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Overview

- Using the hierarchy
- Retrieving product use and quality concepts
- Preview of complex changes
- SMQ *Medication errors* update
MedDRA Hierarchy: Help or Hindrance?

- Grouping terms: HLGT and HLT
- Help in coding
  - Provides groupings in which to search
- Help in retrieval
  - Groups related terms for presentation and analysis
- Hindrance
  - Specificity is not uniform throughout MedDRA
  - Terms related to a medical condition can be in more than one SOC

Top-Down Approach to Coding

- For medication errors and product quality issues especially, “top-down” navigation in HLGTs is best approach for term selection
- See Concept Descriptions
  - Appendix B of MedDRA Introductory Guide
  - New Web-Based Browser
Top-Down Approach to Coding (cont)

“Drug was contaminated with Staphylococcus”

- General description and administration site conditions
- Administration site reactions
- Body temperature conditions
- Complications associated with device
- Device issues
- Fatal outcomes
- General system disorders NEC
- Product quality issues
  - Product contamination and sterility issues
  - Product contamination and sterility issues selected
- Product contamination
  - Product contamination chemical
    - Product contamination chemical selected
  - Product contamination chemical microbial
    - Product contamination chemical microbial selected
- Product contamination physical
- Product contamination with body fluid
- Product stability lacking
- Suspected transmission of an infectious agent via product
- Transmission of an infectious agent via product

Bottom-Up Approach to Coding

“6 year old boy accidentally ingested drug X”

- Injury, poisoning and procedural complications
- Administration site reactions
- Bone and joint injuries
- Exposures, chemical injuries and poisoning
- Injuries by physical agents
- Injuries NEC
- Medication errors
  - Accidental exposures to product
    - Accidental ingestion
      - Accidental ingestion of drug
        - Accidental ingestion of drug selected
      - Accidental ingestion of product
        - Accidental ingestion of product selected
      - Accidental ingestion of drug and product
        - Accidental ingestion of drug by child
          - Accidental ingestion of drug by child selected
        - Accidental ingestion of drug by child
          - Accidental ingestion of drug by child selected

Search Options:
- Use Synonym List
- Use Browser
- Use Symptom List
- Use Diagnosis List
- Use Comorbidity List

Total Search Results: 1
Details: LLT (1)

Use “Go to Browser”
## Use of HLTs

<table>
<thead>
<tr>
<th>Adverse Event (MedDRA v17.0)</th>
<th>25 mg MyDrug (N=44)</th>
<th>Placebo (N=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOC Investigations</td>
<td>13 (29.5%)</td>
<td>2 (13.3%)</td>
</tr>
<tr>
<td>HLT Liver function analyses</td>
<td>16</td>
<td>0</td>
</tr>
<tr>
<td>HLT Tissue enzyme analyses NEC</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>HLT Digestive enzymes</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>HLT White blood cell analyses</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>HLT Skeletal and cardiac muscle analyses</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>HLT Carbohydrate tolerance analyses (incl diabetes)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>HLT Faecal analyses NEC</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>HLT Vascular tests NEC (incl blood pressure)</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>HLT Renal function analyses</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>HLT Urinalysis NEC</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Patients may have more than one event reported

## Caution

▲ Ensure all terms are relevant to output

- HLT Vascular tests NEC (incl blood pressure)
  - PT Blood pressure decreased
  - PT Blood pressure increased

▲ Related PTs in different locations in SOC

- HLT Bullous conditions
  - PT Stevens-Johnson syndrome
- HLT Exfoliative conditions
  - PT Dermatitis exfoliative
Standardised MedDRA Queries

▲ Groupings of terms from one or more MedDRA System Organ Classes (SOCs) related to defined medical condition or area of interest
▲ Included terms may relate to signs, symptoms, diagnoses, syndromes, physical findings, laboratory and other physiologic test data, etc., related to medical condition or area of interest

SMQs in Production - Examples

▲ As of Version 17.1, a total of 96 in production

- Agranulocytosis
- Anaphylactic reaction
- Cerebrovascular disorders
- Convulsions
- Depression and suicide/self-injury
- Hepatic disorders
- Hypersensitivity
- Ischaemic heart disease
- Lack of efficacy/effect
- Osteonecrosis
- Peripheral neuropathy
- Pregnancy and neonatal topics
- Pseudomembranous colitis
- Rhabdomyolysis/myopathy
- Severe cutaneous adverse reactions
- Systemic lupus erythematosus
Recital 17

Member States should operate a pharmacovigilance system to collect information that is useful for the monitoring of medicinal products, including information on suspected adverse reactions arising from use of a medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, including overdose, misuse, abuse and medication errors, and suspected adverse reactions associated with occupational exposure.

Occupational Exposures

- Injury, poisoning and procedural complications
  - Administration site reactions
  - Bone and joint injuries
  - Exposures, chemical injuries and poisoning
    - Chemical injuries
    - Exposures associated with pregnancy, delivery and lactation
    - Exposures to agents or circumstances NEC
    - Fetal and neonatal conditions associated with product exposure
  - Non-occupational environmental exposures
    - Occupational exposures
      - Occupational exposure to air contaminants
      - Occupational exposure to dust
      - Occupational exposure to extreme temperature
      - Occupational exposure to noise
      - Occupational exposure to product
      - Occupational exposure to radiation
      - Occupational exposure to toxic agent
      - Occupational exposure to vibration
      - Organic dust toxic syndrome
    - Pathways and sources of exposure
      - Poisoning and toxicity
    - Injuries by physical agents
      - Injuries NEC
    - Medication errors
    - Procedural related injuries and complications NEC
Product Use Concepts

- MedDRA Term Selection: Points to Consider, Section 3.16.

<table>
<thead>
<tr>
<th>Concept</th>
<th>Intentional?</th>
<th>By Whom?</th>
<th>Therapeutic Use?</th>
<th>Additional Sections in this Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misuse</td>
<td>Yes</td>
<td>Patient/consumer</td>
<td>Yes (3.16.1)</td>
<td></td>
</tr>
<tr>
<td>Abuse</td>
<td>Yes</td>
<td>Patient/consumer</td>
<td>No (3.16.2)</td>
<td></td>
</tr>
<tr>
<td>Addiction</td>
<td>Yes</td>
<td>Patient/consumer</td>
<td>No (3.16.3)</td>
<td></td>
</tr>
<tr>
<td>Medication error</td>
<td>No</td>
<td>Patient/consumer</td>
<td>Yes (3.15)</td>
<td></td>
</tr>
<tr>
<td>Off label use</td>
<td>Yes</td>
<td>Healthcare provider</td>
<td>Yes (3.27)</td>
<td></td>
</tr>
</tbody>
</table>

*Definitions of misuse may not always include the concept of therapeutic use; misuse may be similar to the concept of abuse in some regions.

HLGT Medication errors – Challenges

- Contains terms which are not medication errors
- HLT Overdoses leads to noise in signal detection
- Also, PT Intentional underdose in HLT Maladministrations
Off Label Use and Misuse - Challenges

- In HLT *Therapeutic procedures NEC* in Surgical SOC
- Some LLTs not specific to PT concept
  - Adult product administered to child could be ME, OLU or misuse
- Need to code and aggregate OLU more precisely

Solution – Complex Changes in MedDRA

- To be implemented in MedDRA Version 18.0
- HLGT *Medication errors*; off label use and misuse concepts together in new HLGT *Product use issues* in Injury SOC
- Abuse concepts remain in Psychiatric SOC
  - Multi-axial links to Injury SOC needed in future?
- Separate HLTs for overdoses and underdoses (non-MEs)
- HLT *Off label use*
  - Can be expanded
- HLT *Product use issues NEC*
  - Intentional and unqualified concepts
SMQ Medication errors

- Even with new coding guidance and changes to hierarchy, retrieval challenges remain
- Terms outside HLGT Medication errors may also retrieve ME cases
  - HLT Overdoses NEC and HLT Underdoses NEC
  - HLT Product use issues NEC
  - Product quality terms (General SOC)
  - Device terms (General SOC)
  - Compliance terms (Social SOC)
- SMQ Medication errors now in development
  - Preliminary term lists drawn up
  - Testing to start
Product Quality Issues

- HLGT *Product quality issues* in General SOC
- 27th SOC in MedDRA Version 19.0 (March 2016)
  - Existing terms from HLGT *Product quality issues*
  - Additional manufacturing product quality terms
  - Organization and contents to be determined

Thank you

Questions?