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

ICH harmonisation for better health

MedDRA

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

MedDRA

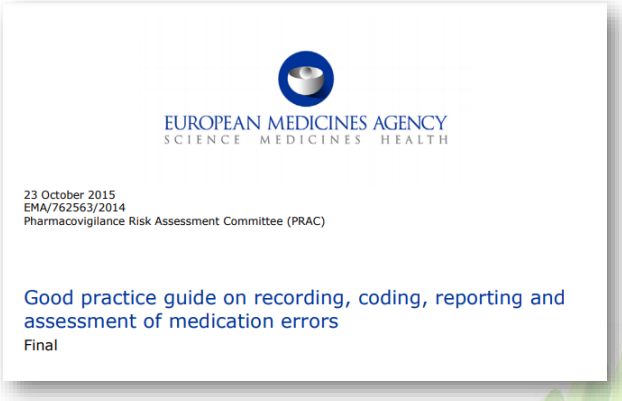
Regulatory Background

MedDRA

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

EMA Good Practice Guide


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 October 2015
EMA/762563/2014
Pharmacovigilance Risk Assessment Committee (PRAC)

Good practice guide on recording, coding, reporting and assessment of medication errors
Final

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

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- Draft Guidance for Industry: Best Practices in Developing Proprietary Names for Drugs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

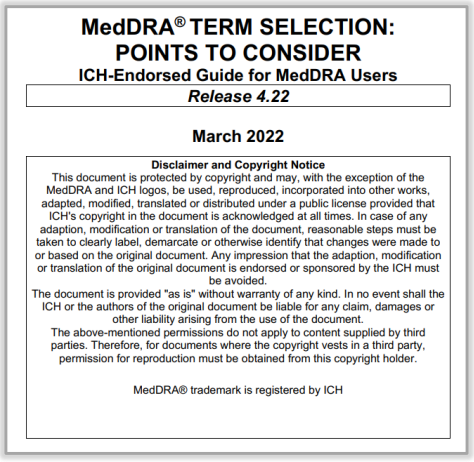
https://www.fda.gov/drugs/drug-safety-and-availability/medication-errors-related-cder-regulated-drug-products

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

ICH Guidance Documents

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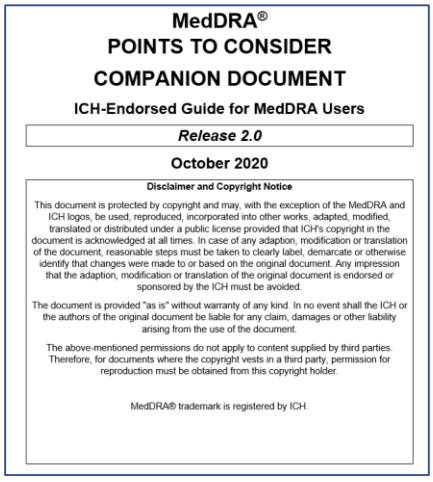
- Provides term selection advice for industry and regulatory purposes
- Objective is to promote accurate and consistent term selection to facilitate a common understanding of shared data
- Recommended to be used as basis for individual organization's own coding conventions

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

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

000733

13

MedDRA Points to Consider Companion Document

000733

14

MedDRA

Definitions

MedDRA

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.

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.

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
Page 31

Consider the Context

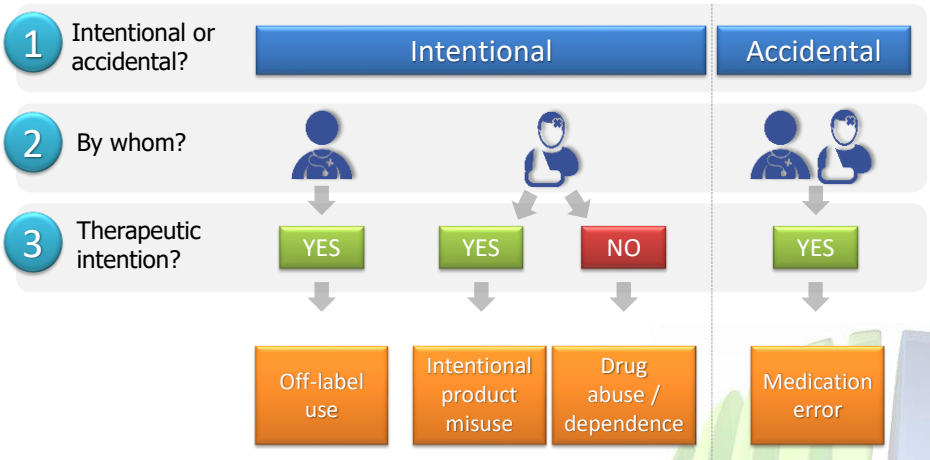
Lisa is stressed at work and so her doctor prescribed one tablet of XY nightly. Last night she was still awake at 3 a.m. so took a second tablet.
Scenario: DRUG MISUSE

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

High Level Classification of Product Use Concepts



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19

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?

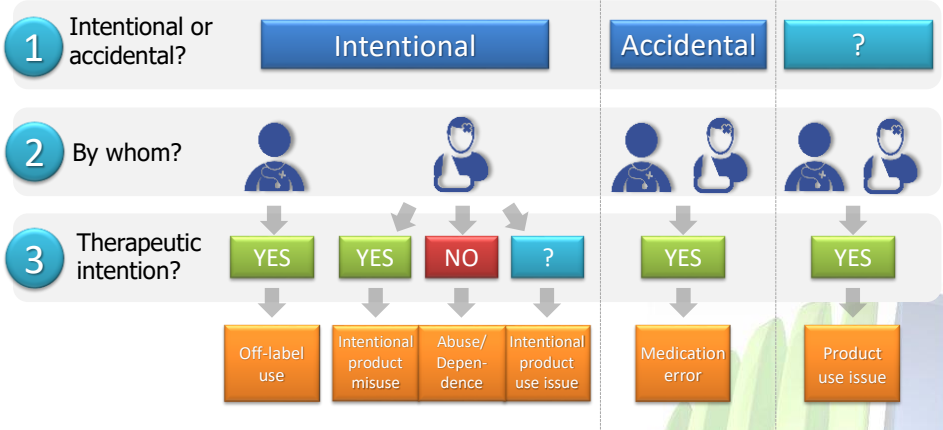
000733

20

'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.

Comprehensive Classification of Product Use Concepts



‘Neutral’ Preferred Terms

- HLT Product administration errors and issues
  - 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
  - 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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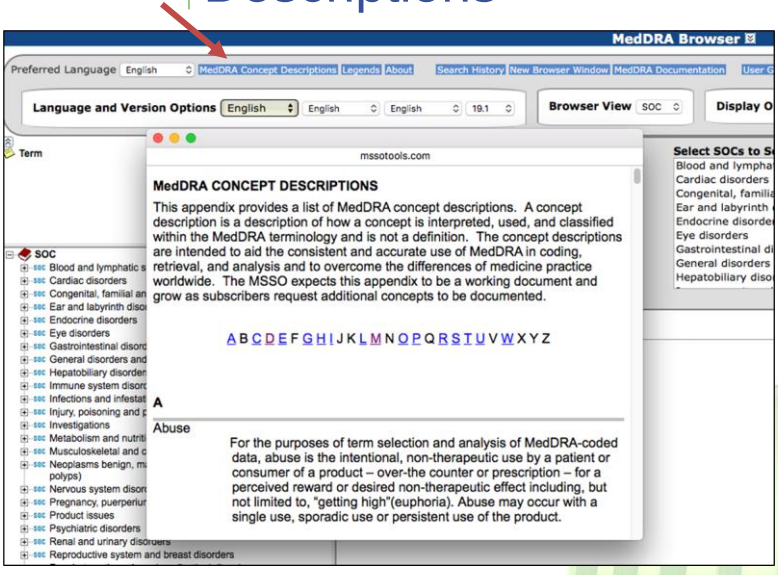
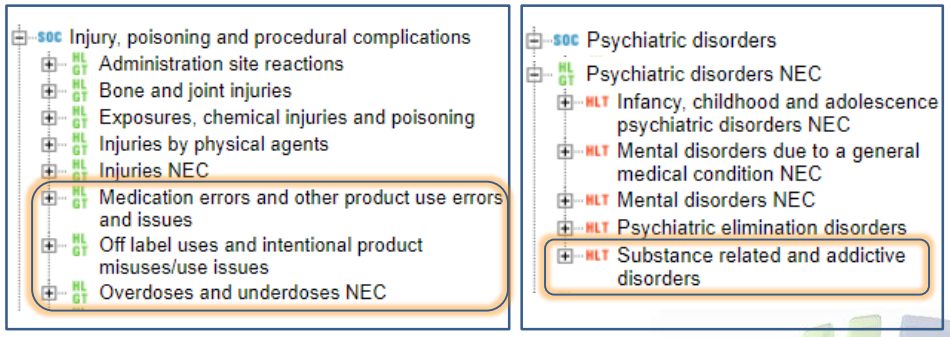
Let's Browse MedDRA

MedDRA Concept Descriptions



MedDRA Hierarchy



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27

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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28

General Principles for Coding Medication Errors

MedDRA Coding - General Principles

MedDRA® TERM SELECTION: POINTS TO CONSIDER

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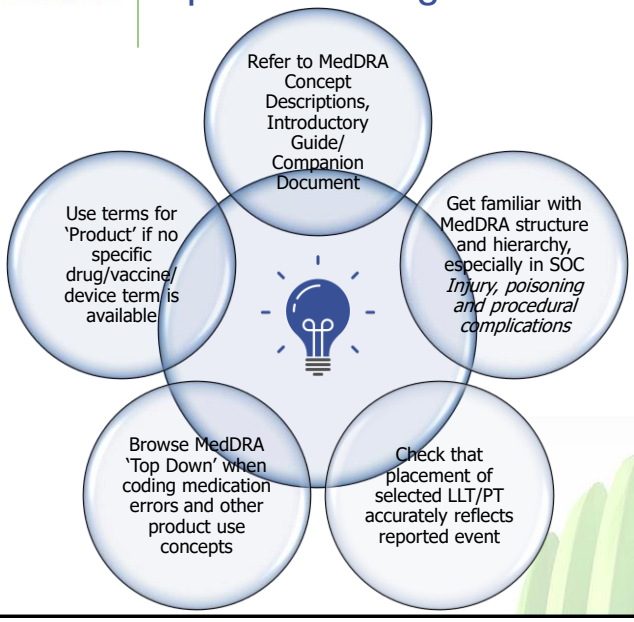
Assess and clarify unclear reports → Select closest LLT → Code as reported → Use only current LLTs

MedDRA

Tips for Coding Medication Errors



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

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

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*

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

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)

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.

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*

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

4 - Potential Medication Errors (cont.)

EXAMPLE

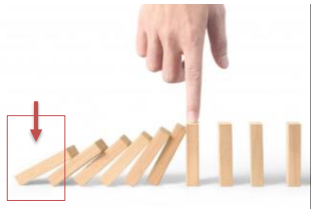
"Pharmacist reported that the blurred print on the drug label could lead to the wrong dose being given."

✓ Potential error
- LLT *Circumstance or information capable of leading to medication error*
  - PT *Circumstance or information capable of leading to medication error*

✓ Contributing scenario
- LLT *Product label text illegible*
  - PT *Product label issue*

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

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*

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*)

REMEMBER Capture <u>both</u> 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

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

REMEMBER Capture <u>both</u> 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

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

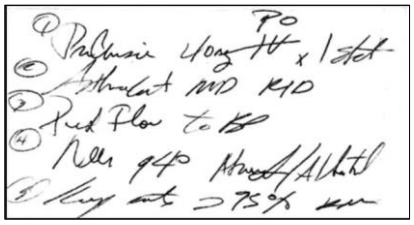
✓ Resulting error

✓ Root Cause

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*

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

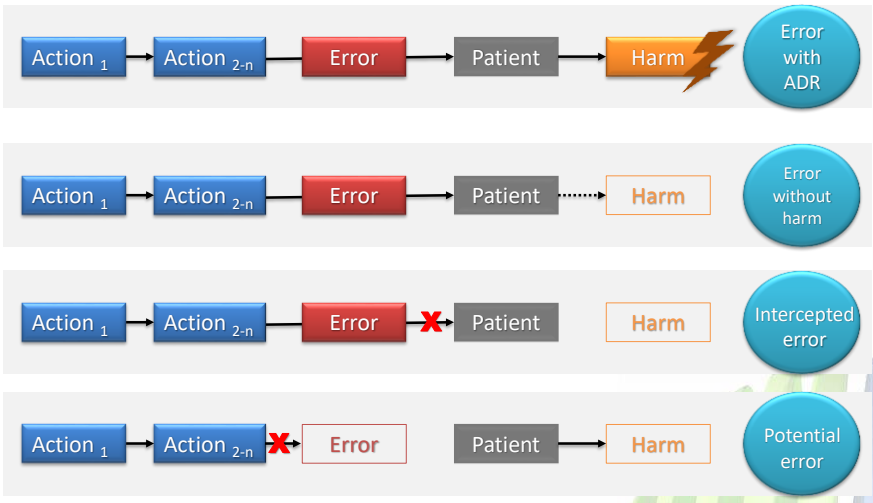
7 - Do not Infer a Medication Error (cont.)

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.

Classification of Medication Error Reports



000733 https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practice-guide-recording-coding-reporting-assessment-medication-errors_en.pdf

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

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.

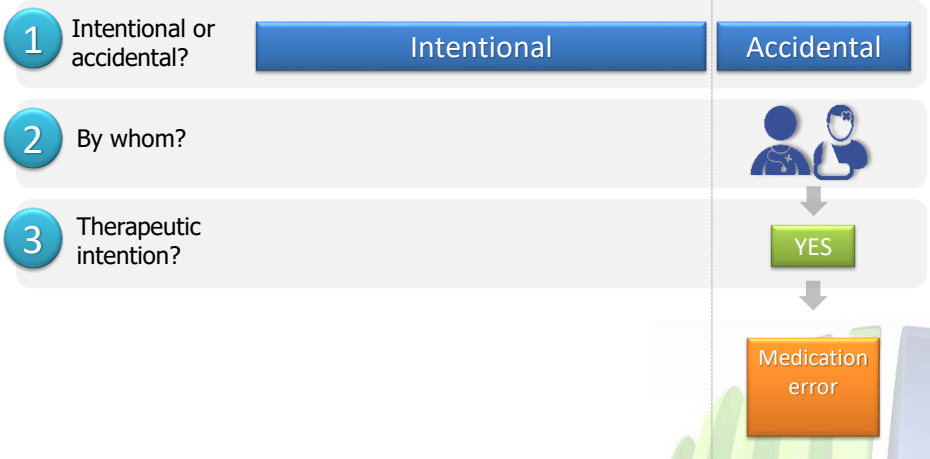
Coding Demonstration #1 - Consider…

"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? ☒

Decision Making

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



Let's Browse MedDRA

- SOC Injury, poisoning and procedural complications
  - HLGT Medication errors and other product use errors and issues
    - HLT 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

- SOC Injury, poisoning and procedural complications
  - HLGT Medication errors and other product use errors and issues
    - HLT 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
  - HLGT Therapeutic procedures and supportive care NEC
    - HLT Therapeutic procedures NEC
      - PT Therapy interrupted
        - LLT Temporary interruption of therapy
        - LLT Therapy interrupted

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*

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? ☒

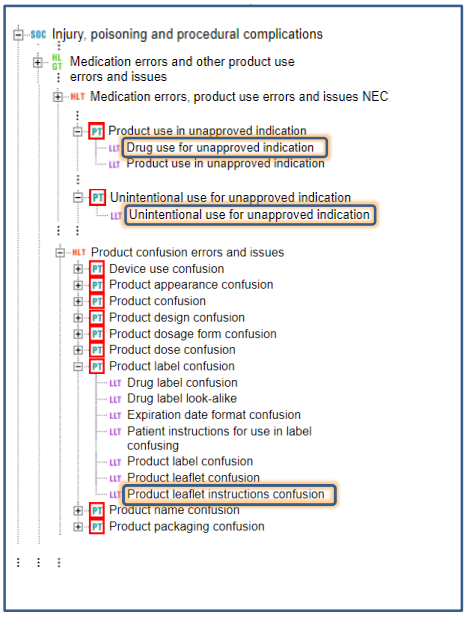
Decision Making

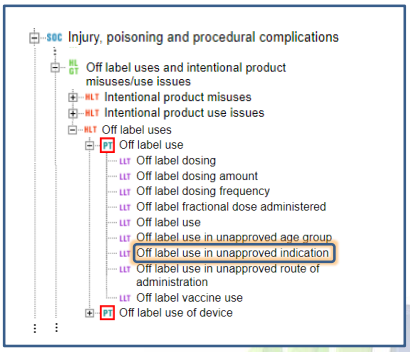
"Patient did not read instructions thoroughly and took drug X for prophylaxis instead of treatment of the approved indication."

1. Intentional or accidental?
2. By whom?
3. Therapeutic intention?

Intentional	Accidental
	
	YES
	Medication error

Let's Browse MedDRA





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*

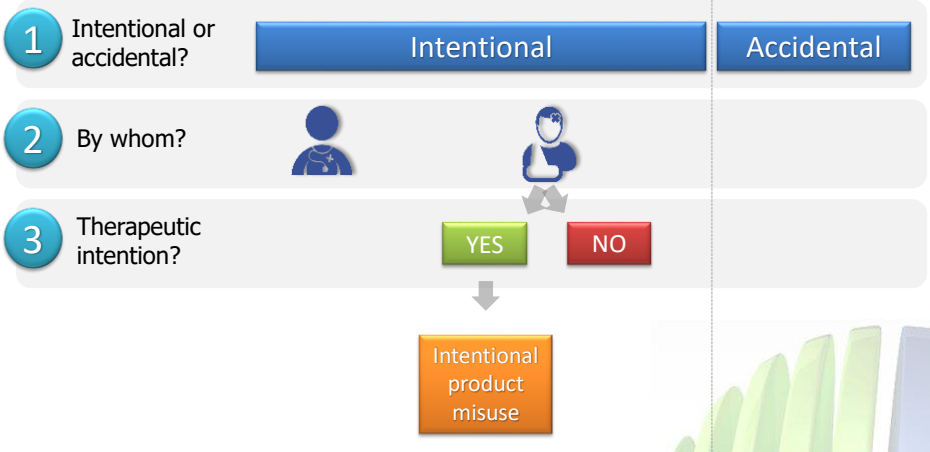
Coding Demonstration #3 - Consider…

"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? ☒

Decision Making

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



Let's Browse MedDRA

- SOC Injury, poisoning and procedural complications
  - NLGT Medication errors and other product use errors and issues
  - HLT 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
  - HLT Product administration errors and issues
    - PT Incorrect dosage administered
      - LLT **Incorrect dosage administered**
    - PT Incorrect dose administered
      - LLT Inappropriate dose of drug administered
      - LLT Inappropriate dose of vaccine administered
      - LLT Inappropriate product dose administered
      - LLT Incomplete dose administered
      - LLT **Incorrect dose administered**
      - LLT Incorrect dose administered from multidose vaccine vial
      - LLT Loading dose not administered
      - LLT Wrong dose administered
      - LLT Wrong drug strength administered

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

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*

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? ☒

MedDRA

Decision Making

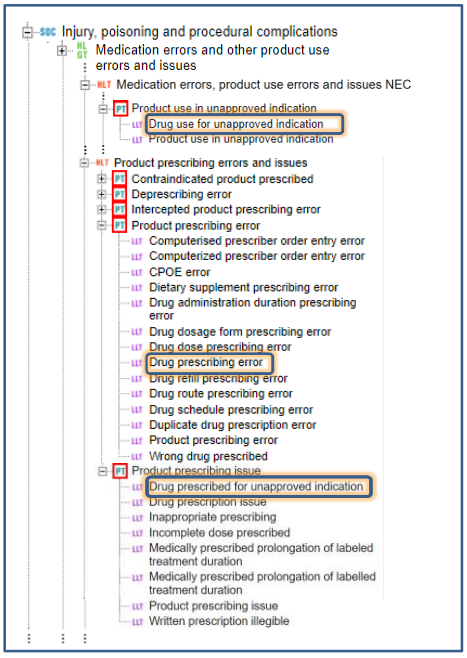
"Doctor prescribed drug A to suppress pre-term labor after careful risk/ benefit assessment (not covered by label)."

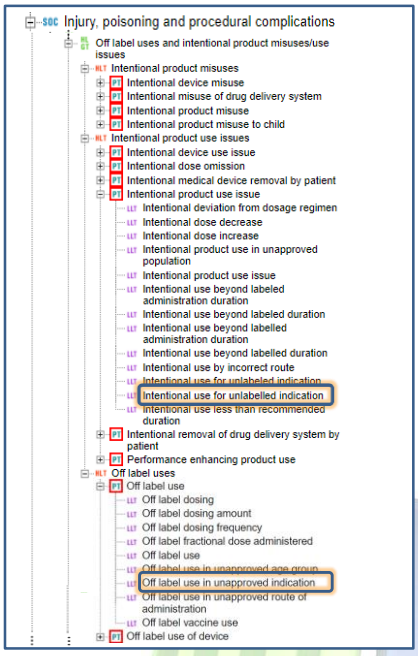
1. Intentional or accidental? — Intentional | Accidental
2. By whom?
3. Therapeutic intention? — YES

Off-label use

MedDRA

Let's Browse MedDRA





MedDRA

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*

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? ☑

Decision Making

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

1. Intentional or accidental? — Intentional | Accidental
2. By whom? — 
3. Therapeutic intention? — YES

Medication error

Let's Browse MedDRA

- SOC Injury, poisoning and procedural complications
  - HLGT Medication errors and other product use errors and issues
    - HLT Medication errors, product use errors and issues NEC
      - PT Wrong drug
        - LLT Wrong drug
    - HLT Product administration errors and issues
      - PT Wrong product administered
        - LLT Wrong drug administered
        - LLT Wrong product administered
        - LLT Wrong vaccine administered
    - HLT Product confusion errors and issues
      - PT Device use confusion
      - PT Product appearance confusion
      - PT Product confusion
        - LLT Product confusion
      - PT Product design confusion
      - PT Product dosage form confusion
      - PT Product dose confusion
      - PT Product label confusion
      - PT Product name confusion
        - LLT Device name confusion
        - LLT Drug name confusion
        - LLT Drug name look-alike
        - LLT Drug name sound-alike
        - LLT Product name confusion
      - PT Product packaging confusion

- SOC Injury, poisoning and procedural complications
  - HLGT Medication errors and other product use errors and issues
    - HLT 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

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*

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

MedDRA

Question and Answer Session

MedDRA

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)

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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