



Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

May 2014 – Volume 2 Issue 3

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What a productive spring. Thanks to all the sites who have had first enrollments, broken their previous enrollment records and especially to those sites that have gone above and beyond to enroll in SHINE. This quarter's newsletter will highlight all of your special efforts. We are introducing a new recognition point system, and also new, the SHINE Bravo Zulu flag which you can read about in the following pages. We also thank you for your input when

you've encountered unique situations or challenging cases with the trial protocol. We have added new FAQs and clarifications based on your suggestions. We will highlight the hypoglycemia protocol clarification in this newsletter.

We continue to bring up new sites and are excited to be working with 5 StrokeNet sites that are not currently enrolling in SHINE but have expressed interest in joining the trial. Since our last newsletter, the following sites have been activated to begin enrolling : University of Kansas Hospital (spoke of Minnesota), UTSW Parkland Hospital, Buffalo General Medical Center and Vanderbilt University Medical Center. In addition, congratulations to the teams at Abington Memorial Hospital a spoke of UPenn, Maimonides Medical Center, a spoke of SUNY Downstate, and University of Arizona Medical Center for their recent first enrollments.

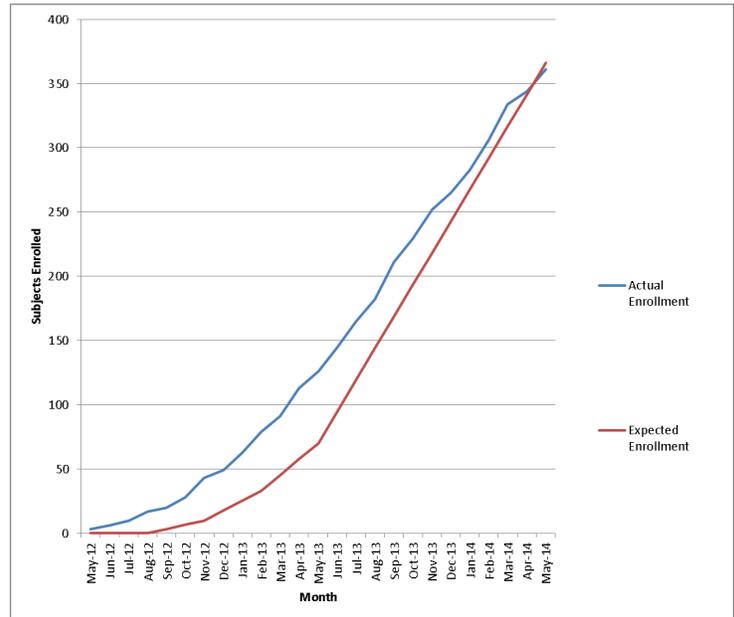
We continue to thank you all for your hard work. We are here to support you in your efforts to make SHINE a continued success. Please contact us if we can help in any way.

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

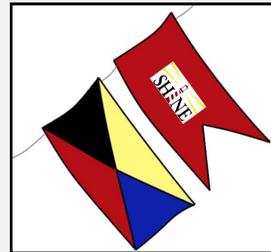
Welcome New SHINE Sites

We would like to extend a warm welcome to the following teams that have recently started the readiness process with SHINE. Northwestern University, University of Wisconsin, Madison, University of Iowa and the New York Collaborative are some of the StrokeNet sites not currently enrolling in SHINE that will be joining our team. Welcome!

SHINE Recruitment—April 2012-May 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.

The SHINE team will assign the SHINE Bravo Zulu flag to one team each quarter for a job well done that has substantially benefitted the entire SHINE team. The flag will be flown for the awarded team for the entire next quarter and be displayed at all SHINE meetings. Additionally, the sites deserving of this special recognition will be named on the study website with a running list of all past winners.

We would like to congratulate the team at **Columbia University Medical Center (CUMC)** for recently enrolling the 50th subject at their site. Our thanks to Dr. Jan Claassen, Cristina Faló, Angela Velasquez, Emma Meyers and the entire team. Columbia will be the first recipient of the SHINE Bravo Zulu flag. Congrats again!

Special thanks to...

1. University of Pennsylvania enrolled 2 SHINE patients in 1 night in fact within 2 hours of each other earlier in May. **Dr.**

Scott Kasner and **Jeanie Luciano**-Stroke Nurse Practitioner were present in house after hours to help with the enrollment. Dr. Kasner put in a call to the PI Line with a quick question and then he exclaimed "gotta go! We have another patient to enroll!"

The team credits the efforts of **Melissa Kruszewsky, Jason Marshall** and the **Neuro ICU Nurses** for their success. Strategic steps taken to minimize confusion while managing two simultaneous enrollments in the same treatment group included: patients not bedded side by side, different RNs, SHINE laptops located well apart and labeled clearly with the correct subject's name. All involved at U Penn agree the backbone of this tremendous success story was the entire Neuro ICU Nursing staff who rallied together to orchestrate this complex task of managing 2 SHINE patients on protocol at once! Congratulations!

2. Maimonides Hospital , a spoke of SUNY Downstate, successfully enrolled their first patient in May. **Dr. Steve Rudolph** stayed in house at the hospital overnight to personally support those earliest critical hours on protocol; then for the next 2 nights he checked in countless times. We are truly humbled and inspired by the incredible dedication of our New York collaborators.

3. Thanks to the creative preparedness, keen memory and sheer determination of **Olive Sanchez** from **Valley Baptist, a spoke of UT Houston**, their team was able to track down a subject who was unreachable after hospital discharge. Recognizing the risk posed by the fact the patient was out of work, Olive recorded his address and phone but also got to know him personally and his habit of frequenting the public library. She also met a friend and neighbor who visited the patient while he was hospitalized – and remembered him when it counted. So Olive, in the finest tradition that is trademark of the entire UT Houston NETT Hub and spoke team complex, with substantial effort, tracked him down via the public library and through having a comprehensive approach to retention.

These contributions earned admiration from all of the SHINE investigators as well as bonus points for their teams in the new SHINE Recognition system. Amazing feats in support of SHINE are happening nearly every day across the country, but we only know if you tell us!!! Please nominate your colleagues whenever you see their exceptional contributions – we love to tell the story and award bonus points!!!

Dr. Chris Hall, SHINE Recruitment PI



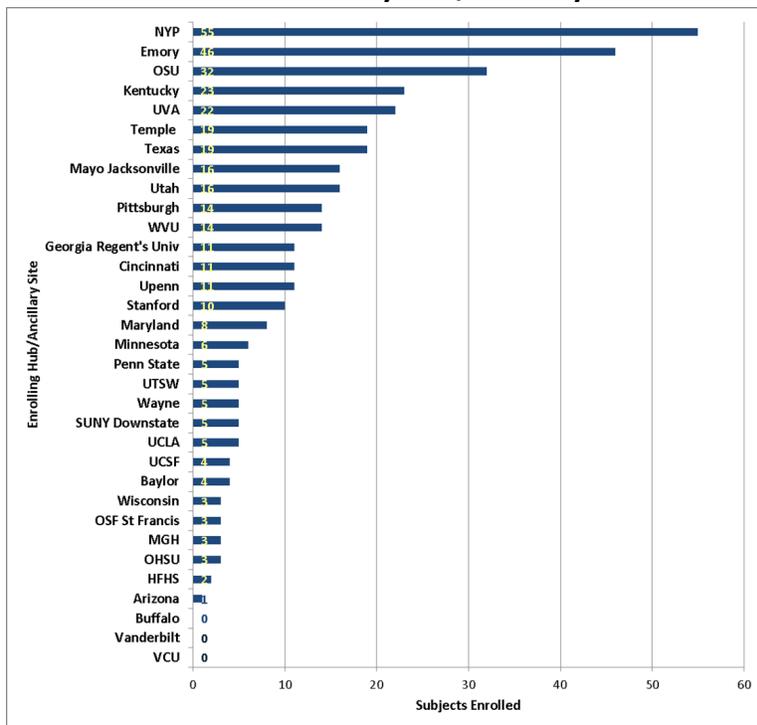
SHINE is everywhere

A picture taken near Temple University Hospital

Submitted by Vern Kalugdan and Brent Freeman, SHINE study team members at our Temple hub.



SHINE Enrollment by Hub/Ancillary Site



SHINE Recognition System—Go Live May 2014

Our goal for recruitment is to enroll a minimum of 25 subjects per month. We have created a SHINE recognition system to inspire a friendly competition between the sites and also recognize the varied efforts of our study teams. This system is completely independent of the NETT report cards and is SHINE-specific only. There are points available in 8 categories:

- Enrollment
- Retention
- CRF completion
- DCR Responses
- CRF completion
- Attendance on calls
- Updated regulatory documents
- Bonus points

Additional bonus points are available for exemplary effort and we welcome nominations from the sites. We are rewarding sites on exceeding their individual highest monthly enrollment ever as well as their highest quarterly enrollment ever. We will be recognizing sites at the end of every quarter based upon this point system and we'll be doing this through the various newsletters as well as on the coordinator calls. This recognition system went live May 1 and is reset quarterly in conjunction with the recruitment reports. Please nominate a colleague who has gone above and beyond for the SHINE trial.

Katrina van de Bruinhorst
SHINE Recruitment Specialist



Frequently Asked Questions (FAQs)

Q: We enrolled a patient who was cleared for a PO diet as soon as she was admitted to the stroke unit. At each meal, however, she has eaten none or nearly none of the food on the tray. Do we need to be giving her the SQ saline injections at 09:00 and 21:00 since she is not eating?

A: SQ saline should only be ordered for patients who are NPO or on continuous tube feeds. SQ meal insulin should be ordered for patients who have been cleared for a PO diet or are on bolus tube feeds. If a patient is cleared to eat but is not eating, do NOT give SQ saline. The decision about which SQ study treatment is appropriate in the intervention group should be based on the active diet order.

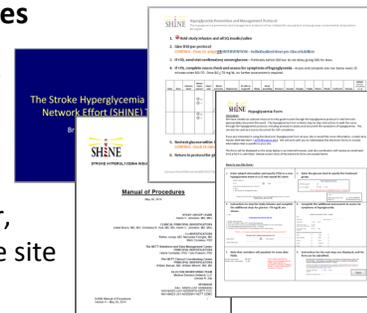
Q: We had a patient scheduled for his 90 day follow up visit that had to be rescheduled due to weather. Because this appointment got canceled, he will be out of the target window for the visit, but he will return to clinic next week. Are we able to do his study visit then?

A: Yes. The target for the 90 day visit will be (+/-) 14 days. Late data will be collected and analyzed for the 90 day visit with a window of (+30 days/-14 days) for the primary outcome. In the event that the study team cannot make contact with the participant/LAR, the mRS may be assessed using information provided by caregivers or other individuals with current knowledge of the patient's condition. Late data may be collected and analyzed for the 90 day visit with a window of (+90 days/-14 days) for secondary analyses. In the event that a subject is not lost to follow up but has missed the target for the primary analysis, it is recommended that the 90 day outcomes are captured whenever possible. SAEs will be captured from the time of randomization until the end of the study. End of study may be past 90days from randomization if the final study visit is conducted late however SAEs will not be captured past 120days from randomization or end of study, whichever occurs first.

New Study Resources

MOP Version 4 (20MAY2014) -

Note that a new version of the MOP has been released. The MOP is not required to be submitted to the IRB. However, based on local guidelines, some site IRBs might require this to be submitted for approval. For those sites whose IRBs require it, please submit and upload acknowledgement as once approval has been received.



Hypoglycemia and Meals Forms

Optional electronic forms have been developed for hypoglycemia and mealtimes. If a site chooses, these forms can be displayed on the study laptop in an internet browser, and site coordinators will receive an email each time a form is submitted. The forms contain step by step instructions that are specific to each treatment group to walk the nurse through the hypoglycemia protocol, including prompts to assess and document the symptoms of hypoglycemia and carry out the protocol for meals. If you are interested in more information, contact Amy Fansler (acf7h@virginia.edu). A more user-friendly hard copy hypoglycemia symptomatic questionnaire is also now available.

Materials for new team members, residents & fellows

Knowing that this time of year is filled with personnel changes and transitions, we want to make you aware of resources available to help train new team members. Please visit this study website or contact Amy Fansler (acf7h@virginia.edu) for one-on-one training options as well.

- Brief protocol refresher & full protocol training slides
- Mock patients resources with answer keys
- Treatment protocol reminders and cases



Introducing Mercedes Falciglia, MD

Please join us in welcoming Mercedes Falciglia, MD, as the new SHINE trial endocrinologist. Dr. Falciglia has played an integral role in SHINE at the University of Cincinnati and will now also be supporting the trial at the national level.

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

Total Enrollment: 42
I-SPOT Sites: 46

Congratulations to West Virginia University and UPMC Presbyterian on their first I-SPOT enrollments! And UKY (2), Mayo Jacksonville, Grady, University of Cincinnati, and Ohio State Wexner for their enrollments during this quarter!

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@musc.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