU team for enrolling 3 subjects in August, two of which were back to back enrollments. Way to GO WVU!
- Congratulations to Memorial Hermann Texas for enrolling 3 subjects this past quarter even though short staffed! Your team is a role model for us all.

The SHINE leadership team congratulates you on your endless hard work, dedication, and commitment to excellence. Our thanks to the entire team for your outstanding efforts to screen and enroll in the SHINE trial.

SHINE Executive Team

Clinician Stroke Training Webinar (CME/CE credit eligible)

Nurses and physicians may earn up to 2.0 *AMA PRA Category 1 credit™* (s) for completing the training (one time only). The University of Virginia CME office will track course completion and credit. *Please use* Firefox, Chrome, Safari, or Internet Explorer 9 and above. This link is located on the NETT site in Nurse Education & Tools tab.

A special *thank you to* UVA's Sonya Gunter for creating a flyer to help inform our study teams of the CME Stroke Training Webinar. Please share with your teams. The flyer is posted to the Toolbox under Other and can be *edited* to include your specific site's contact information.

Heather M. Haughey
SHINE Project Director

***Special Announcement:* A Novel Stroke Clinical Trials Screening and Enrolling Survey Tool has been Developed**

Drs. Ilana Spokoyny and Karen Hirsch, Neurologists at Stanford University, have developed a **web-based** stroke clinical trials screening and enrolling survey tool utilizing the Research Electronic Data Capture (REDCap) database. They chose to develop their survey tool in REDCap because: 1) it is institutionally approved for protected health information, HIPAA-complaint, 2) it is free for their researchers and accessible via a weblink from any internet browser via either cellular or Wi-Fi networks, and 3) the survey uses conditional logic ("branching logic" in REDCap) to sort the applicable trial eligibility choices.

Once the clinical team enters basic demographics, stroke type, NIHSS, and time since last known well, the survey then presents a list of trials for which the patient may be eligible, along with a brief description of each trial and a list of inclusion criteria. The stroke clinicians/fellows complete a survey within 30 minutes of notification about a patient, and REDCap automatically generates a secure email to the study coordinators with the screening results. The primary Investigator(s) for certain time-sensitive trials also receive automated email notifications if a patient screens eligible for their trial.

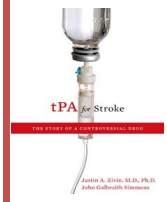
After twelve weeks of use, there was an increase in enrollment from 16.5% of patients screened to 23.4% of patients screened ($p<0.05$). Clinicians and coordinators reported increased satisfaction with the process and improved ease of screening.

Importantly, **this tool lends itself to adaptation at other sites** and in other medical fields and the framework could be implemented on different platforms. If your site has REDCap and you would like to implement this tool at your institution, please Contact: khirsch@stanford.edu for more information.

Spokoyny I and Hirsch KG. A Novel Web-Based Semi-Automated Tool Improves Stroke Clinical Trial Screening and Enrollment. *Stroke.* 2016 *in press*

I-SPOT
Insights on Selected Procoagulation markers and Outcomes in stroke Trial

Total Enrollment:129
IV tPA subjects: 21



With the addition of IV tPA subjects I-SPOT enrollment has greatly increased this past quarter. A big thank you to all teams who enrolled in I-SPOT!

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

Hannah Reimer, I-SPOT Project Manager

SHINE and Daylight Savings Time

Daylight saving time begins on **Sunday, November 6th, at 2:00AM** local time. Because the time change will affect management of the trial protocol, the SHINE PI's on call are ready to help support our study teams. Please contact the study hotline (800-915-7320) if you have an enrolled study patient during this time.

Windows Updates

Please maintain a schedule to check and update the laptops monthly and at the time of each enrollment.

SHINE

WebDCU™ Data → Information → Knowledge

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

I-SPOT