



MedDRA Coding Workshop

8 November 2018

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MedDRA

Session Overview

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



MedDRA

What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities





MedDRA

MedDRA Definition

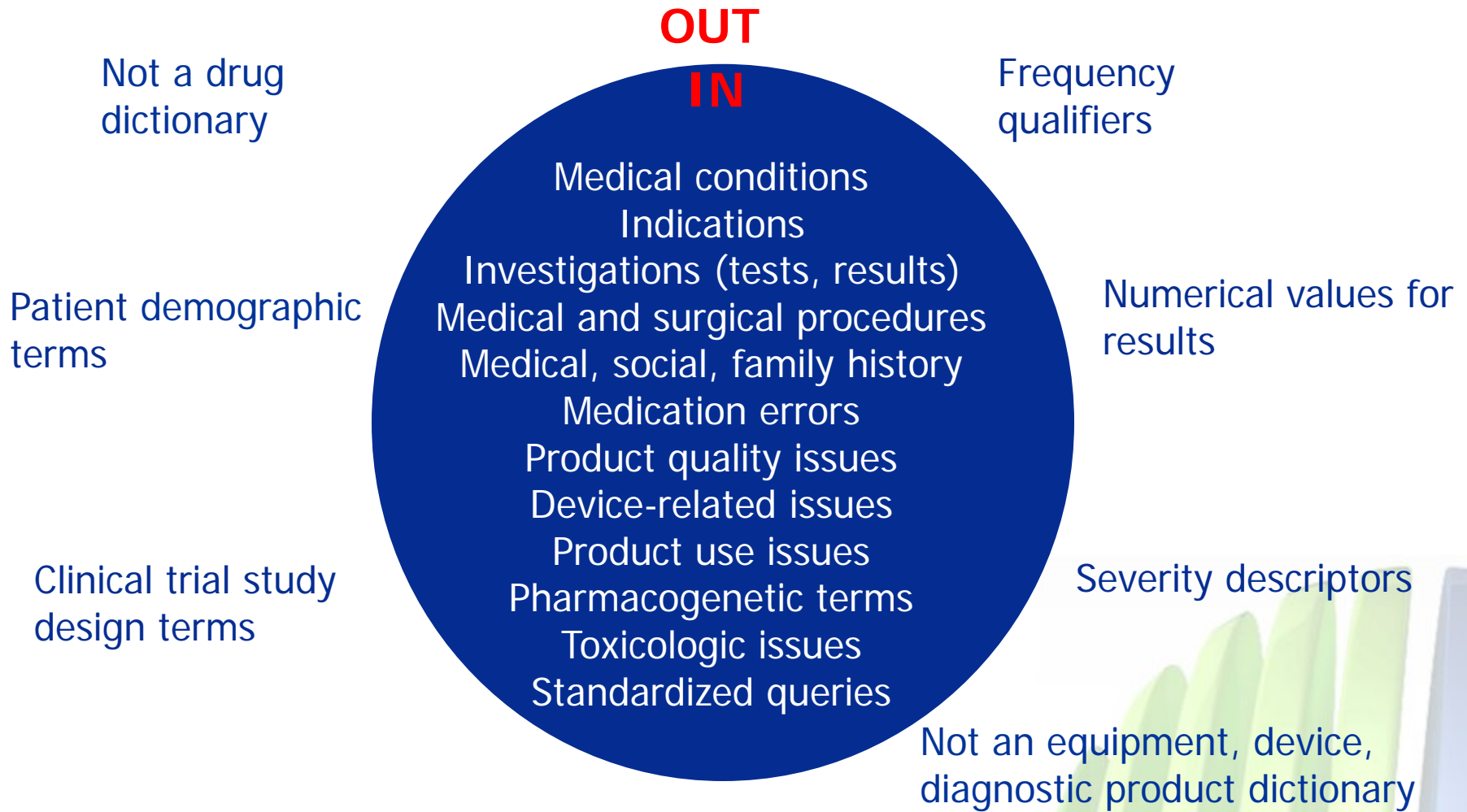
MedDRA is a clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation.





MedDRA

Scope of MedDRA





MedDRA

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)



MedDRA

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



MedDRA

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- Terms that are vague, ambiguous, outdated, truncated, or misspelled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



MedDRA

MedDRA Codes

- 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



MedDRA

Codes and Languages



Electronic Submission





MedDRA

A Multi-Axial Terminology

- Multi-axial = the representation of a medical concept in multiple SOC's
 - 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)

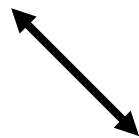
SOC = Respiratory, thoracic and
mediastinal disorders
(Secondary SOC)



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



Primary SOC Priority

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*





A Multi-Axial Terminology (cont)

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?

PT	HLT	HLGT	SOC
Congenital HIV infection	Viral infections congenital	Infections and infestations congenital	Congenital, familial and genetic disorders
	Congenital neonatal infections	Neonatal and perinatal conditions	Pregnancy, puerperium and perinatal conditions
	Retroviral infections	Viral infectious disorders	Infections and infestations
	Acquired immunodeficiency syndromes	Immunodeficiency syndromes	Immune system disorders



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/>
- 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



MedDRA

MedDRA Browser Demonstration





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.



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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

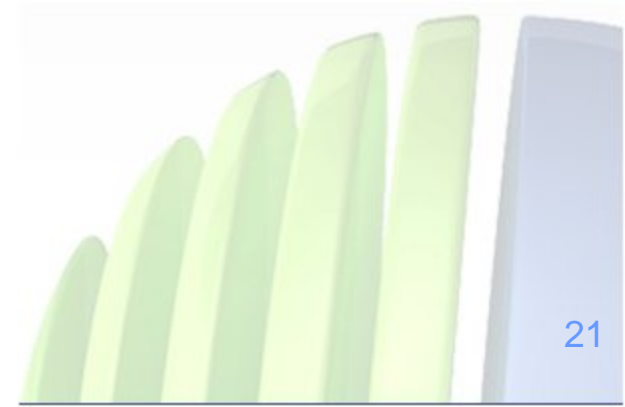


MedDRA

Exercise 1

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

_____ LLT → _____ PT





Exercise 2

Lab results indicate an increase in erythrocytes.

_____ LLT → _____ PT





MedDRA

Exercise 3

Drug was contaminated with Staphylococcus.

_____ LLT → _____ PT

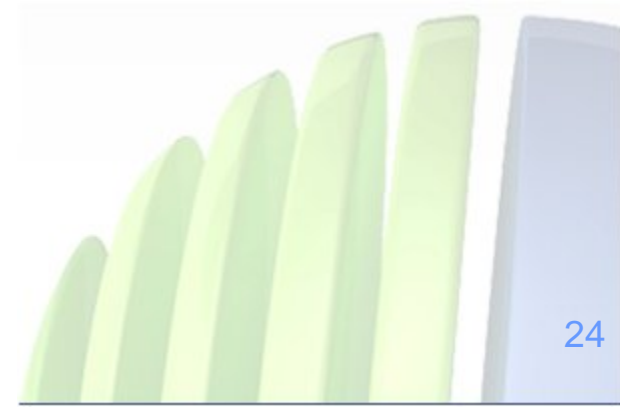




Exercise 4

A six year old boy was admitted for toxicity after accidentally ingesting the remaining antihypertensive tablets in the bottle.

_____ LLT → _____ PT
_____ LLT → _____ PT





MedDRA

Exercise 5

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

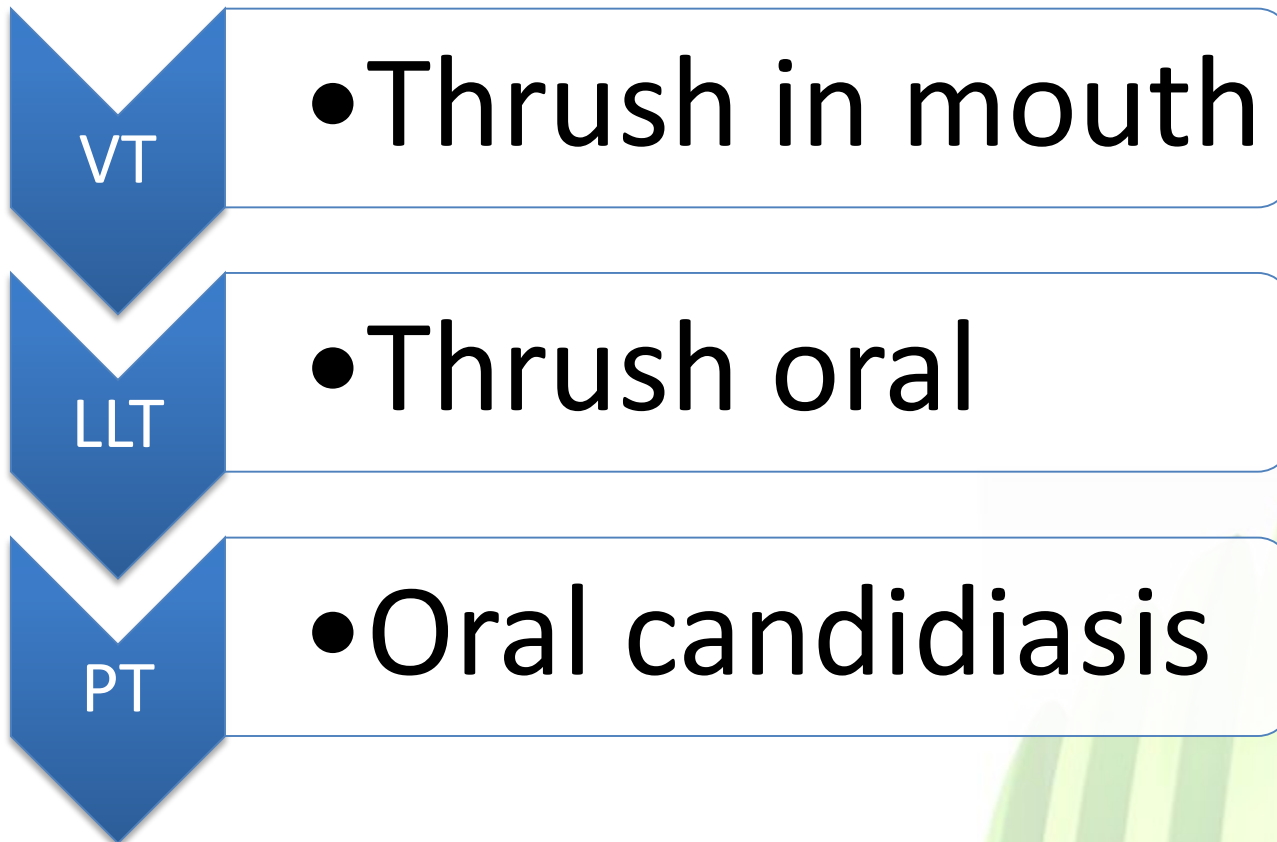
- Patient Safety





Principles of Coding – 1

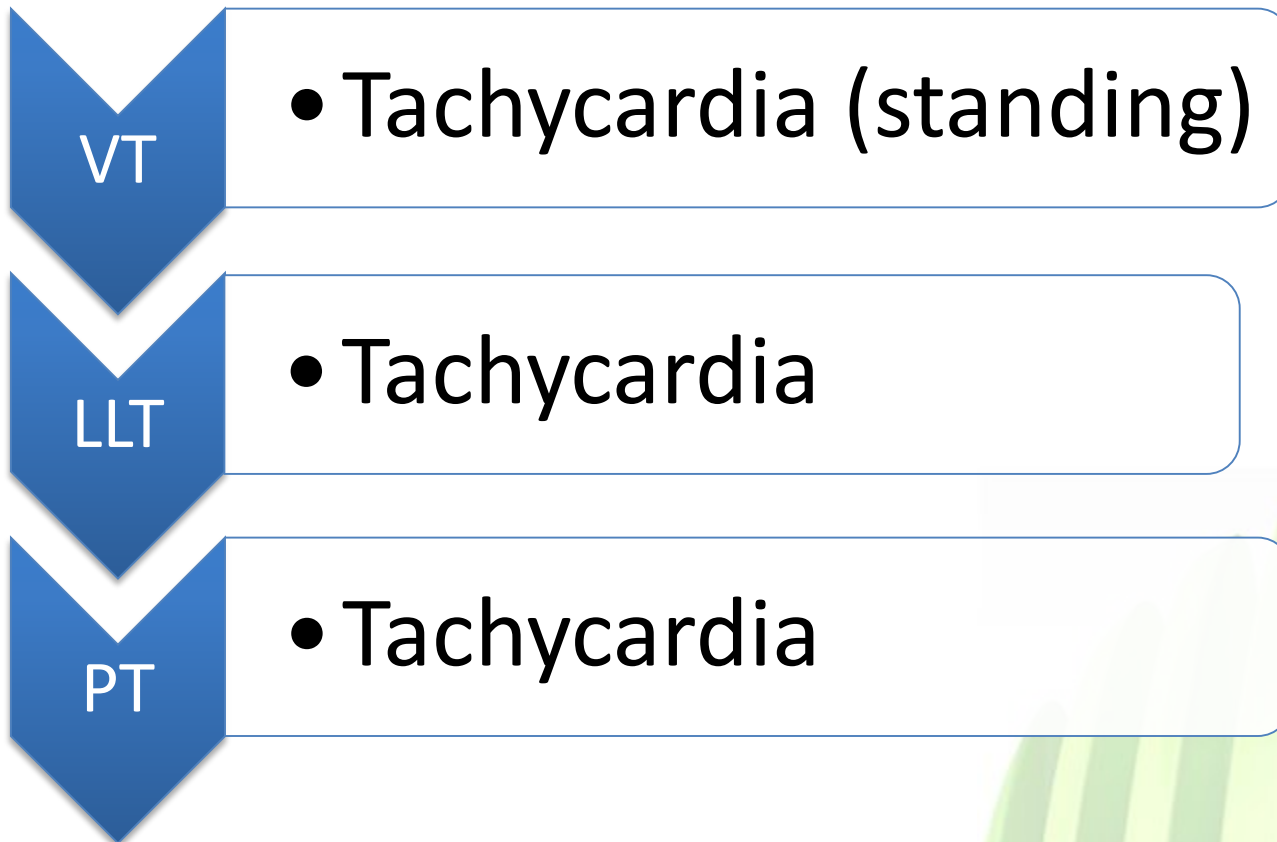
- Select the closest matching LLT to capture all the reported information





Principles of Coding - 2

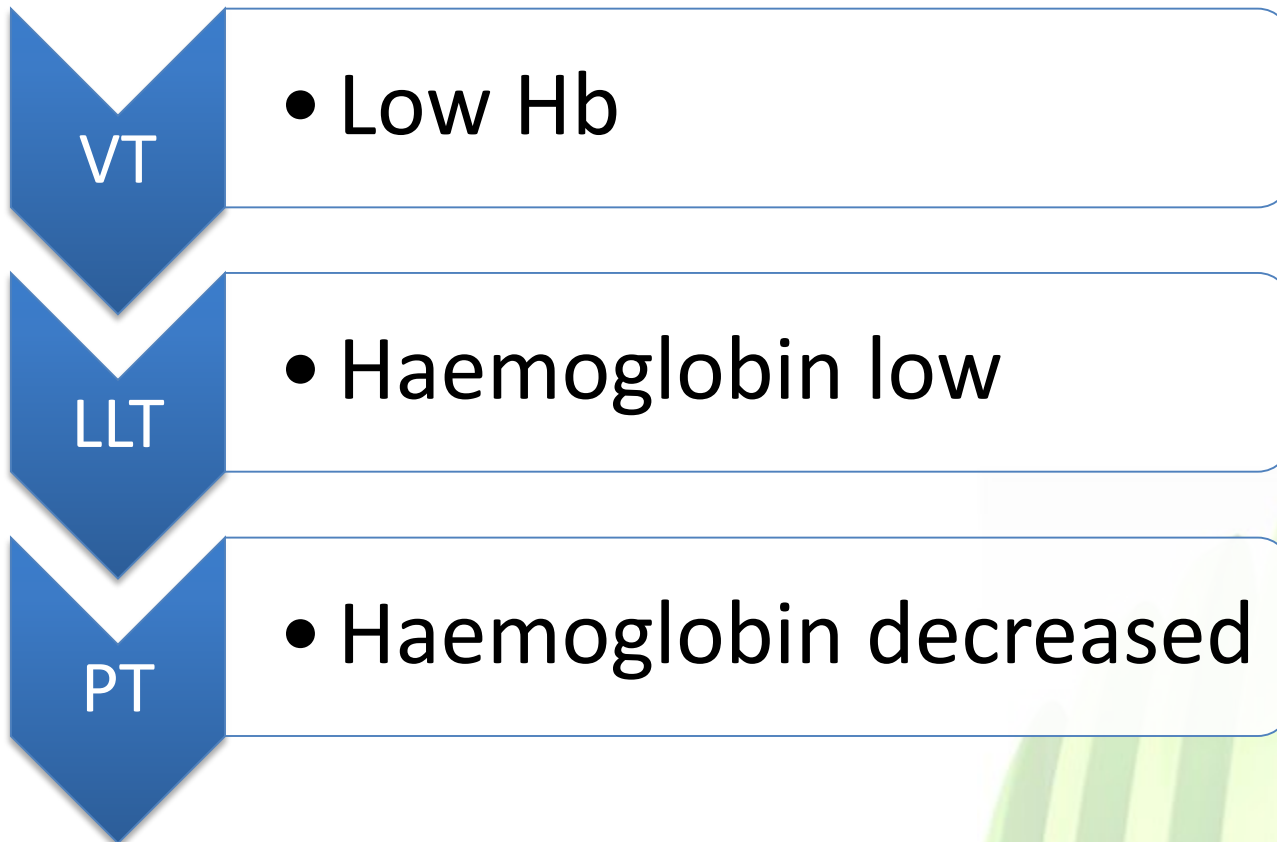
- Do not add information





Principles of Coding - 3

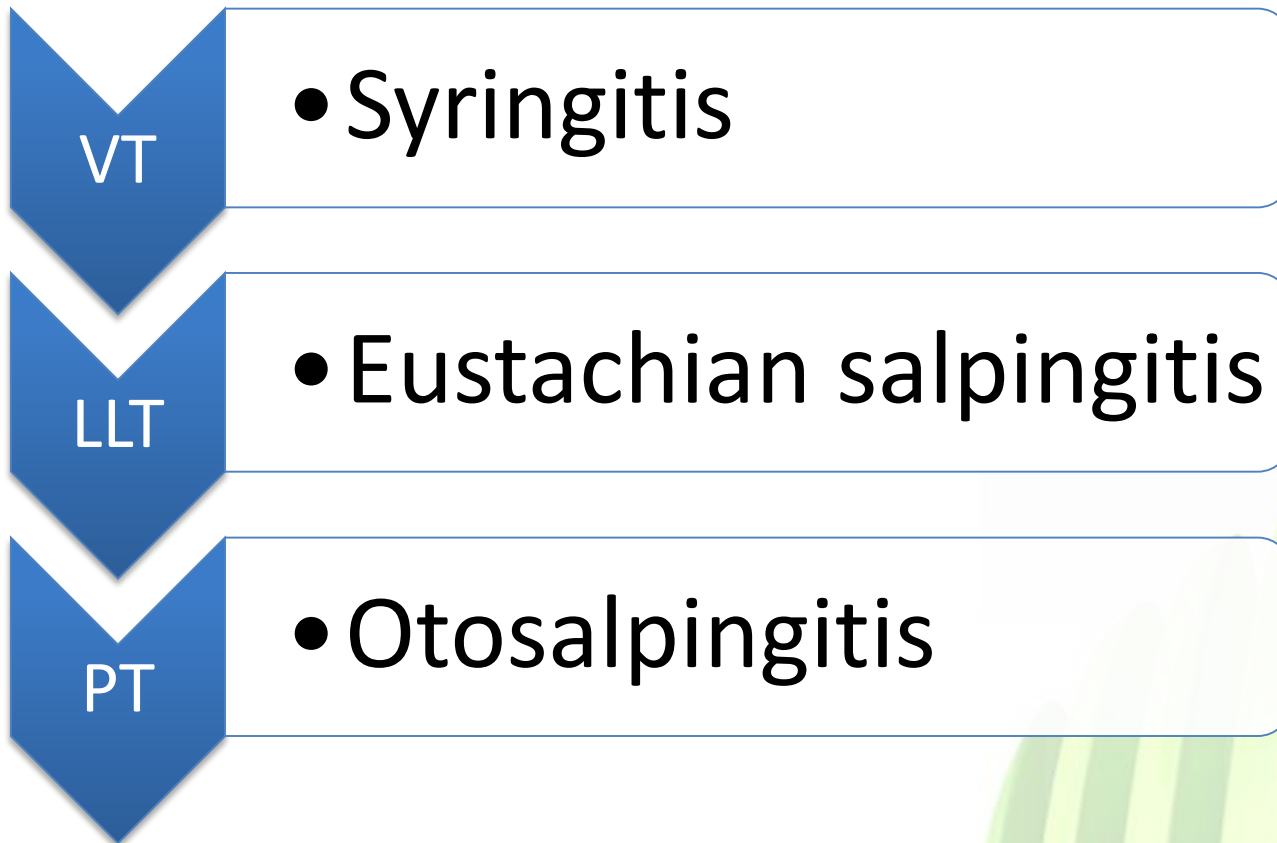
- Do not interpret or diagnose





Principles of Coding - 4

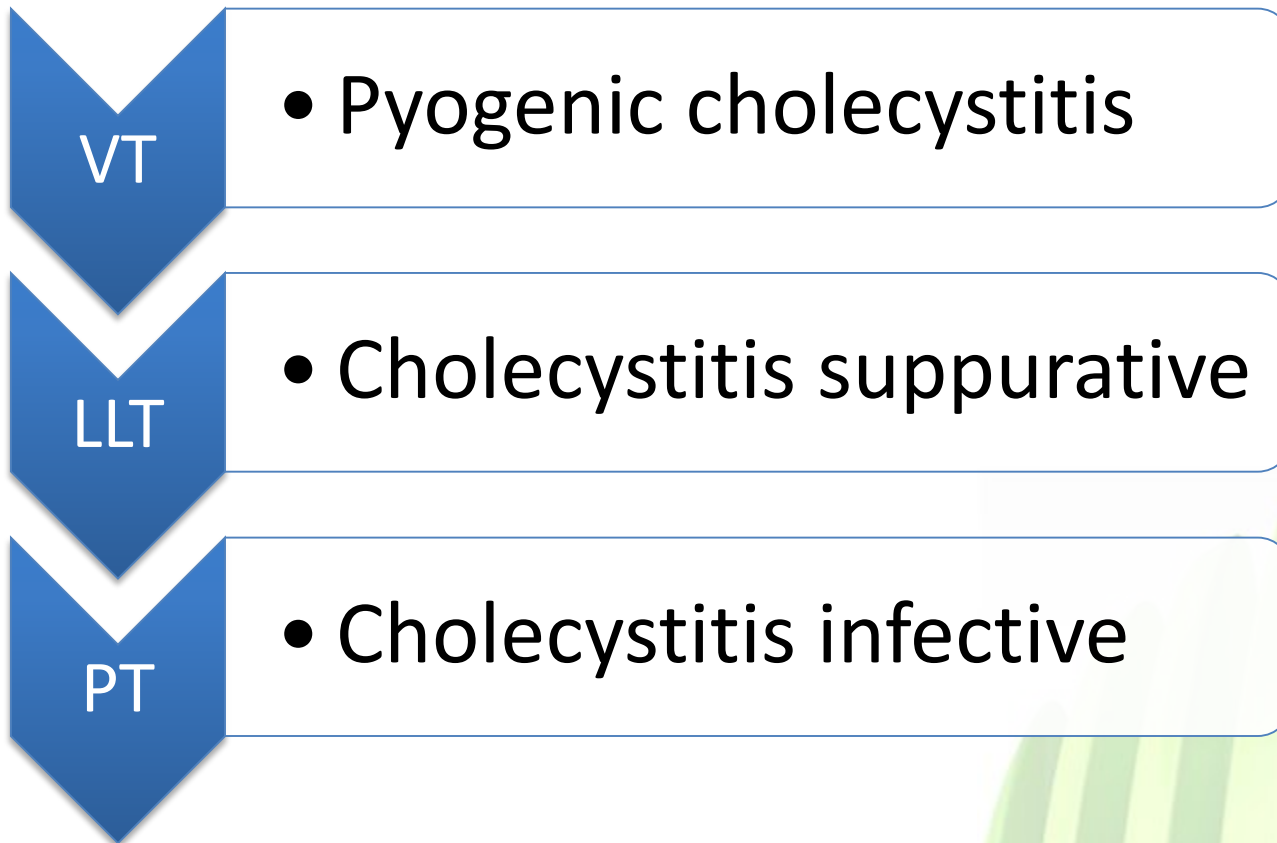
- Use medical judgment and references





Principles of Coding - 5

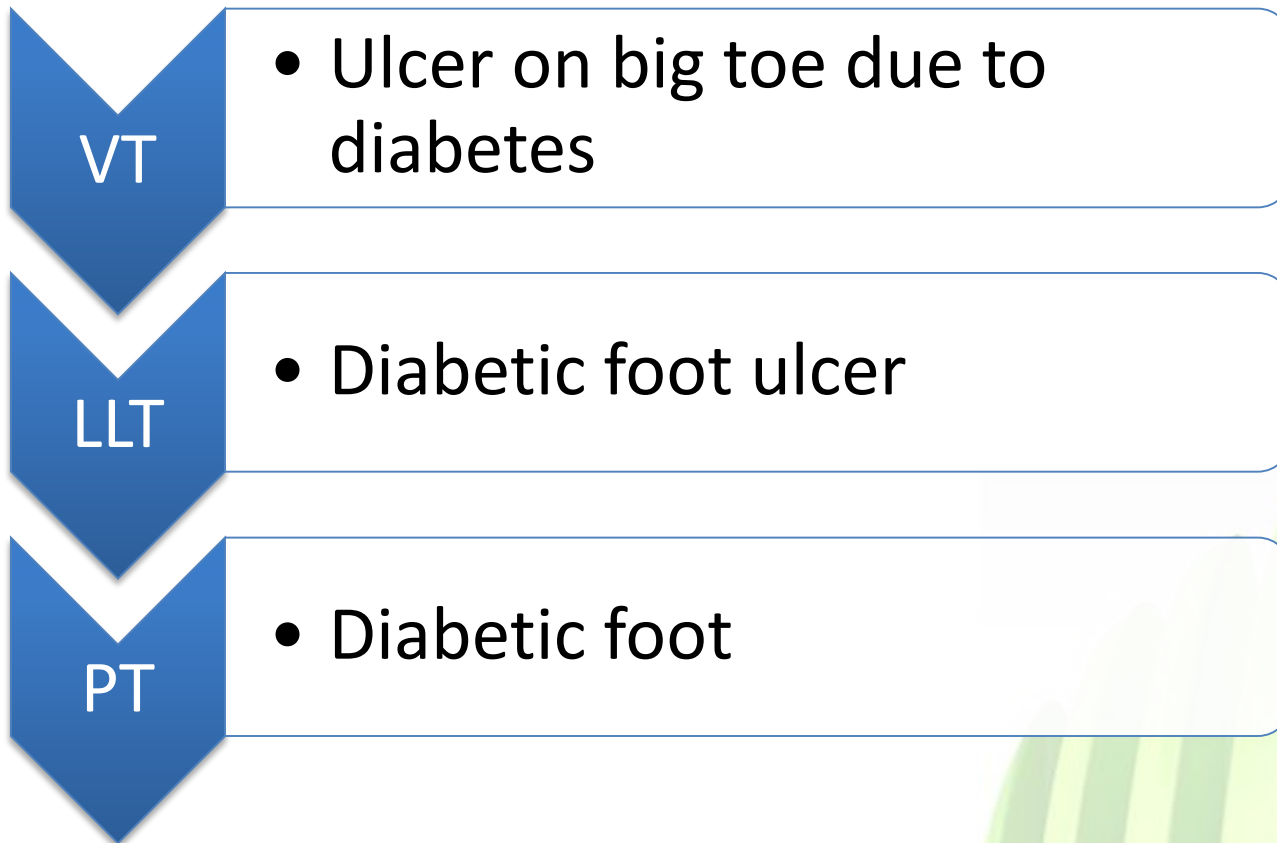
- Check the MedDRA hierarchy





Principles of Coding - 6

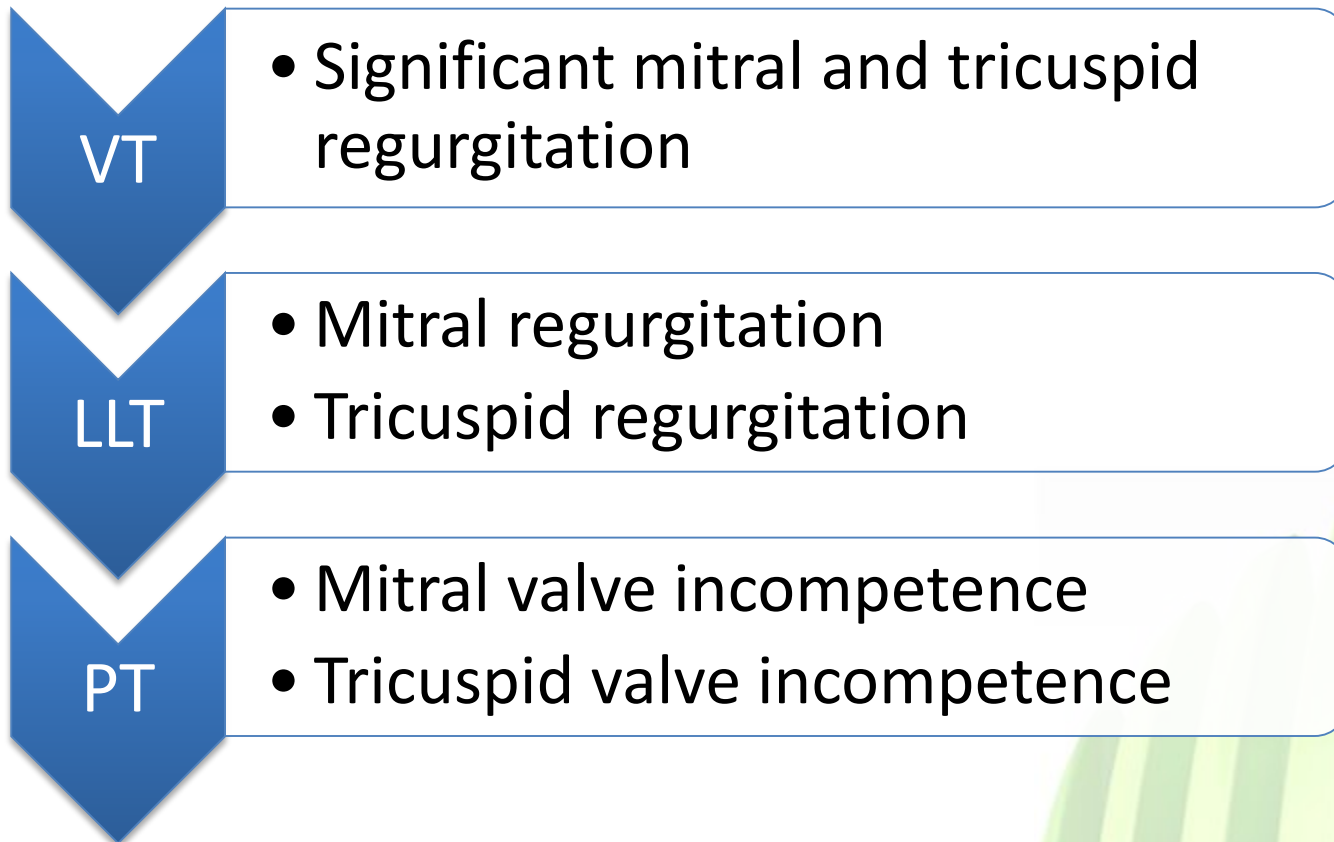
- Know how to handle combination events





Principles of Coding – 6 (Contd.)

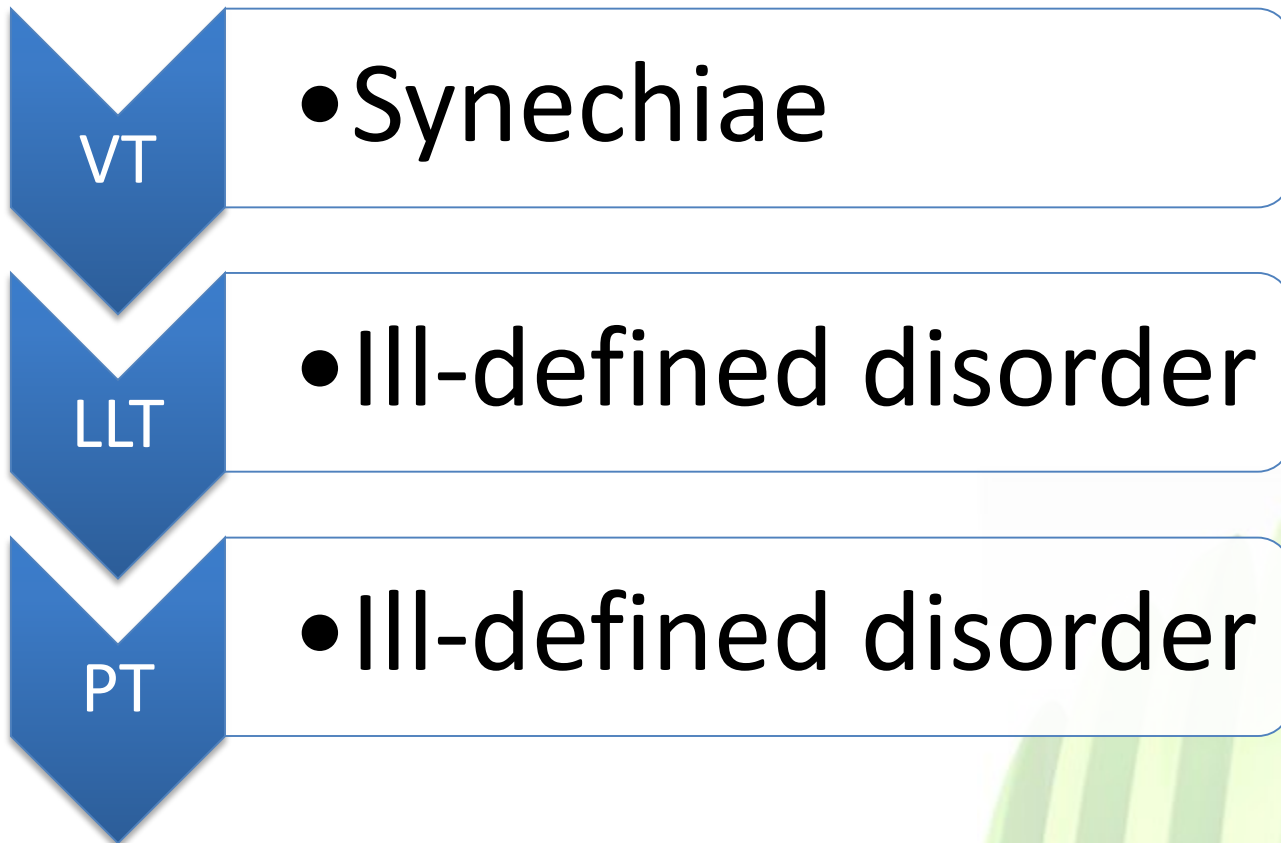
- Know how to handle combination events





Principles of Coding - 7

- Seek clarification if unclear or ambiguous





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

MedDRA® TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Release 4.16

Based on MedDRA Version 21.1

1 September 2018

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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: 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





MTS:PTC Points of Note

- 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.

Reported	LLT Selected	Preferred Option	Comment
Respiratory chlamydial infection	Chlamydial infection Respiratory infection	✓	Represents both microorganism-specific infection and anatomic location
	Respiratory infection		Represents location-specific infection
	Chlamydial infection		Represents microorganism-specific infection

Example: Diagnosis and Signs/Symptoms

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

SUMMARY OF PREFERRED AND ALTERNATE OPTIONS	
SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	PROVISIONAL DIAGNOSIS
<p>Single definitive diagnosis without signs/symptoms</p> <ul style="list-style-type: none"> • Diagnosis (only possible option) 	<p>Single provisional diagnosis without signs/symptoms</p> <ul style="list-style-type: none"> • Provisional diagnosis (only possible option)
<p>Single definitive diagnosis with signs/symptoms</p> <ul style="list-style-type: none"> • Preferred: Diagnosis only • Alternate: Diagnosis and signs/symptoms <p><i>Note: Always include signs/symptoms not associated with diagnosis</i></p> <p>SEE EXAMPLE 1</p>	<p>Single provisional diagnosis with signs/symptoms</p> <ul style="list-style-type: none"> • Preferred: Provisional diagnosis and signs/symptoms • Alternate: Signs/symptoms only <p><i>Note: Always include signs/symptoms not associated with diagnosis</i></p> <p>SEE EXAMPLE 2</p>

Example: Combination Reports

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

Reported	LLT Selected
Hepatic function disorder (acute hepatitis)	Hepatitis acute
Arrhythmia due to atrial fibrillation	Atrial fibrillation



Example: Combination Reports

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

Reported	LLT Selected
Retinopathy due to diabetes	Diabetic retinopathy
Rash with itching	Itchy rash



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

Reported	LLT Selected
Diarrhoea and vomiting	Diarrhoea Vomiting
Wrist fracture due to fall	Wrist fracture Fall

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



Haemophilus influenzae identified from bronchoscopy specimen

Haemophilus influenzae infection

Haemophilus influenzae test positive

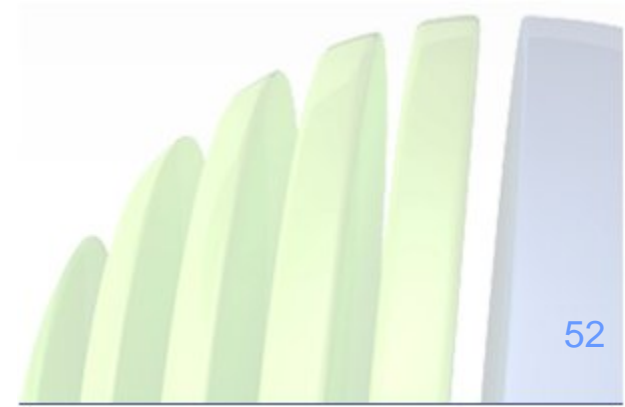
Post procedural infection

Bronchoscopy abnormal



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



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



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

Upper back pain and also low back pain

Upper back pain

Low back pain

Upper back pain
AND Low back pain

Back pain



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



How do we code this...?

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



Turned very greasy

- A. Ill-defined disorder
- B. Unevaluable event
- C. Skin greasy
- D. Unevaluable reaction



Became color blind in adolescence

Color blindness

Blindness color

Colour blindness
acquired

Color blindness
acquired



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



Infection after surgery

- A. Infection
- B. Postoperative wound infection
- C. Surgical wound infection
- D. Postoperative infection

Had MI

Myocardial
infarction

Ill-defined
disorder

MI

Unevalu-
able
event



Had MI

- A. Myocardial infarction
- B. ICD-defined disorder
- C. MI
- D. Unevaluable event



Death from cerebral haemorrhage

Sudden death

Death

Cerebral
haemorrhage

Death AND Cerebral
haemorrhage



Death from cerebral haemorrhage

- A. Sudden death
- B. Death
- C. Cerebral haemorrhage
- D. Death AND Cerebral haemorrhage



MedDRA

Useful Resources

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

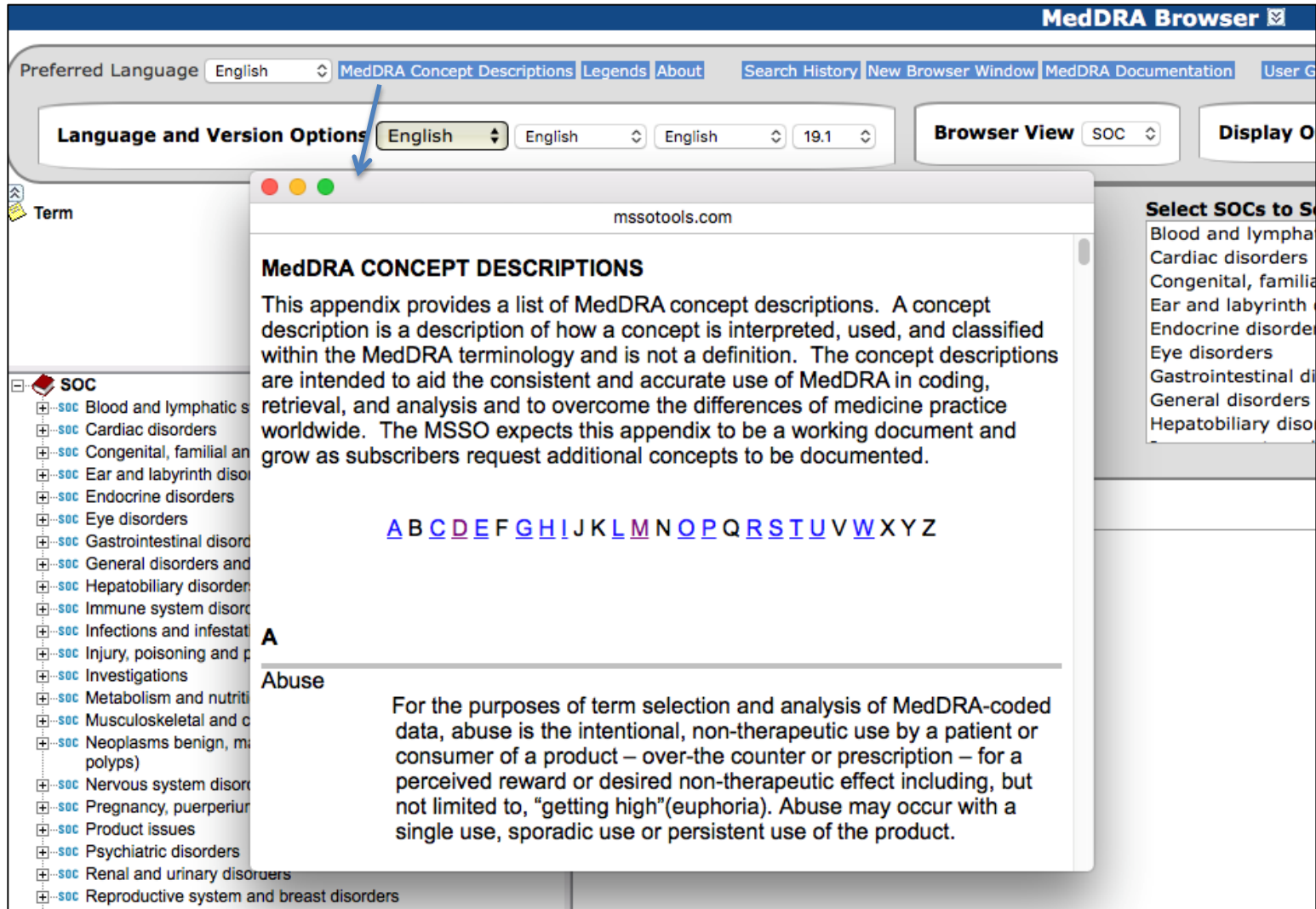


MedDRA

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)



The screenshot shows the MedDRA Browser interface. At the top, there are navigation links: "MedDRA Concept Descriptions", "Legends", "About", "Search History", "New Browser Window", "MedDRA Documentation", and "User G". Below this is a "Language and Version Options" section with dropdown menus for "English", "English", "English", and "19.1". To the right, there are "Browser View" (SOC) and "Display O" buttons.

The main content area is titled "MedDRA CONCEPT DESCRIPTIONS" and contains the following text:

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.

Below the text is a navigation bar with letters A through Z. The letter "A" is selected, and the "Abuse" concept is displayed with its description:

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.

On the left side of the browser, there is a "Term" section with a "SOC" (System Organ Class) list. The list includes various categories such as "Blood and lymphatic s", "Cardiac disorders", "Congenital, familial an", "Ear and labyrinth disor", "Endocrine disorders", "Eye disorders", "Gastrointestinal disor", "General disorders and", "Hepatobiliary disorder", "Immune system disor", "Infections and infestat", "Injury, poisoning and p", "Investigations", "Metabolism and nutriti", "Musculoskeletal and c", "Neoplasms benign, ma", "polyyps)", "Nervous system disor", "Pregnancy, puerperiu", "Product issues", "Psychiatric disorders", "Renal and urinary disorders", and "Reproductive system and breast disorders".

On the right side, there is a "Select SOCs to S" section with a list of SOCs including "Blood and lymphat", "Cardiac disorders", "Congenital, familia", "Ear and labyrinth", "Endocrine disorder", "Eye disorders", "Gastrointestinal di", "General disorders", and "Hepatobiliary diso".



MedDRA

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



MedDRA

MedDRA Documentation

- 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



MedDRA

MedDRA Website



MedDRA

Medical Dictionary for
Regulatory Activities

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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

15 September 2018



MedDRA

MSSO Contacts

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





MedDRA

Medical Dictionary
for Regulatory Activities

Thank You

Questions?

