



Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

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As winter gives way to spring we are very excited to share with you updates on the SHINE trial and share some helpful SHINE trial tips.

In this issue of the newsletter, we highlight and congratulate our sites on their enrollment progress toward our new milestone goal, #roadto1000.

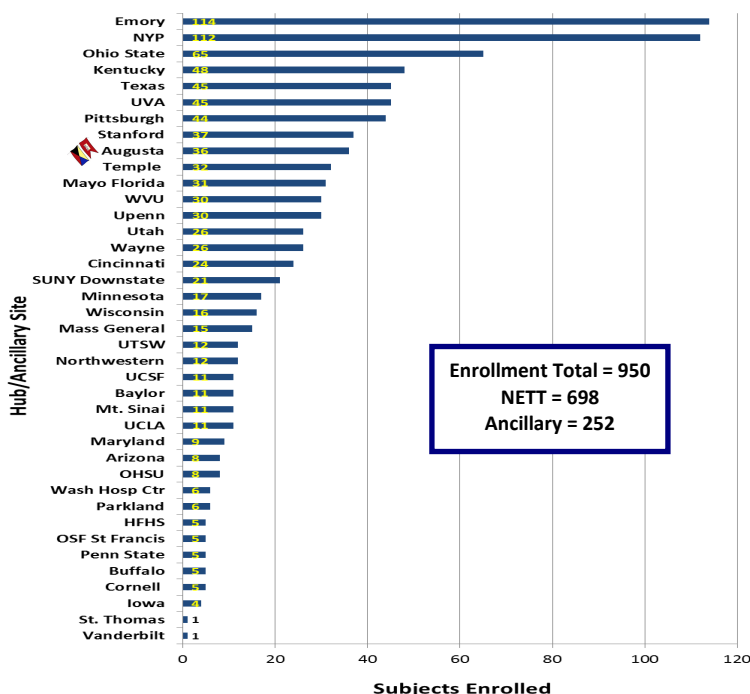
We are also highlighting **equipoise screening tips**, and introducing a **NEW SHINE Goals report** that allows sites to see their yearly global contribution to the SHINE trial and to help visualize and motivate us all to reach our new yearly enrollment goals. This year at the ISC meeting SHINE held a small Coordinator Focus Group meeting, to tackle the question, "How can we increase SHINE enrollments across all sites?" Here we share some tidbits that came out of that meeting as well.

Currently, we now have 45 sites actively enrolling in SHINE, including 32 NETT sites and 13 SHINE Ancillary Sites.

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

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

SHINE Enrollment by Site through March 28, 2017



#roadto1000

912 Temple	933 Northwestern
913 Froedtert	934 Northwestern
914 UPMC Presbyterian	935 Augusta
915 Grady	936 NYP Columbia
916 Memorial Hermann	937 Grady
917 UCLA Ronald Regan	938 NYP Columbia
918 UVA	939 Augusta
919 Stanford	940 MGH
920 Mayo	941 Grady
921 OSU Wexner	942 Stanford
922 Grady	943 Grady
923 NYP Columbia	944 Augusta
924 Kentucky	945 NYP Columbia
925 Grady	946 Mayo
926 Harborview	947 Kentucky
927 Grady	948 Augusta
928 Augusta	949 Kentucky
929 Stanford	950 UTSW Zale
930 UVA	
931 Grady	
932 Augusta	



Thanks to Sites who beat their previous years enrollment!

Baylor College
Wayne State University
Hennepin County Medical Center
UT Houston
UT Southwestern
University of Cincinnati Medical Center
University of Iowa
University of Kentucky

Thanks to all the SHINE sites for their hard work!



SHINE Bravo Zulu Award

Our sincere congratulations to our SHINE study team at **Augusta**, 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 Augusta is one of our PI sites with our protocol adherence PI Askiel Bruno, MD leading the charge locally. **Kudos** to the Augusta team for enrolling **6 subjects** in 3 months (**5 in March!**), and for having 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!

Congratulations to Dr. Bruno, Natalie and the rest of the Augusta team!



Augusta Team Members from left to right: Dr. Fenwick Nichols, Dr. Askiel Bruno, Natalie Bishop, and Dr. Jeffrey Switzer
Katrina van de Bruinhorst , Recruitment Specialist

Equipoise Screening Tips

1. Screening a Subject with very high glucose level

- Enrollment is per judgment of clinical investigator/treating team
- Equipoise requires team is OK with subject getting control or intervention treatment
- Remember any BG > 500 requires calling the **Study Hotline**
- Subject almost always will be d/c 'd from study treatment for safety and followed for 6 week and 90 day outcomes
- **Please call the Study Hotline to discuss any uncertainty**

2. Screening a Subject who has high home daily insulin requirement

- Consider subjects home insulin dose
- Equipoise requires team is OK with subject getting control or intervention treatment
- If total daily dose > 32 units of insulin at home, consider **Control** protocol limitations.
 - * Max insulin on day 1 with BG > 450 would be 32 units in 24h
 - * Increase in daily insulin can occur on Level 2 @ 24h
- **Please call the Study Hotline to discuss any uncertainty**

ask finger stick glucose Q 1 hr for the first 4 hours, then Q 3hrs (3:00, 6:00, 9:00, 12:00, 3:00, 6:00, 9:00, 12:00)
sq insulin if indicated only 4/day (6:00, 12:00, 18:00, 0:00)

SQ insulin Regular Insulin

Start at Level 1. If at the end of the first 24 hours, the previous two glucose levels remain $\geq 180\text{mg/dL}$, proceed to Level 2. In Level 3, give pre-determined day's entire insulin.

Glucose (mg/dL)	Level 1 Insulin dose (units)
>450	8
400-450	7
351-399	6
300-350	5
251-299	4
200-250	3
180-199	2
80-179	0
<80	0

NEW SHINE Enrollment and Goals Status Report

The recruitment team has developed a **NEW SHINE Enrollment and Goals Report** specific to your Hub or ancillary site, which you all received on Wednesday, March 15th. We developed this report so that each site's historical performance per year since entering the trial could be easily visualized. This new report is a bit different from the quarterly report in that this report provides a broader view of your site's performance since entering the trial.

Our hope is that this report will motivate each site to reach its new yearly enrollment goal. Each enrollment goal was derived by using 80% of your site's best performing year. The SHINE's Trial minimum site enrollment goal is 4 enrollments per year as set by our DSMB. Finally, the last part of this report is the big-picture with numbers regarding last enrollment and the total number enrolled in the trial to date.

Kevin Barrett, MD SHINE Recruitment PI

SHINE ISC Coordinator Focus Group Tidbits

During the Coordinator Focus Group we asked **"If you had a magic wand and could only wish for one more tool or resource for the SHINE trial what would it be or look like?"**

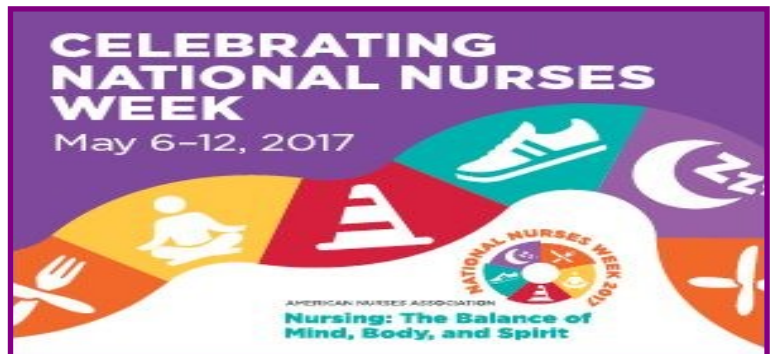
One participant replied, "A magic troll to help with care of the patient!" This got us thinking, how have sites increased personnel for SHINE? And where can you find an extra pair of hands? One way sites have found more people to share the load is by piggybacking onto existing programs such as college research programs where students earn credit; work study programs; colleges of nursing and medicine. At Temple we started using the existing medical student summer work study program to supplement our research staff. The existing program trained students to do common tasks in the ED such as EKGs, phlebotomy, POC glucose sticks, etc. We expanded the program to have a research component. The research medical students still learn how to do tasks but their primary responsibility is to screen for all ED research studies and assist staff. When a SHINE subject is enrolled the students are stationed with the patient. They keep an eye out for the meal tray, remind the staff nurse where the SHINE study reference binder is, make sure no one breaks the blind and contact the research staff whenever a question arises. The students love this program and we always have far more applicants than available slots.

Hannah Reimer, I-SPOT Project Manager



May is National Stroke Awareness Month.

F	A	S	T
FACE	ARM	SPEECH	TIME
Does one side of the face droop?	Does one arm drift downward?	Does the speech sound slurred or strange?	If you observe any of these signs, call 911.



I-SPOT

Insights on Selected Procoagulation markers and Outcomes in stroke Trial

Total Enrollment: 170
IV tPA subjects: 41

Please check your lab kit supplies and email Hannah if you need more kits: hreimer@temple.edu

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

Hannah Reimer, I-SPOT Project Manager

Quote of the Quarter

"When it rains it SHINE's"

- Shyam Prabhakaran,
Northwestern Memorial Hospital
(enrolled 2 subjects in 1 day)



WHO TO CONTACT

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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

