



Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

June 2018– Volume 6, Issue 3

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Congratulations SHINE team—as of June 28 we have now enrolled a total of 1133 into the SHINE trial **#shinefinishline1400**. We are almost there. Thanks to all of you we are in the final stretch of enrolling in SHINE with only 267 patients to go! Keep up the excellent work, and remember fingersticks can be repeated for patients who have glucoses that are close to eligible but not quite there. Our goal is for every site to enroll at least 1 subject every other month (6 enrollments per year). Congratulations to our SHINE sites who enrolled in May (**Augusta, Kings County, Columbia, OSU, Henry Ford, U Penn, UVA, WVU, and UT Southwestern**).

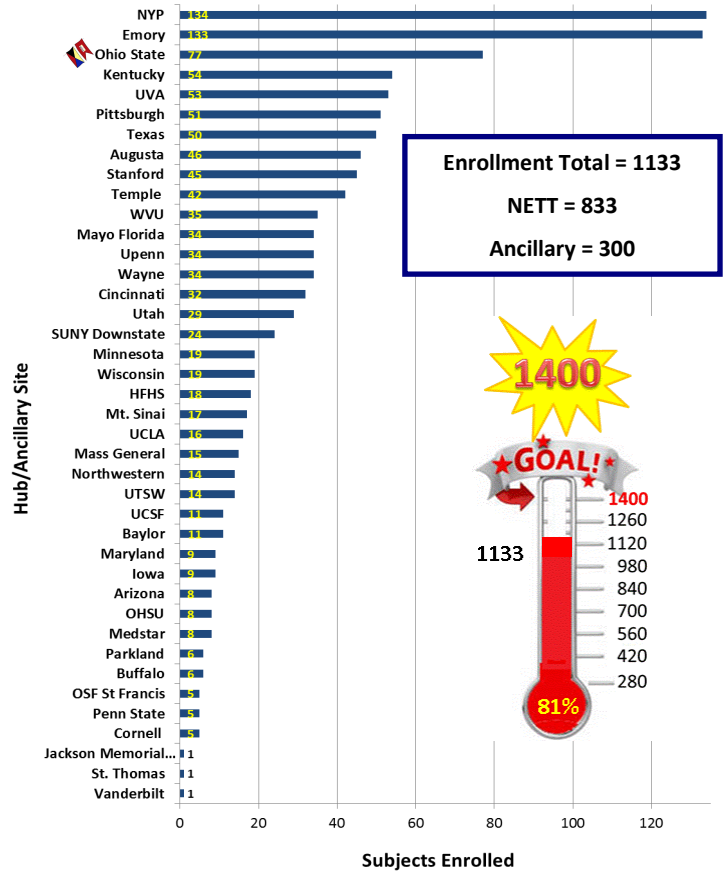
Currently, 41 sites are actively enrolling in SHINE. Kudos to all top enrolling sites (**Columbia, Grady, OSU, UVA, and Kentucky**) and to all actively enrolling sites! Thanks to all for your hard work.

Congratulations go out to our newest Bravo Zulu Flag Awardee: **The Ohio State University Wexner Medical Center!** They have been wonderful contributors to the SHINE trial.

We have all kinds of SHINE tips and kudos in this issue. We hope it is helpful and we always welcome your input. Thanks again for all your continuing efforts on SHINE.

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

SHINE Enrollment by Site through June 28, 2018



SHINE Enrollment Goals:

Our SHINE goal for every site is to enroll at least 1 subject every other month (Grady, Columbia and OSU are killing this!!). We have seen an increase in “missed subjects” on the screen fail logs this year. If every site can capture one almost missed subject, that is another 41 subjects! **#SHINEnoMisses!**



Congratulations to the point Team!!!

The SHINE team would like to extend our most sincere congratulations to all who participated in the POINT trial.

The success of the POINT trial and the impact it is having on our entire stroke community is inspiring. We thank you all for your contributions to the POINT trial success!

Reminder of SHINE Clinical Online Training Opportunities

Clinician Online Training opportunity for new faculty, trainees and staff. Nurses and physicians may earn up to 2.0 AMA PRA Category 1 credit™ (s) for completing the training (one time only). The University of Virginia CME office will track course completion and credit.

<https://nett.umich.edu/clinical-trials/shine/nurse-education-training-tools>



SHINE Bravo Zulu Award

Our sincere congratulations to one of our SHINE study teams at **THE OHIO STATE UNIVERSITY WEXNER MEDICAL CENTER** 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.

Kudos to the SHINE study team at the OSU WEXNER. This team is always responsive to emails and queries, they continuously go out of their way to retain their subjects, and continue to exceed in enrollment. The SHINE leadership team thanks them for; their nearly perfect 90 day mRS retention rate, timeliness in query response, and for their excellent data submission in window rate. It is this kind of commitment to the SHINE trial that will continue to make SHINE a successful study!



From left to right are the following: Muhammad Nasir, Eder Ceaser, Weiping Ye, Dr. Archana Hinduja, Areej Tariq, Dr. Michel Torbey, Sara urio, Mohammed Hamed, Rayvn cash RN, Dr. Greene Chandos, Dr. Deepak Gulati, and Randher Yadav RN

SHINE Treatment Protocol Reminders : Level changes, pauses, carb coverage



CONTROL GROUP – Treatment Protocol Reminders

BG target: 80-179 mg/dL

Glucose checks: q1-q3 hours (+/- 15 min)

Drip: IV saline drip – 0, 4 or 5 mL/hr

SQ injections: SQ insulin (human regular per sliding scale) and basal insulin (only at 48 hrs if indicated)

Timing of checks

Q1 hr – Do one check when ready to start IV saline (Q0) and then check hourly for next four hours (Q0, Q1, Q2, Q3, Q4)

Q3 hr – Then transition to q3 hour schedule (3, 6, 9, 12, 18, 21, 24)

Dosing

Adjust IV saline with EACH glucose check

Give SQ insulin ONLY at dosing times (6, 12, 18, 24)

- If hourly check is within 30 mins of next dosing time, give dose (i.e. if check is due at 11:41, you're within 30 min → give dose)
- If you cross a dosing time during the hourly checks, give dose (i.e. 1st check 05:20, 2nd check 06:20 → give SQ dose as crossed 6AM)

Level changes

All patients on Level 1 for first 24 hrs

Level changes assessed every 24 hrs from time of randomization

If latest 2 glucose checks are ≥ 180 , advance to next level

Level 3

- Includes a one-time dose of SQ glargine/Lantus as close as possible to 48 hrs after randomization
- Dose = 40% of total SQ insulin (count all 4 dosing times) given in prev 24 hrs

Meals

60 gm CHO/meal plus protocol approved snacks

HOLD meal until after glucose check/SQ dose (6, 12, 18)

Dysphagia diet/bolus tube feeds must also be 60 gm CHO

Continuous tube feeds ~180 gm CHO daily

Pauses

- Stop drip and document in study laptop & med record
- Upon return, restart protocol based on if check/dose missed



INTERVENTION GROUP – Treatment Protocol Reminders

BG target: 80-130 mg/dL

Glucose checks: Timing -q1-q2 hrs recommended by GlucoStabilizer® (+/- 15 min)

Drip: IV insulin per GlucoStabilizer®

SQ injections: SQ meal insulin (or saline if NPO)

Timing of checks – q1hr per GlucoStabilizer® until BG stabilized (may change to q2hrs then)

Dosing

Adjust IV insulin per recommendation of GlucoStabilizer®

Subcutaneous injections

- If NPO or on continuous tube feeds, give 0.05mL normal saline SQ at glucose check closest to 0900 and 2100
- If PO or on bolus tube feeds, give meal insulin per GlucoStabilizer®

Meals

60 gm CHO/meal plus protocol approved snacks

Dysphagia diet/bolus tube feeds must also be 60 gm CHO

Continuous tube feeds ~180 gm CHO daily

Estimating meal consumption

- Assesses meal tray ~20 minutes after start of meal
- Estimating PO meal consumption, then use Cover Carbs function
 - All or nearly all → Enter 60
 - None or nearly none → No entry in GlucoStabilizer®
 - Partial → Enter 30
- Do NOT enter any numbers other than 30 or 60
- Dose immediately based on GlucoStabilizer® recommendation

Pauses

Stop drip and document in study laptop & med record

Upon return, restart protocol based on following

- If <3 hours since stop drip, Select 'Resume drip' (most recent drip run) and follow recommendation from GlucoStabilizer® for timing of next check/dose
- If ≥ 3 hours, Select Start a new drip; when ready to start insulin infusion, do a check and enter in GlucoStabilizer®

https://nett.umich.edu/sites/default/files/docs/shine_treatment_protocol_reminders.docx

Please call Heather M Haughey with any questions!

**264 I-SPOT Subjects
(113 IV tPA subjects)**

Enrollment Goals:

195 I-SPOT

+

120 ISPOt-tPA

for a total of 315 subjects



**THANKS TO ALL SITES WHO
ENROLLED THIS PAST
QUARTER
AND TO EVERYONE WHO
CONTINUES TO SCREEN
FOR I-SPOT!!**

Hannah Reimer, I-SPOT Project Manager

ISPOt study Hotline 1-774-234 7768

**NEW FAQ: Clarification of the admission
glucose used to determine eligibility**

Q: When screening patients for SHINE eligibility, what qualifies as the admission glucose?

A: An admission glucose is the most recent qualifying finger-stick blood glucose obtained at the enrolling facility within the 12 hour window.

See: **Eligibility Criteria Pocket Card v.3 (Updated 6-12-18)** at <https://nett.umich.edu/clinical-trials/shine/toolbox#Screening>

Ruth Lewis, SHINE Regulatory Manager

SHINE Enrollment has Slowed Nationally

Please use this final phase of recruitment to internally reassess SHINE procedures at your sites—we can reverse the declining recruitment trend and get to the finish line with everyone's help. Items to discuss with your teams:

- SHINE screening: Process to reliably capture of transfer patients
- Process to recheck finger stick BG for ineligible patients (FSBG <110 DMII or <150 w/o DMII) during first 12 hours from symptom onset
- Process to recheck NIHSS in ineligible patients whose scores are close to eligible (NIHSS 3-22) during the first 12 hours from symptom onset
- Process to reassess eligibility following mechanical thrombectomy
- Protocols for bed availability in units able to manage insulin infusions
- Education of housestaff on eligibility for new academic year

Kevin Barrett, SHINE Recruitment PI

WebDCU™ SHINE Database Freeze July 9, 2018

Please reconcile all:

- Rule violations
- Open DCRs

Please complete all:

- Overdue CRFs
- Past due visits

Thank you in advance for everyone's efforts on this!

Kavita Patel, SHINE Database Manager

WHO TO CONTACT

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Recruitment/retention — Katrina van de Bruinhorst — katrina.vandebuinhorst@utsouthwestern.edu; 214-648-9248
CRF completion/data management — Kavita Patel — pateka@muscc.edu; 843-876-1167
Ancillary contracts/invoicing — Emily Gray — eaw8t@virginia.edu; 434-982-6773

24 hour Emergency Contacts:

SHINE Study Hotline — 800-915-7320

WebDCU Emergency Randomization Hotline — 866-450-2016

