



Stroke Hyperglycemia Insulin Network Effort Trial Newsletter



December 2017 – Volume 6, Issue 1

IN THIS ISSUE

- Enrollment
- Top Sites for CRFs Entered in Window
- Bravo Zulu Award
- Guidance on NS IV bag Shortage
- Updated FAQ & eCRF Clarification
- SHINE Laptop Tidbits
- I-SPOT
- ISC 2018 Announcement

Winter is here and as we look forward to the New Year we would like to congratulate all of our SHINE sites for their hard work and continued dedication to enrolling and capturing high quality outcomes data. Enrollment has surpassed 1050 patients and the trial is now at 76% completion. We are steadily getting closer to the **#SHINEfinishline1400**, thanks to all of you!

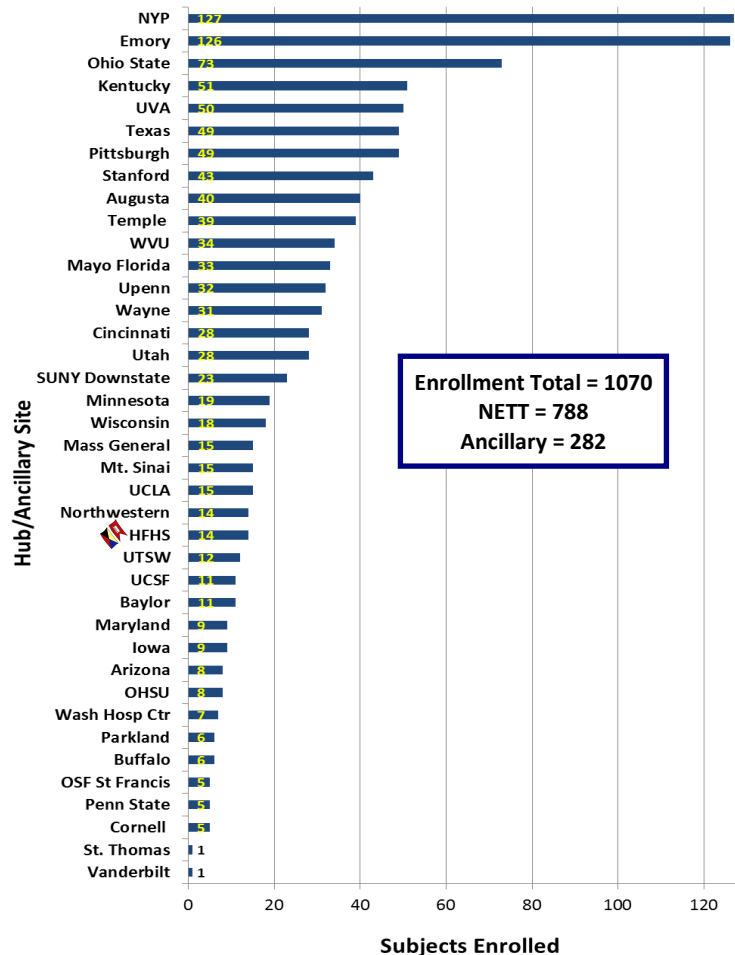
Currently, 44 sites are actively enrolling in SHINE, including 31 NETT sites and 13 Ancillary Sites. This year we had 8 sites that have enrolled 7 or more subjects this year! In addition, the following sites exceeded their 2017 enrollment goals: **Augusta University, Henry Ford Hospital, University of Iowa, Northwestern University, and UCLA Ronald Reagan!** Thanks to all for your hard work.

Congratulations to our 2017 Bravo Zulu Flag holders: **Augusta University, Summa Akron City Hospital, and Henry Ford Hospital.** It has been our pleasure to recognize your outstanding efforts each quarter by presenting each of you with the Bravo Zulu flag.

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 Enrollment by Site through Dec 19th 2017



Top Active SHINE Sites with High Percentages for CRFs First Submitted in Window

(90 - 100%)

WellSpan York Hospital
UTSW Zale Lipshy University Hospital
University of Michigan University Hospital
University of Minnesota Medical Center
Buffalo General Medical Center
UVA Medical Center
University of Iowa
Memorial Hermann Texas Medical Center
Parkland Hospital
SUNY Downstate Medical Center

(80 - 89%)

Hennepin County Medical Center
Temple University Hospital
Stanford University Medical Center
Emory University Hospital
WVU Healthcare Ruby Mem. Hospital
Henry Ford Hospital
NYP Columbia University
Sinai-Grace Hospital
University of Utah
University of Cincinnati

(80 - 89%)

Mayo Clinic Jacksonville
Northwestern Memorial Hospital
Froedtert Memorial Lutheran Hospital
Summa Akron City Hospital
Hospital of the University of Penn.

POINT is now closed to enrollment so please consider all NIHSS = 3 patients for SHINE!



SHINE Bravo Zulu Award

Our sincere congratulations to one of our *newest re-activated* SHINE study teams at **Henry Ford Hospital**, this quarter's recipient of the SHINE Bravo Zulu flag. The Bravo Zulu flag is traditionally used by US Naval Forces to publicly recognize a job especially well done.

The SHINE study team at **Henry Ford Hospital**, recently re-activated on **July 5th, 2017**, hit the ground running by enrolling their first 2 subjects in July 2017, and has enrolled a total of 9 subjects within 6 months this year! This team is also very responsive to queries and always has a positive attitude. The SHINE leadership team thanks them for their high 90 day mRS retention rate, timely data submission, and for their high enrollment rate. It is this kind of commitment to the SHINE trial that will continue to make SHINE a successful study!

Back: Chris Lewandowski, MD; Meri Muminovic, MD; Katie Rose, Joseph Miller, MD; Andrew Clark; Front: Shaneela Malik, MD; Kaleem Chaudhry, Shannen Berry, RN; Not Pictured: JoAnn Rammal, John France



Guidance on NS IV bag Shortage Alternatives

Shortages of intravenous (IV) solutions, IV bags and medications are a result of the impact of Hurricane Maria in Puerto Rico. **The supply interruption is ongoing, with expected shortages to last into spring 2018.**

Pharmacy, supply chain, and clinicians must continue to be proactive in adopting conservation measures to optimize the current supply. Alternative options for medication delivery are being implemented across SHINE sites to maximize supplies with the least impact to clinicians and their workload. IV Mini Bags (50 ml and 100 ml) have been most affected (both 0.9% NS and D5 in water), but all IV solutions may eventually be at risk. Below are alternatives to consider with your investigational pharmacy team prior to a critical shortage at your site.

IV Bag Shortage Alternatives to Consider:

- ◆ Use two 50 mL IV bags or one 250 mL bag instead of one 100 mL IV bag for control & intervention groups
- ◆ Use 500 mL IV bags and remove the necessary fluid to create the infusion volume they need.
- ◆ Purchase 50, 100, or 250 mL fillable IV bags to use to make control & intervention group solutions when SHINE subject enrolled.
- ◆ Check with pharmacists to determine whether syringe pumps could be used instead of IV bags for control & intervention groups
- ◆ See if your pharmacists can allocate enough IV bags for 1-2 SHINE patients per month

For up-to-date info www.ashp.org (American Society of Health-System Pharmacists), Click on Current drug shortages

Please feel free to contact Heather M Haughey (8am-5pm, M-F, EST) @ 434-243-8065 or hmh8f@virginia.edu to discuss these and potentially other options.

Updated SHINE Hospitalization FAQ: In Toolbox, FAQ, Follow-up

Q: Is a hospitalization that is due to a planned or elective admission, (to treat a pre-existing condition that is diagnosed before or after randomization), where there is no associated serious outcome (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event) considered an SAE? (UPDATED 11-2-17)

A: No, however, if any untoward medical event occurs during the hospitalization (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event), then an SAE has occurred and should be reported within 24 hours of discovery. **Examples of planned or elective admissions, to treat preexisting conditions that are diagnosed before or after randomization may include**, carotid endarterectomy to treat carotid stenosis, skin biopsy for basal cell carcinoma, colonoscopy to evaluate gastrointestinal symptoms.

Clarification on WebDCU™ Form 22: Neurological Worsening

- ◆ Form 22 should only be completed if the SHINE definition of Neurological Worsening is met. The SHINE study definition of neurological worsening is a clinical change associated with a ≥ 4 point NIHSS score increase from the most recent daily NIHSS score or baseline (whichever is most recent), that persists for ≥ 24 hours.
- ◆ If patient is in a coma or care is withdrawn due to neurological worsening and a full NIHSS score is not completed but documentation of worsening persisting for ≥ 24 hour is available, please complete Form 22 as best as possible and include a note in general comments. If a coma score is used and a documented total NIHSS is completed, please enter this data on Form 22 and include a note in general comments.
- ◆ If the patient dies within 24 hours of neurological worsening, please do not complete Form 22 since this case does not meet the SHINE definition of neurological worsening (i.e. persists for ≥ 24 hours).

Example of neurological worsening case that persists for ≥ 24 hours with a ≥ 4 point NIHSS score:

Please answer the following based on the most recent daily or baseline (whichever is most recent) NIHSS score prior to the neurological worsening.			
2	Date of assessment	10 Dec 2017	(dd-mm-yyyy) Complete
3	Time of assessment	10 : 00	(24hr clock) Complete Time
4	NIHSS score	10	
5	Did sedatives likely affect the score?	<input type="radio"/> No <input type="radio"/> Yes	
Please answer the following based on the first NIHSS score assessed after the score listed in Question 4 above that was 4 or more points higher.			
6	Date of assessment	10 Dec 2017	(dd-mm-yyyy) Complete
7	Time of assessment	18 : 00	(24hr clock) Complete Time
8	NIHSS score	14	
9	Did sedatives likely affect the score?	<input type="radio"/> No <input type="radio"/> Yes	
Please answer the following based on the NIHSS score that was obtained 24hrs (+/- 4hrs) following the score listed in Question 8 above.			
15	Date of the 24 (+/-4) hour NIHSS:	11 Dec	(dd-mm-yyyy) Complete
16	Time of the 24 (+/-4) hour NIHSS:	11 : 00	(24hr clock) Complete Time
17	24 (+/-4) hour NIHSS score:	18	

SHINE Laptop Tidbits**Best Practices:**

- Check internet connectivity, SHINE portal access, and run Windows Updates after every 3rd Tuesday of the month

Most Common Laptop Issues & Fixes:

- **Cannot connect to internet**—Fix: check wifi, restart computer
- **Cannot connect to SHINE trial portal**—Fix: In IE select tools, compatibility view settings, add 'mdninformatics.com'

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@ 434-243-8065 or hmh8f@virginia.edu

I-SPOT

Insights on Selected Procoagulation markers and Outcomes in stroke Trial

I-SPOT is nearing enrollment goals!!

Total : 231

tPA: 84

Please come see us at ISC Hall H #CT P31

Hannah Reimer, I-SPOT Project Manager

Goal 315

Current Enrollment 231

International Stroke Conference 2018

Nursing Symposium & Pre-Con Symposia: Jan. 23, 2018

Sessions: Jan. 24–26, 2018

Los Angeles Convention Center | Los Angeles, Calif.

Please make plans to join the SHINE team at the Ongoing Clinical Trials Poster Session on **Thursday, January 25, from 6:15-6:45PM in Hall H #CT P1**. The poster will highlight the successes of many of our study teams. **After which we can all go grab a drink and a bite to eat!** Hope to see you there.

WHO TO CONTACT

SHINE PIs — Karen C. Johnston — kj4v@virginia.edu Kevin Barrett — barrett.kevin@mayo.edu

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Protocol, laptop & study drug stickers — Heather M. Haughey — hmh8f@virginia.edu

SAE reporting & regulatory — Ruth Lewis — rllewis@med.umich.edu

Recruitment/retention — Katrina van de Bruinhorst — katrina.vandebruinhorst@utsouthwestern.edu

CRF completion/data management — Kavita Patel — pateka@muscc.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 — 774-234-7768



I-SPOT

