Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

February 2013 – Volume 1, Issue 3

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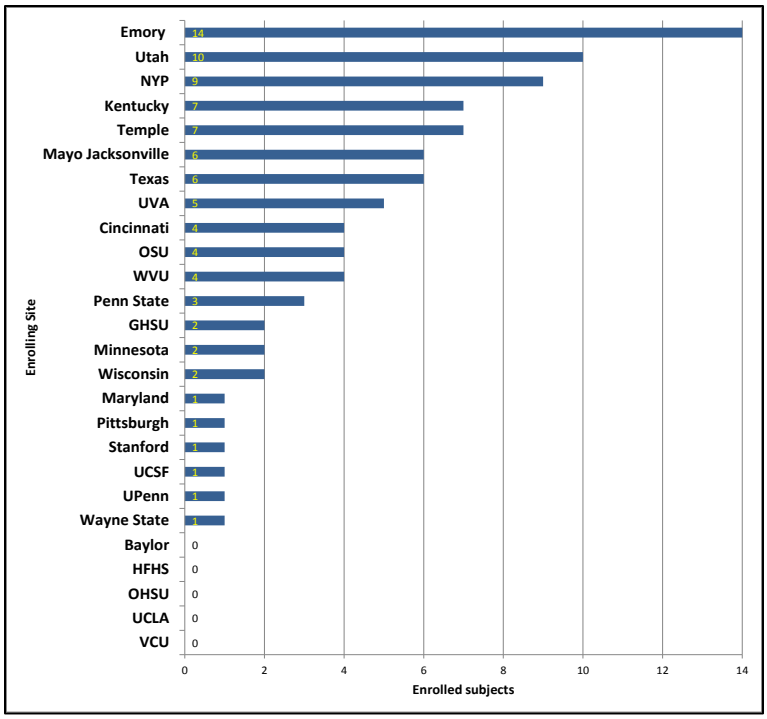
As of February 28, 2013, 91 subjects have been enrolled in SHINE across 24 enrolling sites. A total of 32 sites have completed readiness calls and are activated to enroll. For sites that are pending activation, we would encourage you to prioritize IRB approval, pharmacy orders and confirming laptop connectivity since these have caused delays at some sites. We very much appreciate your efforts and are here to help with the readiness process.

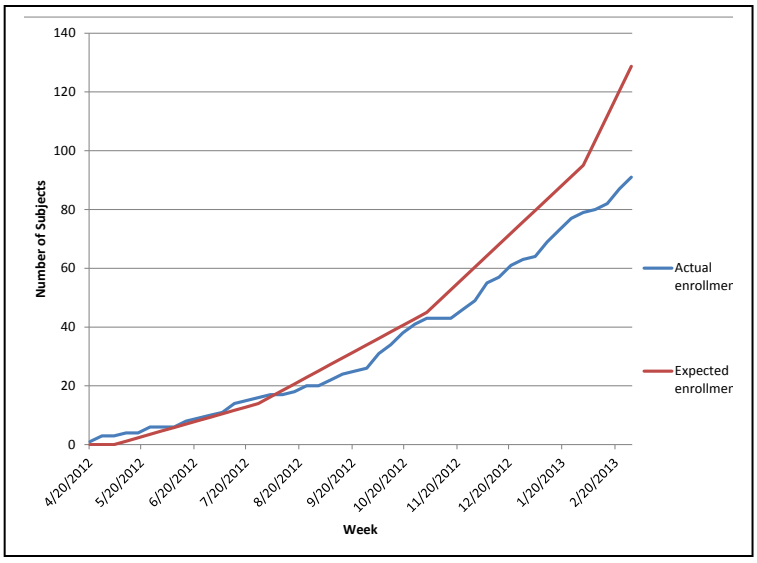
Our thanks to the following teams for their accomplishments during the past 3 months:

- The Emory team is leading study recruitment with 14 subjects enrolled to date.
- The Utah team is in second place with 10 enrollments, followed by NYP (9), Kentucky (7) and Temple (7).
- Temple remains the hub with the most activated spokes.
- OSU was the first new NETT hub to be activated and has enrolled their first 4 subjects in 6 weeks.

SHINE Enrollment by Site



SHINE Enrollment – Apr 2012-Feb 2013



Activated SHINE Sites

Baylor
Cincinnati
- University Hospital*

Emory
- Grady Memorial*

GRU*
Henry Ford
- HFHS
- Michigan

Kentucky
- University of Kentucky*

Maryland
- University of Maryland*

Mayo Jacksonville*
MCW
- Froedtert Memorial*

Minnesota
- UMMC, Fairview*

NYP
- Cornell*
- Columbia*

OHSU
- Harborview MC

OSU
- Wexner MC*

Penn State Hershey*
Stanford
- Stanford UMC*

Temple
- Allegheny General*
- Hackensack
- Jefferson*
- Temple University*

UCLA
- Ronald Reagan MC

UCSF
- San Francisco General*

UPenn
- University of Pennsylvania*

UPMC
- Presbyterian*

UT Houston
- Memorial Hermann*

Utah*
UVA*
VCU
WSU
- Beaumont Royal Oak
- Detroit Receiving*

WVU*

***indicates site with subject enrollment**

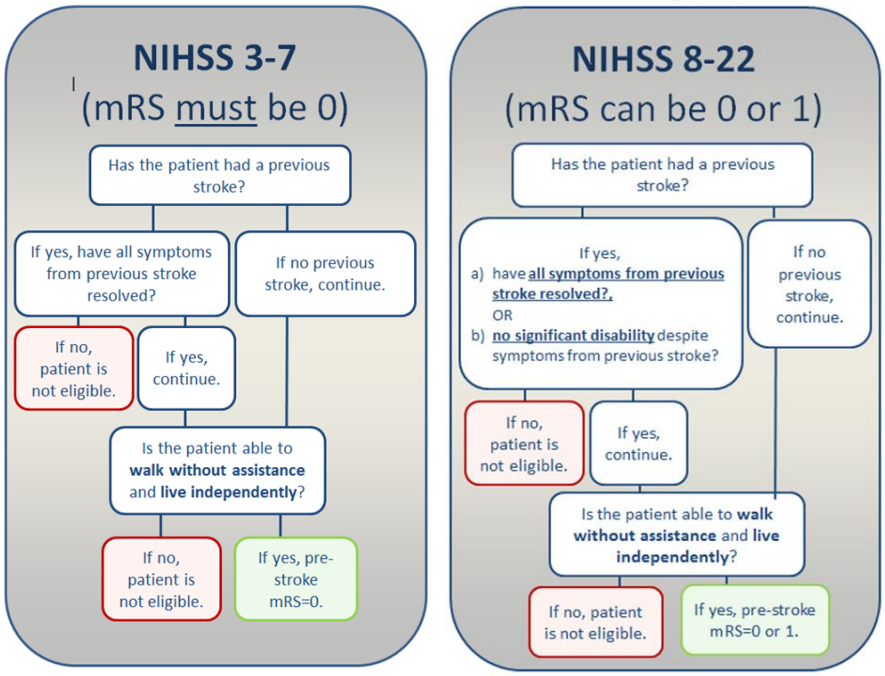
SHINE Protocol v2 Amendment

Thanks to all of the sites that have submitted the SHINE Version 2 protocol modification. Please remember to upload the Full IRB application submittal, Investigator Agreement, SHINE Protocol v2 Approval and SHINE IRB Approved ICF v3 in WebDCU. Contact Arthi Ramakrishnan (arthrama@med.umich.edu) with questions about the modification or regulatory documents.

Key changes in V2 include:

- 3 hour rule now recommended but not required
- Pre-stroke mRS of 0 for NIHSS of 3-7 or pre-stroke mRS of 0 or 1 for NIHSS of 8-22 (see scoring diagram)
- Increased # of FSBG checks from 8-14 to 8-20 in ICF template
- Added I-SPOT ancillary study

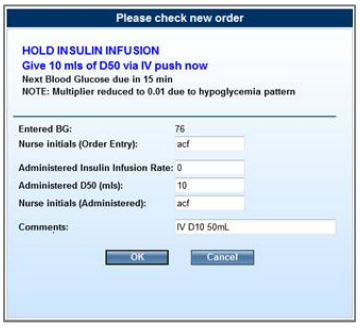
Pre-stroke modified Rankin Scale Scoring (v2)

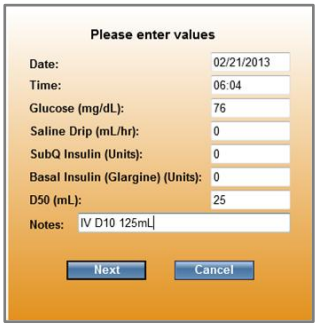


Q: We are curious what are you and other sites doing in view of the D50 National Shortage? Our hospital is facing a shortage which could affect the study protocol.

A: Due to manufacturing delays and increased demand, there is a national shortage of D50. This shortage may or may not affect your site. If your site is one that is affected the shortage, we would recommend that you work with your pharmacy to consider the use of D50 bags. If D50 bags are not available, D10 or D25 may be used (multiply IV D50 doses by 5 for equivalent IV D10 dose or D25 and multiply IV D50 doses by 2 for the equivalent IV D25 dose). Please update your study orders and the hypoglycemia prevention and management protocol to reflect these options.

In the study laptop, record the equivalent dose of D50 administered. In the intervention group, accept the D50 dose recommendation and note the volume of D10 or D25 administered in the Comments field. In the control group, enter D50 25mL in the New entry pop up and document the volume of D10 or D25 administered in the Notes field.





Questions about updating your hypoglycemia protocol should be directed to Amy Fansler (acf7h@virginia.edu).

I-SPOT

Insights on ***S***elected ***P***rocoagulation markers and ***O***utcomes in ***S***troke ***T***rial

Congratulations to the following sites that have been released to enroll for I-SPOT: Kentucky, HFHS, Temple, Allegheny and Texas. Contact Hannah Reimer (hreimer@temple.edu) with questions about the ancillary trial and readiness.

Study Reminders

Screen failure logs *- Remember that only primary ischemic strokes within 12 hours of symptom onset (or time last seen well) with a glucose greater than 110 should be reported in the SFL. Primary ICH should not be included. If your site does not have 24/7 coverage, please report any screen failures whether actively screening or not at the time of arrival. As always, screen fail logs are due on the 10th of every month.* *~ Katrina van de Bruinhorst*

Laptop software updates *– Thanks to the many coordinators for such a prompt response to making the recent study laptop software updates. If we have not yet updated your laptop, please contact me to set aside time for this quick update.* *~Amy Fansler*

Who to contact

Protocol questions - Amy Fansler - (434) 982-6027 or acf7h@virginia.edu
Regulatory & site readiness - Arthi Ramakrishnan - (734) 936-2454 or arthrama@umich.edu
Laptop questions- Amy Fansler - (434) 982-6027 or acf7h@virginia.edu
WebDCU support – Karen Briggs - (843) 792-3980 or briggsk@musc.edu
Education and training – Joy Pinkerton - (734) 232-2138 or joypink@umich.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