

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

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MedDRA

Medical Dictionary
for Regulatory Activities

Information Day on Medication Errors
20 October 2016 | London, UK

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Outline

- ▶ Background to hierarchy revision
- ▶ Overview of new hierarchy
- ▶ Impact on coding medication errors
- ▶ Retrieval considerations

EU Pharmacovigilance Directive



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.

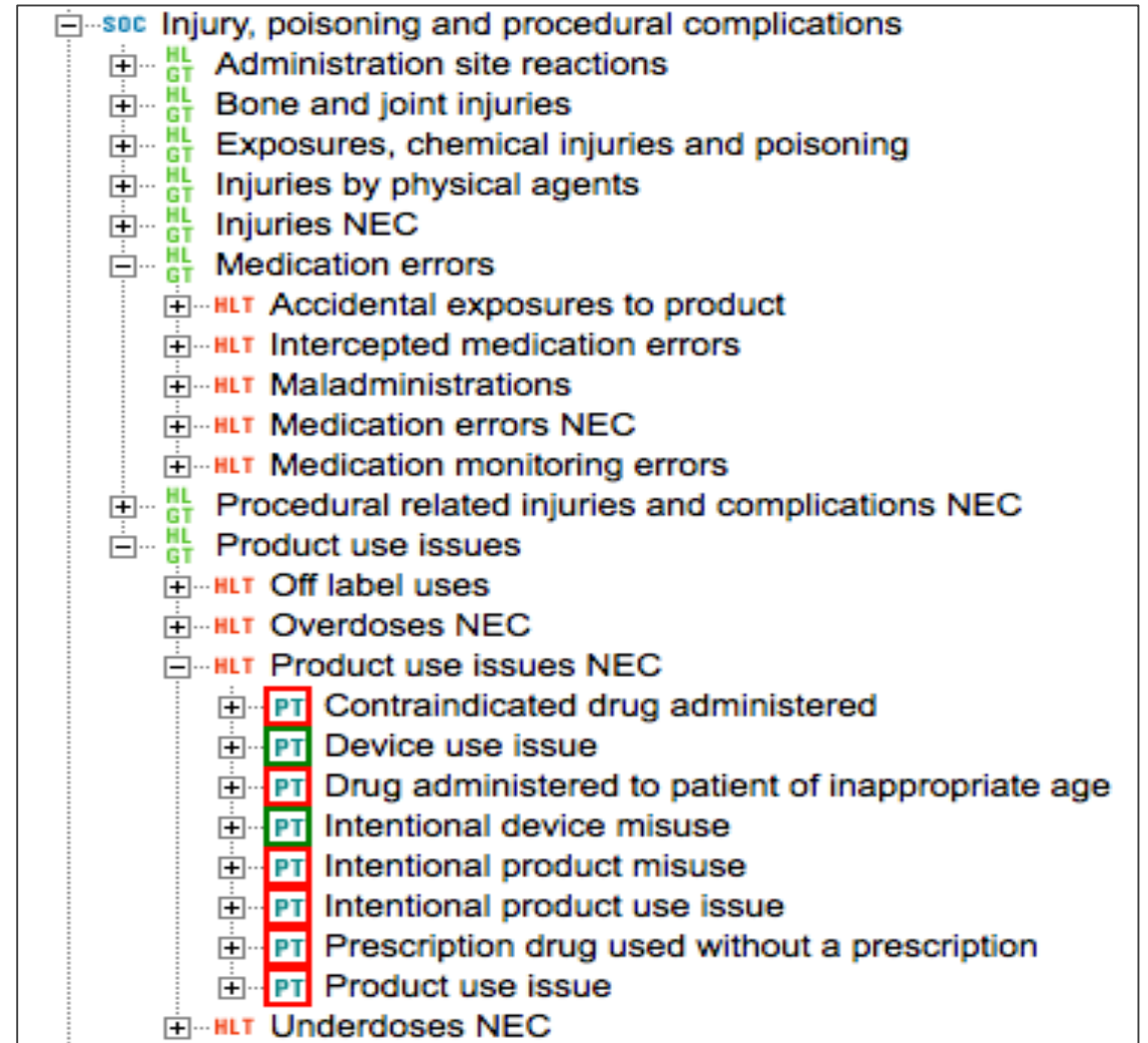
Previous Revision

► Revised March 2015

- MedDRA Version 18.0

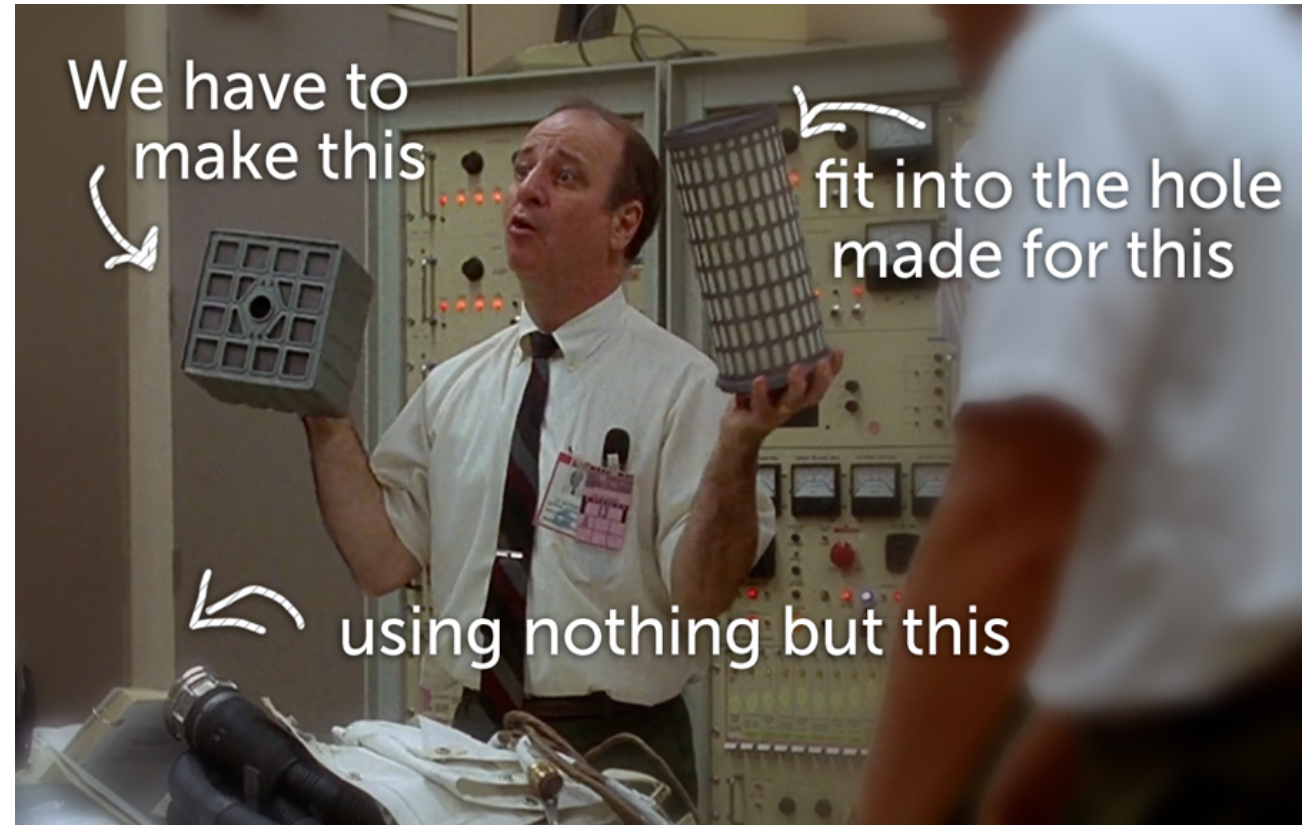
► Hierarchy helps

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



Previous Revision (cont)

- ▶ 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*



Google Images

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

Preview of New Hierarchy

► 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 communication issues

Existing grouping term

New grouping term

Preview of New Hierarchy (cont)

- ▶ **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”

	LLT	PT	HLT	HLGT
Current hierarchy (MedDRA v19.0)	Drug prescribing error	Drug prescribing error	Medication errors NEC	Medication errors
	Adult product administered to child	Drug administered to patient of inappropriate age	Product use issues NEC	Product use issues
New hierarchy ✓Stages of error represented ✓Terms in same HLGT	Drug prescribing error	Drug prescribing error	Product prescribing errors and issues	Medication errors and other product use errors and issues
	Adult product administered to child	Drug administered to patient of inappropriate age	Product administration errors and issues	Medication errors and other product use errors and issues

Coding Example 2

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

	LLT	PT	HLT	HLGT
Current hierarchy (MedDRA v19.0)	Wrong device dispensed	Wrong device dispensed	Device issues NEC	Device issues (SOC product issues)
	Drug administered in wrong device	Drug administered in wrong device	Maladministrations	Medication errors
New hierarchy ✓Stages of error represented ✓“Product” covers devices ✓Terms in same HLGT and SOC	Wrong device dispensed	Wrong device dispensed	Product dispensing errors and issues	Medication errors and other product use errors and issues
	Drug administered in wrong device	Drug administered in wrong device	Product administration errors and issues	Medication errors and other product use errors and issues

Retrieval Considerations

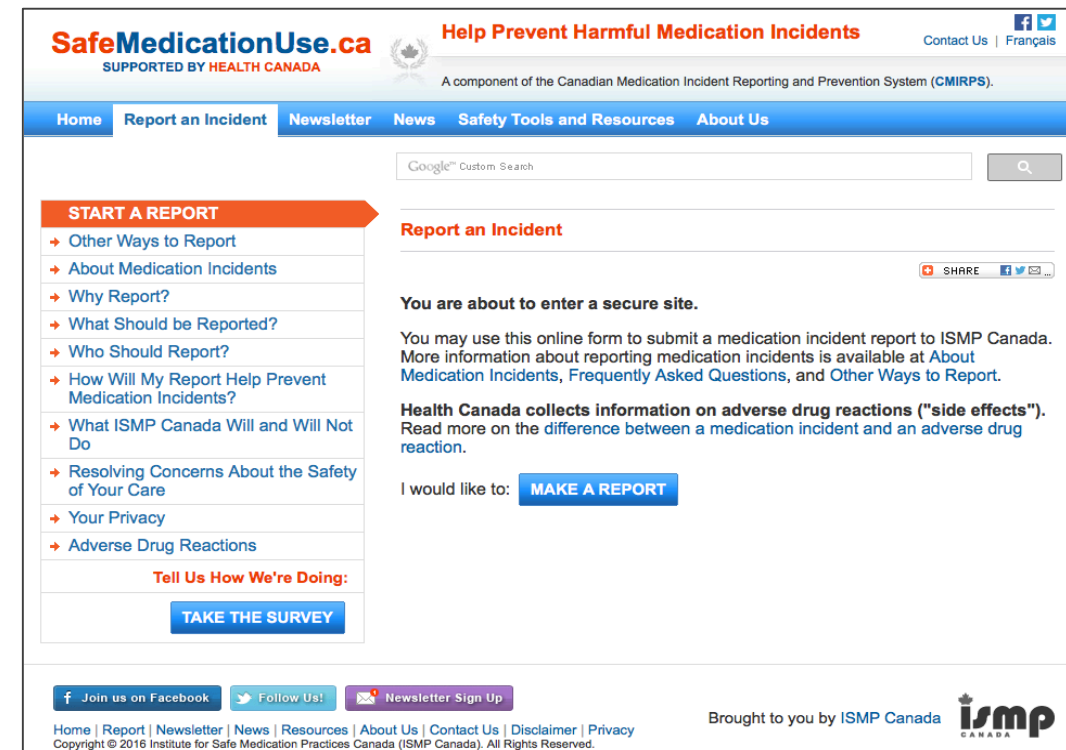
- ▶ New HLGT combines medication (product) errors and unspecified use issues
 - Advantage: Retrieve true errors and use issues often associated with MEs
 - Disadvantage: May be “noisy” if want to retrieve only true MEs
- ▶ Other terms that aren’t specifically MEs but have potential to identify MEs because 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*



Twitter



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A component of the Canadian Medication Incident Reporting and Prevention System (CMIRPS).

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- Other Ways to Report
- About Medication Incidents
- Why Report?
- What Should be Reported?
- Who Should Report?
- How Will My Report Help Prevent Medication Incidents?
- What ISMP Canada Will and Will Not Do
- Resolving Concerns About the Safety of Your Care
- Your Privacy
- Adverse Drug Reactions

Tell Us How We're Doing:

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Report an Incident

SHARE

You are about to enter a secure site.

You may use this online form to submit a medication incident report to ISMP Canada. More information about reporting medication incidents is available at [About Medication Incidents](#), [Frequently Asked Questions](#), and [Other Ways to Report](#).

Health Canada collects information on adverse drug reactions ("side effects"). Read more on the difference between a medication incident and an adverse drug reaction.

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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

