MedDRA Coding Workshop
8 November 2018
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Session Overview

• MedDRA background, structure and scope
• Principles of Coding
• MedDRA Term Selection: Points to Consider document
• Examples and Hands-on coding exercises
What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities
MedDRA is a clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation.
Scope of MedDRA

**IN**
- Medical conditions
- Indications
- Investigations (tests, results)
- Medical and surgical procedures
- Medical, social, family history
- Medication errors
- Product quality issues
- Device-related issues
- Product use issues
- Pharmacogenetic terms
- Toxicologic issues
- Standardized queries

**OUT**
- Frequency qualifiers
- Numerical values for results
- Severity descriptors
- Not an equipment, device, diagnostic product dictionary
- Patient demographic terms
- Clinical trial study design terms
- Not a drug dictionary
MedDRA Structure

System Organ Class (SOC) (27)

High Level Group Term (HLGT) (337)

High Level Term (HLT) (1,737)

Preferred Term (PT) (23,389)

Lowest Level Term (LLT) (79,507)
System Organ Classes

- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders and administration site conditions
- 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
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
- Vascular disorders
Non-Current Terms

- Flagged at the LLT level in MedDRA
- Not recommended for continued use
- Retained to preserve historical data for retrieval and analysis
- Terms that are vague, ambiguous, outdated, truncated, or misspelled
- Terms derived from other terminologies that do not fit MedDRA rules
• Each MedDRA term assigned an 8-digit numeric code starting with “1”
• The code is non-expressive
• Codes can fulfill a data field in various electronic submission types (e.g., E2B)
• New terms are assigned sequentially
A Multi-Axial Terminology

• Multi-axial = the representation of a medical concept in multiple SOCs
  – Allows grouping by different classifications
  – Allows retrieval and presentation via different data sets
• All PTs assigned a primary SOC
  – Determines which SOC will represent a PT during cumulative data outputs
  – Prevents “double counting”
  – Supports standardized data presentation
  – Pre-defined allocations should not be changed by users
A Multi-Axial Terminology (cont)

SOC = Respiratory, thoracic and mediastinal disorders (Secondary SOC)

HLGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

PT = Influenza

SOC = Infections and infestations (Primary SOC)

HLGT = Viral infectious disorders

HLT = Influenza viral infections
Rules for Primary SOC Allocation

- PTs represented in only one SOC are automatically assigned that SOC as primary
- PTs for diseases, signs and symptoms are assigned to prime manifestation site SOC
- Congenital and hereditary anomalies terms have SOC Congenital, familial and genetic disorders as Primary SOC
- Neoplasms terms have SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) as Primary SOC
  - Exception: Cysts and polyps have prime manifestation site SOC as Primary SOC
- Infections and infestations terms have SOC Infections and infestations as Primary SOC
If a PT links to more than one of the exceptions, the following priority will be used to determine primary SOC:

1st: Congenital, familial and genetic disorders
2nd: Neoplasms benign, malignant and unspecified (incl cysts and polyps)
3rd: Infections and infestations
PTs in the following SOCs only appear in that particular SOC and not in others, i.e., they are not multi-axial

- Investigations
- Surgical and medical procedures
- Social circumstances
### Can You Select the Primary SOC for This PT?

<table>
<thead>
<tr>
<th>PT</th>
<th>HLT</th>
<th>HLGT</th>
<th>SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital HIV infection</td>
<td>Viral infections congenital</td>
<td>Infections and infestations congenital</td>
<td>Congenital, familial and genetic disorders</td>
</tr>
<tr>
<td>Congenital neonatal infections</td>
<td>Neonatal and perinatal conditions</td>
<td></td>
<td>Pregnancy, puerperium and perinatal conditions</td>
</tr>
<tr>
<td>Retroviral infections</td>
<td>Viral infectious disorders</td>
<td></td>
<td>Infections and infestations</td>
</tr>
<tr>
<td>Acquired immunodeficiency syndromes</td>
<td>Immunodeficiency syndromes</td>
<td></td>
<td>Immune system disorders</td>
</tr>
</tbody>
</table>
MSSO’s MedDRA Browsers

- **MedDRA Desktop Browser (MDB)**
  - Download MDB and release files from MedDRA website

- **MedDRA Web-Based Browser (WBB)**
  - [https://tools.meddra.org/wbb/](https://tools.meddra.org/wbb/)

- **Features**
  - Both require MedDRA ID and password
  - View/search MedDRA and SMQs
  - Support for all MedDRA languages
  - Language specific interface
  - Ability to export search results and Research Bin to local file system
Assessing the Reported Information

- Consider what is being reported. Is it a:
  - Clinical condition - Diagnosis, sign or symptom?
  - Indication?
  - Test result?
  - Injury?
  - Procedure?
  - Medication error?
  - Product use issue?
  - Product quality issue?
  - Social circumstance?
  - Device issue?
  - Procedural complication?

- Is it a combination of these?

The type of report will influence the way you search for a suitable LLT. It may indicate in which SOC you expect to find the closest match.
MedDRA Browsing Tips

• First, try using actual words from reporter
• Use “top-down” and “bottom-up” approaches
• Look at the “neighbors” and check the hierarchy
• Consider synonyms, e.g., “Liver” and “Hepatic”
• Use word stems, e.g., “Pancrea”
• Use available resources for difficult verbatim terms (web search, medical dictionaries, colleagues)
• Become familiar with MedDRA Concept Descriptions
Exercise 1

The patient states she has been experiencing **weakness in her legs**.

___________________ LLT → ___________________ PT
Lab results indicate an increase in erythrocytes.

___________________ LLT → ___________________ PT
Drug was contaminated with *Staphylococcus*.

_________________________ LLT → _________________________ PT
A six year old boy was admitted for toxicity after accidentally ingesting the remaining antihypertensive tablets in the bottle.
The patient requires a revision of his hip replacement because the femoral stem has worked loose within the bone.

_________________ LLT → __________________ PT
Importance of Coding

- Accuracy
- Consistency
- Transparency
- Standardisation
- Analysis
- Evaluation
- Patient Safety
Principles of Coding – 1

• Select the closest matching LLT to capture all the reported information

- VT
  • Thrus in mouth

- LLT
  • Thrus oral

- PT
  • Oral candidiasis
• Do not add information

VT
• Tachycardia (standing)

LLT
• Tachycardia

PT
• Tachycardia
Principles of Coding - 3

• Do not interpret or diagnose

VT
• Low Hb

LLT
• Haemoglobin low

PT
• Haemoglobin decreased
• Use medical judgment and references

- VT: • Syringitis
- LLT: • Eustachian salpingitis
- PT: • Otosalpingitis
• Check the MedDRA hierarchy

VT
• Pyogenic cholecystitis

LLT
• Cholecystitis suppurative

PT
• Cholecystitis infective
Principles of Coding - 6

• Know how to handle combination events

VT
• Ulcer on big toe due to diabetes

LLT
• Diabetic foot ulcer

PT
• Diabetic foot
• Know how to handle combination events

VT
• Significant mitral and tricuspid regurgitation

LLT
• Mitral regurgitation
• Tricuspid regurgitation

PT
• Mitral valve incompetence
• Tricuspid valve incompetence
• Seek clarification if unclear or ambiguous

- VT
  • Synechiae

- LLT
  • Ill-defined disorder

- PT
  • Ill-defined disorder
MedDRA Term Selection: Points to Consider (MTS:PTC)

- 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: PTC (cont)

• Developed by a working group of the ICH Management Committee
• Updated twice yearly with each MedDRA release
• Available on MedDRA and JMO websites
  – English and Japanese
  – Word (“clean” and “redlined”), PDF, HTML formats
  – “Redlined” document identifies changes made from previous to current release of document
General Term Selection Principles

- Quality of Source Data
- Quality Assurance
- Do Not Alter MedDRA
- Always Select a Lowest Level Term
- Select Only Current Lowest Level Terms
- When to Request a Term
- Use of Medical Judgment in Term Selection
- Selecting More than One Term
- Check the Hierarchy
- Select Terms for All Reported Information, Do Not Add Information
Term Selection Points

- Diagnoses and Provisional Diagnoses with or without Signs and Symptoms
- Death and Other Patient Outcomes
- Suicide and Self-Harm
- Conflicting/Ambiguous/Vague Information
- Combination Terms
- Age vs. Event Specificity
- Body Site vs. Event Specificity
- Location-Specific vs. Microorganism-Specific Information
- Modification of Pre-existing Conditions
- Exposures During Pregnancy and Breast Feeding
- Congenital Terms
- Neoplasms
- Medical and Surgical Procedures
- Investigations
Term Selection Points (cont)

- Medication Errors, Accidental Exposures and Occupational Exposures
- Misuse, Abuse and Addiction
- Transmission of Infectious Agent via Product
- Overdose, Toxicity and Poisoning
- Device-related Terms
- Drug Interactions
- No Adverse Effect and “Normal” Terms
- Unexpected Therapeutic Effect
- Modification of Effect
- Social Circumstances
- Medical and Social History
- Indication for Product Use
- Off Label Use
- Product Quality Issues
• In some cases with more than one option for selecting terms, a “preferred option” is identified but this does not limit MedDRA users to applying that option. Organizations should be consistent in their choice of option.

• Section 4.1 – Versioning (Appendix)
  – 4.1.1 Versioning methodologies
  – 4.1.2 Timing of version implementation
Example: Infections

- In most cases MedDRA terms capture both site and pathogen, but not always
- Excerpt from MedDRA Term Selection: Points to Consider

3.8.2 No available MedDRA term includes both microorganism and anatomic location

The preferred option is to select terms for both the microorganism-specific infection and the anatomic location.

Alternatively, select a term that reflects the anatomic location or select a term that reflects the microorganism-specific infection. Medical judgment should be used in deciding whether anatomic location or the microorganism-specific infection should take priority.

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Preferred Option</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory chlamydial infection</td>
<td>Chlamydial infection</td>
<td>✓</td>
<td>Represents both microorganism-specific infection and anatomic location</td>
</tr>
<tr>
<td></td>
<td>Respiratory infection</td>
<td></td>
<td>Represents location-specific infection</td>
</tr>
<tr>
<td></td>
<td>Chlamydial infection</td>
<td></td>
<td>Represents microorganism-specific infection</td>
</tr>
</tbody>
</table>
Example: Diagnosis and Signs/Symptoms

- Diagnosis reported with/without signs and symptoms
- Excerpt from MedDRA Term Selection: Points to Consider

<table>
<thead>
<tr>
<th>SINGLE DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DEFINITIVE DIAGNOSIS</strong></td>
</tr>
<tr>
<td>Single definitive diagnosis without signs/symptoms</td>
</tr>
<tr>
<td>- Diagnosis (only possible option)</td>
</tr>
<tr>
<td>Single definitive diagnosis with signs/symptoms</td>
</tr>
<tr>
<td>- Preferred: Diagnosis only</td>
</tr>
<tr>
<td>- Alternate: Diagnosis and signs/symptoms</td>
</tr>
<tr>
<td>Note: Always include signs/symptoms not associated with diagnosis</td>
</tr>
<tr>
<td>SEE EXAMPLE 1</td>
</tr>
</tbody>
</table>
3.5.2 One reported condition is more specific than the other

If two conditions are reported in combination, and one is more specific than the other, select a term for the more specific condition.

Example

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatic function disorder (acute hepatitis)</td>
<td>Hepatitis acute</td>
</tr>
<tr>
<td>Arrhythmia due to atrial fibrillation</td>
<td>Atrial fibrillation</td>
</tr>
</tbody>
</table>
3.5.3  A MedDRA combination term is available
If two conditions are reported in combination, and a single MedDRA combination term is available to represent them, select that term.

Example

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinopathy due to diabetes</td>
<td>Diabetic retinopathy</td>
</tr>
<tr>
<td>Rash with itching</td>
<td>Itchy rash</td>
</tr>
</tbody>
</table>
Example: Combination Reports

3.5.4 When to “split” into more than one MedDRA term
If “splitting” the reported ARs/AEs provides more clinical information, select more than one MedDRA term.

Example

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhoea and vomiting</td>
<td>Diarrhoea</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
</tr>
<tr>
<td>Wrist fracture due to fall</td>
<td>Wrist fracture</td>
</tr>
<tr>
<td></td>
<td>Fall</td>
</tr>
</tbody>
</table>

Exercise medical judgment so that information is not lost when “splitting” a reported term. Always check the MedDRA hierarchy above the selected term to be sure it is appropriate for the reported information.
Terms for Discussion

- Haemorrhagic stroke on left side with right hemiplegia, severe aphasia and dysphagia
- Gastric ulcer with indigestion, abdo pain, fainting, black diarrhoea and vomiting blood
- Post-menopausal incontinence
- Displaying symptoms of possible meningitis, stiff neck, rash, fever, photophobia & depression
Pancreatitis due to CMV infection

- Pancreatitis
- CMV Infection
- Cytomegalovirus pancreatitis
- Pancreatitis AND CMV Infection
Pancreatitis due to CMV infection

A. Pancreatitis
B. CMV infection
C. Cytomegalovirus pancreatitis
D. Pancreatitis AND CMV Infection
Citrobacter conjunctivitis

Conjunctivitis

Citrobacter infection

Conjunctivitis AND Citrobacter infection

Bacterial conjunctivitis
Citrobacter conjunctivitis

A. Conjunctivitis
B. Citrobacter infection
C. Conjunctivitis AND Citrobacter infection
D. Conjunctivitis bacterial
<table>
<thead>
<tr>
<th>Haemophilus influenzae identified from bronchoscopy specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemophilus influenzae infection</td>
</tr>
<tr>
<td>Haemophilus influenzae test positive</td>
</tr>
<tr>
<td>Post procedural infection</td>
</tr>
<tr>
<td>Bronchoscopy abnormal</td>
</tr>
</tbody>
</table>
How do we code this…?

Haemophilus influenzae identified from bronchoscopy specimen

A. Haemophilus influenzae infection
B. Haemophilus influenzae test positive
C. Post procedural infection
D. Bronchoscopy abnormal
Hip pain due to trochanteric bursitis

- Hip pain
- Trochanteric bursitis
- Hip pain AND Trochanteric bursitis
- Infective bursitis
How do we code this…?

Hip pain with trochanteric bursitis

A. Hip pain
B. Trochanteric bursitis
C. Hip pain AND Trochanteric bursitis
D. Bursitis infective
Recurring *C. difficile* infection with diarrhoea

- Clostridium difficile infection recurrence
- *C. difficile* diarrhoea
- Clostridium difficile test positive
- Intestinal infection due to *clostridium difficile*
How do we code this…?

Recurring c. difficile infection with diarrhoea

A. Clostridium difficile infection recurrence
B. C. difficile diarrhoea
C. Clostridium difficile test positive
D. Intestinal infection due to clostridium difficile
How do we code this…?

Upper back pain and also low back pain

A. Upper back pain
B. Low back pain
C. Upper back pain AND Low back pain
D. Back pain
Unable to hear fully after contracting mumps as a baby

Hearing impaired

Hereditary hearing disorder

Mumps deafness

Mumps
Unable to hear fully after contracting mumps as a baby

A. Hearing impaired  
B. Hereditary hearing disorder  
C. Mumps deafness  
D. Mumps

Post-meeting note: This slide has been updated with the correct answer, as highlighted by the audience during the presentation.
Turned very greasy

Ill-defined disorder

Unevaluable event

Skin greasy

Unevaluable reaction
How do we code this…?

Turned very greasy

A. Ill-defined disorder
B. Unevaluable event
C. Skin greasy
D. Unevaluable reaction
<table>
<thead>
<tr>
<th>Color blindness</th>
<th>Blindness color</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour blindness acquired</td>
<td>Color blindness acquired</td>
</tr>
</tbody>
</table>
How do we code this…?

Became color blind in adolescence

A. Color blindness
B. Blindness color
C. Colour blindness acquired
D. Color blindness acquired
Infection after surgery

- Infection
  - Postoperative wound infection
  - Surgical wound infection
  - Postoperative infection
How do we code this…?

Infection after surgery

A. Infection
B. Postoperative wound infection
C. Surgical wound infection
D. Postoperative infection
Had MI

Myocardial infarction

Ill-defined disorder

MI

Unevaluable event
How do we code this…?

Had MI

A. Myocardial infarction
B. Ill-defined disorder
C. MI
D. Unevaluable event
Death from cerebral haemorrhage

- Sudden death
- Death
- Cerebral haemorrhage
- Death AND Cerebral haemorrhage
How do we code this…?

Death from cerebral haemorrhage

A. Sudden death
B. Death
C. Cerebral haemorrhage
D. Death AND Cerebral haemorrhage
Useful Resources

- MedDRA Concept Descriptions
- MedDRA Introductory Guide
- MedDRA Term Selection: Points to Consider
- MTS: PTC Companion Document
- MedDRA Website
- MedDRA Version Reports
Concept Descriptions

• Descriptions of how a concept is interpreted, used, and classified in MedDRA
• Not a definition
• Intended to aid accurate and consistent use of MedDRA in coding and retrieval
• Overcome differences in medical practice worldwide
  – Descriptions aim to be broadly consistent with definitions across different regulatory regions
• See Appendix B of MedDRA Introductory Guide
• Accessible in MSSO's Browsers
Concept Descriptions (cont)

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 in medicine practice worldwide. The MSSO expects this appendix to be a working document and grow as subscribers request additional concepts to be documented.

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

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.
Recent Release....

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

- New document providing details, examples and further guidance on specific topics
- ‘Living’ document updated based on users’ needs, not tied to biannual MedDRA releases
- Detailed guidance on coding Medication errors
• All documentation is available on the MedDRA website
• MedDRA Introductory Guide and Points to Consider document are updated for each new release
• MedDRA Term Selection: Points to Consider Companion Document is a living document
• Version report is downloaded with MedDRA content
Welcome to MedDRA

In the late 1990s, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) developed MedDRA, a rich and highly specific standardised medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans... (more)

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Help to Shape the MedDRA Terminology
by submitting change requests. Your contribution will then be considered by the MSSO/JMO.

WebCR

Recent News
18 September 2018
WBB and MVAT Downtime on 28 September
MedDRA WBB and MVAT might be down for a few hours for maintenance

45 September 2018
MSSO Contacts

- Website
  - www.meddra.org
- Email
  - mssohelp@meddra.org
- Frequently Asked Questions
  - www.meddra.org/faq
Thank You

Questions?