Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial Bedding for SHINE

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Recruitment PI

Bedding for SHINE Patients

- Different hospitals have different regulations for where/ what level of care is required for running of an insulin drip
- For the 72 hours of study treatment (exception if discharged from hospital) all patients must be bedded in a location that would support and allow delivery of insulin drip therapy.
- Absolutely must not differentially bed active insulin drip patients vs control patients as this will irreparably bias the study due to differential level of care

Bedding for SHINE Patients

What this means:

- If your hospital supports insulin drip therapy in ICU, step down, Stroke unit and floor level settings then:
  - May bed any patient in any one of these insulin drip supporting environments purely according to clinical need

- If your hospital supports insulin drip therapy in ICU, step down, Stroke unit BUT NOT in floor level settings then:
  - May only bed any SHINE Patient in ICU, SDU, ASU and may not bed any patient on the floor during the 72 hour study treatment period even if you know they are receiving active control SQ insulin as their study Tx.

Bedding for SHINE Patients

What this means:

- If your hospital supports insulin drip therapy in ICU Then:
  - Protocol states all SHINE patients must be cared for in ICU for 72 hours unless discharged

  OR
  - There must be a special plan in place with your institution to manage this
  - For the few of you this affects I think there are already solid plans in place
  - If anyone is realizing this for first time at this moment please meet with me here right after the Q&A session to work on a plan


SHINE

Final National Coverage Decision

- Effective for items and services furnished on or after September 19, 2000, Medicare covers the routine costs of qualifying clinical trials.
- Routine costs include all items and services generally available to Medicare beneficiaries provided in either the experimental or the control arms of a clinical trial.

Medicare Billing Requirements

- Diagnosis code V70.7 is required as a secondary diagnosis for clinical trials
- Routine costs are reported to Medicare with modifiers
  - Q0 - Investigational clinical service provided in a clinical research study that is in an approved qualified trial
  - Q1 - Routine clinical service provided in a clinical research study that is in an approved qualified trial