



MedDRA Coding of Medication Errors (Part 1) – General Principles



MedDRA was developed under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Committee, which is composed of the ICH parties, the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the WHO (as Observer).



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Course Overview

- Explore the regulatory background for the topic medication errors
- Discuss definitions and terminologies for product use concepts based on the ICH Guidance documents
- Understand general principles for coding of medication errors
- Apply these principles in exercises
- Conclude with a question and answer session

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Regulatory Background

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Medication Errors



- Medication errors (MEs) have a high impact on patient safety and health care systems worldwide
- MEs are the most common **preventable** reason for adverse events in the medicinal product use process
- MEs are in focus of regulatory guidance
 - Support recording, coding, reporting and assessment activities of the errors made
 - Understand the causes, contributing factors and clinical consequences of the errors
 - Increase the safe use of medicines by mitigating actions and solutions

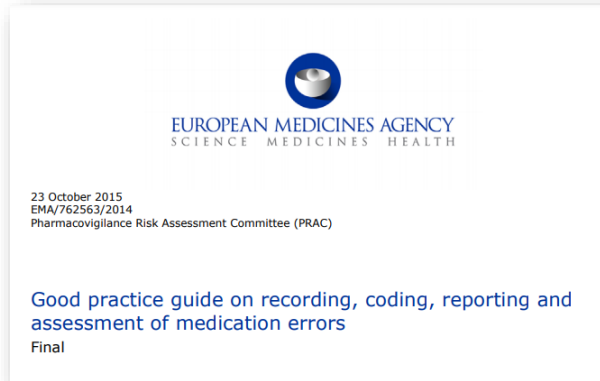
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EMA Good Practice Guide



https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practice-guide-recording-coding-reporting-assessment-medication-errors_en.pdf

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FDA Guidances

Guidances

We update guidances periodically. For the most recent version of a guidance, see [FDA's website on guidance documents](#)

- [Guidance for Industry: Safety Considerations for Product Design to Minimize Medication Errors](#)
- [Guidance for Industry: Contents of a Complete Submission for the Evaluation of Proprietary Names](#)
- [Draft Guidance for Industry: Best Practices in Developing Proprietary Names for Drugs](#)
- [Draft Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors](#)
- [Draft Guidance for Industry: Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to Drug and Biologic Applications](#)
- [Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Medical Devices](#)
- [PDUFA Pilot Project: Proprietary Name Review - Concept Paper](#)

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<https://www.fda.gov/drugs/drug-safety-and-availability/medication-errors-related-cder-regulated-drug-products>

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Medication Errors and MedDRA

- MedDRA was expanded with new terms and its hierarchy was re-structured to better support data retrieval and assessment of MEs and other types of product use concepts
- MedDRA Term Selection Points to Consider (MTS:PTC) document and the Points to Consider Companion Document were updated and supplemented to provide MedDRA users with more guidance on this topic

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ICH Guidance Documents

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MedDRA

MedDRA Term Selection: Points to Consider (MTS:PTC)

**MedDRA® TERM SELECTION:
POINTS TO CONSIDER
ICH-Endorsed Guide for MedDRA Users
Release 4.22**

March 2022

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- Provides term selection advice for industry and regulatory purposes
- Objective is to promote accurate and consistent term selection to facilitate a common understanding of shared data
- Recommended to be used as basis for individual organization's own coding conventions



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MedDRA Term Selection: Points to Consider (MTS:PTC)

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MedDRA Points to Consider Companion Document

MedDRA®
POINTS TO CONSIDER
COMPANION DOCUMENT
ICH-Endorsed Guide for MedDRA Users

Release 2.0

October 2020

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- Provides more detailed information, examples, and guidance on MEs and other types of product use concepts
- Intended as a “living” document with frequent updates based on users’ needs

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MedDRA Points to Consider Companion Document

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Definitions

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Medication Error Definition



A medication error is any **preventable** event that may cause or lead to inappropriate medication use or patient harm while the medication is **in the control of a healthcare provider, patient, or consumer.**

Such events may be related to professional practice, health care products, procedures and systems, including prescribing, order communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.

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National Coordinating Council for Medication Error Reporting and Prevention (US); 2001. About medication errors. <https://www.nccmerp.org/about-medication-errors>. Accessed 1 March, 2020.

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Product Use Concepts

Concept	Intentional?	By Whom?	Therapeutic Use?	Additional Sections in this Document
Misuse	Yes	Patient/consumer	Yes*	3.16.1
Abuse	Yes	Patient/consumer	No	3.16.2
Addiction	Yes	Patient/consumer	No	3.16.3
Medication error	No	Patient/consumer or healthcare professional	Yes	3.15
Off label use	Yes	Healthcare professional	Yes	3.27

https://admin.meddra.org/sites/default/files/guidance/file/000714_termselptc_r4_22_mar2022.pdf
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Consider the Context

Lisa is stressed at work and so her doctor prescribed one tablet of XY nightly. Last night she was still awake at 3 a.m. so took a second tablet.

Scenario: DRUG MISUSE

Lisa is stressed at work and has insomnia but sleeping tablets leave her drowsy. Her doctor prescribed an unapproved analgesic medication instead.

Scenario: OFF LABEL USE



Lisa is stressed at work and went online for painkillers to calm her down, based on advice of a friend. One dose became two and this week she's been taking four a day.

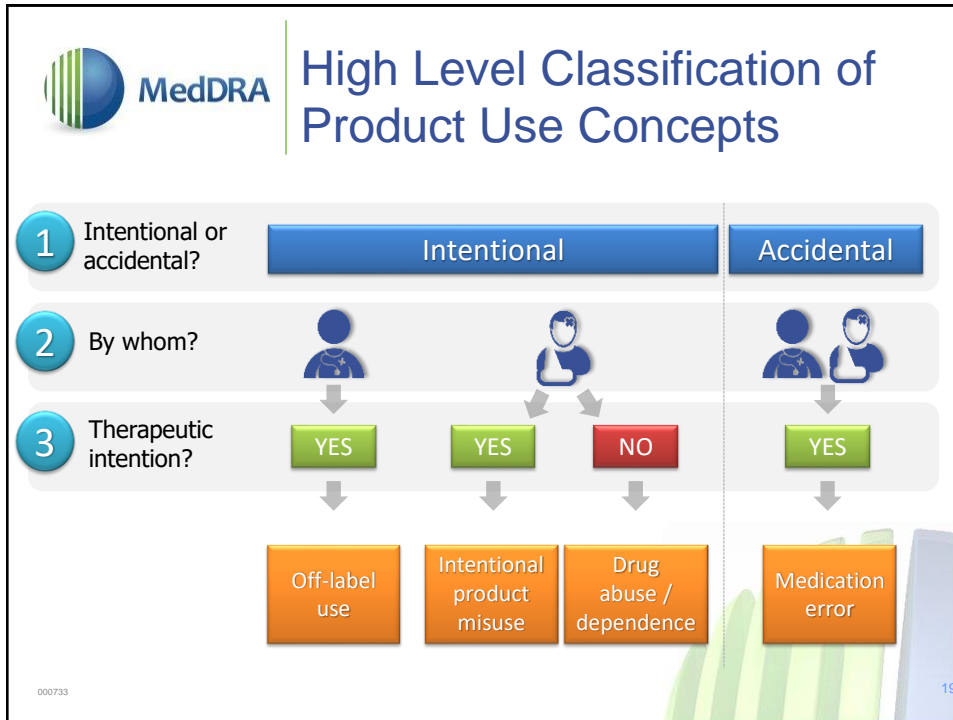
Scenario: DRUG ABUSE


Lisa is stressed at work and is having trouble remembering things. Today she forgot she had already taken her medication and took it twice.

Scenario: MEDICATION ERROR


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 **Incomplete Information**

- When the reporter does not describe an event fully, it may not be clear whether it was accidental or intentional
- *“For the past month, she has been taking an extra tablet at bedtime”*



Why did this happen?

- She misunderstood the instructions?
- Her doctor prescribed the wrong schedule?
- Her symptoms are always worse at night?
- Her doctor believes this is more effective?

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'Neutral' Preferred Terms

- Some PTs are not specific and therefore useful in situations where we are unsure if the event was accidental or not and whether an intentional deviation was for therapeutic reasons
 - PT *Product use issue*
 - PT *Intentional product use issue*
- When the background is clear, "neutral" terms can also be selected in combination with another MedDRA term for the misuse, off label use or medication error. They allow us to capture the details of what actually happened.

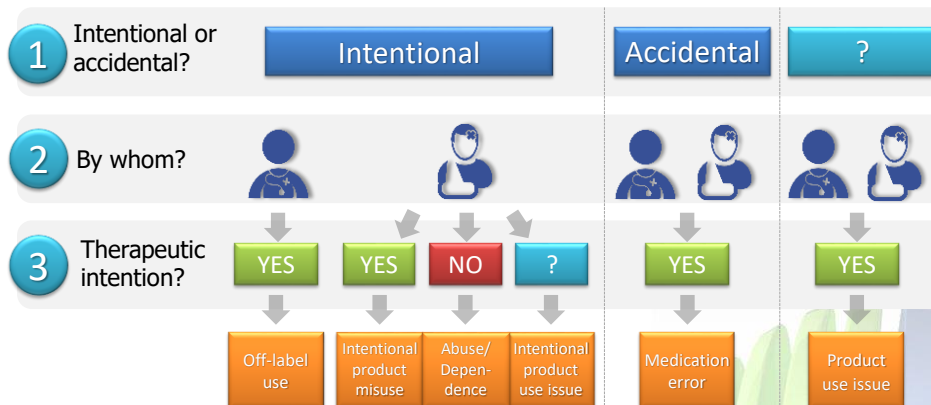
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Comprehensive Classification of Product Use Concepts



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MedDRA 'Neutral' Preferred Terms

<ul style="list-style-type: none"> HLT Product administration errors and issues <ul style="list-style-type: none"> PT Accidental overdose PT Accidental underdose PT Accidental use of placebo PT Booster dose missed PT Contraindicated product administered PT Counterfeit product administered PT Discontinued product administered PT Drug administered in wrong device PT Drug dose omission by device PT Drug dose titration not performed PT Duplicate therapy error PT Expired product administered PT Extra dose administered PT Failure to suspend medication PT Inappropriate schedule of product administration PT Inappropriate schedule of product discontinuation PT Incomplete course of vaccination PT Incorrect dosage administered PT Incorrect dose administered PT Incorrect dose administered by device PT Incorrect dose administered by product PT Incorrect drug administration rate PT Incorrect product administration duration PT Incorrect product dosage form administered PT Incorrect product formulation administered PT Incorrect route of product administration 	<ul style="list-style-type: none"> PT Intercepted product administration error PT Lack of administration site rotation PT Lack of application site rotation PT Lack of infusion site rotation PT Lack of injection site rotation PT Lack of vaccination site rotation PT Paravenous drug administration PT Poor quality product administered PT Product administered at inappropriate site PT Product administered by wrong person PT Product administered from unauthorised provider PT Product administered to patient of inappropriate age PT Product administration error PT Product administration interrupted PT Product dose omission in error PT Product dose omission issue PT Recalled product administered PT Routine immunisation schedule incomplete PT Routine immunisation schedule not administered PT Single component of a two-component product administered PT Transfusion with incompatible blood PT Unknown immunisation status PT Unknown route of product administration PT Unknown schedule of product administration PT Unknown vaccine product administered PT Wrong patient received product PT Wrong product administered
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MedDRA Browser Demonstration



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Let's Browse MedDRA



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MedDRA Concept Descriptions

MedDRA Browser

Preferred Language English | **MedDRA Concept Descriptions** | Legends | About | Search History | New Browser Window | MedDRA Documentation | User G

Language and Version Options English | English | English | 19.1 | Browser View SOC | Display O

Term mssotools.com

MedDRA CONCEPT DESCRIPTIONS

This appendix provides a list of MedDRA concept descriptions. A concept description is a description of how a concept is interpreted, used, and classified within the MedDRA terminology and is not a definition. The concept descriptions are intended to aid the consistent and accurate use of MedDRA in coding, retrieval, and analysis and to overcome the differences of medicine practice worldwide. The MSSO expects this appendix to be a working document and grow as subscribers request additional concepts to be documented.

ABCDEFGHIJKLMNOPQRSTUVWXYZ

A

Abuse

For the purposes of term selection and analysis of MedDRA-coded data, abuse is the intentional, non-therapeutic use by a patient or consumer of a product – over-the counter or prescription – for a perceived reward or desired non-therapeutic effect including, but not limited to, “getting high” (euphoria). Abuse may occur with a single use, sporadic use or persistent use of the product.

Select SOCs to S

- Blood and lymphatic disorders
- Cardiac disorders
- Congenital, familial and hereditary disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders and symptoms
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications
- Investigations
- Metabolism and nutrition disorders
- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (incl. cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Product issues
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders

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MedDRA Hierarchy

- soc Injury, poisoning and procedural complications
 - HLGT Administration site reactions
 - HLGT Bone and joint injuries
 - HLGT Exposures, chemical injuries and poisoning
 - HLGT Injuries by physical agents
 - HLGT Injuries NEC
 - HLGT Medication errors and other product use errors and issues
 - HLGT Off label uses and intentional product misuses/use issues
 - HLGT Overdoses and underdoses NEC
- soc Psychiatric disorders
 - HLGT Psychiatric disorders NEC
 - HLT Infancy, childhood and adolescence psychiatric disorders NEC
 - HLT Mental disorders due to a general medical condition NEC
 - HLT Mental disorders NEC
 - HLT Psychiatric elimination disorders
 - HLT Substance related and addictive disorders

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MedDRA | **Terms in HLGT Medication errors and other product use errors and issues**

HLGT Medication errors and other product use errors and issues

- Types of errors**
E.g., PT *Wrong drug*, PT *Wrong dose*, PT *Wrong route*
- Terms combining the type of error with a stage of the medication use system**
E.g., PT *Product prescribing error*
- Intercepted errors that did not reach the patient**
E.g., PT *Intercepted product prescribing error*
- Describing the potential for error**
E.g., PT *Circumstance or information capable of leading to medication error*
- Terms for situations when it is uncertain whether the reported incident is an error**
E.g., PT *Product use issue*

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General Principles for Coding Medication Errors

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MedDRA Coding - General Principles

MedDRA[®] TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Assess and clarify unclear reports


Select closest LLT

Code as reported

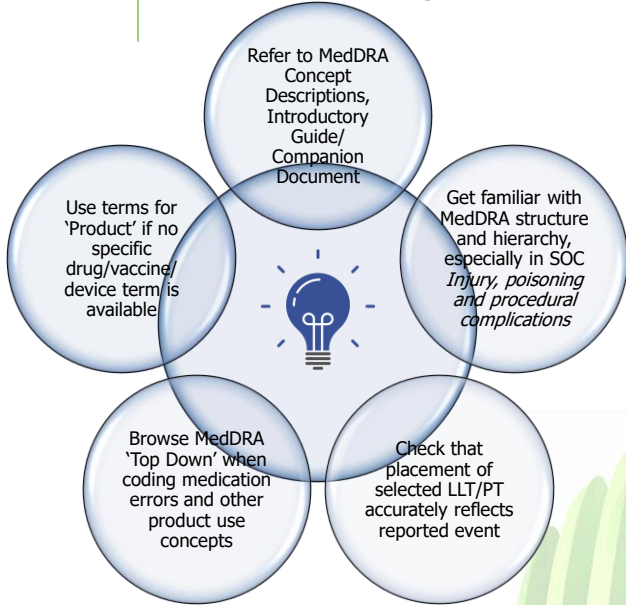
Use only current LLTs

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MedDRA Tips for Coding Medication Errors




- Refer to MedDRA Concept Descriptions, Introductory Guide/ Companion Document
- Get familiar with MedDRA structure and hierarchy, especially in SOC *Injury, poisoning and procedural complications*
- Check that placement of selected LLT/PT accurately reflects reported event
- Browse MedDRA 'Top Down' when coding medication errors and other product use concepts
- Use terms for 'Product' if no specific drug/vaccine/ device term is available

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MedDRA General Principles for Coding MEs



1. Use of PT *Medication error*
2. Selecting more than one term (split-coding)
3. Be clear about the meaning of "off label use"
4. Capture potential & intercepted medication errors
5. Code the specific type of error and the stage of the medication use system where the error occurred
6. Capture the root cause
7. Do not infer a medication error

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1 - Use of PT *Medication error*

AVOID the use of LLT *Medication error*
unless there is NO other information reported

- Check all the LLTs in *HLGT Medication errors and other product use errors and issues* for the most specific term possible
- If a specific error is reported but no suitable LLT is available, submit a Change Request

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1 - Use of PT *Medication error (cont.)*

EXAMPLE

"Patient inadvertently didn't use the medication as prescribed, no further information available."

⊕ LLT *Medication error*
→ PT *Medication error*

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2 - Split-Coding of Chain of Events

Sometimes the initial error results in consequent errors



The **initial error** should be coded as the **priority**

Consequent errors can be coded **if** they are stated in the report



Do not use multiple LLTs to capture a singular error that is reported with both a general and a specific verbatim

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2 - Split-Coding of Chain of Events (cont.)

EXAMPLE

"Nurse miscalculated the dose and the patient received 40 mg instead of 20 mg of his medication. He experienced severe hypotension."

- LLT *Dose calculation error* (PT is the same)
- LLT *Incorrect dose administered* (PT is the same)
- LLT *Hypotension* (PT is the same)

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3 - Be Clear about the Meaning of PT *Off-label use*

Off-label use terms should only be selected when:

- Off-label is specifically reported or
- when case information provides all details needed for classification as off label use



Off Label Use

For the purposes of term selection and analysis of MedDRA-coded data, the concept of “off label use” relates to situations where a healthcare professional intentionally prescribes, dispenses, or recommends a product for a medical purpose not in accordance with the authorised product information. When recording off label use, consider that product information and/or regulations/requirements may differ between regulatory regions.

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3 - Be Clear about the Meaning of PT *Off label use* (cont.)

EXAMPLE

“Pediatrician decided to use COVID-19 vaccine for his 10-year-old high risk patient, although not yet approved for this age group.”



LLT *Off label use in unapproved age group*



PT *Off label use*

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4 - Potential Medication Errors

- Potential errors should be designated as such by selecting
 - LLT *Circumstance or information capable of leading to **medication error***
 - LLT *Circumstance or information capable of leading to **device use error***
- Terms that represent information about the contributing scenario should also be selected
 - e.g. (LLT *Drug label look-alike*)



- ✓ Potential error LLT
- ✓ Contributing factor

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4 - Potential Medication Errors (cont.)

EXAMPLE

“Pharmacist reported that the blurred print on the drug label could lead to the wrong dose being given.”



- ✓ Potential error

- ✓ Contributing scenario



LLT *Circumstance or information capable of leading to medication error*



PT *Circumstance or information capable of leading to medication error*




LLT *Product label text illegible*




PT *Product label issue*

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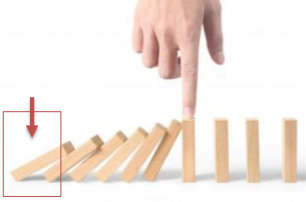


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4 - Intercepted Medication Errors

- An intercepted medication error refers to the situation where a medication error has occurred, but is prevented from reaching the patient



- The intercepted error term should reflect the stage at which the error occurred, rather than the stage at which it was intercepted

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4 - Intercepted Medication Errors (cont.)

EXAMPLE


"Pharmacist dispensed the wrong drug, but the nurse identified the error and did not give it to the patient."

⊕ LLT *Intercepted drug dispensing error*
 → PT *Intercepted product dispensing error*





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5 - Stages of the Medication Use System

Some MedDRA terms capture:


- ✓ both the type of error and stage of the medication use system (e.g., LLT *Wrong drug prescribed*)
- ✓ others only the type of error (e.g., LLT *Wrong drug*) and
- ✓ others only the stage (e.g., LLT *Drug prescribing error*)




Capture both the stage and the type of error where it is known

If the stage is not known, use the terms for the type of error only

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5 - Stages of the Medication Use System (cont.)



Capture both the stage and the type of error where it is known

- **Using a single LLT**

"Pharmacy dispensed the wrong drug"

Both the stage and the type of error can be captured using LLT *Wrong drug dispensed* (instead of two LLTs: LLT *Wrong drug* and LLT *Wrong drug dispensed*)
- **Using more than one LLT**

"Mistakenly prescribed the wrong strength"

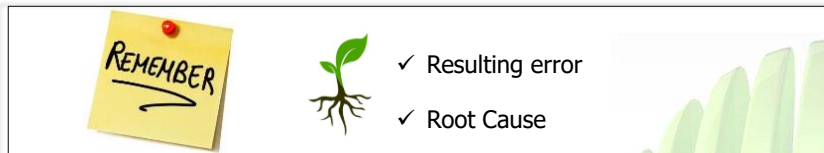
Code to LLT *Wrong strength* and LLT *Drug prescribing error* because no available single term captures the reported information in full

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6 - Coding the Root Cause

- Root causes are critical to understanding why an error occurred and identifying interventions that can be undertaken to prevent the error
 - When the root cause is provided, select a term for the root cause if possible
 - Capture the resulting error in addition



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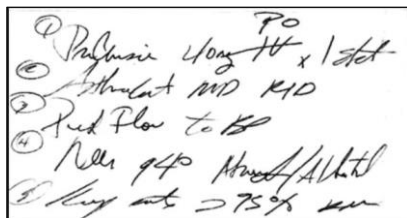
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6 - Coding the Root Cause (cont.)

EXAMPLE

"The doctor wrote a prescription for 40 mg Drug X for angina. But, because of the illegibility of the prescription, the nurse administered the same dosage of Drug Y, a calcium channel blocker used in the treatment of hypertension, for which the maximum daily dose is only 10 mg. A day after taking overdose of Drug Y, the patient had a heart attack and died."



Root Cause

- LLT *Angina pectoris*
- LLT *Written prescription illegible*
- LLT *Wrong drug administered*
- LLT *Accidental overdose*
- LLT *Heart attack*

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7 - Do not Infer a Medication Error

- The selected LLTs should reflect only the information stated in the case report
- It should not be assumed that a medication error occurred if this is not clearly reported as such

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7 - Do not Infer a Medication Error (cont.)

EXAMPLE

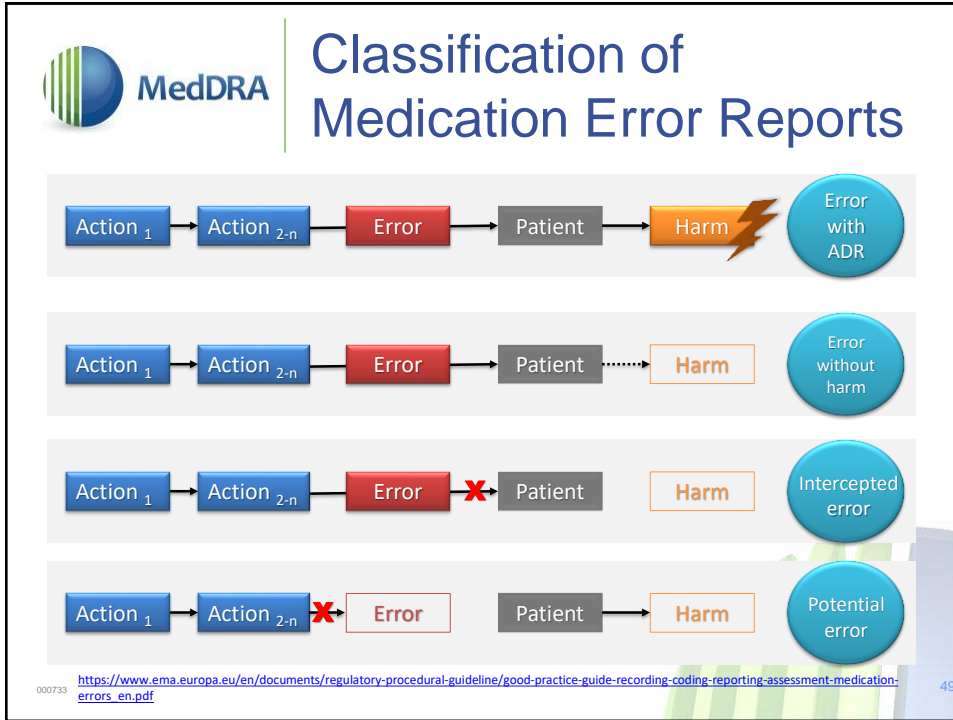
"The nurse administered 50 mg of Drug X."



This is not an informative report and should not be submitted as such; further information should be sought or a dose qualification referencing the prescribing information should be provided in the narrative.

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MedDRA Eudravigilance Reporting

Most frequently reported PTs (HLGT *Medication errors and other product use errors and issues*) (data through March 2021)

	MedDRA Preferred Term	Count
1.	Product use in unapproved indication	61,727
2.	Product dose omission issue	39,649
3.	Inappropriate schedule of product administration	38,596
4.	Product use issue	26,866
5.	Incorrect dose administered	24,238
6.	Wrong technique in product usage process	23,236
7.	Medication error	20,494
8.	Product administration error	16,037
9.	Accidental overdose	14,513
10.	Incorrect route of product administration	11,941

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Medication Errors and other Product Use Concepts – Coding Demonstrations


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Assessing the Reported Information


- Consider what is being reported:
 - Did the incident occur intentionally or unintentionally?
 - Who has caused it?
 - Was there a therapeutic purpose?
 - At which stage in medication practice?
 - Did the initial incident lead to subsequent errors?
 - Did it lead to harm in the patient?
 - What were the contributing factors?
 - Were only circumstances reported, that COULD lead to a medication error?
 - Was the incident intercepted before reaching the patient?



The type of report will influence the way you search for suitable LLTs. It may indicate where you expect to find the closest matches.

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Coding Demonstration #1 - Consider...

"Nurse forgot to administer the second of two chemotherapy treatments to the patient."

- Was it accidental or intentional?
- Who has caused the incident?
- Was it for a therapeutic purpose?
- At which stage in medication practice did the incident occur?
- Was there a root cause that needs to be captured?

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Decision Making

"Nurse forgot to administer the second of two chemotherapy treatments to the patient."

- 1 Intentional or accidental?

Intentional	Accidental
-------------	------------
- 2 By whom?


- 3 Therapeutic intention?

YES

Medication error

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Let's Browse MedDRA



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- SOC Injury, poisoning and procedural complications
 - MLT Medication errors and other product use errors and issues
 - MLT Product administration errors and issues
 - PT Inappropriate schedule of product administration
 - LLT Delayed dose administration
 - LLT Drug dose administration interval too long
 - LLT Drug dose administration interval too short
 - LLT Inappropriate schedule of drug administration
 - LLT Inappropriate schedule of product administration
 - LLT Inappropriate schedule of vaccine administered
 - LLT Once daily dose taken less frequently
 - LLT Once daily dose taken more frequently
 - LLT Once monthly dose taken less frequently
 - LLT Once monthly dose taken more frequently
 - LLT Once weekly dose taken less frequently
 - LLT Once weekly dose taken more frequently
 - LLT Premature start of scheduled drug administration
 - LLT Scheduled daily dosing taken less frequently
 - LLT Scheduled daily dosing taken more frequently
 - LLT Scheduled monthly dosing taken less frequently
 - LLT Scheduled monthly dosing taken more frequently
 - LLT Scheduled weekly dosing taken less frequently
 - LLT Scheduled weekly dosing taken more frequently
 - PT Product dose omission in error
 - LLT Accidental use of training device instead of active product
 - LLT Drug dose omission in error
 - LLT Forgot to take product
 - LLT Missed dose in error
 - LLT Product dose omission in error
 - PT Product dose omission issue
 - LLT Drug dose omission
 - LLT Drug dose omission for unknown reason
 - LLT Missed dose
 - LLT Missed injection
 - LLT Product dose omission
 - LLT Product dose omission issue
 - LLT Vaccine dose omission

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- SOC Injury, poisoning and procedural complications
 - MLT Medication errors and other product use errors and issues
 - MLT Medication errors, product use errors and issues NEC
 - PT Product use issue
 - LLT Drug use for unapproved combination
 - LLT Drug use for unapproved dosing regimen
 - LLT Drug use for unapproved schedule
 - LLT Drug use in unapproved age group
 - LLT Drug use in unapproved population
 - LLT Drug use issue
 - LLT Drug use less than labeled administration duration
 - LLT Drug use less than labelled administration duration
 - LLT Drug use longer than labeled administration duration
 - LLT Drug use longer than labelled administration duration
 - LLT Drug use via unapproved administration route
 - LLT Patient ran out of medication
 - LLT Product use at inappropriate site
 - LLT Product use for unapproved combination
 - LLT Product use in unapproved population
 - LLT Product use issue
 - LLT Unapproved dose administered
 - LLT Unapproved starting dose administered

- SOC Surgical and medical procedures
 - MLT Therapeutic procedures and supportive care NEC
 - MLT Therapeutic procedures NEC
 - PT Therapy interrupted
 - LLT Temporary interruption of therapy
 - LLT Therapy interrupted

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Coding Demonstration #1 - Final Proposal

"Nurse forgot to administer the second of two chemotherapy treatments to the patient."



LLT *Drug dose omission in error*



PT *Product dose omission in error*

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Coding Demonstration #2 - Consider...

"Patient did not read instructions thoroughly and took drug X for prophylaxis instead of treatment of the approved indication."

- Was it accidental or intentional?
- Who has caused the incident?
- Was it for a therapeutic purpose?
- At which stage in medication practice did the incident occur?
- Was there a root cause that needs to be captured?



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 **MedDRA Decision Making**

"Patient did not read instructions thoroughly and took drug X for prophylaxis instead of treatment of the approved indication."

1 Intentional or accidental? **Intentional** | **Accidental**

2 By whom? 

3 Therapeutic intention? **YES**

Medication error

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 **MedDRA Let's Browse MedDRA**



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Medication errors and other product use errors and issues

- Medication errors, product use errors and issues NEC
 - Product use in unapproved indication
 - Drug use for unapproved indication
 - Product use in unapproved indication
 - Unintentional use for unapproved indication
 - Unintentional use for unapproved indication
- Product confusion errors and issues
 - Device use confusion
 - Product appearance confusion
 - Product confusion
 - Product design confusion
 - Product dosage form confusion
 - Product dose confusion
 - Product label confusion
 - Drug label confusion
 - Drug label look-alike
 - Expiration date format confusion
 - Patient instructions for use in label confusing
 - Product label confusion
 - Product leaflet confusion
 - Product leaflet instructions confusion
 - Product name confusion
 - Product packaging confusion

Off label uses and intentional product misuses/use issues

- Intentional product misuses
- Intentional product use issues
- Off label uses
 - Off label use
 - Off label dosing
 - Off label dosing amount
 - Off label dosing frequency
 - Off label fractional dose administered
 - Off label use
 - Off label use in unapproved age group
 - Off label use in unapproved indication
 - Off label use in unapproved route of administration
 - Off label vaccine use
 - Off label use of device

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Coding Demonstration #2 - Final Proposal

“Patient did not read instructions thoroughly and used drug XY for prophylaxis instead of treatment of the approved indication.”

+ LLT *Drug administration error*

 → PT *Product administration error*

+ LLT *Drug use for unapproved indication*

 → PT *Product use in unapproved indication*

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Coding Demonstration #3 - Consider...

"Patient took more than the recommended dose to get a better drug effect."

- Was it accidental or intentional?
- Who has caused the incident?
- Was it for a therapeutic purpose?
- At which stage in medication practice did the incident occur?
- Was there a root cause that needs to be captured?

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Decision Making

"Patient took more than the recommended dose to get a better drug effect."



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- [-] sec Injury, poisoning and procedural complications
 - [-] HL Medication errors and other product use errors and issues
 - [-] HLT Medication errors, product use errors and issues NEC
 - [-] PT Product use issue
 - [-] LU Drug use for unapproved combination
 - [-] LU Drug use for unapproved dosing regimen
 - [-] LU Drug use for unapproved schedule
 - [-] LU Drug use in unapproved age group
 - [-] LU Drug use in unapproved population
 - [-] LU Drug use issue
 - [-] LU Drug use less than labeled administration duration
 - [-] LU Drug use less than labelled administration duration
 - [-] LU Drug use longer than labeled administration duration
 - [-] LU Drug use longer than labelled administration duration
 - [-] LU Drug use via unapproved administration route
 - [-] LU Patient ran out of medication
 - [-] LU Product use at inappropriate site
 - [-] LU Product use for unapproved combination
 - [-] LU Product use in unapproved population
 - [-] LU Product use issue
 - [-] LU Unapproved dose administered
 - [-] LU Unapproved starting dose administered
 - [-] PT Product administration errors and issues
 - [-] PT Incorrect dosage administered
 - [-] LU Incorrect dosage administered
 - [-] PT Incorrect dose administered
 - [-] LU Inappropriate dose of drug administered
 - [-] LU Inappropriate dose of vaccine administered
 - [-] LU Inappropriate product dose administered
 - [-] LU Incomplete dose administered
 - [-] LU Incorrect dose administered
 - [-] LU Incorrect dose administered from multidose vaccine vial
 - [-] LU Loading dose not administered
 - [-] LU Wrong dose administered
 - [-] LU Wrong drug strength administered

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- [-] sec Injury, poisoning and procedural complications
 - [-] HL Off label uses and intentional product misuses/use issues
 - [-] HL Intentional product misuses
 - [-] PT Intentional device misuse
 - [-] LU Intentional misuse of drug delivery system
 - [-] PT Intentional product misuse
 - [-] LU Intentional drug misuse
 - [-] LU Intentional misuse
 - [-] LU Intentional misuse by dose change
 - [-] LU Intentional misuse in dosing frequency
 - [-] LU Intentional misuse in product use duration
 - [-] LU Intentional product misuse
 - [-] PT Intentional product misuse to child
 - [-] LU Intentional product use issues
 - [-] HL Off label uses
 - [-] HL Overdoses and underdoses NEC
 - [-] HL Overdoses NEC
 - [-] PT Intentional overdose
 - [-] LU Deliberate overdose
 - [-] LU Drug overdose deliberate self-inflicted
 - [-] LU Intentional overdose
 - [-] LU Multiple drug overdose intentional
 - [-] LU Non-accidental overdose
 - [-] LU Overdose deliberate self-inflicted
 - [-] LU Overdose intentional
 - [-] LU Overdose
 - [-] LU Prescribed overdose
 - [-] LU Radiation overdose
 - [-] HL Underdoses NEC
 - [-] LU Underdoses NEC

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Coding Demonstration #3 - Final Proposal

"Patient took more than the recommended dose to get a better drug effect."



LLT *Intentional misuse by dose change*



PT *Intentional product misuse*

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Coding Demonstration #4 - Consider...


"Doctor prescribed drug A to suppress pre-term labor after careful risk/ benefit assessment (not covered by label)."

- Was it accidental or intentional?
- Who has caused the incident?
- Was it for a therapeutic purpose?
- At which stage in medication practice did the incident occur?
- Was there a root cause that needs to be captured?



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MedDRA Decision Making

"Doctor prescribed drug A to suppress pre-term labor after careful risk/benefit assessment (not covered by label)."

- 1 Intentional or accidental?
 - Intentional
 - Accidental
- 2 By whom?
 - Physician icon
 - Pharmacist icon
- 3 Therapeutic intention?
 - YES

Off-label use

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sec Injury, poisoning and procedural complications


- Medication errors and other product use errors and issues
 - Medication errors, product use errors and issues NEC
 - PT **Product use in unapproved indication**
 - LLT Drug use for unapproved indication
 - LLT Product use in unapproved indication
- Product prescribing errors and issues
 - PT **Contraindicated product prescribed**
 - PT **Deprescribing error**
 - PT **Intercepted product prescribing error**
 - PT **Product prescribing error**
 - LLT Computerised prescriber order entry error
 - LLT Computerized prescriber order entry error
 - LLT CPOE error
 - LLT Dietary supplement prescribing error
 - LLT Drug administration duration prescribing error
 - LLT Drug dosage form prescribing error
 - LLT **Drug dose prescribing error**
 - LLT **Drug prescribing error**
 - LLT Drug refill prescribing error
 - LLT Drug route prescribing error
 - LLT Drug schedule prescribing error
 - LLT Duplicate drug prescription error
 - LLT Product prescribing error
 - LLT Wrong drug prescribed
 - PT **Product prescribing issue**
 - LLT **Drug prescribed for unapproved indication**
 - LLT Drug prescription issue
 - LLT Inappropriate prescribing
 - LLT Incomplete dose prescribed
 - LLT Medically prescribed prolongation of labeled treatment duration
 - LLT Medically prescribed prolongation of labelled treatment duration
 - LLT Product prescribing issue
 - LLT Written prescription illegible

sec Injury, poisoning and procedural complications

- Off label uses and intentional product misuses/use issues
 - MLT Intentional product misuses
 - PT **Intentional device misuse**
 - PT **Intentional misuse of drug delivery system**
 - PT **Intentional product misuse**
 - PT **Intentional product misuse to child**
 - MLT Intentional product use issues
 - PT **Intentional device use issue**
 - PT **Intentional dose omission**
 - PT **Intentional medical device removal by patient**
 - PT **Intentional product use issue**
 - LLT Intentional deviation from dosage regimen
 - LLT Intentional dose decrease
 - LLT Intentional dose increase
 - LLT Intentional product use in unapproved population
 - LLT Intentional product use issue
 - LLT Intentional use beyond labeled administration duration
 - LLT Intentional use beyond labeled duration
 - LLT Intentional use beyond labelled administration duration
 - LLT Intentional use beyond labelled duration
 - LLT Intentional use by incorrect route
 - LLT **Intentional use for unlabelled indication**
 - LLT **Intentional use for unlabelled indication**
 - LLT Intentional use less than recommended duration
 - PT **Intentional removal of drug delivery system by patient**
 - PT **Performance enhancing product use**
 - MLT Off label uses
 - PT **Off label use**
 - LLT Off label dosing
 - LLT Off label dosing amount
 - LLT Off label dosing frequency
 - LLT Off label fractional dose administered
 - LLT Off label use
 - LLT **Off label use in unapproved age group**
 - LLT **Off label use in unapproved indication**
 - LLT Off label use in unapproved route of administration
 - LLT Off label vaccine use
 - PT **Off label use of device**

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Coding Demonstration #4 - Final Proposal

"Doctor prescribed drug A to suppress pre-term labor after careful risk/ benefit assessment (not covered by label)."

+ LLT *Off label use in unapproved indication*

→ PT *Off label use*



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Coding Demonstration #5 - Consider...

"Doctor mixed up the drug names because they look similar and prescribed the wrong medication."

- Was it accidental or intentional?
- Who has caused the incident?
- Was it for a therapeutic purpose?
- At which stage in medication practice did the incident occur?
- Was there a root cause that needs to be captured?

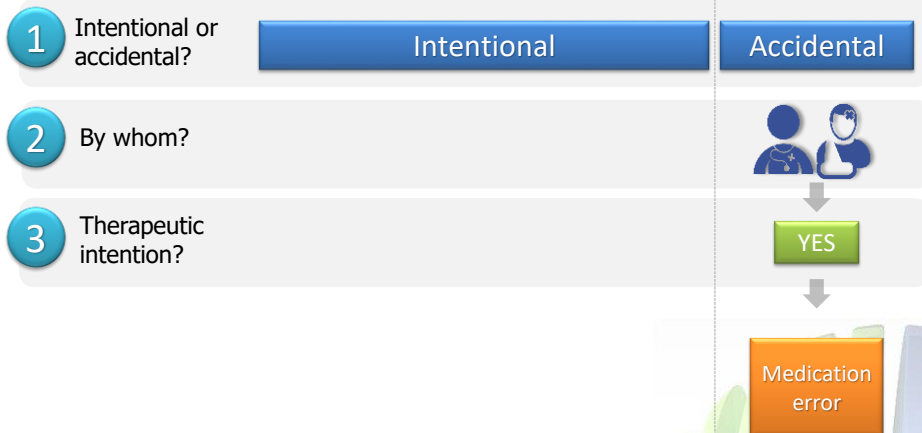
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Decision Making

"Doctor mixed up the drug names because they look similar and prescribed the wrong medication."



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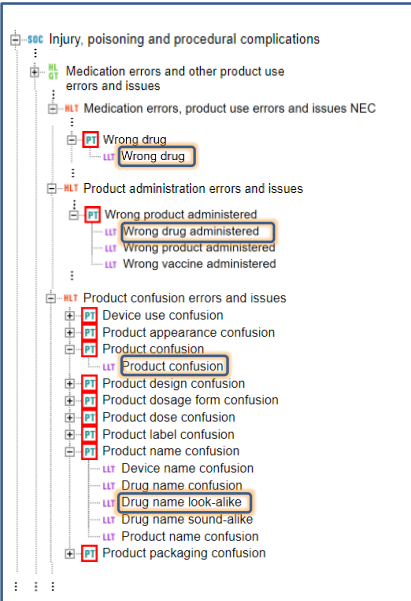
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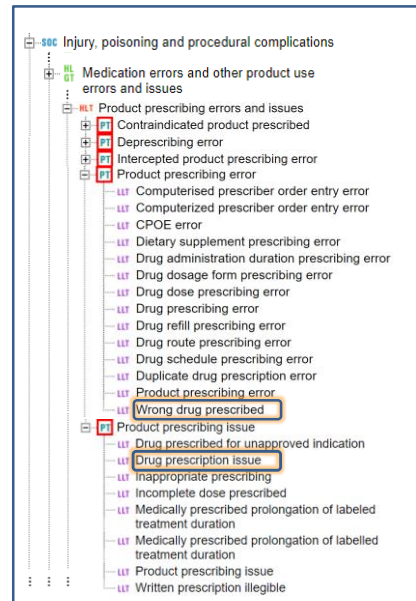


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Coding Demonstration #5 - Final Proposal

*“Doctor mixed up the drug names because they look similar
and prescribed the wrong medication.”*



LLT *Wrong drug prescribed*



PT *Product prescribing error*



LLT *Drug name look-alike*



PT *Product name confusion*

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Summary

In this course, we:

- Discussed the regulatory background for the topic “Medication errors”
- Introduced helpful ICH Guidance documents
- Discussed definitions for product use concepts and related MedDRA Concept Descriptions
- Discussed the general principles for coding of medication errors and looked into related coding demonstrations

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Question and Answer Session

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MSSO Contacts

- Website
 - www.meddra.org
- Email
 - mssohelp@meddra.org
- Frequently Asked Questions
 - www.meddra.org/faq
- MedDRA Browsers
 - <https://www.meddra.org/meddra-desktop-browsers> (Desktop Browser)
 - <https://tools.meddra.org/wbb/> (Web-Based Browser)
 - <https://mmb.meddra.org> (Mobile Browser)

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MedDRA MSSO Contacts (cont)

- Change Request Submission
 - <https://www.meddra.org/how-to-use/change-requests>
- Training Schedule
 - <https://www.meddra.org/training/schedule>
- MedDRA Support Documentation
 - <https://www.meddra.org/how-to-use/support-documentation>

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Contact

MedDRA MSSO
7575 Colshire Drive
McLean, VA 22102
USA
E-mail: masohelp@meddra.org or use the form below.
Toll Free International: +1 877 258 8280
Direct: +1 703 556 2950
Fax: +1 703 556 1744

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Medical Dictionary
for Regulatory Activities

Thank You!

