Hypoglycemia Form

Overview:
We have created an optional resource to help guide nurses through the hypoglycemia protocol in real time and appropriately document the event. The Hypoglycemia Form contains step by step instructions to walk the nurse through the hypoglycemia protocol, including prompts to assess and document the symptoms of hypoglycemia. This can also be used as a source document for CRF completion.

If you are interested in using the electronic Hypoglycemia Form at your site or would like more information, contact Amy Fansler (434-982-6027 / acf7h@virginia.edu). We will work with you to individualize the electronic forms to include information that is specific to your site.

This form will be displayed on the study laptop on an internet browser, and site coordinators will receive an email each time a form is submitted. Sample screen shots of the electronic forms are posted below.

How to use the form:

1. Enter subject information and specify if this is a new hypoglycemia event or a 15 min repeat BG check

<table>
<thead>
<tr>
<th>SHINE Subject ID:</th>
<th>DATE:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TIME:</td>
</tr>
</tbody>
</table>

Is this a new hypoglycemia event to report? *
- YES
- NO, this is a 15 min repeat BG check

Contact the SHINE Study Hotline if there are 3 or more hypoglycemic events in 24 hours
SHINE Hotline: 800-915-7220

2. Enter the glucose level & specify the treatment group.

New Hypoglycemia Event

POC BG (mg/dL)
- 62
- 60 to 70 mg/dL
- NO

**NOTE—Study team must be stat paged for any BG < 40 mg/dL.**

3. Instructions to stop the study infusion and complete the additional steps for glucose <70 mg/dL are shown.

<70

**INTERVENTION GROUP (BLUE)**

1. STOP study infusion
2. If BG < 70 mg/dL, draw STAT serum blood glucose
3. Give D50 slow IV push per GlucoseStabilizer recommendation on the study laptop
4. Complete additional assessments for BG < 70 mg/dL
5. Recheck BG as determined by GlucoseStabilizer on the study laptop

**NOTE—do not delay administration of D50 if unable to obtain serum BG**

Dextrose 50% (D50) Administration (IV)

Date Given: [ ]
Dose Given (mL): [ ]
Time Given: [ ]

4. Complete the additional assessments to assess for symptoms of hypoglycemia.

Additional Assessments for BG > 70 mg/dL

<table>
<thead>
<tr>
<th>Symptom</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shaky</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tired</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart Pounding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nervous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weak</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swallow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contacted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hungry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drowsy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. Note that reminders will populate for some data fields.

Did the event cause sudden neuro-worsening?
- YES
- NO

If yes, contact study team to assess if neuro change meets the SHINE study definition of neurological worsening (change in NIHSS ≥ 4 points that persists for 24 hours (≤ 4 hours)).

6. Instructions for the next steps are displayed, and the form can be submitted.

For the protocol, recheck BG ≤ 16 minutes (≥ 8 minutes) from the latest glucose check, until BG > 90 mg/dL. Also complete a neuro check and assess for symptoms of hypoglycemia using the Hypoglycemia Form for each BG < 70 mg/dL.

Once BG ≥ 70 mg/dL, no further assessments are required. The timing of the glucose checks and infusion rate will again be determined by the control treatment screen (Control Group OR ORANGE or GlucoseStabilizer [Intervention Group BLUE]).

Was the study subject needed?
- YES
- NO

RN Name completing form: [ ]

Submit