MedDRA Coding and Medication Error Topics

Patrick Revelle (MSSO)
Topics for Presentation

• MSSO's MedDRA maintenance role
• MedDRA's history with medication errors
• Developmental efforts
• FAERS and ICSRs
• MedDRA LLT level for coding
• Examples of coding issues
MedDRA Maintenance

- Maintenance and Support Services Organization (MSSO)
  - Receives requests for new terms or changes to existing terms
  - Team includes 8 MDs to review and respond to requests
  - MedDRA released twice a year in 11 languages
Number of Implemented Changes over time
MedDRA 17.1 Changes

- New Terms: 782
- Mods to Existing Terms: 584
- SMQ CRs: 191
- Translation CRs: 439
Expansion of Medication Error Terms

• Prior to MedDRA Version 8.0 (March 2005), only one term existed - PT Medication error

• Medication error section expanded in v8.0
  – Added HLGT Medication errors in Injury, poisoning and procedural complications SOC
    • HLT Maladministrations
    • HLT Medication errors due to accidental exposures
    • HLT Medication monitoring errors
    • HLT Overdoses
    • HLT Medication errors NEC
Expansion Of Medication Error Terms (cont)

• FDA requested the initial set of Medication Errors terms to be added to MedDRA
  – Support goal of accurately capturing various types of medication errors and ultimately preventing them
  – HLGT *Medication errors* was added in *Injury, poisoning and procedural complications SOC*
• HLTs added to support stage at which the error occurred in the patient care system, the types of medication errors
Medication Errors – Terms in MedDRA

- Approx. 200 terms under HLGT *Medication errors*
  - Examples
    - *LLT Intramuscular formulation administered by other route*
    - *LLT Wrong drug dispensed*
EU Action Plan on Medication Errors

• Since July 2012 EU pharmacovigilance legislation requires
  – Reporting of ADRs associated with medication errors
  – Involvement of patient safety organizations
  – Facilitation of direct patient reporting

• EU regulatory network agreed on several deliverables to be completed by September 2015
  – Includes “Good practice guide on coding and reporting medication errors”

• EU requested PtC WG to provide consultation on sections of good practice guide that reference PtC documents
Concept Descriptions

• Appendix B in MedDRA Introductory Guide
• To assist in understanding and appropriate use of medication error and product quality issue terms in regulatory reporting
• Medication error descriptions developed by FDA and MSSO
Medication Error
Concept Description

• **Documented hypersensitivity to administered drug:** This medication error refers to the situation when a patient is administered a drug that is documented in the patient's medical file to cause a hypersensitivity reaction in the patient. Example: Despite the fact that the patient's medical record indicated "sulfa allergy," the physician prescribed a sulfa antibiotic. Subsequently, the patient took the antibiotic and experienced hives.
MedDRA PTC Documents

- Two PTC documents
  - Term Selection
  - Data Retrieval and Presentation

- Using MedDRA is a big step forward
- Using MedDRA the same way is a leap toward harmonization
• 3.15.1 Medication/Administration Errors
  – 3.15.1.1 Medication errors reported with clinical consequences
  – 3.15.1.2 Medication errors and potential medication errors reported without clinical consequences
  – 3.15.1.3 Medication errors in the context of labeled interactions
  – 3.15.1.4 Do not infer a medication error
Developmental Efforts

• Medication monitoring errors – changes in v17.1
  – New medication monitoring error terms
  – Expanded section with examples in MTS:PTC

• Complex change proposals for v18.0
  – Change placement of HLT *Overdoses* and new HLT *Underdoses*
    • Rationale: intentional overdose/underdose concepts are not medication errors and are not appropriately placed under HLGT *Medication errors*
  – Add new HLT *Off label uses*
    • Rationale: Need more specificity for coding and retrieving reports of off label use; currently only one PT *Off label use*

• Changes to MedDRA and updated guidance in PtC documents will be in MedDRA Version 18.0 in March 2015
SMQ *Medication errors*

**Rationale for development**
- Not all medication error concepts are in HLGT *Medication errors*
- Compliance terms in SOC *Social circumstances*
- Exposure and poisoning terms (SOC Injury, poisoning and procedural complications)
- Product quality terms (SOC *General disorders and administration site conditions*)

**Current status**
- Approved by ICH Advisory Panel for development
- Term list developed by CIOMS SMQ team of regulators and industry representatives (including the MSSO)
- CIOMS SMQ Working Group starting testing
Thank you for your attention

Any Questions?