HALF-PINT Form 7: Adverse Event

Note: Complete questions 1 through 6 and follow-up questions as appropriate.

Section: Required Questions

1.	Start date/time of adverse event (AE)	/ / : *24-hour clock*
2.	Protocol specified HALF-PINT AE?	○ Yes If Yes, specify: ○ Hypoglycemia <60 mg/dL – **Answer Section A** ○ Hyperglycemia >250 mg/dL (>6 hours after initiation of insulin infusion) - **Answer Section B** ○ Hypokalemia <2.5 mmol/L - **Answer Section C** ○ New seizure (in subject without a known seizure disorder) - **Answer Section D** ○ Catheter-associated bloodstream infection (CA-BSI) - **Answer Section E** ○ Catheter-associated urinary tract infection (CA-UTI) - **Answer Section F** ○ Surgical site infection (SSI) - **Answer Section G** ○ Ventilator-associated pneumonia (VAP) - **Answer Section H** ○ Other hospital-acquired infection - **Answer Section I** ○ Continuous Glucose Monitor (CGM) related adverse event, bleeding or other (that did not involve hypoglycemia, hyperglycemia, or infection) - **Answer Section J** ○ Bedside glucose meter related adverse event (that did not involve hypoglycemia, hyperglycemia, or infection) - **Answer Section K** ○ VAMP related adverse event - **Answer Section L** ○ Computerized insulin dosing protocol related adverse event (that did not result in a hypoglycemia or hyperglycemia event) - **Answer Section M** ○ Insulin dosing error (that did not result in a hypoglycemia or hyperglycemia event) - **Answer Section N** ○ No, describe the non-specified AE:
3.	Was this AE expected?	○ Expected ○ Unexpected
4.	What is the severity of this AE? **Note:** Classify hypoglycemia <40 mg/dL as "Severe".	○ Mild: Did not impact (in any way) the subject's course of illness ○ Moderate: May have impacted the subject's course of illness, but did not prolong existing hospitalization ○ Severe If Severe: ○ Fatal ○ Immediately life-threatening ○ Severely incapacitating ○ Permanently disabling ○ Prolongs existing hospitalization

		◯ May require medical or surgical intervention to prevent one of the other outcomes listed in this definition
5.	What is the causal relationship of this AE to the study procedures?	◯ Not related ◯ Possibly related ◯ Probably related ◯ Definitely related
6.	Was this AE reported to the local IRB?	◯ Yes ◯ No, not required by the local IRB
Section A: Hypoglycemia <60 mg/dL: Follow-up questions		
7.	How was the low blood glucose first discovered?	◯ CGM sensor alarm ◯ Bedside glucose meter reading ◯ Central laboratory or blood gas analyzer ◯ Clinical symptoms
8.	What was the lowest blood glucose measured by the bedside glucose meter during the episode before any therapy was given?	____ mg/dL __ / __ / ____ __ : __ *24-hour clock* Source: ◯ Artery ◯ Central vein ◯ Peripheral vein ◯ Capillary ☐ Not Done
9.	What was the lowest blood glucose measured by the central laboratory or blood gas analyzer during the episode before any therapy was given?	____ mg/dL __ / __ / ____ __ : __ *24-hour clock* Source: ◯ Artery ◯ Central vein ◯ Peripheral vein ◯ Capillary ☐ Not Done
10.	If BG <40 mg/dL, enter the following lab values taken within 1 hour after the hypoglycemic event	☐ BG not <40 mg/dL Serum triglycerides: ____ mg/dL ☐ Not Done

		HDL-C: ☐ mg/dL ☐ Not Done LDL-C: ☐ mg/dL ☐ Not Done Total cholesterol: ☐ mg/dL ☐ Not Done Free fatty acids: ☐ mmol/L ☐ Not Done Lactate: ☐ mmol/L ☐ Not Done
11.	At any point during the hypoglycemia episode, did the subject exhibit the following clinical symptoms? (Check all that apply)	☐ Seizure ☐ Altered mental status ☐ Other, specify: ☐ None of the above ☐ Unable to assess due to subject's condition or current medications
12.	What was the lowest temperature of the subject within 1 hour prior to this event?	☐ C ☐ Not Done
13.	Was there a decrease in enteral or parenteral nutrition in the 6 hours prior to this event?	○ Yes, explain: ○ No
14.	Was there a decrease in glucose containing fluids (not including parenteral nutrition) in the 6 hours prior to this event?	○ Yes, explain: ○ No
15.	Was the subject receiving at least 5 mg/kg/min of glucose if < 6 years of age or at least 2.5 mg/kg/min of glucose if ≥ 6 years of age at the time of the event?	○ Yes ○ No
16.	Did the subject receive insulin within 3 hours prior to this event?	○ Yes ○ No
17.	Did the subject receive insulin within 24 hours prior to this event?	○ Yes ○ No
18.	Was there an insulin dosing error leading up to this event?	○ Yes, explain: If Yes, i. Was there a keystroke error or mistake in the glucose value entered into the insulin protocol that was either unnoticed or unable to be corrected within the allotted 5 minutes? ○ Yes ○ No

		ii. Was there a problem in programming the insulin pump? ◯ Yes, explain: ◯ No iii. Was there a significant time delay between when the recommendation was given and when the insulin rate was changed? ◯ Yes, min ◯ No ◯ No
19.	Was there a suspected glucose measurement error (not associated with an insulin dosing error) leading up to this event?	◯ Yes, explain: ◯ No
20.	Did the subject receive renal replacement therapy in the 6 hours prior to this event?	◯ Yes ◯ No
21.	Was the subject transported outside the ICU for any intervention (e.g., surgery, diagnostic procedure) within 6 hours prior to this event?	◯ Yes, explain: ◯ No
22.	Was there a decrease in the subject's inotropic support in the 6 hours prior to this event?	◯ Yes ◯ No
23.	Was there a decrease in the subject's corticosteroid medication dose in the 24 hours prior to this event?	◯ Yes ◯ No
Section B: Hyperglycemia >250 mg/dL (>6 hours after initiation of insulin infusion): Follow-up questions		
24.	How was the high blood glucose first discovered?	◯ CGM sensor ◯ Bedside glucose meter reading ◯ Central laboratory or blood gas analyzer
25.	What was the highest blood glucose measured by the bedside glucose meter during the episode before any therapy was given?	mg/dL / / : *24-hour clock* ◯ Artery ◯ Central vein ◯ Peripheral vein ◯ Capillary

		☐ Not Done
26.	What was the highest blood glucose measured by the central laboratory or blood gas analyzer during the episode before any therapy was given?	____ mg/dL __ / __ / ____ __ : __ *24-hour clock* Source: ◯ Artery ◯ Central vein ◯ Peripheral vein ◯ Capillary ☐ Not Done
27.	What was the temperature of the subject within 1 hour prior to this event?	____ C ☐ Not Done
28.	Was there an increase in enteral or parenteral nutrition in the 6 hours prior to this event?	◯ Yes, explain: ____ ◯ No
29.	Was there an increase in glucose containing fluids (not including parenteral nutrition) in the 6 hours prior to this event?	◯ Yes, explain: ____ ◯ No
30.	Was there an insulin dosing error leading up to this event?	◯ Yes, explain: ____ If Yes, i. Was there a keystroke error or mistake in the glucose value entered into the insulin protocol that was either unnoticed or unable to be corrected within the allotted 5 minutes? ◯ Yes ◯ No ii. Was there a problem in programming the insulin pump? ◯ Yes, explain: ____ ◯ No iii. Was there a significant time delay between when the recommendation was given and when the insulin rate was changed? ◯ Yes, ____ min ◯ No

		○ No
31.	Was there a suspected glucose measurement error (not associated with an insulin dosing error) leading up to this event?	○ Yes, explain: ____ ○ No
32.	Did the subject receive renal replacement therapy in the 6 hours prior to this event?	○ Yes ○ No
33.	Was the subject transported outside the ICU for any intervention (e.g., surgery, diagnostic procedure) in the 6 hours prior to this event?	○ Yes, explain: ____ ○ No
34.	Was there an increase in the subject's inotropic support in the 6 hours prior to this event?	○ Yes ○ No
35.	Was there an increase in the subject's corticosteroid medication dose in the 24 hours prior to this event?	○ Yes ○ No
Section C: Hypokalemia <2.5 mmol/L: Follow-up questions		
36.	What was the potassium concentration?	____ mmol/L
37.	What was the previous potassium concentration?	____ mmol/L __ / __ / __ __ : __ *24-hour clock*
38.	Was there a cardiac rhythm disturbance that required therapy during this episode of hypokalemia? (Do not include u-wave.)	○ Yes, explain: ____ ○ No
39.	Did the subject receive beta-agonist therapy in the 6 hours prior to the event?	○ Yes ○ No
40.	Was the subject receiving a loop diuretic (e.g., furosemide, bumetanide) in the 12 hours prior to the event?	○ Yes ○ No
41.	Did the subject receive insulin within 3 hours prior to this event?	○ Yes ○ No
42.	Did the subject receive insulin within 24 hours prior to this event?	○ Yes ○ No
Section D: New seizure (in subject without a known seizure disorder): Follow-up questions		
43.	Describe the nature, duration, and treatment of	____

	the seizure	
44.	What was the subject's blood glucose at the time of the seizure? (record value believed to be the most accurate by the clinical team)	mg/dL / / : *24-hour clock* Source: Bedside glucose meter reading Central laboratory or blood gas analyzer Not Done
45.	To what does the clinical team attribute the onset of seizure activity?	Suspected neurological source of infection Neurological injury at the time of hospital admission Suspected decreased oxygen delivery to the brain (e.g., hypoperfusion, hypoxia) Other, specify:
Section E: Catheter-associated bloodstream infection (CA-BSI): Follow-up questions		
46.	Was the CA-BSI adjudicated by the local infectious disease officer (RN/MD)?	Yes No
Section F: Catheter-associated urinary tract infection (CA-UTI): Follow-up questions		
47.	Was the CA-UTI adjudicated by the local infectious disease officer (RN/MD)?	Yes No
Section G: Surgical site infection (SSI): Follow-up questions		
48.	Was the SSI adjudicated by the local infectious disease officer (RN/MD)?	Yes No
Section H: Ventilator-associated pneumonia (VAP): Follow-up questions		
49.	Was the VAP adjudicated by the local infectious disease officer (RN/MD)?	Yes No
Section I: Other hospital-acquired infection: Follow-up questions		
50.	Identify the type of hospital-acquired infection	Urinary tract infection (UTI) not associated with a urinary catheter Wound infection associated with either the site of the subcutaneous monitor or a fingerprick Other wound infection Blood stream infection not associated with catheter Lower respiratory tract infection not associated with ventilator (e.g., pneumonia) Upper respiratory tract infection (e.g., tracheitis) Other, specify:

Section J: Continuous Glucose Monitor (CGM) related adverse event, bleeding or other (that did not involve hypoglycemia, hyperglycemia, or infection): Follow-up questions		
51.	Was there a significant amount of bleeding from the sensor site (i.e., greater than 1cc)?	◯ Yes If Yes, was the subject on anticoagulant therapy? ◯ Yes ◯ No ◯ No If no bleeding, describe the event:
52.	At the time of this event, did the subject have any of the following at the site of the sensor? (Check all that apply)	☐ Edema ☐ Poor perfusion ☐ None of the above ☐ Unknown
Section K: Bedside glucose meter related adverse event (that did not involve hypoglycemia, hyperglycemia, or infection): Follow-up questions		
53.	Describe the problem	
54.	What is the serial number of the bedside glucose meter involved in this event?	
55.	Enter the most recent vitals and lab values within 2 hours preceding this event	Systolic blood pressure: ____ mmHg ☐ Not Done Diastolic blood pressure: ____ mmHg ☐ Not Done Mean arterial pressure: ____ mmHg ☐ Not Done SpO_2: ____ % ☐ Not Done Heart rate: ____ bpm ☐ Not Done Respiration: ____ breaths/min ☐ Not Done Peripheral edema: ◯ Yes ◯ No ☐ Not Assessed
56.	Enter the most recent lab values	Hematocrit: ____ % ☐ Not Done Hemoglobin: ____ g/dL ☐ Not Done
57.	Did the subject have delayed capillary refill (>3 seconds) at the time the sample was drawn?	◯ Yes ◯ No ◯ Unknown
Section L: VAMP related adverse event: Follow-up questions		
58.	Describe the problem	

59.	What type of line was the VAMP placed on?	◯ Arterial ◯ CVL ◯ PIV ◯ PICC
60.	How many hours prior to the event was the VAMP placed?	☐ hr
61.	Were air bubbles visible in the VAMP?	◯ Yes ◯ No ◯ Unknown
62.	Was there disconnection or breakage of any parts of the VAMP?	◯ Yes ◯ No
63.	Were there any visible blood clots in the VAMP?	◯ Yes ◯ No
64.	Did the event require the placement of a new catheter?	◯ Yes ◯ No
65.	Did the subject require any additional interventions as a result of this event?	◯ Yes, explain: ☐ ◯ No
Section M: Computerized insulin dosing protocol related adverse event (that did not result in a hypoglycemia or hyperglycemia event): Follow-up questions		
66.	Describe the problem	☐
67.	Was the problem related to the spreadsheet?	◯ Yes ◯ No
68.	Was the problem related to the laptop computer?	◯ Yes ◯ No
69.	Was the problem related to the internet connection not working?	◯ Yes ◯ No
70.	Was there a keystroke error or mistake in the glucose value entered into the insulin protocol that was either unnoticed or unable to be corrected within the allotted 5 minutes?	◯ Yes ◯ No
Section N: Insulin dosing error (that did not result in a hypoglycemia or hyperglycemia event): Follow-up questions		
71.	Describe the problem	☐
72.	Was there a problem in programming the insulin	◯ Yes, explain: ☐

	pump?	No
73.	Was there a significant time delay between when the recommendation was given and when the insulin pump was changed?	Yes, min No