Mock Patients for *HALF-PINT* Data Entry Training Demonstration

The following are five mock patients screened on Monday, February 27, 2012.

Mock Screen Patient 1-

Study Screening (Daily Screening Form & Form 1):
Maria L. Martinez is a 5 year old white, Hispanic female who was admitted to your ICU on 2/27/12 at 05:25 for respiratory failure. Following a prolonged seizure, she was intubated in the Emergency Department at 04:00 due to apnea during seizure and is currently ventilated. After review of Maria's history, the staff discovers she has type 1 diabetes. She meets no other exclusion criteria. The last 3 digits of her medical record are 997, and she is in Bed 5 of your ICU.

Mock Screen Patient 2-

Study Screening (Daily Screening Form & Form 1):
Carlos B. Manuel is a two month old white, Hispanic male who was admitted to your ICU on 2/27/12 at 05:45 for new onset seizures. He was recently diagnosed with Timothy Syndrome with long QT syndrome. He was desaturating on room air and is currently maintaining an oxygen saturation of 92-94% on 4 L/min nasal cannula. Carlos is not currently receiving vasopressors or inotropes and meets no exclusion criteria. The last 3 digits of his MRN are 811, and he is in Bed 7 of your ICU.

Mock Screen Patient 3-

Study Screening (Daily Screening Form & Form 1):

Peter M. Novak is a 2 year old white, non-Hispanic male who was admitted to your ICU on 2/26/12 at 20:00 from an outside hospital for hemodynamic instability in the setting of 3 days of fever, headache and neck pain. His current treatment includes dopamine 6 mcg/kg/min, first prescribed on 2/26/12 at 22:00. The last 3 digits of his medical record are 389, and he is in Bed 8 of your ICU.

The patient was screened by the study team and met all eligibility requirements for enrollment. However, Peter's family is from Croatia and his parents do not speak English. Your site does not have a Short Form for Croatian, and the family is unable to provide consent.

Mock Screen Patient 4-

Study Screening (Daily Screening Form & Form 1):
Claudia J. Worsham is a 6 year old non-Hispanic, African American female admitted to your ICU on 2/27/12 at 05:30 for altered mental status and mechanical ventilation, and to assess tumor

progression. (She was diagnosed with diffuse pontine glioma in November, 2011.) She was intubated at 06:00 this day. The last three digits of her medical record number are 840, and she is in Bed 2 of your ICU.

The patient was screened by the *HALF-PINT* team and deemed eligible for enrollment. The attending signed off permission to approach the patient's parent/guardian, confirming she is not pregnant. The family was then approached by research staff, and they agreed to participate. Research staff received consent on 2/27/12 at 10:15. Research staff began tracking upon consent and the subject remained on ventilator.

Tracking (Consented Subject Tracking Sheet & Form 2):

Blood Glucose Checks:

Date	*Glucose value*	*Time*
2/27/12	142 mg/dL	1030
	128 mg/dL	1415
	149 mg/dL	2022
2/28/12	124 mg/dL	0801
	132 mg/dL	1415
	120 mg/dL	2022
2/29/12	138 mg/dL	0801
	145 mg/dL	1415
	129 mg/dL	2022
3/1/12	120 mg/dL	0810
	125 mg/dL	1400
	118 mg/dL	1950

After four days of tracking, the subject was discharged from your ICU on 3/1/12 at 21:30. She did not have a blood glucose value ≥ 150 mg/dL before discharge.

Mock Screen Patient 5-

Study Screening (Daily Screening Form & Form 1):

Patrick M. McNally is a 14 month old white, non-Hispanic male who arrived at your Emergency Department on 2/26/12 at 22:00. He was admitted to your ICU from the ED at 22:45 for respiratory insufficiency secondary to meningococcal meningitis, and he was intubated on 2/26/12 at 23:00.

The patient was screened by the *HALF-PINT* team and deemed eligible for enrollment. The attending signed off permission to approach the patient's parent/guardian. The family was then approached by research staff and consented to participate in the trial on 2/27/12 at 10:00. The last 3 digits of his medical record are 598, and he is in Bed 3 of your ICU.

Tracking (Consented Subject Tracking Sheet & Form 2):

Blood Glucose Checks:

Date	*Glucose value*	*Time*
2/27/12	140 mg/dL	1025
	149 mg/dL	1415
	158 mg/dL	2015
	165 mg/dL	2020

After a blood glucose value ≥ 150 mg/dL was measured and a second confirmatory value obtained, the subject was ready for randomization. He did not become ineligible during the tracking period. Staff went through all necessary modules on the website, and the subject was randomized this day at 22:00 into the TGC-2 group.

Medical History and Clinical Information (Form 3):

Medical History:
Patrick was born on 12/21/10. He was born premature (36 weeks post-menstrual age). He has no known genetic syndrome and his baseline mental status is normal for his age and he demonstrates good overall performance.

Admission:
The subject was admitted to your ICU on 2/26/12 at 22:45, directly from the ED, the primary reason for admission being respiratory infection. His height was 76 cm and weight 9.5 kg upon admission.

Respiratory Failure:
The subject was intubated on 2/26/12 at 23:00 and remains intubated at randomization. The primary reason for initiation of mechanical ventilation was acute respiratory failure related to sepsis. A chest x-ray was obtained this day and no acute onset bilateral infiltrates/opacities were identified. An arterial blood gas was obtained this day as well: PaO_2= 25 mmHg; FiO_2= 0.40; and mean airway pressure= 10 cmH_2O. Prior to this illness, Patrick was not on non-invasive ventilation or supported with ventilation via a tracheostomy overnight or during sleep.

Cardiovascular Failure:
The subject was not treated with vasopressors or inotropes at the time of consent.

Miscellaneous:
Patrick did not receive insulin prior to randomization.

The *HALF-PINT* study team completed the Contact and Demographic Information form with the parents and it was stored securely. The CBCL and PedsQL were completed and faxed to the HALF-PINT CCC secure fax number on 2/28/12 while the subject was still in the ICU.

Risk of Mortality at ICU Admission (Form 4):

PIM2: Data from first contact through the first hour of ICU admission (22:00 to 23:45 on 2/26/12)

PRISM III-12: Data from the first 12 hours of ICU admission (22:45 on 2/26/12 to 10:45 on 2/27/12)

Cardiovascular:

	Lowest	*Highest*
Temperature – *1st 12 hours*	38.3 C	40.0 C
Heart rate – *1st 12 hours*	152 bpm	176 bpm
Systolic blood pressure – *1st hour*	83 mmHg	N/A
Systolic blood pressure – *1st 12 hours*	79 mmHg	108 mmHg
Hemoglobin – *1st hour*	12.0 g/dL	N/A
Calculated HCO_3 – *1st hour*	38 mmol/L	N/A
pH from blood gas – *1st hour*	7.40	N/A

Neurological:

Pupillary response – *1st hour*	Both responsive	
Worst pupillary response – *1st 12 hours*	Both responsive	
Worst Glasgow Coma Score (GCS) – *1st 12 hours*	Eye Opening	3
	Verbal Response	4
	Motor Response	5
Worst level of consciousness – *1st 12 hours*	Lethargy	

Respiratory:

The subject was mechanically ventilated during the first hour.

PaO_2 – *1st hour*	95 mmHg
PaO_2 – *1st 12 hours (lowest)*	95 mmHg
FiO_2 – *1st hour*	0.70

Labs: *1st 12 hours*

	Lowest	*Highest*
pH	7.30	7.40
PCO_2	37 mmHg	42 mmHg
White blood cell count	30.0 K/µL	38.0 K/µL
Platelet count	350 K/µL	380 K/µL
Potassium	3.0 mmol/L	3.5 mmol/L
Total CO_2	28 mmol/L	30 mmol/L
Glucose	118 mg/dL	142 mg/dL
BUN	N/A	15 mg/dL
Creatinine	N/A	1.1 mg/dL
AST (SGOT)	N/A	25 IU/L
Prothrombin Time (PT)	N/A	11.0 sec
Partial Thromboplastin Time (PTT)	N/A	28.0 sec

Miscellaneous:
This admission to the ICU from the ED was not elective and Patrick was not recovering from a surgery, procedure, or cardiac bypass. He has not been diagnosed with any of the high-risk or low-risk diagnoses listed. He has not had any previous ICU admissions during this hospital stay, has not been diagnosed with diabetes, oncologic disease, or cardiovascular disease. He did not have pre-ICU CPR requiring chest compressions and has no known chromosomal abnormalities.

Note: For the purpose of data entry demonstration, this subject was given an abbreviated course.

Daily Data – Study Day 0 (2/27/12)

DOV:
The subject was randomized on 2/27/12 at 22:00 and remains in the participating ICU.

Daily ICU (Form 5):

Daily Assessment:
The subject remains intubated for the remainder of the day. The subject currently has an arterial line, CVL, PIV, and bladder catheter. He has no other devices this day. He has not received CPR or ECMO/VAD.

Medications: The subject is receiving treatment antibiotics and steroids this study day. He has not received inotropes, paralytic drip, or diuretics.

Nutrition: No nutrition was given during this study day.

Daily PELOD Score:
This subject has been diagnosed with meningococcal meningitis, an acute CNS disease.

Lowest Glasgow Coma Score (GCS)	Eye Opening	Not Done
	Verbal Response	Not Done
	Motor Response	Not Done
Worst pupillary response	Both responsive	

	Lowest	*Highest*
Heart rate	112 bpm	133 bpm
Systolic blood pressure	72 mmHg	112 mmHg
Creatinine	Not Done	
PF ratio - PaO_2	48 mmHg	62 mmHg
PF ratio - FiO_2	0.40	0.50
$PaCO_2$	39 mmHg	42 mmHg
White blood cell count	Not Done	
Platelet count	Not Done	
AST (SGOT)	Not Done	
Prothrombin Time (PT)	Not Done	
INR	Not Done	

Adverse Events:
No adverse events occurred this day.

Study Discharge:
The subject was not eligible for study discharge this day.

Daily Data – Study Day 1 (2/28/12)

DOV:
This is the first full day on study in the participating ICU.

Daily ICU (Form 5):

Daily Assessment:
The subject was extubated at 15:00 this study day. After extubation, the subject was supported by Humified High Flow Nasal Cannula (HHFNC) at 6 L/min of Oxygen flow for the remainder of the day. The subject currently has an arterial line, PIV, enteral feeding tube, and bladder catheter. He has no other devices this day. He has not received CPR or ECMO/VAD.

Medications: The subject is receiving steroids and treatment antibiotics this study day. He has not received inotropes, paralytic drip, or diuretics.

Nutrition: The subject received enteral nutrition this day. CHO = 326 kcal, Protein = 96 kcal, Lipid = 72 kcal. Total caloric intake = 494 kcal.

Daily PELOD Score:
This subject has been diagnosed with meningococcal meningitis, an acute CNS disease.

Lowest Glasgow Coma Score (GCS)	Eye Opening	4
	Verbal Response	4
	Motor Response	5
Worst pupillary response	Both responsive	

	Lowest	*Highest*
Heart rate	120 bpm	149 bpm
Systolic blood pressure	88 mmHg	115 mmHg
Creatinine	1.0 mg/dL	1.8 mg/dL
PF ratio - PaO_2	55 mmHg	68 mmHg
PF ratio - FiO_2	0.49	0.58
$PaCO_2$	37 mmHg	40 mmHg
White blood cell count	One Draw Only	20.0 K/µL
Platelet count	One Draw Only	366 K/µL
AST (SGOT)	One Draw Only	22 IU/L
Prothrombin Time (PT)	One Draw Only	10.3 sec
INR	One Draw Only	1.0

Adverse Events:
The subject experienced a seizure this day. He has no known seizure disorder. See next page for details.

Study Discharge:
The subject was not eligible for study discharge this day.

Adverse Event (Form 7):

The event, seizure, occurred at 06:45 and lasted for 2 minutes. It was expected and moderate in severity. The event is not related to the study. As this event was expected, it was not reported to the local IRB.

The nature of the seizure was tonic-clonic and the event was treated with diastat. The clinical team attributes the onset of the seizure to increased inflammation secondary to diagnosis of meningococcal meningitis.

A blood glucose value from the bedside glucose meter was 102 mg/dL at 06:50.

Daily Data – Study Day 2 (2/29/12)

DOV:
The subject was transferred to a non-ICU inpatient unit at 23:00 on 2/28/12.

Daily ICU (Form 5N):

The subject was supported by Humified High Flow Nasal Cannula (HHFNC) at 6 L/min of Oxygen flow until 21:00 this day.

The subject was eligible for study discharge this study day. He was extubated the previous day at 15:00. Non-invasive ventilation was discontinued at 21:00 this study day (and it was confirmed that non-invasive ventilation was not restarted in the subsequent 24-hour period). He was not administered intravenous vasopressors or inotropes during his hospital stay.

Discharge (Form 6):

Study Withdrawal:
The subject was not withdrawn early from the study.

Date Verification:
The subject was extubated at 15:00 on 2/28/12. Humidified High Flow Nasal Cannula at 6 L/min of Oxygen flow was administered until 2/29/12 at 21:00 and never restarted.

ICU Discharge:
The subject left the ICU at 23:00 on 2/28/12 to an inpatient non-ICU area. He did not have any surgical procedures during this ICU stay. He is too young to provide assent.

Hospital Discharge:
The subject was discharged from the hospital on 3/5/12 to his home. At time of discharge, his mental status was normal and he demonstrated good overall performance.

Subject Death:
The subject did not die in your hospital.