



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session 2 Reporting

Good practice: MedDRA coding of case reports resulting in harm

Medication-errors workshop
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An agency of the European Union





Overview

- What is MedDRA
- Scope of MedDRA
- MedDRA multi-axial terminology
- MedDRA Term Selection: Points to Consider (MTS:PTC)
 - Medication errors reported WITH clinical consequences
 - Medication errors WITHOUT clinical consequences
 - Medication errors in the context of labeled interactions
 - Do NOT infer a medication error
 - Product quality issue vs. medication error
- Medication errors in EudraVigilance
- Summary



What is MedDRA

- Medical Dictionary for Regulatory Activities
- Developed under auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- Maintained by MedDRA Maintenance and Support Services Organization (MSSO)
- Overseen by an ICH MedDRA Management Board, composed of the six ICH parties (EU, EFPIA, MHLW, JPMA, FDA, PhRMA), the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and WHO (as Observer)



What is MedDRA

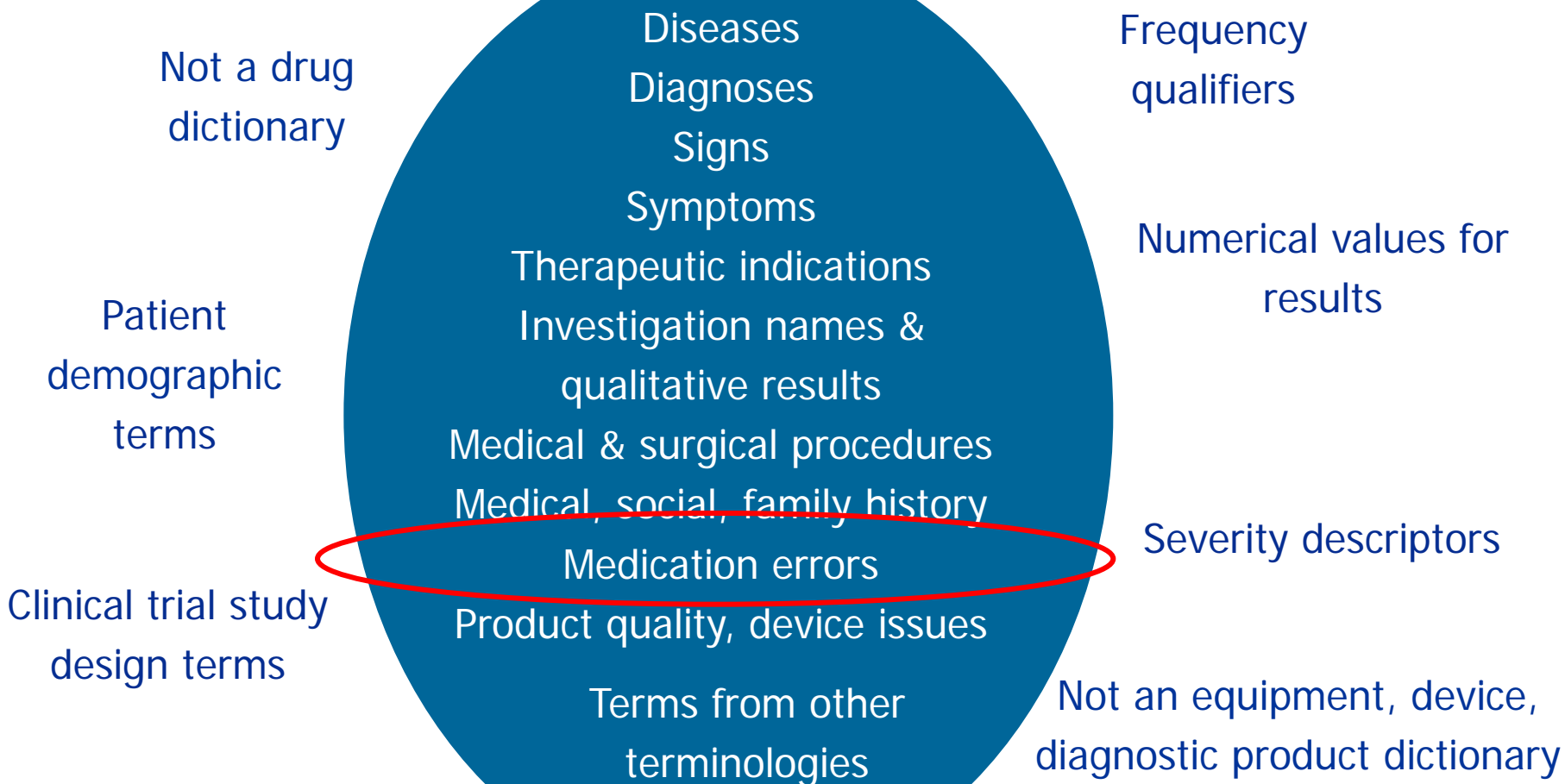
- Clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry
 - Mandated for use in the EU in the pharmaceutical domain
- Terminology used through the entire regulatory process, from pre-marketing to post-marketing
- Provides a classification for a wide range of clinical information



Scope of MedDRA

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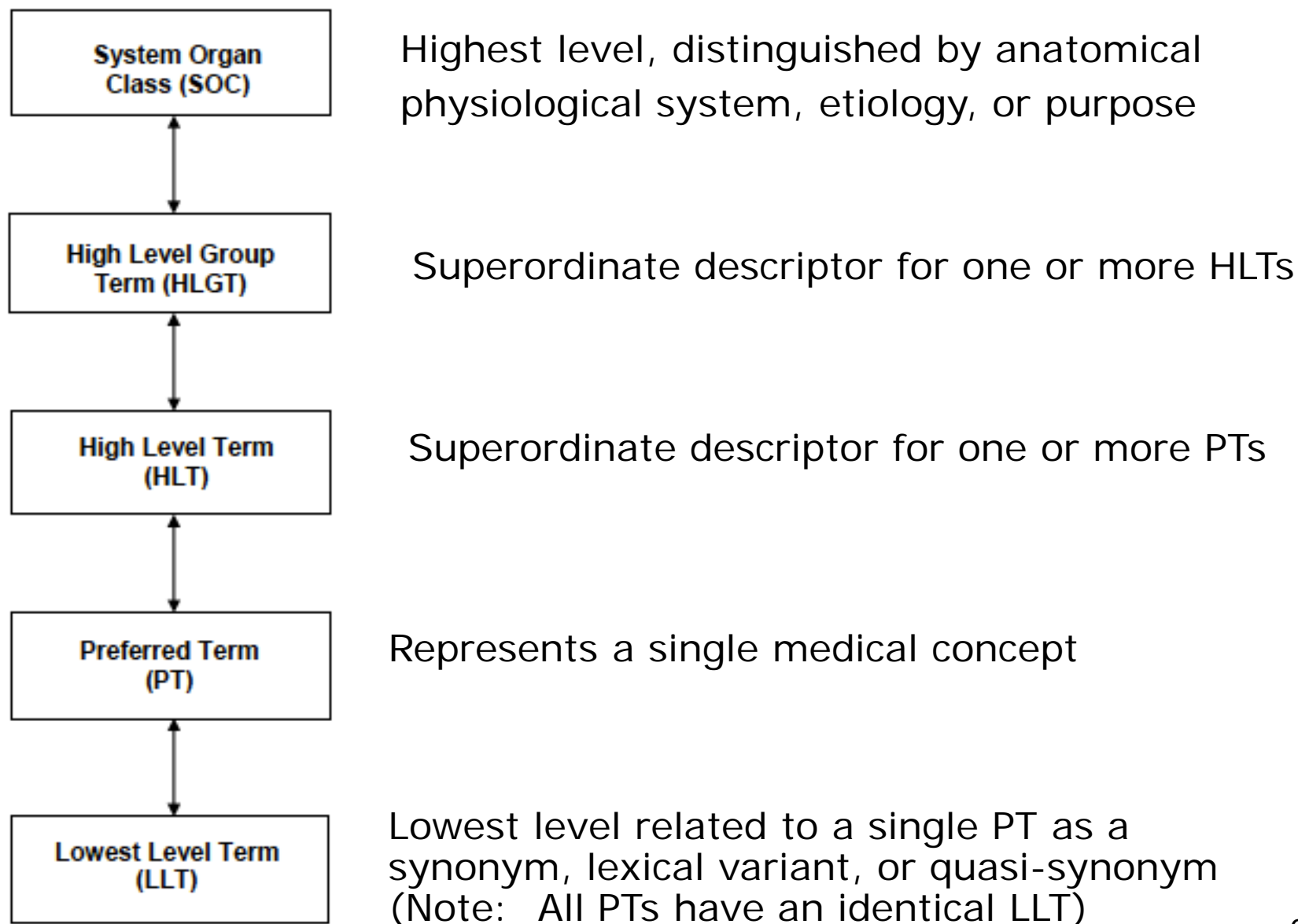
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MedDRA – a multi-axial terminology

- *Code - Retrieve – Present - Analyse - Communicate*
 - Representation of a medical concept in multiple SOCs
 - Allows grouping by different classifications
 - Allows retrieval and presentation via different data sets
 - Purpose of Primary SOC
 - Determines which SOC will represent a PT during cumulative data outputs
 - Is used to support consistent data presentation for reporting to regulators





Medication error terms in v15.1 MedDRA

- [-] SOC Injury, poisoning and procedural complications
 - [+] HL GT Administration site reactions
 - [+] HL GT Bone and joint injuries
 - [+] HL GT Exposures, chemical injuries and poisoning
 - [+] HL GT Injuries by physical agents
 - [+] HL GT Injuries NEC
 - [-] HL GT Medication errors
 - [+] HLT Maladministrations
 - [+] HLT Medication errors due to accidental exposures
 - [+] HLT Medication errors NEC
 - [+] HLT Medication monitoring errors
 - [+] HLT Overdoses



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

- An ICH-endorsed guide for MedDRA users
 - Updated examples and guidance presented are currently under finalisation by the ICH Points To Consider (PTC) Working Group and are expected for release with MedDRA version 16.0
- Developed to promote medically accurate and consistent use of MedDRA in exchange of data (ultimately, for “medically meaningful” retrieval and analysis)
- Developed by the MedDRA Points to Consider Working Group of the ICH Steering Committee
- Published on MedDRA MSSO Web site





Medication errors reported WITH clinical consequences

- If a medication error is reported with clinical consequences, select terms for both the medication error and the clinical consequences (MTS:PTC)

Examples:

<i>Reported</i>	<i>LLT Selected</i>
Patient was administered wrong drug and experienced hypotension	Wrong drug administered Hypotension
Because of similar sounding drug names, the patient took the wrong drug and experienced a rash	Drug name confusion Wrong drug administered Rash



Medication errors WITHOUT clinical consequences

- Medication errors without clinical consequences are not adverse reactions (MTS:PTC)
- However, it is important to record the occurrence or potential occurrence of a medication error
- Select a term that is closest to the description of medication error reported
- If specifically reported that no adverse effect has occurred, it is acceptable to select LLT 'No adverse effect'
- In instances where the medication did not reach the patient, it is acceptable to select LLT 'Drug not taken in context of intercepted medication error'



Medication errors WITHOUT clinical consequences

Examples:

Reported	LLT Selected
Medication was given intravenously instead of intramuscularly	Intramuscular formulation administered by other route
Medication was given intravenously instead of intramuscularly without sequelae	Intramuscular formulation administered by other route No adverse effect
Patient was dispensed the wrong drug. The error was detected prior to patient administration	Intercepted drug dispensing error



Medication errors WITHOUT clinical consequences

Examples:

Reported	LLT Selected
Pharmacist notices that the names of two drugs are similar and is concerned that this may result in a medication error	Circumstance or information capable of leading to medication error
Drug inadvertently administered. The error was noticed soon afterwards	Drug administration error



Medication errors in the context of labeled interactions

- If the label describes known effects when the product is co-administered with specific drugs, with specific foods, or to patients with specific disease states, then select a medication error term for the type of interaction (MTS:PTC):

Examples:

Medication Error Terms – Labeled Interactions

Labelled drug-drug interaction medication error

Labelled drug-food interaction medication error

Labelled drug-disease interaction medication error

Documented hypersensitivity to administered drug



Medication errors in the context of labeled interactions

Examples:

<i>Reported</i>	<i>LLT Selected</i>
Patient became pregnant whilst taking an antifungal drug and an oral contraceptive	Labelled drug-drug interaction medication error Pregnancy on oral contraceptive
Patient drank grapefruit juice whilst taking a calcium channel blocker	Labelled drug-food interaction medication error
Patient with renal failure is prescribed a drug that is contraindicated in renal failure	Labelled drug-disease interaction medication error
Patient is administered a sulfonamide-based drug	Documented hypersensitivity to administered drug



Do NOT infer a medication error

- Do not infer that a medication error has occurred unless specific information is provided
 - Includes inferring that extra dosing, overdose, or underdose has occurred (MTS:PTC)

Examples:

<i>Reported</i>	<i>LLT Selected</i>
Antibiotic was prescribed for a week, and the patient stopped treatment after 2 days because of bitter taste	Prescribed dosing duration not completed Taste bitter
Incorrect dosing by patient	Incorrect dose administered



Product quality issue vs. medication error

- It is important to distinguish between a product quality issue and a medication error
- Examples:

<i>Reported</i>	<i>LLT Selected</i>	<i>Comment</i>
Pharmacist dispensing Drug A inadvertently attached a product label for Drug B	Wrong label placed on medication during dispensing	Medication error
The drug store clerk noted that the wrong product label was attached to some bottles in a shipment	Product label on wrong product	Product quality issue
The mother administered insufficient amount of prescribed antibiotic because the lines on the dropper were hard to read	Product dropper calibration unreadable Insufficient dosage	Product quality issue and medication error



Medication errors reported to EudraVigilance

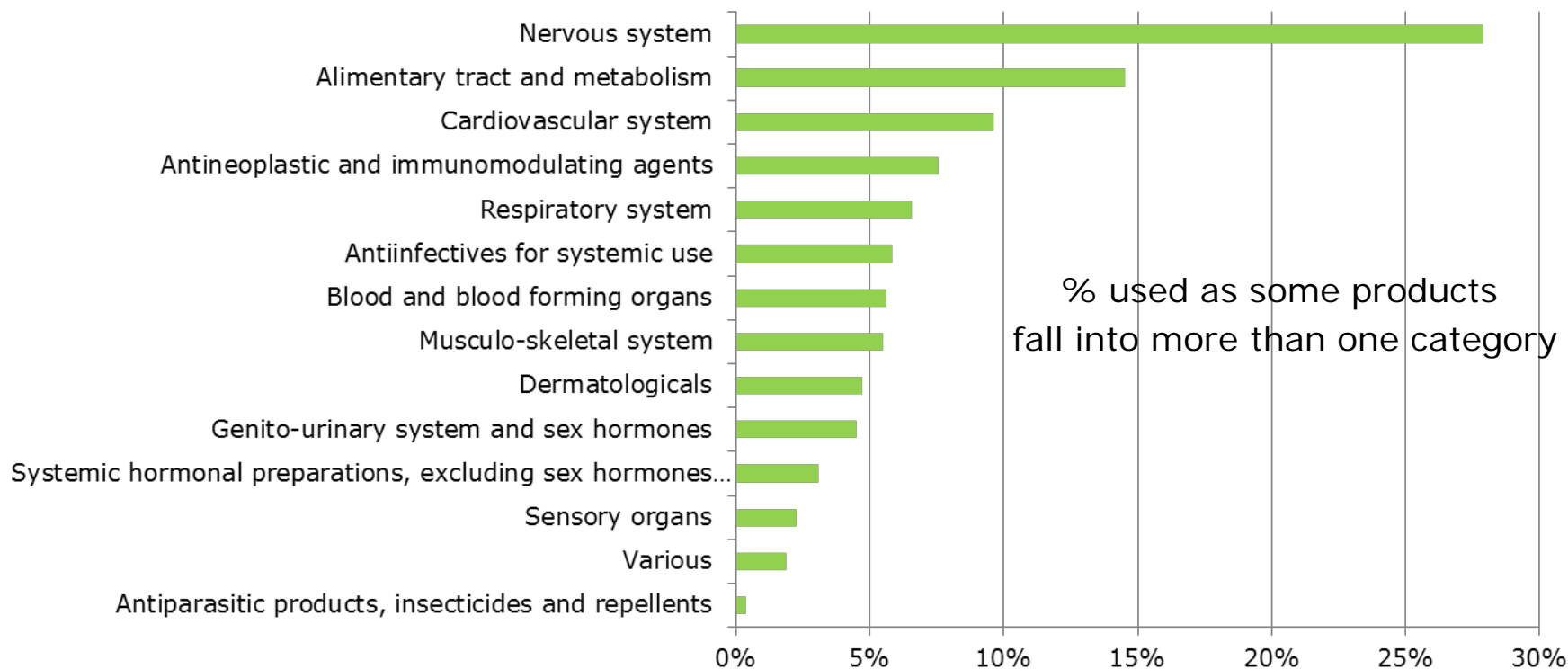
Methodology

- Selected medication error terms from MedDRA (Overdose terms excluded)
- Grouped MedDRA medication error terms according to WHO prescribing, dispensing, medicine preparation, administration and monitoring error categories
- Grouped medication error terms related to medicines by WHO Anatomical Therapeutic Chemical (ATC) classification system, level 1
- Retrieved individual cases reported to EV in post-authorisation phase (includes non-serious adverse reactions and medication errors reported periodically for CAPs in accordance with previous Volume 9A)



Medication errors associated with serious ADRs grouped by ATC classification of medicines

Percentage of serious reports in EEA of medication error by ATC description





MedDRA Preferred Terms Grouped according to Draft WHO Medication Errors Classification

Prescribing

Circumstance or information capable of leading to medication error

- Documented hypersensitivity to administered drug
- Drug administered to patient of inappropriate age
- Drug name confusion
- Drug prescribing error
- Incomplete course of vaccination
- Intercepted drug prescribing error
- Intercepted medication error
- Labelled drug-disease interaction medication error
- Labelled drug-drug interaction medication error
- Labelled drug-food interaction medication error
- Medication error
- Product dosage form confusion
- Vaccination error
- Product name confusion*
- Product substitution issue*
- Drug chemical incompatibility*
- Drug physiologic incompatibility*
- Drug therapeutic incompatibility*
- Contraindication to vaccine*
- Contraindication to medical treatment*

Dispensing

Circumstance or information capable of leading to medication error

- Documented hypersensitivity to administered drug
- Drug administered to patient of inappropriate age
- Drug dispensing error
- Drug label confusion
- Drug name confusion
- Incorrect storage of drug
- Intercepted drug dispensing error
- Intercepted medication error
- Labelled drug-disease interaction medication error
- Labelled drug-drug interaction medication error
- Labelled drug-food interaction medication error
- Medication error
- Product dosage form confusion
- Vaccination error
- Product label confusion*
- Product name confusion*
- Product label on wrong product*
- Product substitution issue*
- Incorrect product storage*
- Drug chemical incompatibility*
- Drug physiologic incompatibility*
- Drug therapeutic incompatibility*
- Contraindication to vaccine*
- Contraindication to medical treatment*

Preparation

Circumstance or information capable of leading to medication error

- Drug label confusion
- Drug name confusion
- Expired drug administered
- Incorrect drug dosage form administered
- Incorrect storage of drug
- Intercepted medication error
- Medication error
- Poor quality drug administered
- Product dosage form confusion
- Vaccination error
- Wrong technique in drug usage
- Product label confusion*
- Product name confusion*
- Product label on wrong product*
- Incorrect product storage*
- Drug chemical incompatibility*
- Product expiration date issue*

Administration

Circumstance or information capable of leading to medication error

- Counterfeit drug administered
- Drug administered at inappropriate site
- Drug administered in wrong device
- Drug administered to patient of inappropriate age
- Drug administration error
- Drug dose omission
- Drug label confusion
- Drug name confusion
- Expired drug administered
- Inappropriate schedule of drug administration
- Incomplete course of vaccination
- Incorrect dose administered
- Incorrect dose administered by device
- Incorrect drug administration duration
- Incorrect drug administration rate
- Incorrect drug dosage form administered
- Incorrect route of drug administration
- Intercepted drug administration error
- Intercepted medication error
- Medication error
- Multiple use of single-use product
- Poor quality drug administered
- Product dosage form confusion
- Vaccination error
- Wrong drug administered
- Wrong technique in drug usage process
- Product label confusion*
- Product name confusion*
- Treatment noncompliance*

Monitoring

Circumstance or information capable of leading to medication error

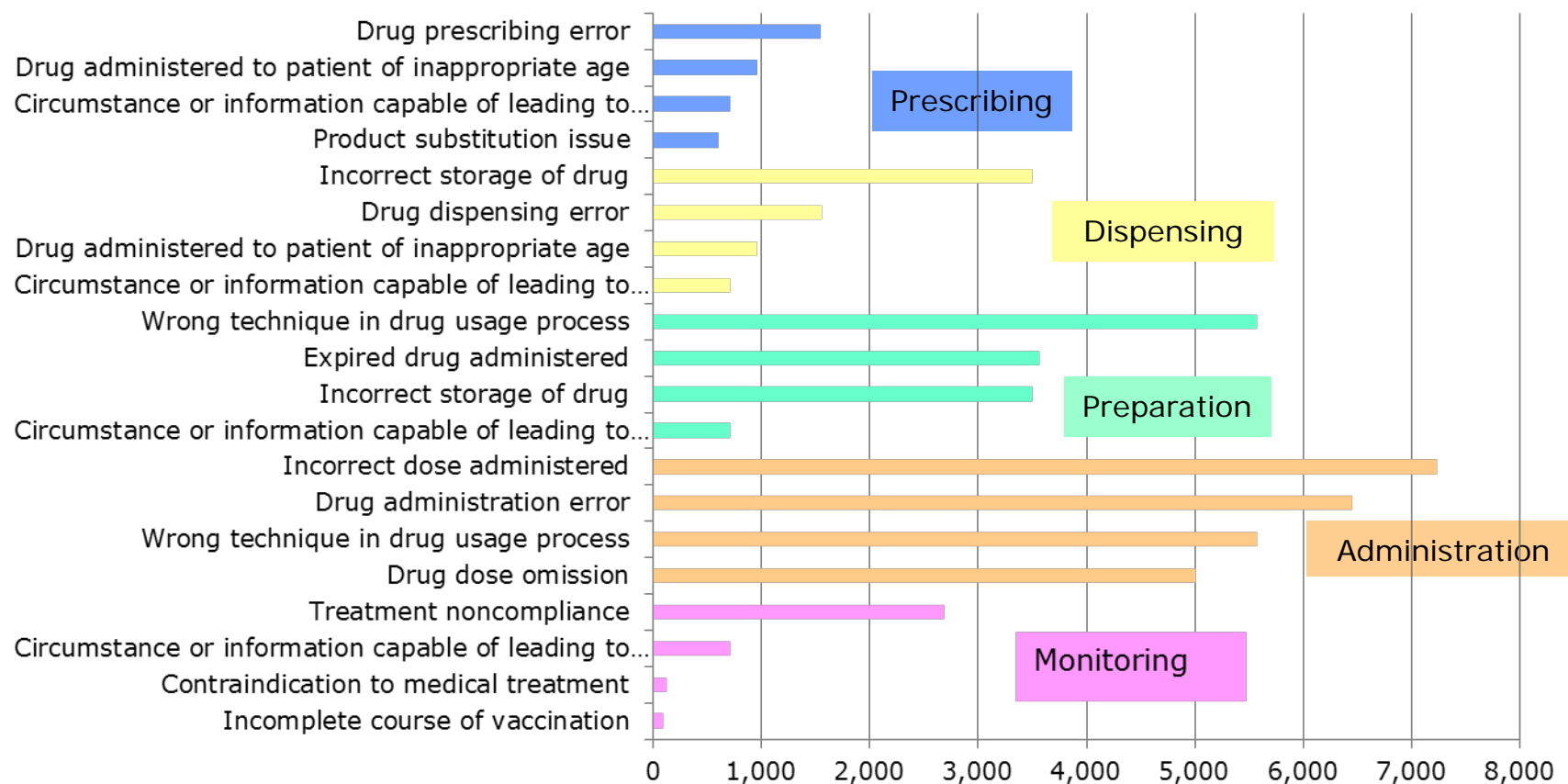
- Incomplete course of vaccination
- Medication error
- Treatment noncompliance*
- Contraindication to medical treatment*

MedDRA (15.1) HLGT Medication Errors minus HLT Overdose
 MedDRA (15.1) HLGT Product Quality Issues



Top 4 medication errors according to draft WHO medication errors classification

Top 4 medication errors for 5 WHO categories





Summary

- MedDRA provides an internationally agreed standard terminology to code, retrieve, present, analyse and communicate medication errors
- Following a request by the EU, the ICH MedDRA Points to Consider Working Group is in a process of further improving guidance on coding medication errors - this will result in better data quality
- MedDRA MSSO is providing training to end users for MedDRA coding and data retrieval
- EudraVigilance is an important tool to monitor, analysis and prevent medication errors associated with adverse reactions



Thank you



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