Understanding AE Reporting

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Overview

- General Overview/Introduction
- Study Specific as to which Version is used
- Example Senario

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What is an Adverse Event?

"An adverse Event (AE) is an untoward medical occurrence involving a patient or a subject in a clinical trial which does not necessarily have a causal relationship to the treatment."

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Translation

- Adverse events are unwanted and, many times, harmful outcomes.
- Serious Adverse Events (SAE's)
- They may or may not be related to the treatment.
- Not the same as a side effect or an adverse reaction because it is not always clear that the treatment caused the effect.

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How are AE's Identified?

- Direct Patient Interaction
- Interaction with the physician and clinical staff
- Medical Record Review

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What is the next step?

- Using the appropriate CTCAE version, find the adverse event
- Identify the Grade according to the symptomatology
- Determine the attribution with the assistance of the physician
- Are they classified as expected and unexpected.

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Direct patient interaction

- Ask questions
  - “How do you feel?” - is too generic. Tailor your questions to the patient, the drug, the procedure
  - Ask specific questions
  - When a symptom is brought up, ask more questions to help to determine the severity of the event
  - Don’t be afraid to take notes so that nothing is omitted

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Interaction with physician and staff

- Talk with the clinical staff about their observations
- Read their visit documentation and ask about potential events you may identify
- REMEMBER: What is important from a clinical perspective may not be the same as from a research perspective, so don’t be afraid to ask questions

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Medical Record Review

- Lab results, radiology reports, nursing and physician notes
- Be sure to note what diagnoses the patient had upon admission
- Surgical trials rely heavily on medical record review
- Review hospitalizations which may occur between visits/treatments
- Remember to cross check results/report/notes
- Check for the accuracy of the notes

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Adverse Events Senario

- A 79 year old white female underwent a right VATS, right upper segmentectomy and lymph node dissection. She was randomized to sublobar resection as a participant in the CALGB 140503 study.
- On postoperative day 2, she developed a fever of 101. Urine was cloudy. Chest X-ray showed atelectasis.
- On postoperative day 3, urine culture confirmed UTI. Chest X-ray showed improvement in the atelectasis. IV antibiotics were ordered to treat the UTI
- On postoperative day 5, a general surgery intern documented that the patient was in acute renal failure.

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Fever

- Found under “Constitutional Symptoms” section
- Fever (in absence of neutropenia, where neutropenia is defined as ANC <1.0 x 109/L)
- 38.0 -3.90˚ C (100.4 – 102.2˚ F), Grade 1
- Most trials provide a list of expected AE’s to suit their purposes. Fever is not on the list provided for this trial, so it an unexpected AE.

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Urinary Tract Infection

- Found under “Infection” section
- Infection with unknown ANC –Select from listing at the end of the section) “Urinary Tract NOS”
- Grade 3 – IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated
- Unexpected AE

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Atelectasis (a collapse of a portion of the lung)

- Found under the “Pulmonary/Respiratory” Section
- Atelectasis
- Grade 1 – asymptomatic with radiologic evidence only
- 1-Expected AE, as it appears of the list provided, and is a common complication of a lung resection

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Acute Renal Failure

- This is one of those times when you must be alert and not believe everything you read.
- The patient's admission H&P identified her as having "Chronic Renal Failure" Her preoperative GFR was 43.
- On postoperative day 5, when the intern documented her as being in acute renal failure, her GFR was 43.
- Does this constitute an adverse event?

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Attribution

- Was the AE related to the treatment? (Unrelated, unlikely, possible, probable, definite)
- Assign the attribution (with assistance of the physician)
- Have the physician sign documentation regarding the attribution for the study binder.

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Senario Attributions

- Fever – possible
  - Could be related to the atelectasis, though unlikely. Probably symptom of UTI, but pt could have entered the hospital in an asymptomatic condition.
- Urinary Tract Infection – possible
  - Could be caused by the indwelling catheter, which was inserted for the surgical procedure.
- Atelectasis – definite
  - Atelectasis is a common complication of lung resection, therefore there is little doubt of its relation.

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Conclusion

- Adverse Event Reporting is an important part of clinical research.
- Be sure you use the correct CTCAE version for the study.
- All events should be reported so that their attributions can be determined.
- If you are not sure of something, ask your supervisor, research nurse, or physician.
- Make sure you document your findings and the reasons behind the decisions that were made. And include the physician's signature (electronic or actual)

- Questions?

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