Advanced MedDRA Coding

Instructor's Name

Webinar Date

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Course Overview

- Discuss advanced principles in the MedDRA Term Selection: Points to Consider (MTS:PTC) document

- Discuss MedDRA Concept Descriptions

- Show several examples of proper coding of advanced principles

- Use browser and polling application to test your understanding of advanced coding principles

- Present some MedDRA coding "pearls"

- Conclude with a question and answer session

Get ready to participate !

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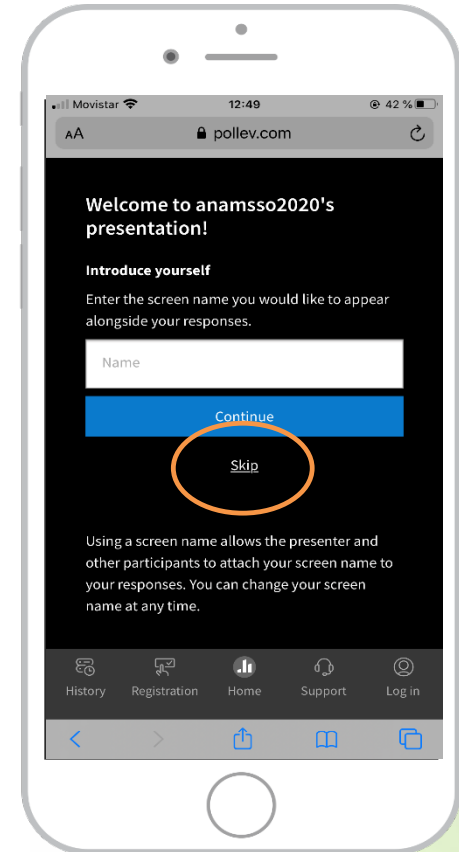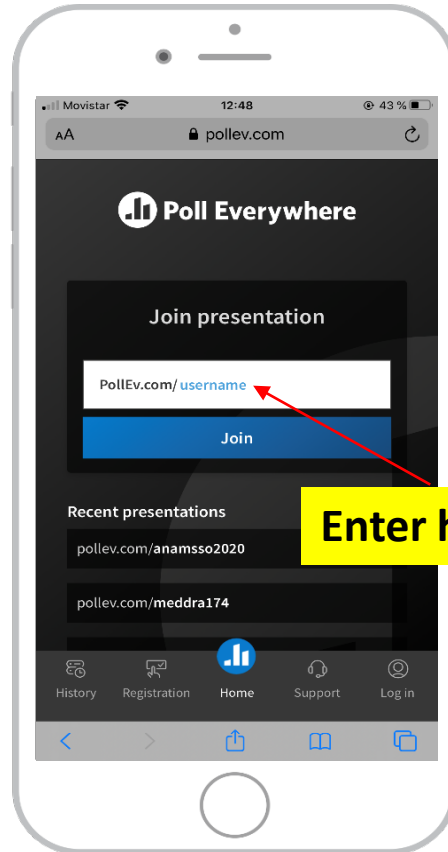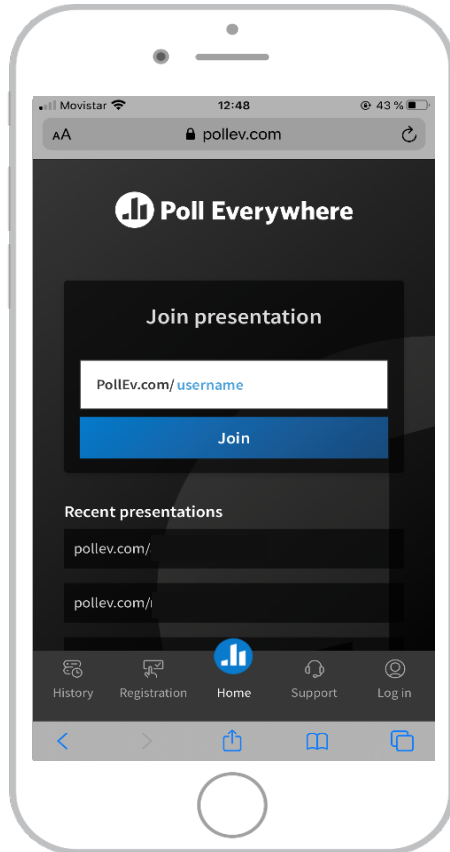
1. Open an internet browser on your computer or cell phone
2. Go to **PollEv.com**

3. Enter **xxxxxxxx** as the "username"
4. Click **Join**

5. Click **Skip**
6. Respond to activity

Instructors should insert slide with a screenshot of their QR code

MedDRA Term Selection:
Points to Consider Document

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 common understanding of shared data
- Recommended to be used as basis for individual organization's own coding conventions

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MedDRA Term Selection: PTC (cont)

- Developed by a working group of the ICH Management Committee
- Updated annually in March
- Complete versions available in
  - English, Japanese, Chinese, Korean, Spanish, and Russian
- Condensed versions available for other MedDRA languages
- Available on MedDRA and JMO websites

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 Infection
- Modification of Pre-existing Conditions
- Exposures During Pregnancy and Breast Feeding
- Congenital Terms
- Neoplasms
- Medical and Surgical Procedures
- Investigations

Term Selection Points

MedDRA

- 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
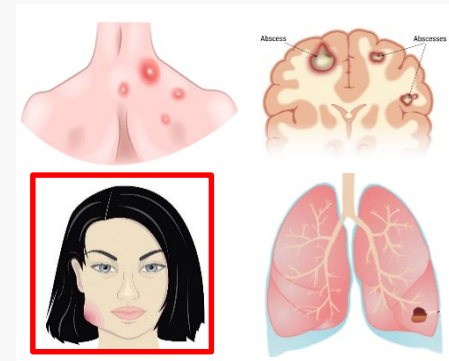
![MedDRA logo] # General Principles

- **Always Select a Lowest Level Term Select Only Current LLTs**

✓ Select the Lowest Level Term that **most accurately reflects the reported verbatim** information

"Abscess on face"

→ Do not simply select LLT *Abscess*

→ Select a term with greater specificity   LLT *Facial abscess*

✓ Select current LLTs only
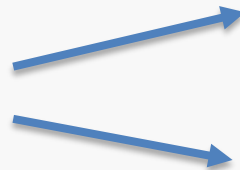 – Non-current terms for legacy conversion/historical purposes

General Principles

Selecting More Than One Term

✓ Can select more than one LLT to represent reported information.
  – Selecting one term may lead to loss of specificity
  – Selecting more than one term may lead to redundant counts

⚠ **Document your procedures!**

Report: "Metastatic gingival cancer"

→ Select LLT Gingival cancer **OR** LLT Metastatic carcinoma

→ Select LLT Gingival cancer **AND** LLT Metastatic carcinoma

General Principles

- **Check the Hierarchy**

✓ Check the hierarchy above a selected LLT (PT, HLT, HLGT, SOC) to ensure placement accurately reflects meaning of reported term

You need to code a report of "low energy" but don't see an exact match in MedDRA.

You decide to use LLT *Worn out*.

You check the PT above this LLT and see that it is "Fatigue". You are now more comfortable about the LLT you selected.
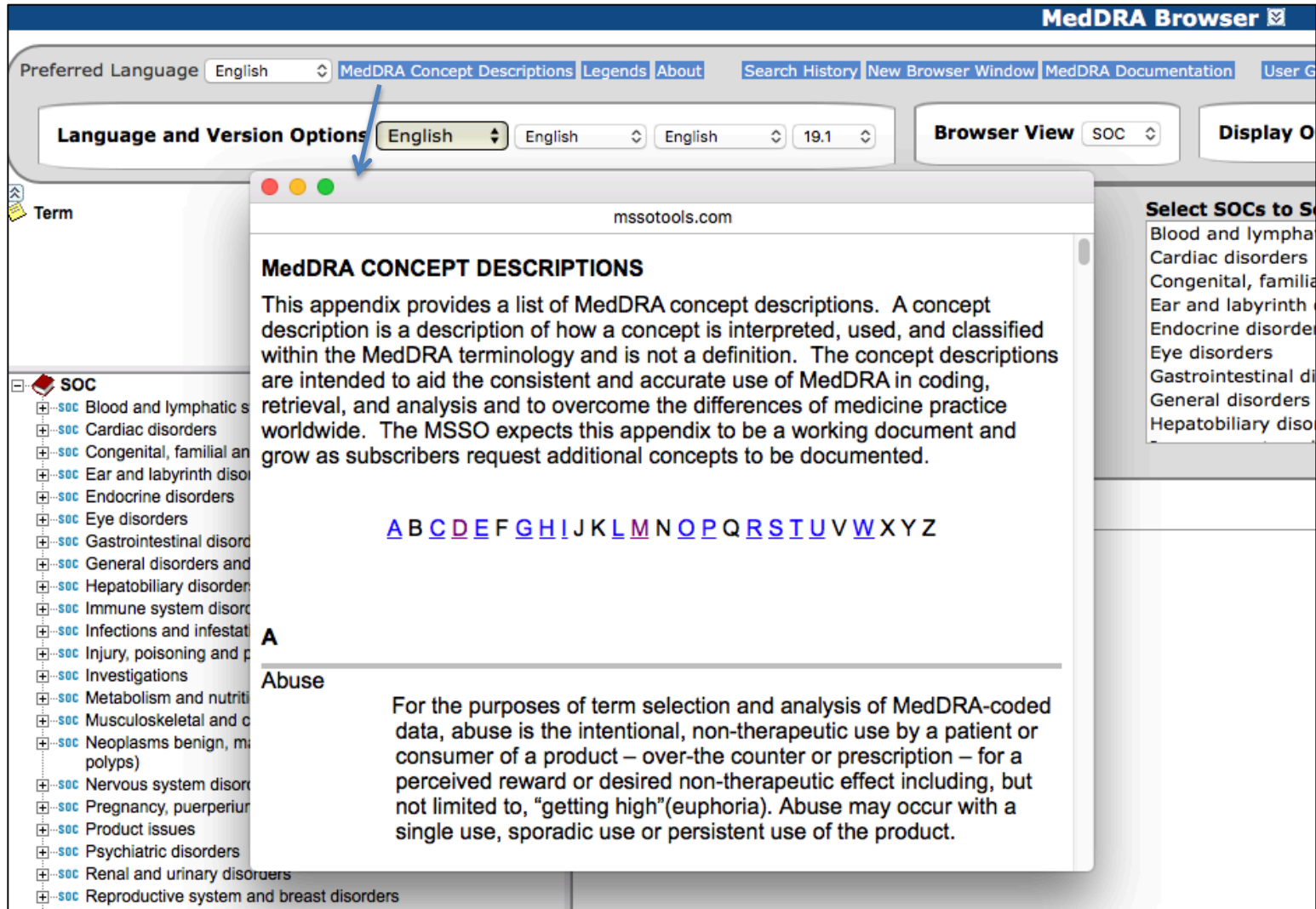
Concept Descriptions

- Descriptions of how a concept is interpreted, used, and classified in MedDRA

- Not a definition

- Intended to aid accurate and consistent use of MedDRA

- Overcome differences in medical practice worldwide

- Accessible in MSSO's browsers

Concept Descriptions (cont)

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Advanced Principles in MedDRA Term Selection: Points to Consider Document

Diagnoses and Provisional Diagnoses

SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	**PROVISIONAL DIAGNOSIS**
Single diagnosis without signs and symptoms •Diagnosis (only possible option)	Single provisional diagnosis without signs and symptoms •Provisional diagnosis (only possible option)
Example: *"Myocardial infarction"* → select *"Myocardial infarction"*	Example: *"Possible myocardial infarction"* → select *"Myocardial infarction"* (select term as if definitive diagnosis)

TiP Similar principles apply for multiple diagnoses

Diagnoses and Provisional Diagnoses (cont)

SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	**PROVISIONAL DIAGNOSIS**
Single diagnosis with signs/ symptoms •Preferred: Diagnosis only	Single provisional diagnosis with signs/symptoms •Preferred: Provisional diagnosis and signs/symptoms
Example: *"Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm"* → select *"Anaphylactic reaction"*	Example: *"Possible myocardial infarction with chest pain, dyspnoea, diaphoresis"* → select *"Myocardial infarction"* "Chest pain", "Dyspnoea", and "Diaphoresis"*

TIP Similar principles apply for multiple diagnoses

Diagnoses and Provisional Diagnoses (cont)

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SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	**PROVISIONAL DIAGNOSIS**
Single diagnosis with signs/symptoms •Alternate: Diagnosis and signs/symptoms	Single provisional diagnosis with signs/symptoms •Alternate: Signs/symptoms only (as provisional diagnosis may change)
Example: *"Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm"* → select *"Anaphylactic reaction"*, *"Rash"*, *"Dyspnoea"*, *Hypotension"*, and *"Laryngospasm"*	Example: "*Possible myocardial infarction with chest pain, dyspnoea, diaphoresis*" → select "*Chest pain*", "*Dyspnoea*", and "*Diaphoresis*"

TiP Similar principles apply for multiple diagnoses

- Always include signs/symptoms not associated with diagnosis

Reported	LLT Selected
Myocardial infarction, chest pain, dyspnoea, diaphoresis, ECG changes and jaundice	Myocardial infarction Jaundice (note that jaundice is not typically associated with myocardial infarction)

What Terms to Select?

- Sepsis leading to shock from possible spontaneous bacterial peritonitis or bowel perforation

  Sepsis

  Shock

  Septic shock

  Spontaneous bacterial peritonitis

  Bowel perforation

Conflicting/Ambiguous Information

- First, try to obtain more specific information

Reported	LLT Selected	Comment
Hyperkalaemia with a serum potassium of 1.6 mEq/L	Serum potassium abnormal	LLT *Serum potassium abnormal* covers both of the reported concepts (note: serum potassium of 1.6 mEq/L is a low result, not high)
GU pain	Pain	"GU" could be either "genito-urinary" or "gastric ulcer". If additional information is not available, then select a term to reflect the information that is known, i.e., LLT *Pain*

Vague Information

- First, try to obtain more specific information

Reported	LLT Selected	Comment
Turned green	Unevaluable event	"Turned green" reported alone is vague; this could refer to a patient condition or even to a product (e.g., pills)
Patient had a medical problem of unclear type	Ill-defined disorder	Since it is known that there is some form of a medical disorder, LLT *Ill-defined disorder* can be selected

What Terms to Select?

- Clinical complication of IUD

  IUD complication (PT Complication associated with device)
  Intra-uterine death (PT Foetal death)
  Unevaluable event

- Hypoglycemia (blood glucose = 200 mg/dL)

  Blood glucose abnormal
  Blood glucose increased
  Hypoglycemia
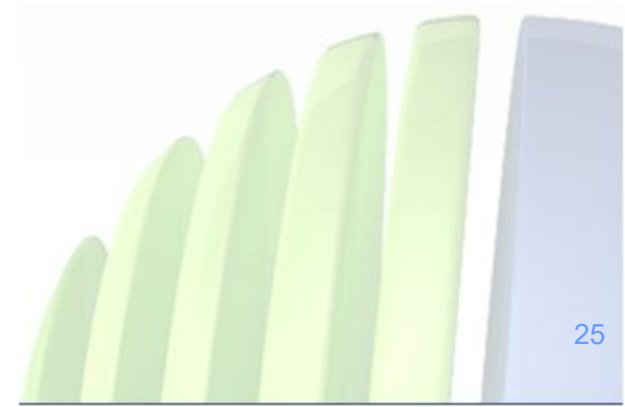
Investigations

- Medical condition vs. investigation result

Reported	LLT Selected	Comment
Hypoglycaemia	Hypoglycaemia	LLT *Hypoglycaemia* links to SOC *Metabolism and nutrition disorders*
Decreased glucose	Glucose decreased	LLT *Glucose decreased* links to SOC *Investigations*

- Unambiguous investigation result

Reported	LLT Selected	Comment
Glucose 40 mg/dL	Glucose low	Glucose is clearly below the reference range

- Ambiguous investigation result

Reported	LLT Selected	Comment
His glucose was 40	Glucose abnormal	No units have been reported. Select LLT *Glucose abnormal* if clarification cannot be obtained.

Investigations (cont)

- Investigation results consistent with diagnosis

Reported	LLT Selected	Comment
Elevated potassium, K 7.0 mmol/L, and hyperkalaemia	Hyperkalaemia	It is not necessary to select LLT *Potassium increased*

- Grouped investigation result terms

Reported	LLT Selected	Comment
Increased alkaline phosphatase, increased SGPT, increased SGOT and elevated LDH	Alkaline phosphatase increased SGPT increased SGOT increased LDH increased	Select four individual terms. A single term such as LLT *Liver function tests abnormal* should not be selected.

What Terms to Select?

- Testing showed increased serum creatinine and BUN, with increased BUN/creatinine ratio

    Increased serum creatinine
    BUN increased
    Blood urea nitrogen/creatinine ratio increased
    Renal function tests NOS abnormal

- Patient had features of aldosterone excess

    Aldosterone increased
    Aldosteronism
    Blood aldosterone abnormal

MedDRA | Combination Terms

- ## One condition is more specific than the other

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

- ## A MedDRA combination term is available

Reported	LLT Selected
Retinopathy due to diabetes	Diabetic retinopathy
Rash with itching	Itchy rash
Breast cancer (HER2 positive)	HER2 positive breast cancer

Combination Terms (cont)

- If splitting provides more clinical information, select more than one term
- In all cases of combination terms, apply medical judgment

Reported	LLT Selected
Diarrhoea and vomiting	Diarrhoea Vomiting
Wrist fracture due to fall	Wrist fracture Fall
BRAF positive malignant melanoma	BRAF gene mutation Malignant melanoma

What Terms to Select?

- Retinal disease from HIV with near total blindness (R and L)

  Retinal damage
  Retinal disorder
  HIV disease
  Blindness
  HIV retinopathy
  Blindness, both eyes

Medication Errors

- See MedDRA Concept Descriptions

- Discussed in MedDRA Points to Consider Companion Document – Section 3
  - Detailed examples
  - "Questions and Answers" about medication errors

- "Top-down" navigation in HLGT *Medication errors and other product use errors and issues* is best approach for term selection

Medication Errors (cont)

- Medication error <u>with</u> clinical consequences

Reported	LLT Selected	Comment
Patient was administered wrong drug and experienced hypotension	Wrong drug administered Hypotension	
Insulin was given using the wrong syringe resulting in the administration of an overdose. The patient developed hypoglycaemia.	Drug administered in wrong device Accidental overdose Hypoglycaemia	If an overdose is reported in the context of a medication error, the more specific term *LLT Accidental overdose* can be selected

Medication Errors (cont)

- Medication error <u>without</u> clinical consequences

Reported	LLT Selected	Preferred Option
Medication was given intravenously instead of intramuscularly without any adverse effect	Intramuscular formulation administered by other route	✔
	Intramuscular formulation administered by other route No adverse effect	

Medication Errors (cont)

- Important to record potential occurrence of medication error
- Unlikely to be reported as an adverse event but may need to be recorded in periodic safety reports

Reported	LLT Selected	Comment
Pharmacist notices that the names of two drugs look similar and is concerned that this may result in a medication error	Drug name look-alike\n\nCircumstance or information capable of leading to medication error	Note: this example is a potential medication error. LLT *Drug name look-alike* provides additional information about the nature of the potential medication error, and LLT *Circumstance or information capable of leading to medication error* indicates that there is a potential medication error.

Overdose, Toxicity and Poisoning

If overdose, poisoning or toxicity is explicitly reported, select the appropriate term

- Overdose <u>with</u> clinical consequences

Reported	LLT Selected
Stomach upset from study drug Overdose	Stomach upset Overdose

- Overdose <u>without</u> clinical consequences

Reported	LLT Selected	Preferred Option
Patient received an overdose of medicine without any adverse consequences	Overdose	✔
	Overdose No adverse effect	

What Term(s) to Select?

- The patient's renal function was measured every six months instead of on the monthly schedule recommended in the label for the drug

  Medication monitoring error

  Renal function test abnormal

  Drug monitoring procedure incorrectly performed

- Unintentionally took more than maximum recommended dose due to dispensing error

  Accidental overdose

  Incorrect dose administered

  Drug dispensing error

Death and Other Patient Outcomes

- Death, disability and hospitalization are considered outcomes and not usually coded as adverse events (AE) or adverse reactions (AR)

- If one of these outcomes is the <u>only</u> reported information, select an appropriate LLT for coding

- If a death term in MedDRA adds important clinical information, code it along with reported ARs/AEs

Reported	LLT Selected
Patient experienced a rash and had sudden cardiac death	Rash Sudden cardiac death

Drug Interactions

- Term includes reactions between drugs (including biologic products) and other drugs, foods, devices and alcohol

- If reporter states an interaction, select terms for interaction term and reported medical event(s)

Reported	LLT Selected
Patient drank cranberry juice which interacted with anticoagulant drug causing an INR increase	Food interaction INR increased

- If reporter does not specifically state an interaction, select terms for reported medical event(s) only

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Suicide and Self-Harm

- Coding of suicide attempts, completed suicides and self-harm should be accurate and consistent
- Do not assume that an overdose, even if intentional, is a suicide attempt
- If a self-harm report does not mention suicide or suicide attempt, only code self-injury term
- If a suicide attempt is fatal, select a term that reflects the outcome instead of the attempt

Reported	LLT Selected	Comment
Suicide attempt resulted in death	Completed suicide	Report death as an outcome

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- Death from cerebral hemorrhage

Sudden death
Death
Cerebral hemorrhage
Brain death

What Term to Select?

- Patient was found dead

  Death from natural causes
  Death
  Died in sleep
  Found dead

What Term(s) to Select?

- After taking an antihistamine along with her prescription proton pump inhibitor, a 53-year-old woman developed vertigo

  Drug interaction NOS
  Vertigo subjective
  Vertigo
  Drug interaction

What Term(s) to Select?

- ## Deliberately took an overdose

  Intentional overdose
  Suicide attempt
  Deliberate overdose
  Overdose NOS

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Coding Exercises

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.

Which LLT Would You Select?

Verbatim: "Man with decreased fertility."

A. Infertility

B. Fertility decreased male

C. Infertility male

D. Fertility decreased

"Man with decreased fertility"

Infertility

Fertility decreased male

Infertility male

Fertility decreased

Which LLT Would You Select?

Verbatim: "Man with decreased fertility."

A. Infertility
B. Fertility decreased male
C. Infertility male
D. Fertility decreased

Which LLT Would You Select?

Verbatim: "Became color blind in adolescence"

A. Color blindness
B. Blindness color
C. Colour blindness acquired
D. Color blindness acquired

"Became color blind in adolescence"

A. Color blindness **A**

B. Blindness color **B**

C. Colour blindness acquired **C**

D. Color blindness acquired **D**

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Which LLT Would You Select?

Verbatim: "Became color blind in adolescence"

A. Color blindness
B. Blindness color
C. Colour blindness acquired
D. Color blindness acquired

Which LLT Would You Select?

Verbatim: "Turned very greasy"

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

"Turned very greasy"

Ill-defined disoder

Unevaluable event

Skin greasy

Unevaluable reaction

Which LLT Would You Select?

Verbatim: "Turned very greasy"

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

Which LLT Would You Select?

Verbatim: "Patient reported medical problem"

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

"Patient reported medical problem"

Adverse event

Unevaluable event

Unevaluable reaction

Ill-defined disorder

Which LLT Would You Select?

Verbatim: "Patient reported medical problem"

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

Which LLT Would You Select?

Verbatim: "The 2-year-old accidentally took his mother's medication"

A. Accidental product intake by child
B. Accidental exposure to product by child
C. Accidental drug intake by child
D. Unintended ingestion of product by child

"The 2-year-old accidentally took his mother's medication"

Accidental product intake by child

Accidental exposure to product by child

Accidental drug intake by child

Unintended ingestion of product by child

Which LLT Would You Select?

Verbatim: "The 2-year-old accidentally took his mother's medication"

A. Accidental product intake by child

B. Accidental exposure to product by child

C. Accidental drug intake by child

D. Unintended ingestion of product by child

Which LLT Would You Select?

Verbatim: "Infection after surgery"

A. Infection

B. Postoperative wound infection

C. Surgical wound infection

D. Postoperative infection

"Infection after surgery"

Infection

Postoperative wound infection

Surgical wound infection

Postoperative infection

Which LLT Would You Select?

Verbatim: "Infection after surgery"

A. Infection

B. Postoperative wound infection

C. Surgical wound infection

D. Postoperative infection

Which LLT Would You Select?

Verbatim: "He sold his father's medication"

A. Drug diversion

B. Intentional product misuse

C. Drug use for unapproved indication

D. Intentional drug misuse

"He sold his father's medication"

Drug diversion

Intentional product misuse

Drug use for unapproved indication

Intentional drug misuse

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Which LLT Would You Select?

Verbatim: "He sold his father's medication"

A. Drug diversion

B. Intentional product misuse

C. Drug use for unapproved indication

D. Intentional drug misuse

Which LLT Would You Select?

Verbatim: "Had MI"

A. Myocardial infarction

B. Mitral incompetence

C. MI

D. Unevaluable event

"Had MI"

A. Myocardial infarction

B. Ill-defined disorder

C. MI

D. Unevaluable event

MedDRA

<u>Verbatim</u>: "Had MI"

A. Myocardial infarction
B. Mitral incompetence
C. MI
D. Unevaluable event

Which LLT Would You Select?

Verbatim:

"Hypernatraemia (Serum sodium = 115 mEq/L)"

A. Serum sodium abnormal
B. Hypernatraemia
C. Hyponatraemia
D. Serum sodium decreased

"Hypernatraemia (Serum sodium = 115 mEq/L)"

Serum sodium abnormal

Hypernatraemia

Hyponatraemia

Serum sodium decreased

Which LLT Would You Select?

Verbatim:

"Hypernatraemia (Serum sodium = 115 mEq/L)"

A. Serum sodium abnormal
B. Hypernatraemia
C. Hyponatraemia
D. Serum sodium decreased

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Which LLT Would You Select?

Verbatim: "She accidentally missed the morning dose"

A. Missed dose
B. Temporary interruption of therapy
C. Intentional dose omission
D. Missed dose in error

"She accidentally missed the morning dose"

Missed dose

Temporary interruption of therapy

Intentional dose omission

Missed dose in error

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Which LLT Would You Select?

Verbatim: "She accidentally missed the morning dose"

A. Missed dose
B. Temporary interruption of therapy
C. Intentional dose omission
D. Missed dose in error

Which LLT Would You Select?

Verbatim: "The doctor mistakenly prescribed the wrong drug; the pharmacist noticed the error and did not dispense the drug"

A. Wrong drug dispensed
B. Medication error
C. Intercepted drug prescribing error
D. Intercepted drug dispensing error

"The doctor mistakenly prescribed the wrong drug; the pharmacist noted the error and did not dispense the drug"

Wrong drug dispensed

Medication error

Intercepted drug prescribing error

Intercepted drug dispensing error

Which LLT Would You Select?

Verbatim: "The doctor mistakenly prescribed the wrong drug; the pharmacist noticed the error and did not dispense the drug"

A. Wrong drug dispensed
B. Medication error
C. Intercepted drug prescribing error
D. Intercepted drug dispensing error

Which LLT(s) Would You Select?

Verbatim: "The patient reported a loss of smell and thought that he might have a COVID-19 infection"

A. Anosmia
B. Suspected COVID-19
C. Loss of smell
D. COVID-19

"The patient reported a loss of smell and thought he might have a COVID-19 infection"

Suspected COVID-19

Suspected COVID-19/Loss of smell

Loss of smell/COVID-19

Anosmia/Suspected COVID-19

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Which LLT(s) Would You Select?

Verbatim: "The patient reported a loss of smell and thought that he might have a COVID-19 infection"

A. Anosmia
B. Suspected COVID-19
C. Loss of smell
D. COVID-19

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Which LLT Would You Select?

Verbatim: "Dose taken was below the minimum recommended dose in the product label"

A. Underdose
B. Drug administration error
C. Accidental underdose
D. Incorrect dosage administered

"Dose taken was below the minimum recommended dose in the product label"

Underdose

Drug administation error

Accidental underdose

Incorrect dosage administered

Which LLT Would You Select?

Verbatim: "Dose taken was below the minimum recommended dose in the product label"

A. Underdose
B. Drug administration error
C. Accidental underdose
D. Incorrect dosage administered

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Verbatim: "Because his package of medication contained too much drug, the patient received an overdose of medication and developed severe nausea. He was diagnosed with gastritis"

A. Product physical issue
B. Overdose
C. Nausea
D. Gastritis
E. Accidental overdose
F. Package volume overfill

Which LLT Would You Select?

Verbatim: "Abused by her husband"

A. Physical abuse
B. Battered wife
C. Spousal abuse
D. Victim of spousal abuse

"Abused by her husband"

Physical abuse

Battered wife

Spousal abuse

Victim of spousal abuse

Verbatim: "Abused by her husband"

A. Physical abuse

B. Battered wife

C. Spousal abuse

D. Victim of spousal abuse

Which LLT Would You Select?

Verbatim: "The patient created a false belief that her relatives were stealing from her"

A. Theft
B. Stealing
C. Delusion of theft
D. Victim of crime

"The patient created a false belief that her relatives were stealing from her"

Theft

Stealing

Delusion of theft

Victim of crime

Which LLT Would You Select?

Verbatim: "The patient created a false belief that her relatives were stealing from her"

A. Theft
B. Stealing
C. Delusion of theft
D. Victim of crime

Which LLT Would You Select?

<u>Verbatim</u>: "The patient was treated with Drug Z for rosacea, which is an off label use of this medication. Unfortunately, she developed severe dizziness"

What is the preferred option for the LLT(s) to be selected?

A. Rosacea
B. Off label use in unapproved indication
C. Off label use
D. Dizziness

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"The patient was treated with Drug Z for rosacea, which is an off label use of this medication. Unfortunately, she developed severe dizziness""

Answer	Label	Percentage
Rosacea/Dizziness	A	
Off label use/Dizziness	B	38%
Off label use in unapproved indication	C	5%
Rosacea/Off label use in unapproved indication/Dizziness	D	57%

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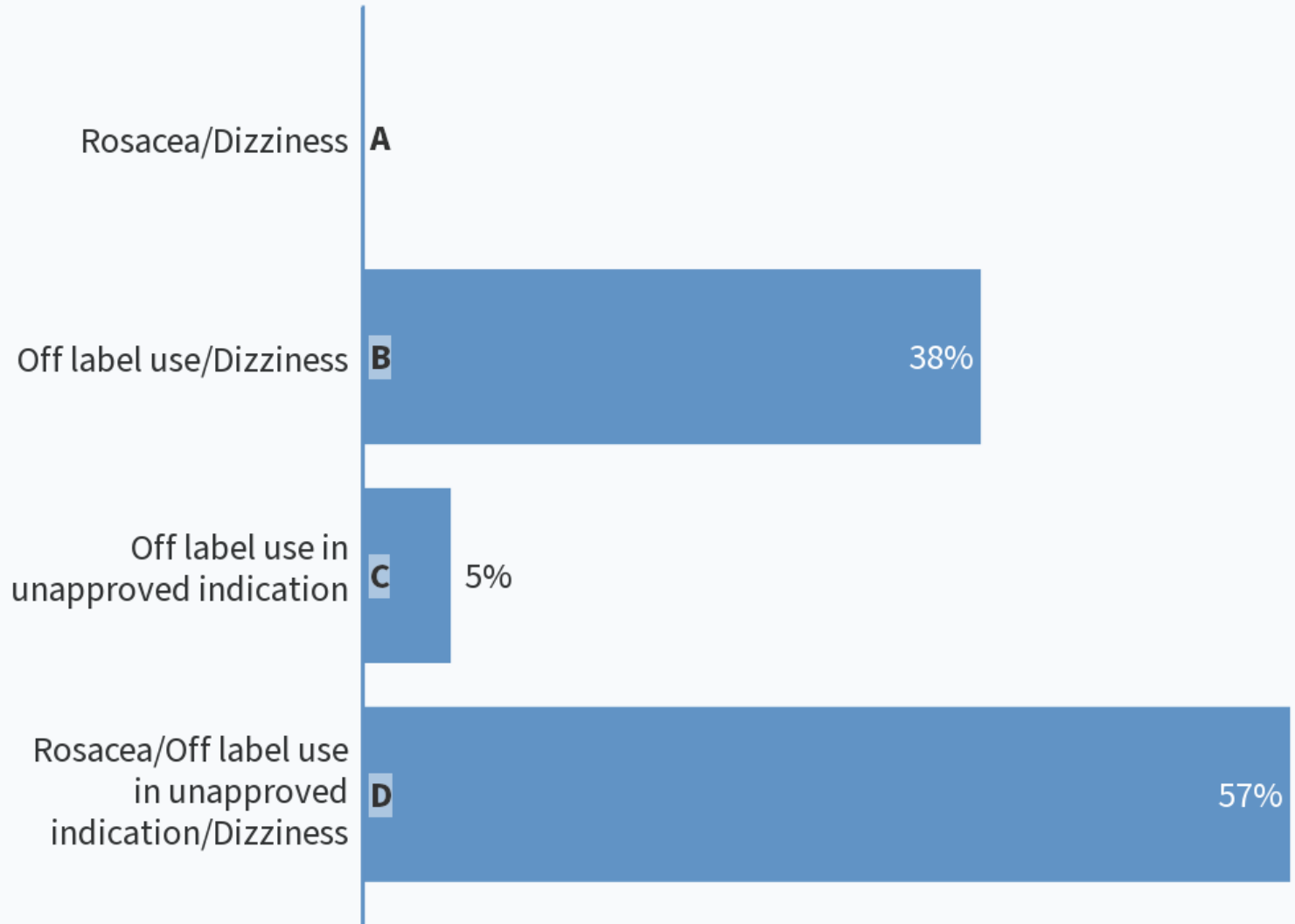
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What is the preferred option for the LLT(s) to be selected?

A. Rosacea
B. Off label use in unapproved indication
C. Off label use
D. Dizziness

Which LLT Would You Select?

Verbatim: "A 27-year-old woman took a 2-week course of antibiotics during her pregnancy. She did not experience any side effects."

What is the preferred option for the LLT(s) to be selected?

A. Maternal exposure during pregnancy
B. No adverse effect
C. Normal pregnancy

Which LLT Would You Select?

Verbatim: "The patient's medication was stored at room temperature instead of in the refrigerator where it belonged."

A. Incorrect storage of drug
B. Improper storage of unused product
C. Intercepted medication error
D. Product storage error temperature too high

"The patient's medication was stored at room temperature instead of in the refrigerator where it belonged"

Incorrect storage of drug

Improper storage of unused drug

Intercepted medication error

Product storage error temperature too high

Which LLT Would You Select?

Verbatim: "The patient's medication was stored at room temperature instead of in the refrigerator where it belonged."

A. Incorrect storage of drug

B. Improper storage of unused product

C. Intercepted medication error

D. Product storage error temperature too high

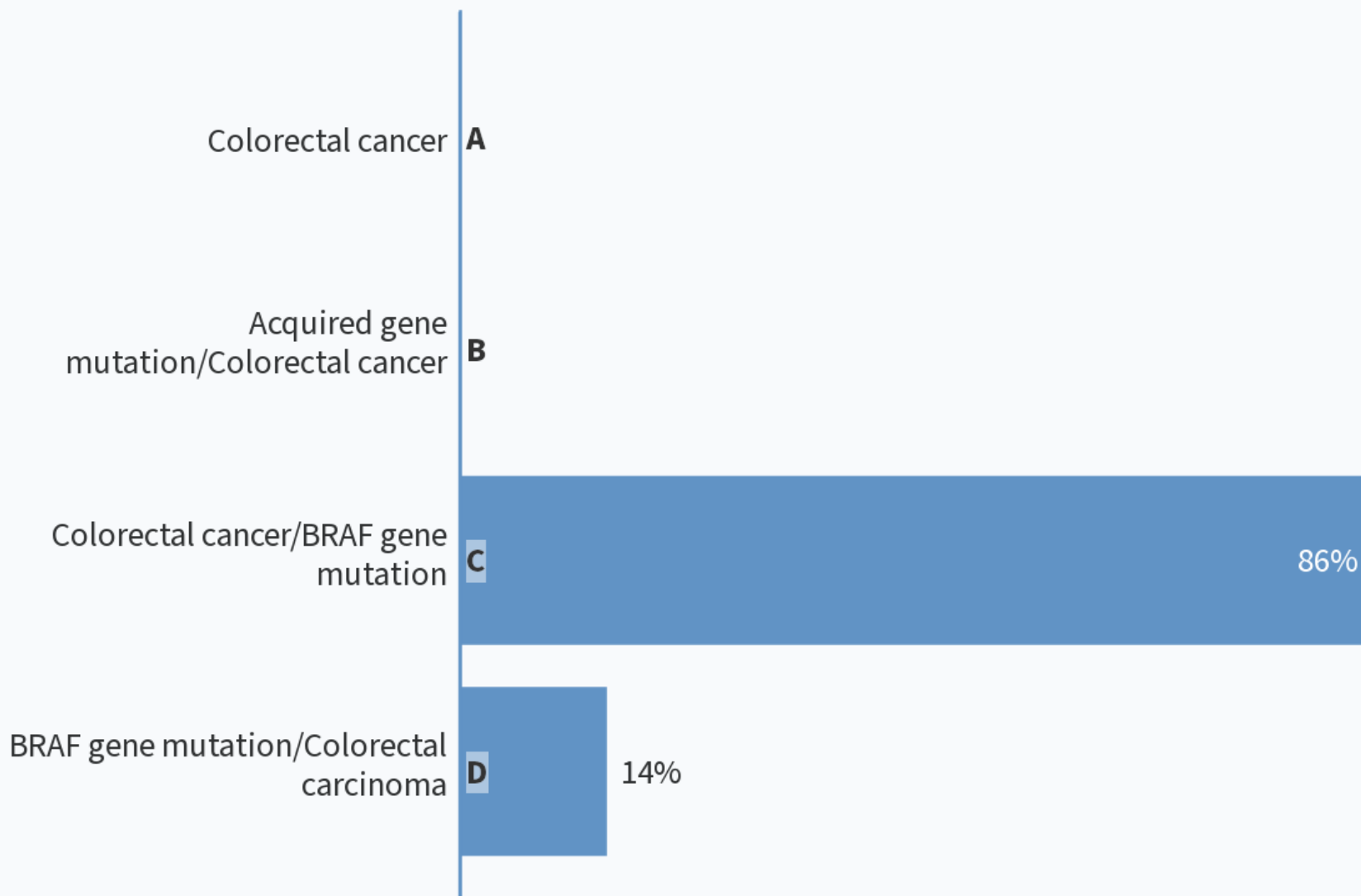# Which LLT(s) Would You Select?

Verbatim: "He was given Drug Y to treat a BRAF gene mutation-related colorectal cancer"

A. Colorectal cancer
B. Acquired gene mutation
C. BRAF gene mutation
D. Colorectal carcinoma

"He was given Drug Y to treat a BRAF gene mutation-related colorectal cancer"

Colorectal cancer **A**

Acquired gene mutation/Colorectal cancer **B**

Colorectal cancer/BRAF gene mutation **C** 86%

BRAF gene mutation/Colorectal carcinoma **D** 14%

Verbatim: "He was given Drug Y to treat a BRAF gene mutation-related colorectal cancer"

A. Colorectal cancer
B. Acquired gene mutation
C. BRAF gene mutation
D. Colorectal carcinoma

Verbatim: "Because the label on the package was missing the wording on dosing information, the patient took the drug twice daily instead of once daily, resulting in the administration of an overdose."

A. Product label issue
B. Product label missing
C. Product label missing text

D. Wrong dose administered
E. Once daily dose taken more frequently
F. Inappropriate schedule of drug administration

G. Overdose
H. Accidental overdose

"Because the label on the package was missing the wording on dosing information, the patient took the drug twice daily instead of once daily, resulting in the administration of an overdose"

Product label issue/Wrong drug admin istered/Accidental ovedose

Product label missing text/Once daily dose taken more frequently/Overdose

Product label missing/Inappropriate schedule of drug administration/Overdose

Product label missing text/Once daily dose taken more frequently/Accidental overdose

Which LLTs Would You Select?

Verbatim: "Because the label on the package was missing the wording on dosing information, the patient took the drug twice daily instead of once daily, resulting in the administration of an overdose."

A. Product label issue
B. Product label missing
C. Product label missing text

D. Wrong dose administered
E. Once daily dose taken more frequently
F. Inappropriate schedule of drug administration

G. Overdose
H. Accidental overdose

Some MedDRA Coding "Pearls"

Remember That MedDRA Can Be Used to Code More Than AEs

Narrative vignette

A 75-year-old male receiving Drug X for <u>rheumatoid arthritis</u> developed symptomatic <u>aortic valve stenosis</u>. The patient's medical history is significant for <u>colon cancer</u> and <u>cigarette smoking</u>. He underwent an <u>aortic valve replacement</u> and developed a <u>sternal</u> <u>wound infection</u> three days <u>post-surgery</u>.

MedDRA Coding "Pearls"

- First, try using reporter's actual words

- Be aware of MedDRA's specificity

- Exploit MedDRA's hierarchy – if an LLT is <u>close</u> to what you need, look at its "siblings" and "parent"

- Check where the LLT lies in MedDRA (i.e., check the hierarchy above to be sure it represents the verbatim term accurately)

MedDRA Coding "Pearls" (cont)

- Use "top-down" and "bottom-up" navigation

- Use available resources for difficult verbatim terms (web search, medical dictionaries, colleagues)

- Use advanced Boolean search terms features (i.e., "begins with", "exact match", "ends with", "not contains", "and", "or") when needed

- Become familiar with MedDRA Concept Descriptions

MedDRA Coding "Pearls" (cont)

And most important of all... get more coding training!

Summary

✓ Discussed important advanced principles presented in the MTS:PTC Document

✓ Discussed MedDRA Concept Descriptions

✓ Showed examples of coding of advanced principles

✓ Used browser and polling application to test your understanding of advanced coding principles

✓ Presented some MedDRA coding "pearls"

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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Question and Answer Session