

HALF-PINT

Data Entry Training

Part 1: Screening and Tracking

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Outline

- Part 1: Screening and Tracking
 - I. Welcome and objectives
 - II. Screening and tracking procedures
- Part 2: InForm (see Part 2 slide set)
 - III. Introduction to InForm data management system
 - IV. HALF-PINT case report forms flowchart
 - V. Data entry demonstration
 - VI. Data entry certification process
 - Appendix. InForm reference slides

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Part 1. Screening and Tracking

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I. Objectives

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Objectives

- After this training you will be able to:
 - Understand the screening and tracking procedures
 - Complete the paper logs
 - Understand the basic flow of the case report forms
 - Enter a new patient into InForm
 - Enter patient data into InForm

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II. Screening and Tracking Procedures

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Logs Related to Screening & Tracking

- There are 4 paper logs related to *HALF-PINT* screening and tracking procedures
 - Patient Study ID Log (site-specific)
 - Daily Screening Form
 - Consent Log
 - Consented Subject Tracking Sheet
- The Data Coordinating Center (DCC) will send each site their Patient Study ID Log
- The other 3 paper logs will be available on the *HALF-PINT* website

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Screening

- Screening is to be performed and recorded at each site once daily, between 6 and 10 am, using the **Daily Screening Form**
- For sites with high census and frequent admissions throughout the day, screening may take place at numerous times during the course of the day
- Site directors are responsible for developing an optimal screening mechanism for their site by which eligible patients are identified as soon as possible after meeting criteria

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Screening

- Each morning, screen for patients who are:
 - in the appropriate age range (≥ 2 weeks and corrected gestational age ≥ 42 weeks and < 18 years)
 - newly diagnosed with cardiovascular failure (dopamine or dobutamine > 5 mcg/kg/min, or any dose of epinephrine, norepinephrine, milrinone, or vasopressin if used to treat hypotension) AND/OR respiratory failure (acute mechanical ventilation via ETT or tracheostomy anticipated for > 24 hours)
- Each patient meeting these inclusion criteria is to be assigned a "Sequential Study ID Number" (e.g., 1, 2, 3, ...) and added to the **Daily Screening Form**
- The **Daily Screening Form** is to be completed on a weekly basis (Monday – Sunday)
- We will demonstrate entering mock patients on the **Daily Screening Form**

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Mock Screen Patient #1

- Maria L. Martinez is a 5 year old white, Hispanic female.
- She 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.

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Mock Screen Patient #2

- 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 medical record are 811, and he is in Bed 7 of your ICU.

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Mock Screen Patient #3

- Peter M. Novak is a 2 year old white, non-Hispanic male.
- He 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.
- He meets no exclusion criteria.
- Peter's family is from Croatia and his parents do not speak English.
- Your site does not have a Short Form for Croatian.
- The last 3 digits of his medical record are 389, and he is in Bed 8 of your ICU.

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Mock Screen Patient #4

- Claudia J. Worsham is a 6 year old non-Hispanic, African American female.
- She was 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 on 2/27/12.
- She meets no exclusion criteria and is not pregnant.
- Consent was obtained on 2/27/12 at 10:15.
- The last three digits of her medical record number are 840, and she is in Bed 2 of your ICU.

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Mock Screen Patient #5

- 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.
- He meets no exclusion criteria.
- Consent was obtained 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.

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Patient Study ID and Consent Logs

- The **Patient Study ID Log** is to be completed as you assign “Sequential Study ID Numbers” to patients recorded on the **Daily Screening Form**
- Example Patient Study ID Number: 01-0002-4 = Site Number-Sequential Study ID Number-Final Tracking Digit
- The seven-digit Patient Study ID Number is needed in order to enter a patient into the InForm data management system
- The **Patient Study ID Log** is to be completed for all patients meeting inclusion criteria (including patients with exclusion criteria and eligible but not consented patients)
- Only eligible and consented subjects are to be entered on the **Consent Log**
- We will demonstrate entering the mock patients on the **Patient Study ID Log** and the **Consent Log**

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Tracking

- The **Consented Subject Tracking Sheet** is to be completed every morning summarizing the previous day’s events for all subjects for whom consent was obtained
- Blood glucose values are expected to be tracked multiple times a day
- Tracking continues until one of the following occurs:
 - The subject becomes ineligible (for a reason other than off IV vasopressors/inotropes or extubated; for example, ICU discharge, redirection of care, subject has new cardiac surgery)
 - The subject tracking reaches Study Day C-28
 - The subject has a confirmed blood glucose ≥ 150 mg/dL (total of 2 measurements ≥ 150 mg/dL within a 24 hour period)
- We will demonstrate entering the mock patients on the **Consented Subject Tracking Sheet**

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