Preview of New MedDRA Hierarchy for Medication Errors – Coding and Retrieval Considerations

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Outline

- Background to hierarchy revision
- Overview of new hierarchy
- Impact on coding medication errors
- Retrieval considerations
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.
Revised March 2015

- MedDRA Version 18.0

Hierarchy helps

- Medication errors, misuse, off label use, overdoses, underdoses in same SOC
- Miscellaneous product use issues
  - Intentional
  - Neutral/unspecified
Overlapping concepts

Hierarchy hinders

• Forces distinction between MEs and product use issues, but
  • Some terms in HLGT Medication errors don’t specify error or accidental
  • Neutral terms in HLT Product use issues NEC that could represent medication errors, misuse, or off label use e.g., PT Drug administered to patient of inappropriate age
New Hierarchy

- Discussed with expert groups
  - Points to Consider Working Group
  - MedDRA Expert Panel

- Posted complex change proposal for comments from MedDRA users (July-September 2016)
  - Majority of feedback in favour

- To be implemented in MedDRA Version 20.0 (March 2017)
Advantages

- Avoids force-classification of MEs vs. product use
- Classification by stage in the medication/product process (EMA Good Practice Guide Section 5.5.1)
- Intercepted medication errors under relevant stage HLTs
- Intentional concepts separated from errors/unspecified issues
- “Product” covers medication and other product concepts such as device use/error terms
HLGT Medication errors and other product use errors and issues

- Accidental exposures to product
- Medication errors, product use errors and issues NEC
- Product administration errors and issues
- Product confusion errors and issues
- Product dispensing errors and issues
- Product monitoring errors and issues
- Product preparation errors and issues
- Product prescribing errors and issues
- Product selection errors and issues
- Product storage errors and issues in the product use system
- Product transcribing errors and issues and communication issues
HLGT Off label uses and intentional product misuses/use issues
  • Off label uses
  • Intentional product misuses
  • Intentional product use issues

HLGT Overdoses and underdoses NEC
  • Overdoses NEC
  • Underdoses NEC

Existing grouping term
New grouping term
Coding Principles

- Select LLT that most accurately reflects the reported verbatim information.
- Refer to concept descriptions in MedDRA Introductory Guide.
- May be appropriate to select more than one term.
- Familiarity with hierarchy is essential.
- Navigating “Top down” is optimal approach for medication errors and product use issues.
- Check hierarchy to ensure placement reflects meaning.

MedDRA Term Selection: Points to Consider document
Coding Example 1

"Due to a prescribing error, the child was given drug X which is labelled for use in adults only"

<table>
<thead>
<tr>
<th>LLT</th>
<th>PT</th>
<th>HLT</th>
<th>HLGT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current hierarchy (MedDRA v19.0)</td>
<td>Drug prescribing error</td>
<td>Drug prescribing error</td>
<td>Medication errors</td>
</tr>
<tr>
<td></td>
<td>Drug administered to patient of inappropriate age</td>
<td>Product use issues NEC</td>
<td>Product use issues</td>
</tr>
<tr>
<td>New hierarchy</td>
<td>Drug prescribing error</td>
<td>Drug prescribing error</td>
<td>Product prescribing errors and issues</td>
</tr>
<tr>
<td>✅ Stages of error represented</td>
<td>Drug administered to patient of inappropriate age</td>
<td>Product administration errors and issues</td>
<td>Medication errors and other product use errors and issues</td>
</tr>
<tr>
<td>✅ Terms in same HLGT</td>
<td>Adult product administered to child</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Coding Example 2

“Pharmacist inadvertently dispensed the wrong size syringe. Patient gave himself insulin with the syringe.”

<table>
<thead>
<tr>
<th>LLT</th>
<th>PT</th>
<th>HLT</th>
<th>HLGT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current hierarchy (MedDRA v19.0)</td>
<td>Wrong device dispensed</td>
<td>Wrong device dispensed</td>
<td>Device issues NEC</td>
</tr>
<tr>
<td>Drug administered in wrong device</td>
<td>Drug administered in wrong device</td>
<td>Maladministrations</td>
<td>Medication errors</td>
</tr>
<tr>
<td>New hierarchy ✔ Stages of error represented ✔ &quot;Product&quot; covers devices ✔ Terms in same HLGT and SOC</td>
<td>Wrong device dispensed</td>
<td>Wrong device dispensed</td>
<td>Product dispensing errors and issues</td>
</tr>
<tr>
<td>Drug administered in wrong device</td>
<td>Drug administered in wrong device</td>
<td>Product administration errors and issues</td>
<td>Medication errors and other product use errors and issues</td>
</tr>
</tbody>
</table>
Retrieval Considerations

- New HLGT combines medication (product) errors and unspecified use issues
  - Advantage: Retrieve true errors and use issues often associated with MEs
  - Disadvantage: May be “noisy” if want to retrieve only true MEs

- Other terms that aren’t specifically MEs but have potential to identify MEs because of frequent association
  - Product quality issues
  - Device issues, e.g., malfunctions
  - Exposures
  - Compliance issues

- Hierarchy alone is not sufficient to retrieve potential cases
Hierarchy vs. Hashtag

- Different retrieval approach
- Hashtag (#)
  - Label used on social media to identify specific topics
- Similar concept can be applied to MedDRA data
  - “Tag” terms representing potential MEs independent of vertical hierarchy
- SMQ Medication errors
Tagging Medication Errors in E2B(R3)

- New code list available in E2B (R3) when implemented
- G.k.10.r Additional information on drug (coded)
  - Counterfeit
  - Overdose
  - Drug taken by the father
  - Drug taken beyond expiry date
  - Batch and lot tested and found within specifications
  - Batch and lot tested and found not within specifications
  - Medication error
  - Misuse
  - Abuse
  - Occupational exposure
  - Off label use

- Clear method of classification and identification
Summary

- New hierarchy to be implemented in March 2017
- Addresses issues identified by users
- Supports regulatory requirements for coding and reporting medication errors
Ask