

Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

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Dear SHINE sites,

With the summer months approaching, we write to provide updates on the SHINE trial and share information that we think may be useful to our study teams.

In this issue of the newsletter, we feature a mini training on mRS scoring of in-hospital strokes. Determining

eligibility of such patients can be complex, and we encourage teams to contact the PI on call line with questions related to in-house strokes. We also highlight some engagement strategies to consider during the upcoming orientation of incoming residents and fellows.

Finally, we want to update you on our most recent SHINE DSMB meeting that took place in April 2016. The DSMB recommended that the trial continue and commended the study team on our continued close monitoring of a large number of study sites. As a team, we will also strive to make improvements in recruitment and data quality that they recommended. It is a pleasure to present your successes to our DSMB. As always, we welcome the input of our teams on any issues or ideas related to SHINE. Thanks again for all of your hard work.

We wish everyone a happy and safe summer, and we look forward to hearing from you on our calls, webinars, and the PI on call line.

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

SHINE Bravo Zulu Award

Our sincere congratulations to our SHINE study team at **Wayne State University**, this quarter's

recipient of the SHINE Bravo Zulu flag. The Bravo Zulu flag is traditionally used by US naval forces to

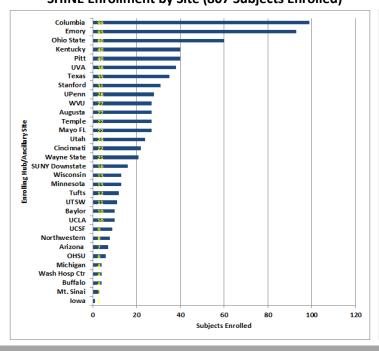
used by US naval forces to publically recognize a job especially well done.

WAYNE STATE UNIVERSITY SCHOOL OF MEDICINE

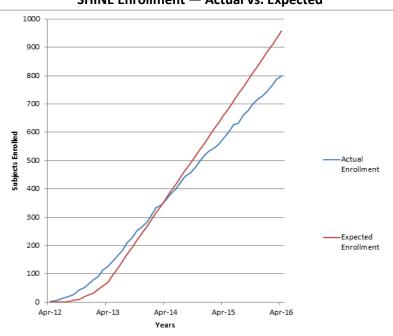
The SHINE study team at Wayne State is led by **Dr. Claire Pearson,** SHINE PI, **Dr. Rob Welch**, HUB PI, and **Valerie Mika**, Primary CRC. We applaud their recent enrollment surge (8 enrollments in 2016), responsiveness to data queries, and overall positive attitude. WSU has enrolled 22 subjects in the trial and has a perfect rate of retention. We salute your performance and look forward to learning from your success. Many thanks for all of your efforts!



SHINE Enrollment by Site (807 Subjects Enrolled)



SHINE Enrollment — Actual vs. Expected



How do I decide if a patient with in-hospital stroke is eligible for SHINE?

This is often very hard to determine, so we recommend to call our 24/7 PI hotline to help you decide. In summary:

- If the stroke occurs during an elective or minor procedure and the patient had mRS = 0 just prior to that procedure, then the patient could be screened for SHINE.
- However, if the stroke occurred during or shortly after a major illness or procedure, then it is impossible to know how well that patient will recover in 90 days. Thus, at 90 days it might be hard to judge how much of an impairment is from the stroke and how much is from the illness or procedure (confounding). Such patients are best excluded from the SHINE trial.
- There are countless potential scenarios of in-hospital stroke that may or may not be good candidates for SHINE, so please feel free to call our 24/7 hotline to discuss with a PI.

Askiel Bruno, MD, MSc **SHINE Protocol Adherence PI**



Where can I find the PI on call line number?

800-915-7320

Study laptop sticker *WebDCU*

SHINE magnets

Study website

MOP *Protocol*

New SHINE Site

The SHINE team would like to extend a warm welcome to our newest site, JFK Medical Center. JFK is a spoke of HUB Temple University. We are excited to have them on board!

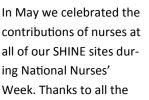


Recruitment Strategies & Reminders

As the 2015-2016 academic year comes to a close, consider your site strategy to engage new housestaff with the SHINE protocol. Many sites have effectively leveraged housestaff to identify potential SHINE-eligible patients as residents/fellows are often first responders to evaluate patients with suspected stroke. Think about the following when engaging and educating new housestaff with the SHINE protocol:

- Include SHINE trial in new housestaff orientation
- Provide SHINE eligibility pocket cards for point of care reference
- Educate housestaff on best contact mechanism for clinical research coordinators
- Introduce housestaff to SHINE nursing champion as resource
- Educate regarding SHINE orders within EMR environment
 - SHINE diet orders
 - Consider appropriate bedding unit for SHINE protocol
- Orient housestaff regarding rationale for SHINE and high-level protocol overview
- Encourage all of your new housestaff and faculty to follow @SHINE_Trial on Twitter

Kevin Barrett, MD SHINE Recruitment PI



all of our SHINE sites during National Nurses' Week. Thanks to all the nurses who are so integral to the continued success of SHINE!



108 Subjects Enrolled

Thanks to all sites who submitted I-SPOT protocol version 2 to their IRBs which allows the inclusion of IV tPA subjects in I-SPOT. Ten subjects who received IV tPA have been enrolled under the new

protocol. Keep up the great work enrolling both non-tPA and IV tPA subjects in I-SPOT!

Hannah Reimer, I-SPOT Project Manager

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

