CLINICAL RELEASE NOTES

Hospital Version 1.2 constitutes a minor release of the AHRQ Common Formats. The most significant changes include: 1) incorporation of new data elements on the Device module to include content for patient safety events related to Health IT, 2) a new module for Venous Thromboembolism, 3) RX Norm identifiers, and 4) compatibility with ICD-9 and ICD-10. Other minor changes are detailed below.

Healthcare Event Reporting Form (HERF) Release Summary

Clarifications

- Neonatal Patient Information questions have been updated with neonate terminology to avoid confusion from the Patient Information section: (Questions 13 - 16 on v 1.1 and Questions 12 - 15 on v 1.2)
  - Neonate's Name
  - Neonate's Date of Birth
  - Neonate Medical Record #
  - Neonate's Gender

Additions

- Venous Thromboembolism has been added as a new category selection of an event or unsafe condition. (Question 7 on v 1.1 and v 1.2)

Deletions

- The following questions have been deleted:
  - Was there any evidence of harm to a patient at the time of this report? (Question 2 on v 1.1)
  - How many patients did the incident reach? (Question 8 on v 1.1)

Patient Information Form (PIF) Release Summary

Clarifications

- The question "Which of the following interventions (rescue) were performed" was changed to ask if the interventions were documented, rather than performed. (Question 8 on v 1.1 and Question 6 on v 1.2)
- The intervention "Surgical intervention" was changed to "Surgical/procedural intervention" to clarify terminology. (Question 8 on v 1.1 and Question 6 on v 1.2)

Additions

- To accommodate new coding, ICD-10-CM was added to the principal diagnosis question: "Enter the patient's ICD-9-CM or ICD-10-CM principal diagnosis code at discharge (if available)." (Question 4 on v 1.1 and v 1.2)
- AHRQ has revised the harm scale. The new harm scale consists of two questions. The extent of harm has been separated from duration of harm. In addition, the number of scale points for the harm scale has been reduced to: Severe harm, Moderate harm, Mild harm, and No harm. (Question 5 on v 1.1 is now Questions 7 and 8 on v 1.2)
- A new question for duration of harm has been added: "What is the anticipated duration of the harm to the patient." Answers available are: Permanent (one year or greater), Temporary (less than one year), or Unknown. (Question 8 on v 1.2)

Summary of Initial Report (SIR) Release Summary

Clarifications

- The date of the report question has been modified to clarify that it is the date of the summary of the initial report. (Question 1 on v 1.1 and v 1.2)
- "Relative" has changed to "family member" for who reported the event or unsafe condition. (Question 3 on v 1.1 and v 1.2)
- NQF Serious Reportable Events have been updated to reflect the 2011 publication of a revised list of events. (Question 12 on v 1.1 and Question 11 on v 1.2)

Additions

- Nursing assistant, housekeeping, maintenance, patient care assistant, and administrator/manager have been added as answer choices for who reported the event or unsafe condition. (Question 3 on v 1.1 and v 1.2)
- The type of healthcare professional reporter has been expanded to include speech, physical and occupational therapist, and dietician. (Question 4 on v 1.1 and v 1.2)

Deletions

- Liaison officer, domestic, hotel service personnel, and anonymous have been removed as answer choices for who reported the event or unsafe condition. (Question 3 on v 1.1 and v 1.2)
- Equipment/device has been removed from the list of contributing factors to the event. (Question 9 on v 1.1 and v 1.2)
- The question regarding health information technology being implicated in the event has been removed. (Question 10 on v 1.1)

Blood Release Summary

Clarifications

- "Event" has been expanded to "event or unsafe condition" for the questions regarding type of blood product and ISBT code. (Questions 1 and 2 on v 1.1 and v 1.2)
- For clarification, the questions asking when the event was discovered and originated have had the answer "Product administration" revised to "Product administration (transfusion or infusion)." (Questions 8 and 9 on v 1.1 and v 1.2)

Device or Medical/Surgical Supply , including Health Information Technology (HIT) Release Summary

Clarifications

- The module has been revised to include specifics for those events where an IT component may have contributed to an event. Thus, the module has been renamed to "Device or Medical/Surgical Supply, including Health Information Technology (HIT)."
- Event has been expanded to "event or unsafe condition", for the question asking about the type of device involved. (Questions 1, 6, and 9 on v 1.1 and Questions 1, 2, 19 on v 1.2)
- Description of the event or unsafe condition answer have been changed from "Operator error" to "Use error." (Question 6 on v 1.1 and Question 1 on v 1.2)
- Description of the event or unsafe condition answer "Device failure" has been expanded to state "Device defect or failure, including HIT". (Question 6 on v 1.1 and Question 1 on v 1.2)
- Involvement of single-use device question has been rephrased for clarification: "Was a device intended for single use reused in the event or unsafe condition (including use of a reprocessed single-use device)?" (Question 9 on v 1.1 and Question 19 on v 1.2)

Additions

- The answer "HIT device" has been added as a type of device. (Question 1 on v 1.1 and Question 2 on v 1.2)
- The question "What is the name (brand or generic) of the device, product, or medical/surgical supply?" has been expanded to include software. (Question 4 on v 1.1 and Question 5 on v 1.2)
- Software version, firmware version, and asset tag were added as additional known identifiers. (Question 10 on v 1.1 and Question 7 on v 1.2)
- The following new questions have been added:
  - What is the software version? (Question 9 on v 1.2)
  - What is the firmware version? (Question 10 on v 1.2)
  - What is the asset tag number? (Question 17 on v 1.2)
  - Was a device intended for a single use involved in the event or unsafe condition? (Question 18 on v 1.2)
  - Did the event or unsafe condition involve a medication or other substance? (Question 20 on v 1.2)
  - Which of the following best characterizes the type of HIT device related to the event or unsafe condition? (Question 21 on v 1.2)
  - Which component of the administrative/billing system? (Question 22 on v 1.2)
  - Which type or component of the EHR? (Question 23 on v 1.2)
  - Which of the following describes the circumstances involving the HIT device in the event or unsafe condition? (Question 24 on v 1.2)
  - Which problem(s) resulted from the equipment/device function problem? (Question 25 on v 1.2)
  - Which ergonomics or human/device interface issue(s)? (Question 26 on v 1.2)

Deletions

- Device involvement and type of operator error questions have been deleted. (Questions 7 and 8 on v 1.1)

Fall Release Summary

Clarifications

- When asked who observed the fall, “visitor, family, or another patient” was clarified with “visitor, family, or another patient, but not staff.” (Question 3 on v 1.1 and v 1.2)
- The question “Prior to the fall, was a fall risk assessment performed” was changed to ask if the fall risk assessment was documented, rather than performed. (Question 7 on v 1.1 and v 1.2)
- For fall prevention, the answer “physical/occupational therapy” has been enhanced to include exercise or mobility program. (Question 9 on v 1.1 and 10 on v 1.2)

Additions

- The answer “skin tear, avulsion, hematoma or significant bruising” was added as a type of injury the patient sustained. (Question 5 on v 1.1 and v 1.2)
- “Navigating bedrails” and “transferring from wheelchair” was added when discussing the activites the patient was doing prior to the fall. (Question 6 on v 1.1 and v 1.2)
- The question “At the time of the fall, were any of the following risk factors present?” has been added. (Question 9 on v 1.2)
- The following answers have been added as part of fall prevention to reflect currect practices: (Question 9 on v 1.1 and Question 10 on v 1.2)
    - Non-slip floor mats
    - Hip and/or joint protectors
    - Supplemental environmental or area lighting (when usual facility lighting is considered insufficient)
    - Visible identification of patient as being at risk for fall (e.g., Falling Star)
- The question “Did restraints, bedrails, or other physical device contribute to the fall (includes tripping over device electrical power cords)?” has been added. (Question 13 on v 1.2)

Deletions

- The answers “Fall alert” and "Side rails" were deleted from fall prevention. (Question 9 on v 1.1 and Question 10 on v 1.2)

Healthcare-associated Infection Release Summary

Clarifications

- “Gastrointestinal system infection” was replaced with “Gastrointestinal system infection – non CDI”, for other type of infection. (Question 9 on v 1.1 and v 1.2)
- The abreviations (PNU1), (PNU2), and (PNU3) were added to VAP classification. (Question 11 on v 1.1 and v 1.2)

Additions

- “Clostridium difficile infection (CDI) - gastrointestinal system infection” was added as a type of HAI being reported. (Question 4 on v 1.1 and v 1.2)

Medication or Other Substance Release Summary

Additions

- The answer "Drug-drug, drug-food, or adverse drug reaction as a result of a prescription and/or administration of a drug and/or food prior to admission" has been added as a type of medication/substance. (Question 1 on v 1.1 and v 1.2)
- Herbal supplements were added as an inclusion for prescription or over-the-counter, when asked type of medication. (Question 2 on v 1.1 and v 1.2)
- The following medication details have been added as new questions, to accommodate RXNORM:
  - Ingredient RXCUI (if known) (Question 18 on v 1.2)
  - Brand name RXCUI (if known) (Question 20 on v 1.2)
  - Clinical drug component RXCUI (if known) (Question 23 on v 1.2)
  - Dose form RXCUI (if known) (Question 25 on v 1.2)

Perinatal Release Summary

Clarifications

- Answers "Mother and fetus(es)" and "Mother and neonate" have been changed to "Fetus(es)" and "Neonate(s)", when asked who was affected by the event. Mother is already a separate answer and a user may check all answer values that apply. (Question 2 on v 1.1 and Question 5 on v 1.2)
- The question "What was the neonate's birthweight?" was replaced with "What was the neonate's birthweight (or weight of stillborn)?" (Question 13 on v 1.1 and Question 15 on v 1.2)

Additions

- The answers for type of neonatal adverse outcome have been modified to incorporate ICD-10 CM. "Birth trauma/injury as listed under ICD-9-CM 767 or ICD-10-CM P10-P15" replaces the previous ICD-9-CM reference. (Question 19 on v 1.1 and Question 11 on v 1.2)
- The answer "Attempted vaginal delivery followed by Cesarean section" has been added as a mode of delivery. (Question 9 on v 1.1 and Question 18 on v 1.2)

Deletions

- "Neonate/fetal injury only" was deleted as an adverse outcome for the mother, since the outcome applies to the neonate or fetus. (Question 14 on v 1.1 and Question 6 on v 1.2)

Pressure Ulcer Release Summary

Clarifications

- The references to "Stage" in answers have been updated to reflect current terminology, "Stage/Category I, II, III, IV." (Questions 1, 2, and 3 on v 1.1 and v 1.2)
- The advanced stage answer "Mucosal ulcer only (no skin involvement)" has been modified to "Mucosal, arterial, or venous ulcer or diabetic foot ulcer or pressure ulcer related to palliative care." (Question 1 on v 1.1 and v 1.2)
- The prevention intervention "Nutritional support" was modified to "Hydration and/or nutritional support." (Question 9 on v 1.1 and v 1.2)

Additions

- "Skin care practices to prevent moisture and shearing" was added as a prevention intervention. (Question 9 on v 1.1 and v 1.2)
- The answer "Restraints" was added as a type of device or appliance involved in the development of the pressure ulcer. (Question 11 on v 1.1 and v 1.2)

Surgery or Anesthesia Release Summary

Clarifications

- The question "What type of anesthesia or sedation was used?" was modified to "Which combination of anesthesia and sedation was used?" (Question 7 on v 1.1 and Question 5 on v 1.2)
- "What type of anesthesia" is now a unique question. (Questions 6 and 7 on v 1.2) It was previously combined in the question "What type of anesthesia or sedation was used?" (Question 7 on v 1.1)
- Dependent on the answer response to which combination of anesthesia and sedation was used, the user will complete the question "What type of anesthesia" or "What was the level of sedation"? (Questions 6, 7, 8, and 9 on v 1.2)
- The question "What was the total length of time of the procedure (i.e., induction of anesthesia to the end of anesthesia)?" has been simplified to "What was the length of time from induction of anesthesia to the end of anesthesia?". (Question 6 on v 1.1 and Question 10 on v 1.2)
- The answer "Before anesthesia started (or no anesthesia used)" was modified to "Before anesthesia started or, if no anesthesia used, before procedure started", when specifying when the event was discovered. (Question 5 on v 1.1 and Question 13 on v 1.2)
- The question asking if the surgical event was an unintentionally retained object has been modified, with "unintentionally" removed. (Question 15 on v 1.1 and Question 18 on v 1.2)

Additions

- To accommodate new coding, ICD-10-CM was added to the procedure code question: "Enter ICD-9-CM or ICD-10-CM procedure code associated with this event." (Question 2 on v 1.1 and v 1.2)

Deletions

- "No sedation (if regional, local, or topical anesthesia)" was deleted as a level of sedation choice. (Question 8 on v 1.1 and Questions 8 and 9 on v 1.2)

Venous Thromboembolism

A new module, Venous Thromboembolism, is available with the Common Formats 1.2 release. The module includes the following questions:

- Which of the following occurred? (Question 1)
- What was the location of the DVT? (Question 2)
- Which diagnostic test confirmed the DVT? (Question 3)
- Which diagnostic test confirmed the PE? (Question 4)
- Prior to the onset of the VTE incident, was a formal VTE risk assessment documented? (Question 5)
- Was use of a VTE prophylaxis order set documented? (Question 6)
- What was the patient's documented risk of VTE? (Question 7)
- Prior to the onset of the VTE incident, what was the documented risk of bleeding, if any? (Question 8)
- Prior to the onset of the VTE incident, was any physical or mechanical prophylaxis (e.g., graduated compression stockings, intermittent pneumatic compression device, venous foot pumps) applied? (Question 9)
- Prior to the onset of the VTE incident, was any pharmacological anticoagulant prophylaxis administered? (Question 10)
- Which of the following best describes why the pharmacologic anticoagulant prophylaxis was not given? (Question 11)