Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

May 2015 – Volume 3, Issue 3

IN THIS ISSUE

- **Recruitment & Enrollment Updates**
- **Bravo Zulu Award**
- **FAQs**
- **WebDCU Updates**
- **StrokeNet and SHINE**
- **Team Member Spotlight**
- **Site Recognition**
- **SHINE on Social Media**
- **ISPOT**
- **Who to Contact**

We would like to welcome one new site, MedStar Washington Hospital Center, to the SHINE team. Washington Hospital Center is our second StrokeNet site that was not previously participating in SHINE to be activated for the trial, and we are excited to have them on board.

Many of our SHINE sites have utilized thoughtful and creative approaches to strengthen recruitment, retention, or develop other study resources. In this issue of the newsletter, we have shared some creative ways our NETT and StrokeNet sites are maximizing resources.

We would also like to extend our sincere thanks to the CCC team for their continued support of the trial. This quarter, we would like to recognize one of our site monitors for the trial, Donna Harsh, for her outstanding contributions.

Several teams within the trial developed novel resources for SHINE. Earlier this quarter, we introduced a video that highlights guiding principles of the informed consent process for SHINE. We have just announced a mobile SHINE app to help with enrollment decisions and hope that it will be launched this week or next. We have also started a SHINE twitter account where we'll be announcing important and fun information about the trial and sites.

As always, we welcome the input of our teams on any issues or ideas related to SHINE. Thanks again for all of your hard work.

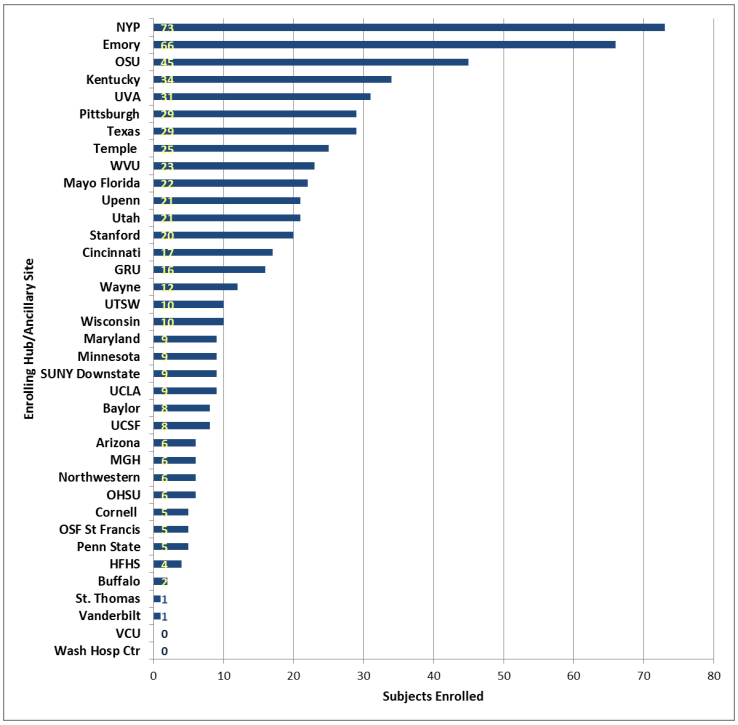
Karen C. Johnston, MD, MSc, SHINE Administrative PI
On behalf of the SHINE Team

SHINE Bravo Zulu Award

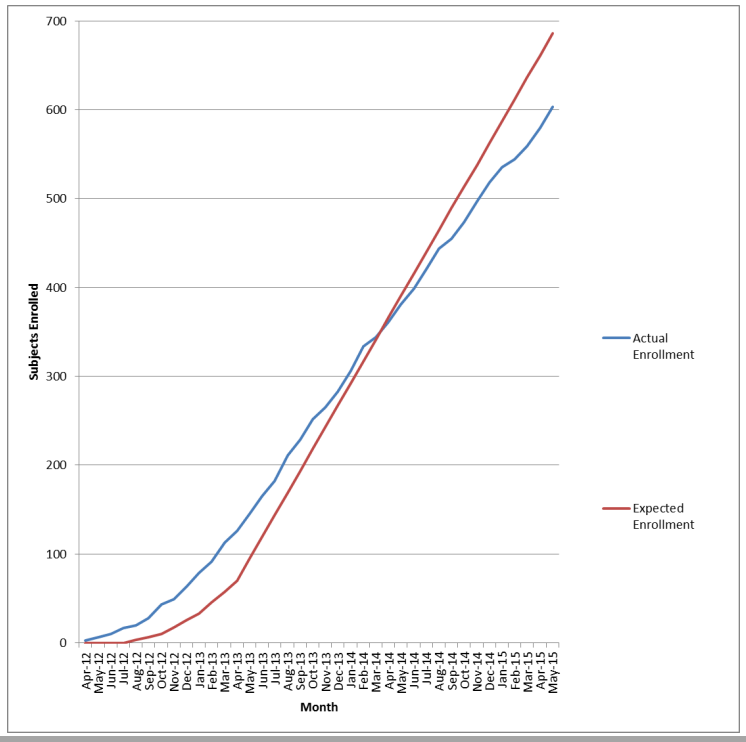
Our sincere congratulations to West Virginia University, this quarter's recipient of the SHINE Bravo Zulu flag! The Bravo Zulu flag is traditionally used by US naval forces to publically recognize a job especially well done.

The trial coordination at WVU is led by **Jay Sherman**, SHINE primary study coordinator, who was recently joined by **Hannah Yetzer.** The site consistently receives high marks for data quality, meeting participation and for being known as an all-around top notch team. On top of that, WVU has enrolled 5 subjects in the last quarter. Many thanks for all of your efforts!

SHINE Enrollment by Site
Apr 2012-May 2015



SHINE Enrollment—Expected vs Actual
Apr 2012-May 2015



Frequently Asked Questions (FAQs)

Q: We are screening a patient who meets all inclusion criteria. However, there is concern that the patient appears to be very insulin resistant and if they are enrolled in the control group, we are concerned about crossing the safety boundary of glucose ≥500 mg/dL. How should we proceed?

A: Sites should use clinical judgment and consult with the local treating team to decide how best to proceed. Please keep in mind that, in the control group, all patients start at Level 1 for the first 24 hours from randomization. This means that the maximum SQ insulin dose per the sliding scale during Day 1 is 32 units based on the patient's blood sugar level. Once enrolled, a call to the study hotline is required for any glucose level of 500 or greater.

Q: Does the time of randomization or the time that the study infusion is started apply when considering the 12 hour rule from symptom onset for SHINE eligibility?

A: All study patients must be randomized within 12 hours of symptom onset or last known well. As a reminder, 3 CRFs – Eligibility, NIHSS and Randomization must be completed in order to randomize. If the time from symptom onset or last known well is greater than 12 hours from the time that the final CRF, the Randomization CRF, is submitted in WebDCU, randomization will be blocked. Treatment should be started as soon as possible after randomization. Whereas emergency randomization is available in case of system technical difficulties within 12 hours of onset, no emergency or alternative randomization is allowed after 12 hours.

Q. In the very rare situation when an acute stroke patient is anticipated to require plasma exchange therapy during the first 3 days post stroke, what would the expected impact be on the glucose levels and insulin treatment?

A. During plasma exchange (PLEX) therapy, it is believed that some insulin dissolved in the plasma portion of blood is removed and dextrose is typically added. Both of these would interfere with blood glucose regulation by the SHINE protocol in both treatment groups. For this reason, patients expecting to receive PLEX during the first 3 days post-stroke should not be enrolled in the SHINE trial. If a patient is enrolled in SHINE and requires PLEX therapy during the treatment period, given the potential interference of the therapy on glucose regulation, contact the study hotline to discuss the safety of continuing on the treatment protocol.

StrokeNet Support of SHINE

Sites with both NETT and StrokeNet funding have been encouraged by NINDS to consider collaborative ways to share resources to support the SHINE Trial. We would like to thank these sites for the hard work they put into developing and implementing the sharing of resources at their institutions. Below are a few examples of what sites have done to support SHINE activity at their institutions.

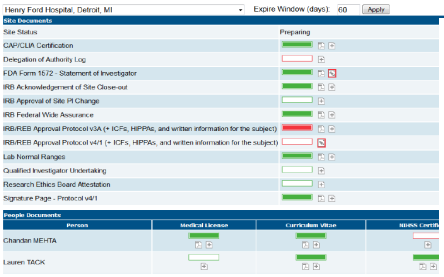
Stanford—The Stanford StrokeNet and NETT teams work together in close collaboration to identify and improve logistical issues around the study. As a recent example, the NETT coordinators identified potential missed eligible patients that were being transferred for interventional procedures. The teams worked together to develop a new protocol for all stroke transfer patients and patients receiving endovascular therapy to have an automatic notification to the NETT team, and the fellows developed a new protocol for serial finger-sticks pre- and post- endovascular therapy.

Emory—The addition of the StrokeNet infrastructure award has afforded Emory an even closer collaboration with our Neurology and Neurointensivist faculty, and has allowed us to explore the option of strengthening our night/weekend coverage by moving away from the current model of on-call coverage 24/7 to one of on-site coverage 24/7 (with a coordinator in hospital and actively screening, as opposed to just being available for enrollment calls). The Emory Hub/RCC strives to be a top tier enroller and performer in all our network trials. We are proud of our #2 ranking in SHINE, but won't really be satisfied until we're #1.

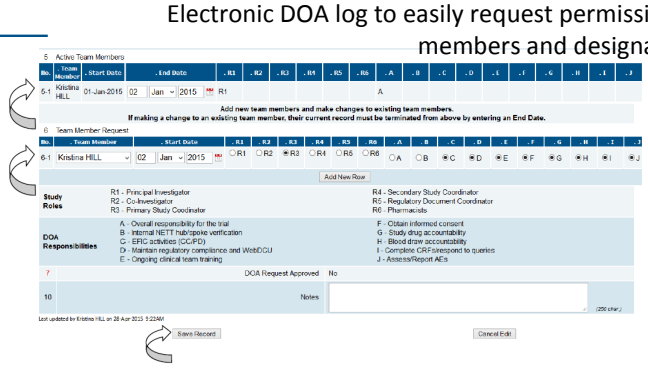
MGH—With StrokeNet support, team infrastructure has been enhanced to maximize the consistent presence of 24/7 on call team members during the protocol when dedicated research nurses are not available. The StrokeNet team has helped support the new "enroll first, plan coverage later" process which has been a driving factor in recent successes with SHINE. The plan requires ongoing commitment from the inpatient clinical teams, and in particular a confidence on the part of the clinical nurses that a research team member will be physically present throughout the protocol.

The complete list of site ideas is posted on the study website. Thanks again for the combined efforts to support the SHINE trial.

WebDCU Updates: Roll out June 2015



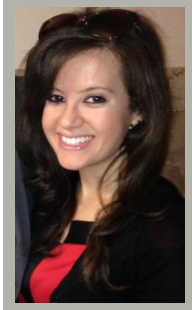
Efficiently update people documents and view upcoming expiration dates.



Electronic DOA log to easily request permissions for study team members and designate responsibilities.

Team Member Spotlight

Donna Harsh, NETT CCC
Clinical Trial Monitor
Donna joined the NETT nearly eight years ago as a clinical trial monitor. She has monitored sites across the US for ALIAS, RAMPART, SHINE, and ATACH-II. Many consider her to be a 'travel warrior' as she logs over 50,000 airline miles per year. In the coming months, remote monitoring (remote source data verification) should cut down the miles and time in airports.
Donna enjoys all aspects of clinical trials from trial design through closeout. Her favorite part is the interaction with study teams. She finds everyone is welcoming and the pride in their work is evident during the monitoring process. Outside of work Donna's favorite things to do: spend time with granddaughters, Isla and Evie, reading (great during airport delays and long flights), gardening and travel.
Donna is a tremendous asset to the SHINE team— thank you!



Valerie Mika, Wayne State University
NETT Project Manager, Primary Study Coordinator
Valerie recently went above and beyond to locate a study subject who would have otherwise been lost to follow up. We want to recognize her creative, out-of-the box thinking. She utilized many different resources, such as contacting local homeless shelters, rehabilitation centers, police stations, doctor's offices and death records to try and locate this subject.
We commend her exceptional retention efforts and dedication to SHINE!

Recognition System Update

Congratulations to the **Emory University Hub** for winning the quarterly recognition system for the HUB/spoke complex division and to the **Ohio State-Wexner** site for winning the individual site competition.

The points reset May 1 for the next quarter.

Want to recognize a team member for a job especially well done? Send your stories about any team member's outstanding efforts to Katrina van de Bruinhorst (katrina.vandebruinhorst@utsouthwestern.edu) to be included in the recognition system.

Recognizing our SHINE sites

Welcome **Medstar Washington Hospital Center**! The study team is led by PI **Richard Benson, MD**. Other team members include study coordinators **TJ Rodriguez** and **Preethy Feit**, and nurse champions **Shannon Burton** and **Karen Moriarty**. As a StrokeNet site, they are also participating in NINDS Intramural Trials and MR Witness. We welcome them to the SHINE team and look forward to their first enrollment!

Congratulations to **Wellspan York Hospital** (spoke of Penn) on their recent first enrollment! The SHINE Leadership Team would like to thank the Wellspan York team for their participation and doing an outstanding job with their first subject.

Left to Right: Brent Becker, MD (PI), Erik Kochert, MD (Co-I), Barbie Stahlman, MS (Study Coord.)

SHINE on Social Media

Download the newly released SHINE app for smartphones and tablets.

The app was developed by Zack Mahdavi, MD, a 4th year Neurology resident at UT Southwestern and is designed to aid study team members in determining eligibility and will be available for download in the iTunes store.

Follow SHINE on Twitter…

Follow the SHINE twitter feed at @SHINE_Trial to hear about study enrollments, protocol tips, study updates, and stroke related news. Instructions on accessing and following can be found on the study website.

I-SPOT

Insights on Selected Procoagulation markers and Outcomes in stroke Trial

Thanks for enrolling - we are BACK ON TRACK with an average of one enrollment per week and no eligible subjects missed at participating sites. Is your site not participating in I-SPOT, please join us...you'll be in very good company!

Hannah Reimer, I-SPOT Project Manager

We Need YOU!

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
Recruitment – Katrina van de Bruinhorst – (214) 648-9248 or katrina.vandebruinhorst@utsouthwestern.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@musc.edu

24 hour emergency contacts:
SHINE Study Hotline – 800-915-7320
WebDCU Emergency Randomization Hotline – 1-866-450-2016
I-SPOT Study Hotline – 774-234-7768