

# MedDRA/FAERS Coding

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# Disclaimer and Acknowledgements

- The information within this presentation represents the views of the presenter, not necessarily those of the FDA or any other referenced organization
- Medical Dictionary for Regulatory Activities (MedDRA®) is the international medical terminology developed under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- MedDRA® trademark is registered by IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) on behalf of ICH

# Learning Objectives

- Understand what is MedDRA and how it is used in FAERS
- Discuss existing framework towards harmonization of terminology, coding and data retrieval
  - ✓ ICH MedDRA Points to Consider and “Companion document”
- Recognize coding accuracy, specificity, uniformity



# What is MedDRA

- MedDRA (Medical Dictionary for Regulatory Activities) is a global international medical terminology used by regulatory authorities and industry
- ICH initiative

The International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

- Used throughout the regulatory cycle
  - pre-marketing to post-marketing
  - data entry, retrieval, evaluation, presentation

# ICH and MedDRA

## ICH MedDRA Points to Consider (PtC) Guides

- *MedDRA Term Selection (MTS:PtC)*
- *MedDRA Data Retrieval and Presentation (DRP:PtC)*

- *MedDRA PtC Companion document*

<http://www.meddra.org/how-to-use/support-documentation>

✓ *global terminology, global usage standard, global version synchronization*

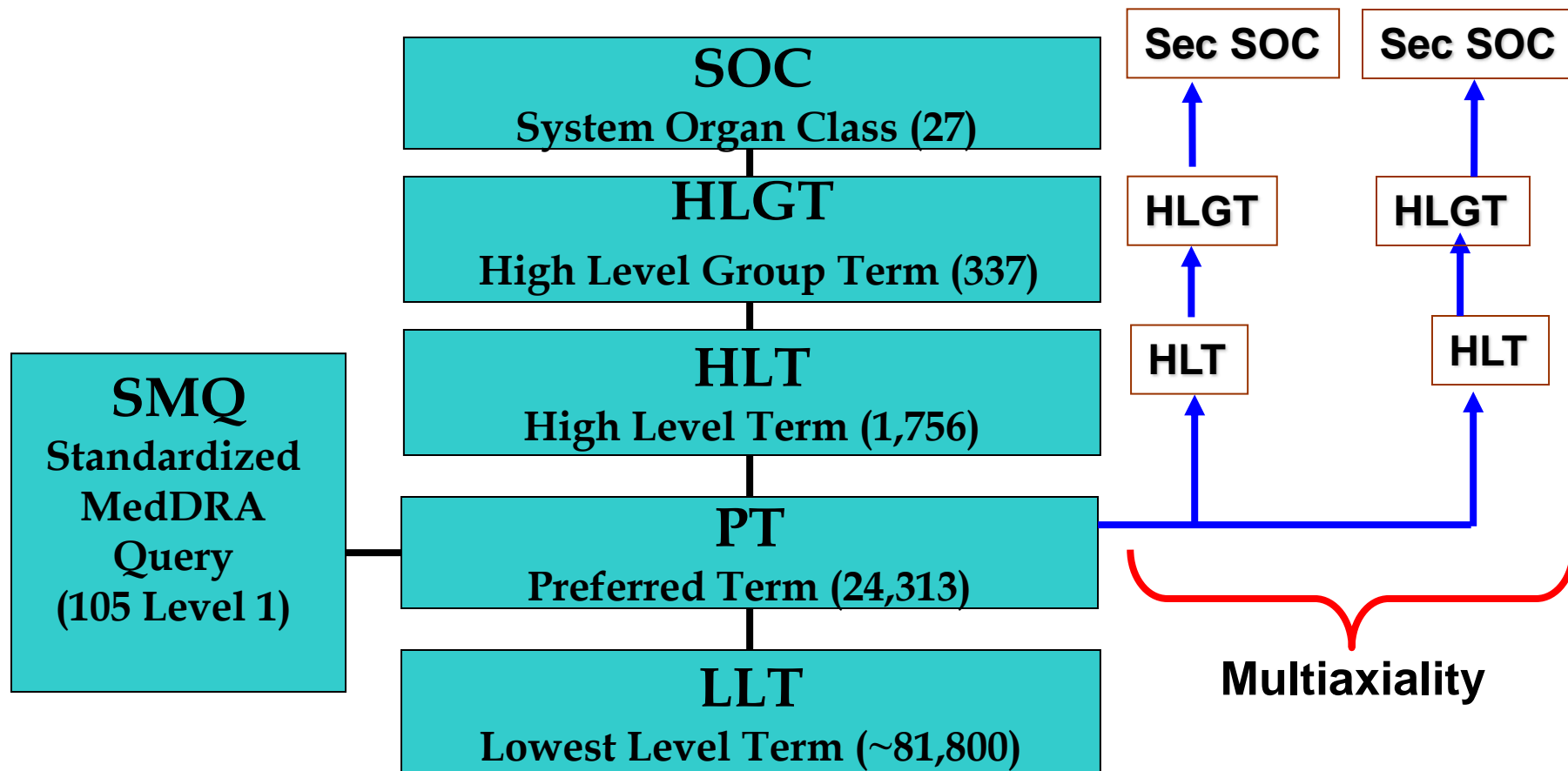


# FAERS\* and MedDRA Coding Standard

- Electronic Individual Case Safety Reports (ICSRs) are submitted to FAERS with MedDRA-coded Indications, Adverse events (AE), Medication errors (ME) and Product quality issues with AEs or MEs.
- FAERS accepts and stores MedDRA codes at the LLT level (Lowest Level Term) in the current MedDRA version

\* FDA Adverse Event Reporting System

# MedDRA Structure



Term frequency in MedDRA version 23.0

# New in MedDRA V23.0 (May 4, 2020)

- The Coronavirus (COVID-19) pandemic has prompted an urgent need for a harmonized, standardized approach to coding and reporting the infection as a global health issue.
- Approximately 80 new COVID-19 related terms and revisions were implemented including a new HLT *Coronavirus infections*.
- The majority of other COVID-19 terms (tests) are in SOC *Investigations* with a smaller set of treatment and exposure terms in SOC *Surgical and medical procedures* and SOC *Injury, poisoning and procedural complications* respectively.



# Examples of New COVID-19 Terms

LLT	PT	HLT	HLGT	Primary SOC
<b>Coronavirus pneumonia</b>	COVID-19 pneumonia	Coronavirus infections	Viral infectious disorders	Infections and infestations
<b>Occupational exposure to SARS-CoV-2</b>	Occupational exposure to SARS-CoV-2	Occupational exposures	Exposures, chemical injuries and poisoning	Injury, poisoning and procedural complications
<b>COVID-19 antibody test positive</b>	SARS-CoV-2 test positive	Virus identification and serology	Microbiology and serology investigations	Investigations
<b>Home quarantine</b>	Quarantine	Therapeutic procedures NEC	Therapeutic procedures and supportive care NEC	Surgical and medical procedures

# Why FDA Evaluates Manufacturer-Submitted MedDRA Coding



- FDA depends on many different companies to submit accurate and complete MedDRA coded reports
  - rely on coded data to perform analyses and generate safety signals
- Inaccurate and/or incomplete coding results in delayed, misdirected or missed safety concerns
- FDA notes inaccurate coding in the area of:
  - missed concepts
  - soft-coding issues (selecting a term which is both less specific and less severe than the reported event, although an appropriate term exists in MedDRA)
  - unspecific coding

# FAERS and Coding Quality Review of Medication Error Cases



- Medication errors are defined as:
  - any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer\*
  - note: (1) medication errors exclude off label use, intentional misuse by patients or care-providers, and abuse; and (2) medication errors may or may not result in an adverse event
- Medication error reporting to FDA is voluntary unless associated with an adverse event; however, FDA encourages reporting of all domestic medication errors
- FAERS Coding QA program includes continuous review of FAERS ME cases for coding quality, with frequent informal feedback to companies

\* National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP)

## Observed challenges



# Medication Error Cases are Incomplete; Coding is Inconsistent/Nonspecific



Case Scenario	Submitted MedDRA Code(s)	FDA Recommended MedDRA Code
"She experienced difficulty pressing on the plunger, it was hard to push down and she could not push it down all the way"	Accidental underdose	Device difficult to use
"Patient died after receiving vecuronium instead of the intended midazolam..."	Incorrect dosage administered	Wrong drug administered
"Patient started DRUG X but forgot to titrate the dose as instructed by provider and recommended in DRUG X label. Experienced GI upset."	Medication error: GI upset	Drug dose titration not performed; GI upset

# Coding Case Report

## Wrong Technique vs. Specific Use Error

**Scenario:** First dose of DRUG X was being infused over 30 minutes [PT: wrong technique in product usage process]. During infusion, the patient had an infusion reaction, developed stridor. DRUG X was permanently discontinued.

Submitted LLTs: *Wrong technique in product usage process, Stridor*

### **FDA Review:**

Narrative does not explain the error, necessitates DRUG X Label review:

*“DRUG X First infusion: Administer infusion over 90 minutes.*

*If no AE on first, administer second infusion over 60 minutes.*

*If no AE on second, administer subsequent infusions over 30 minutes.”*

**FDA comment on coding:** select LLT *Drug administration rate too fast* –Preferred Term (PT) *Incorrect drug administration rate*  
(not LLT-PT *Wrong technique in product usage process*)

# Considerations and Best Practices

- Narrative is expected to contain information that supports all selected codes (e.g., explain in the narrative why a 30-minute first infusion of DRUG X is an error)
- LLT-PT *Wrong technique in product usage process* is a general term, often miscoded in place of a specific use error
- **DO:**
  - Provide complete information in the narratives
  - Select the most specific LLT for the described scenario

# Coding Case Report

## Is it a Medication Error?



### Scenario

Literature report describing 104 decedents who tested positive in postmortem blood samples for driving under the influence of drugs. Patient 1 was a motor vehicle driver suspected of driving under the influence of Gabapentin combined with Lamotrigine. The blood Gabapentin concentration was assessed as 7.5 mg/L. The other drugs detected were Lamotrigine 7.9 mg/L.

Submitted LLTs: *Medication error*

FDA review comment
Not a medication error report, select LLT <i>Impaired driving ability</i>



# Considerations and Best Practices

- Incorrectly inferring a medication error interferes with data summaries, data mining

## DO:

Code what is stated in the narrative.

Obtain needed information to distinguish an adverse event from a medication error, intentional from unintentional uses, quality issues and device malfunctions from a usability issue...

# Coding Case Report “Issues”

## Scenario

Patient admitted to hospital in a comatose state due to an accidental overdose of medication for restless leg syndrome. The labeling on the pharmacy-dispensed container indicated to take three tablets per day, but she was actually prescribed to take only one tablet a day.

Submitted LLTs: *Comatose, Restless leg syndrome, Accidental overdose, Product label issue*

Company-submitted LLTs	FDA review comment
<i>Comatose</i>	Adverse event
<i>Restless leg syndrome</i>	Indication for use, not an AE
<i>Accidental overdose</i>	"Downstream" error
<i>Product label issue</i>	Wrong code, <i>Product label issue</i> is in HLGT <i>Product quality, supply, distribution, manufacturing and quality system issues.</i> <u>Select</u> LLT <i>Wrong directions typed on label</i> – PT <i>Product dispensing error</i> (error code)

# Considerations and Best Practices

- “Issue” terms are often product quality terms (not errors)
- Wrong labeling on the pharmacy dispensed bottle indicates an error, not a product quality issue – select the specific term for this error, LLT *Wrong directions typed on label* – PT *Product dispensing error*
- **DO:**
  - Select the most specific MedDRA LLT for the described scenario
  - Check LLT-PT and up the hierarchy when coding

# General expectations/Recommendations

**Narrative that communicates pertinent information**

**Accurate coding of information**

Example: if reported, “consumer misunderstood the Drug Facts label and used the product longer”, capture LLT *Product label confusion* and LLT *Drug administration duration too long*

## Recommendations

**Specific coding**

Example: if reported “incorrect dose in that an extra dose was administered”, capture only LLT *Extra dose administered*

**Consistent coding**

**ICH “MedDRA Term Selection: Points to Consider” and “Companion Document”**



# Challenge Question #1

**Which of the following is false regarding medication errors**

1. Defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer
2. Medication errors exclude off label use, intentional misuse by patients or care-providers, and abuse.
3. Medication error reporting to FDA is mandatory whether there is an associated adverse event or not.
4. When selecting a LLT-PT to capture a ME, check the hierarchy to ensure the term follows the correct pathway

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## Challenge Question #2

**Which of the following is true?**

1. There are no global guides with examples on identifying and coding of medication errors in post marketing safety reports
2. It is impossible to code medication errors correctly
3. It is sufficient to just code PT *Medication error* for any reported error
4. FAERS Coding QA program includes continuous review of FAERS medication error cases for coding quality, with frequent informal feedback to companies

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Questions ?

