



Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

December 2014 – Volume 3 Issue 1

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We continue to celebrate year 4 of the SHINE trial. Enrollment has surpassed the 500 subject mark which means we are approaching the first planned interim analysis. We thank all of our sites for their continued hard work. As we have shared with you, we plan to activate our remaining 8 sites by early 2015.

We would like to welcome **St. Thomas Hospital**, which is the most recently activated SHINE site. In addition, congratulations to the

following study teams for their recent first enrollments in SHINE: **Sinai-Grace Hospital** (spoke of Wayne State), **William Beaumont Troy Hospital** (spoke of Wayne State), **Emory University Hospital Midtown** (spoke of Emory), **Northwestern University**, **Vanderbilt University Medical Center** and **Buffalo General Medical Center**.

In this edition of the newsletter, we are featuring the study teams at the University of Kentucky, Wayne State University and Northwestern University for their unique contributions in the past quarter. We have included information about follow up visits and the treatment protocol and introduce Dr. Kevin Barrett who has joined our leadership team to support recruitment efforts.

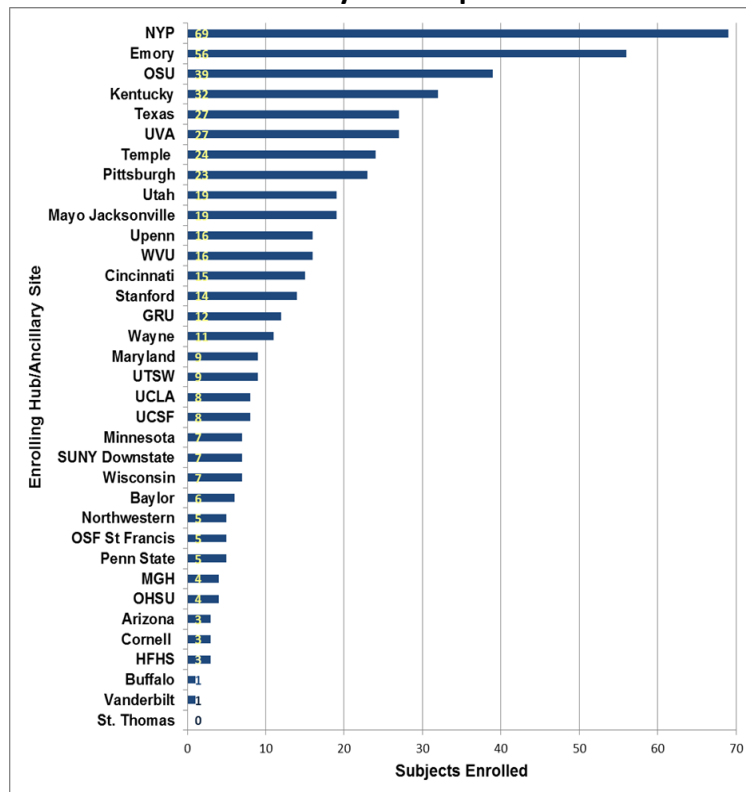
We are here to support you in your efforts to make SHINE a continued success. Please contact us if we can help in any way.

Best,
Karen C. Johnston, MD, MSc, SHINE Administrative PI
On behalf on the SHINE team



Please make plans to join the SHINE leadership team at the Ongoing Clinical Trials Poster Session on Thursday, February 12, from 6:15-6:45PM in Hall D. Again this year, the poster will highlight the successes of many of our study teams. Hope to see you there.

SHINE Enrollment by Site—Apr 2012-Dec 2014



SHINE Bravo Zulu Flag

The Bravo Zulu flag has traditionally been used by US naval forces to indicate a job especially well done. The flag is flown to publically indicate the excellent work of the team.

Our congratulations go to the **University of Kentucky** team for capturing the Bravo Zulu flag for this quarter. This a rock solid team who has been outstanding participants and has gone above and beyond as good citizens in the SHINE trial. They have been consistently high enrollers (6 last quarter and 5 in August), perfect retention, they have incredibly high quality data, and they were our first site to do remote monitoring with the CCC. They have shared materials, advice, and experience with many of us to allow our sites to learn new approaches to being successful in SHINE.

We thank our Kentucky team for all their hard work and congratulate them on the Bravo Zulu flag!

Karen C. Johnston, SHINE PI

Welcome Kevin Barrett, MD, MSc to SHINE

The SHINE team is thrilled to welcome Dr. Kevin Barrett, from Mayo Clinic Florida, to our SHINE recruitment leadership team. Dr. Barrett is an Associate Professor of Neurology at the Mayo Clinic School of Medicine and the local PI for the Mayo Clinic Florida ancillary site.



He is also working with the CREST2 recruitment leadership team, so he will bring some fresh approaches to all of us participating in the SHINE trial. We expect that, if you haven't already, many of our SHINE sites will have a chance to meet him soon via webinar, calls, emails, etc.

We are excited to welcome Kevin to the team!

Karen C. Johnston, SHINE PI

Tips for successful enrollment from Northwestern University

The newly activated SHINE site, Northwestern University led by PI **Shyam Prabhakaran, MD**, and study coordinator, **Carlos Corado**, has had a very successful introduction to the trial. The study team enrolled their first subject in SHINE on Nov 7, 2014, and then their



From left: Shyam Prabhakaran, Carlos Corado, and Holly Wilson,

2nd and 3rd enrollments quickly followed that same week. Within a few short weeks, the Northwestern team has now enrolled 5 subjects in SHINE. While managing a large volume of enrollment activity, the team has also successfully navigated the treatment protocol, and has offered to share the tips below about things to be mindful of during early enrollments.

- 1) Confirm nursing documentation of glucose measurements and study treatment dosing in real time both in the study laptop and medical record.
- 2) Monitor dietary changes and meals.
- 3) Test wireless connectivity throughout any of the locations where a SHINE patient might be admitted.

The team credits their success to a thorough screening process and also to one of their fellows, **Rajbeer Sangha, MD**, for his very valuable contribution to the process. We couldn't be more pleased with their performance and are thrilled to have them on our team.

Amy Fansler, SHINE Project Director



SHINE Recognition System

Congratulations to the **Wayne State** hub for winning the hub-spoke complex division for the last quarter. Wayne State had first enrollments at 2 of its spokes, Beaumont Troy and Sinai-Grace. Additionally, the HUB, Detroit Receiving, enrolled as well. All three sites completed their follow up visits within the primary outcome window and all three received bonus points during the previous quarter.

And further congratulations to **Kentucky** for winning the individual site division for the last quarter. The Kentucky HUB had its best quarter and month ever, having enrolled 6 patients over the previous quarter and 5 in the month of August. Additionally, the site received additional points over the previous quarter for perfect retention, excellent screen fail logs, keeping regulatory documents up to date and for completing CRF's in a timely manner.

Katrina van de Bruinhorst, SHINE Recruitment Specialist

Operation Maximize Retention is up and running and every week reports of remarkable "saves" are coming in from SHINE sites across the country. Our retention rate needle is notching up by degrees as a result but still requires intensive attention to *reach and maintain* maximal retention throughout the trial.

One truly valuable part of our multi-prong program for supporting these crucial retention goals is the NETT/SHINE SOP for a brief review on the weekly NETT Operations call during SHINE time of those frustrating cases that "got away" despite best efforts. The stories always reflect the most difficult follow up cases and dedicated study teams who tried every reasonable approach. The output is to see if the many contributors on the NETT Ops call collectively can generate any novel strategies for the challenges these tough cases highlight and in this way share across all teams in SHINE (and NETT) an ever lengthening list of helpful tactics to help to capture these follow ups even in the most challenging situations as these cases bring out.

Format

- ◇ Briefly Report—2-4 minutes (tell the story) on Wednesday NETT ops call (within 2 weeks of recognition of LTFU)
- ◇ Ideally report is given by the study team member closest to the case who knows it best
- ◇ Group discussion and idea generation among all on the call which is highly supportive with the goal to identify new, different alternative things to try "that might" lead to breakthroughs for future teams with similar challenging cases
- ◇ Discussions are very enthusiastic and VERY supportive
- ◇ ROI for reaching retention goals – Huge!!

Christiana Hall, SHINE PI



SHINE Treatment Protocol Reminders

One of the more common questions on the study hotline is managing the end of the SHINE treatment protocol. Included below are reminders about the protocol for discontinuing treatment and instructions for documenting.

End of Treatment

- Study treatment should be discontinued at 72 hours from the time of randomization or 6 hours in advance of hospital discharge, whichever comes first.
- Please work with your team to make a plan to transition to standard care glucose management. No overlap between protocol and non-protocol treatments is permitted.
- Use the previous glucose level and change the infusion rate to 0 to document the infusion stop. Reference the screen shots below to make the final entry in the study laptop, close the internet browser and power down.

SQ Saline

For intervention patients that are NPO or on continuous tube feeds, SQ saline 0.05mL is administered after the glucose check closest to 09:00 and 21:00 to maintain the blind.

While not required, consider entering a note in the Comments field of the GlucoStabilizer infusion rate recommendation to help prompt the nurse to also administer SQ saline per protocol (see below).

Please contact the SHINE trial hotline (800-915-7320) with urgent questions about the protocol. Non-urgent questions can be directed to Amy Fansler (acf7h@virginia.edu)

Amy Fansler, SHINE Project Director

Updates from the CCC

Regulatory updates:

If your site has a new team member, kindly add them to 'people' table and make them active in the 'project spoke team member table' (PTSM) in WebDCU. In addition update the DoA log with start date along with study responsibilities, as well and upload the updated log. This helps us ensure all trainings and documents are present and current for the new team member.

If a team member has departed, make them inactive in the PSTM table and update DoA with end date of responsibilities and upload document. In addition, follow local IRB guidelines for team member changes. Upload the acknowledgement from IRB as "SHINE IRB Study Modification Notification". Also, when a team member at your spoke has departed, please notify the data manager for that trial to update that person's WebDCU™ permissions.

SAE Templates:

Just a reminder that SAE narrative templates are available for sites to use for events most commonly reported on the SHINE study. Kindly use the SAE templates (posted under SHINE Toolbox) to develop your site's SAE narrative. Please don't hesitate to contact me if you have questions regarding completing the SAE CRF or writing a narrative.

Arthi Ramakrishnan, SHINE Site Manager



Insights on Selected Procoagulation markers and Outcomes in stroke Trial

The **SPOT ON** Award goes to the following sites who enrolled SHINE subjects this quarter and did not miss a single I-SPOT enrollment: Beaumont

Troy, Detroit Receiving, Emory Midtown, Froedtert, Grady, Mayo, Memorial Hermann, Columbia, Sinai-Grace, Temple, University of Kentucky, University of Arizona, Hospital of the UPenn, UPMC Presbyterian, Utah, UVA and Wexner.

Many thanks to the sites who enrolled this quarter: Froedtert, Grady, UPMC Presbyterian and Temple.

Total I-SPOT enrollment is 62.

Hannah Reimer, I-SPOT Project Manager

Who to contact

Protocol questions – Amy Fansler – (434) 982-6027 or acf7h@virginia.edu
 Budget & contracts questions - Amy Fansler – (434) 982-6027 or acf7h@virginia.edu
 General education and training – Joy Pinkerton – (734) 232-2138 or joypink@umich.edu
 I-SPOT questions – Hannah Reimer – 215-707-5483 or hreimer@temple.edu
 Laptop questions – Amy Fansler – (434) 982-6027 or acf7h@virginia.edu
 Regulatory & site readiness – Arthi Ramakrishnan – (734) 936-2454 or arthrama@umich.edu
 WebDCU support – Kavita Patel – (843) 876-1167 or pateka@muscc.edu

24 hour emergency contacts:

SHINE Study Hotline – 800-915-7320 (Ext 1: PI on Call, Ext 2: Safety Monitor)
 WebDCU Emergency Randomization Hotline – 1-866-450-2016
 I-SPOT Study Hotline – 774-234-7768