

## Coding with Confidence

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## Disclosure

- Judy Harrison, M.D. is a consultant to Northrop Grumman Information Systems/MedDRA MSSO
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## Learning Objectives

- Describe how to code clinical safety data accurately and consistently with MedDRA
- Apply the principles described in the ICH-endorsed “MedDRA Term Selection: Points to Consider” document



## Workshop Overview

- MedDRA refresher
- “MedDRA Term Selection: Points to Consider” document
- Browsing and coding tips and tricks
- Practical exercises
- Best practices



## MedDRA Refresher

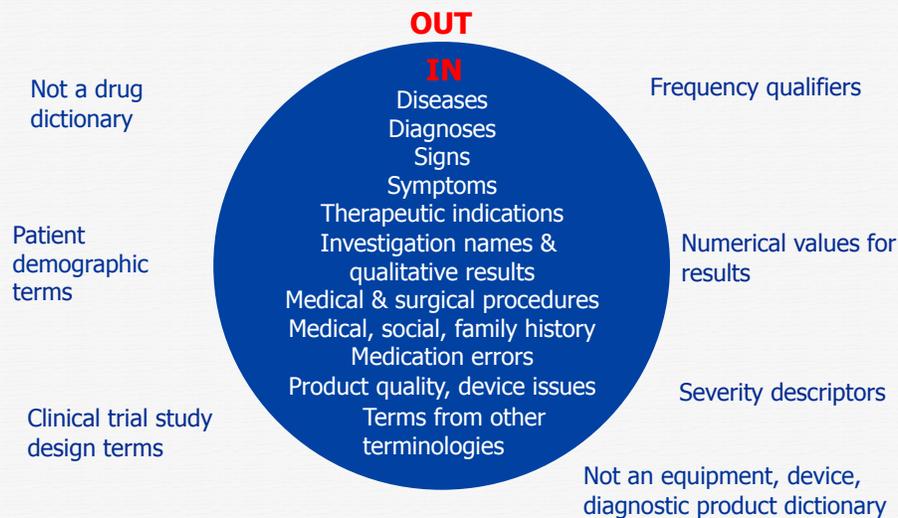


## MedDRA Definition

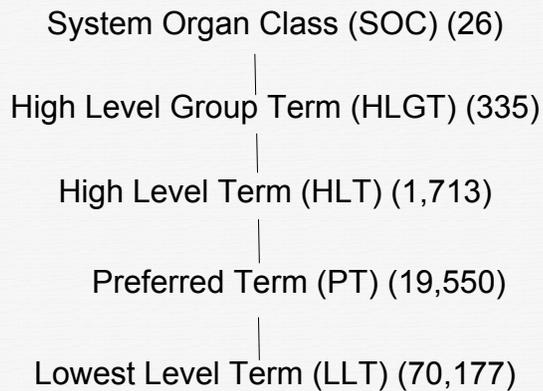
MedDRA is a clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation.



## Scope of MedDRA



# MedDRA Structure



MedDRA Version 15.0

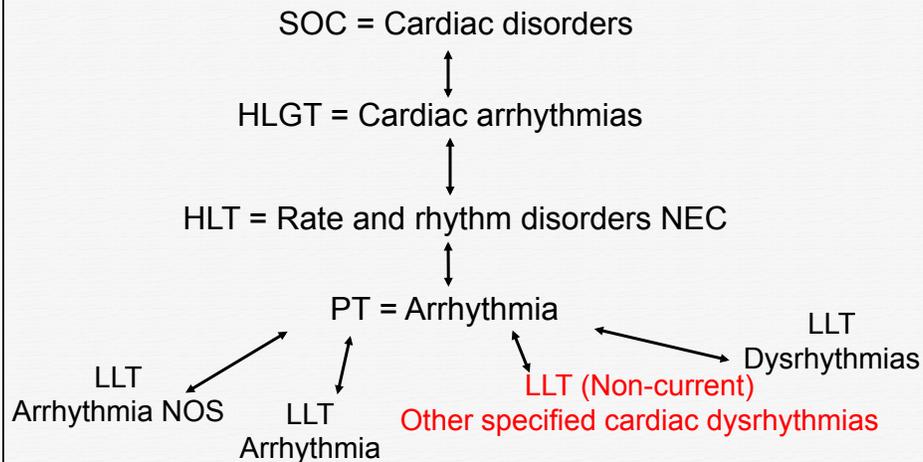


# System Organ Classes

- 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](#)
- 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



## Examples of LLTs



## Non-Current Terms

- Non-current terms are flagged at the LLT level within MedDRA
- Not recommended for continued use
- Retained within the terminology 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 Codes

- Each MedDRA term assigned an 8-digit numeric code
- The code is non-expressive
- Codes can fulfill a data field in various electronic submission types (e.g., E2B)
- Initially assigned alphabetically by term starting with 10000001
  - New terms are assigned sequentially
- Supplemental terms are assigned codes

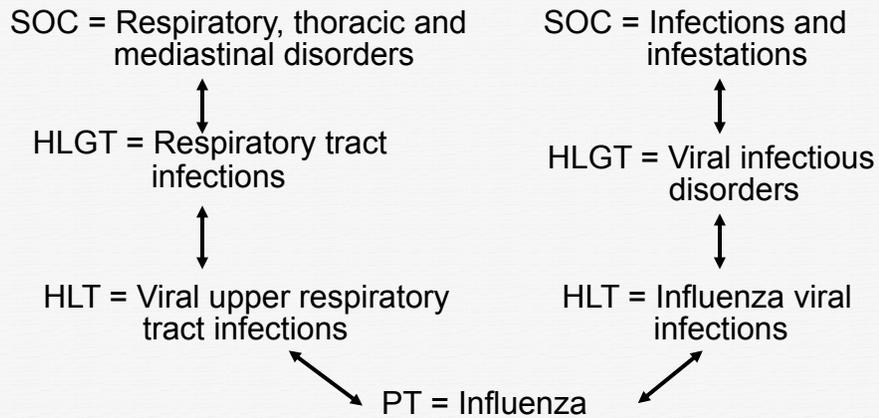


## A Multi-Axial Terminology

- 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
- 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



## A Multi-Axial Terminology (cont)



## A Multi-Axial Terminology (cont)

- PTs in the following SOC only appear in that particular SOC and not in others; i.e., they are not multi-axial:
  - *Investigations*
  - *Surgical and medical procedures*
  - *Social circumstances*

## Rules for Primary SOC Allocation

- 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:
  - 1<sup>st</sup>: Congenital, familial and genetic disorders*
  - 2<sup>nd</sup>: Neoplasms benign, malignant and unspecified (incl cysts and polyps)*
  - 3<sup>rd</sup>: Infections and infestations*



## Conditions vs. Investigations

PT	HLT	HLGT	SOC
Pregnancy test positive	Reproductive hormone analyses	Endocrine investigations (incl sex hormones)	Investigations
Pregnancy	Normal pregnancy, labour and delivery	Pregnancy, labour, delivery and postpartum conditions	Pregnancy, puerperium and perinatal conditions

Be careful to distinguish between a condition and an investigation or a result of an investigation



## “MedDRA Term Selection: Points to Consider” Document



## Why Do We Need Coding Conventions?

- Differences in medical aptitude of coders
- Consistency concerns (many more “choices” to manually code terms in MedDRA compared to older terminologies)
- Even with an autoencoder, will still need manual coding



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

- An ICH-endorsed guide for MedDRA users
- Developed to promote medically accurate and consistent use of MedDRA in exchange of data (ultimately, for “medically meaningful” retrieval and analysis)
- Current version available on MedDRA MSSO Web site ([http://www.meddramsso.com/subscriber\\_library\\_ptc.asp](http://www.meddramsso.com/subscriber_library_ptc.asp))



## MedDRA Term Selection: PTC (cont)

- 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



## 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



## Do Not Alter MedDRA

- MedDRA is a standardized terminology with a pre-defined term hierarchy
- Users must not make *ad hoc* structural alterations, including changing the primary SOC allocation
- If terms are incorrectly placed, submit a change request to the MSSO



## Synonym Lists

- Can be derived from existing term lists or directly from verbatims
- For recurring, but unusual, verbatims – one-time assignment to a MedDRA term
- Enforces consistency by limiting choices once MedDRA term is assigned
- Increases likelihood of autoencoding “hit”
- Natural outgrowth of a legacy data conversion
- Maintenance required



## Synonym List Examples

Verbatim	LLT	Comment
Throbbing above temple Aching all over head Pulsing pain in head	Headache	
Muscular pain in legs	Myalgia of lower extremities	LLT <i>Myalgia of lower extremities</i> is a better choice than LLT <i>Muscular pain</i> since it captures both the event and body site



## Always Select a Lowest Level Term

- Lowest Level Term that most accurately reflects the reported verbatim information should be selected
- Degree of specificity may be challenging
  - Example: “*Abscess on face*” → select “*Facial abscess*,” not simply “*Abscess*”



## 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



## Term Selection Points (cont)

- Investigations
- Medication/Administration Errors and Accidental Exposures
- Transmission of Infectious Agent via Medicinal 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



## Diagnoses and Provisional Diagnoses

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

Similar principles apply for multiple diagnoses



## Diagnoses and Provisional Diagnoses (cont)

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



## Diagnoses and Provisional Diagnoses (cont)

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, dyspnea, hypotension, and laryngospasm" → select "Anaphylactic reaction", "Rash", "Dyspnea", "Hypotension", and "Laryngospasm"	Example: "Possible myocardial infarction with chest pain, dyspnea, diaphoresis" → select "Chest pain", "Dyspnea", and "Diaphoresis"



## Diagnoses and Provisional Diagnoses (cont)

- Always include signs/symptoms not associated with diagnosis

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



## Conflicting/Ambiguous/ Vague Information

- First, attempt to obtain more specific information

Reported	LLT Selected	Comment
Hyperkalemia with a serum potassium of 1.6 mEq/L	Serum potassium abnormal	LLT <i>Serum potassium abnormal</i> 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". Since "pain" is definite, select LLT <i>Pain</i>
Congestion	Unevaluable event	"Congestion" reported alone is vague; this can refer to multiple organs and physiologic processes



## Combination Terms

- One condition is more specific than the other

Reported	LLT Selected
Arrhythmia due to atrial fibrillation	Atrial fibrillation

- A MedDRA combination term is available

Reported	LLT Selected
Retinopathy due to diabetes	Diabetic retinopathy



## 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
Diarrhea and vomiting	Diarrhea Vomiting
Wrist fracture due to fall	Wrist fracture Fall



## Medication Errors

See Appendix B of MedDRA Introductory Guide for Concept Descriptions

- Medication error with clinical consequences

Reported	LLT Selected
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 (cont)

Important to record occurrence or potential occurrence of medication error

- Medication error without clinical consequences

Reported	LLT Selected	Comment
Medication was given intravenously instead of intramuscularly without sequelae	Intramuscular formulation administered by other route No adverse effect	If specifically reported that there is no adverse effect, acceptable to select LLT <i>No adverse effect</i>
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	LLT <i>Drug name confusion</i> could be an optional additional term to select. Note: this example is a potential medication error.



## Product Quality Issues

See Appendix B of MedDRA Introductory Guide  
“Top-down” navigation in HLG *Product quality issues* is optimal approach for term selection

- Product quality issue with clinical consequences

Reported	LLT Selected
New bottle of drug tablets have unusual chemical smell that made me nauseous	Product odor abnormal Nauseous
I switched from one brand to another of my blood pressure medication, and I developed smelly breath	Product substitution issue brand to brand Smelly breath



## Product Quality Issues (cont)

- Product quality issue without clinical consequences

Reported	LLT Selected
Sterile lumbar puncture kit received in broken packaging (sterility compromised)	Product sterile packaging disrupted



## Product Quality Issue vs. Medication Error

Important to distinguish between a product quality issue and a medication error

Reported	LLT Selected	Comment
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



## FDA-Defined Coding Errors

- Missed Concepts
  - All medical concepts described after the product is taken should be coded
  - Example: “*The patient took drug X and developed alopecia, increased LFTs and pancreatitis*”. Manufacturer only codes alopecia and increased LFTs (missed concept of pancreatitis)
  - Example: “*The patient took drug X and developed interstitial nephritis which later deteriorated into renal failure*”. Manufacturer only codes interstitial nephritis (missed renal failure concept)

Acknowledgement: Dr. Toni Piazza-Hepp, Office of Surveillance and Epidemiology, CDER



## FDA-Defined Coding Errors (cont)

- “Soft Coding”
  - Selecting a term which is both less specific and less severe than another MedDRA term is “soft coding”
  - Example: “*Liver failure*” coded as hepatotoxicity or increased LFTs
  - Example: “*Aplastic anemia*” coded as unspecified anemia
  - Example: “*Rash subsequently diagnosed as Stevens Johnson syndrome*” coded as rash

Acknowledgement: Dr. Toni Piazza-Hepp, Office of Surveillance and Epidemiology, CDER



## Animal Pharma: Challenging Verbatims

- Deer ria
- Big fat ugly cow
- Hippo tension
- Wanted to take an elephant dump
- Mousy feeling in chest
- Beasting R arm
- Menstrual clams
- Seeing people in room, seeing chickens at window
- Seeing stars and chicken farting
- Patient recently began new job where he works around chicken wings and barbecue sauce



## Practical Experience Applying Coding Principles and Conventions

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## Speaker Disclosure

- I have no real or apparent relationships to disclose, financial or other, that would affect my ability to make an unbiased presentation on this topic.
- I do not intend to reference unlabeled or unapproved uses of any drug or to promote any product in any way.



## Overview

- Examples: assessing verbatims and selecting MedDRA® terms
- Interactive exercises
- Pitfalls and solutions
- Tips for coding medication errors and product quality issues and for handling abbreviations
- Sharing best practices



## Assessing the reported term

- First step: Consider what is being reported
  - Is it a clinical condition - Diagnosis, sign or symptom?
  - Is it an indication?
  - Is it a test result?
  - Is it trauma?
  - Is it a procedure?
  - Is it a medication error?
  - Is it a product quality issue?
  - Is it a social circumstance?
  - Is it a device issue?
  - Is it a 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

- A good browser is a key component
- Use “top-down” and “bottom-up” approaches
- First, try using actual words from reporter
- Consider synonyms, e.g., “Liver” and “Hepatic”
- Use word stems, e.g., “Pancrea”
- Search different word orders, “and”, “or”, etc.
- Use available resources for difficult verbatim terms (web search, medical dictionaries, colleagues)
- Check the hierarchy
- Look at the “neighbors”



## Example 1: Complications and Outcomes

- “Death due to liver failure secondary to Hep B liver cirrhosis”



## Example 1: Assessing the Verbatim

- “Death due to liver failure secondary to Hep B liver cirrhosis”
  - Hep B = original medical condition
  - Liver cirrhosis = complication of Hep B
  - Liver failure = complication of liver cirrhosis and Hep B, proximal cause of death
  - Death = outcome



## Example 1: Term Selection

- “Death due to liver failure secondary to Hep B liver cirrhosis”
- Check for applicable combination terms – none
- Hep B: LLT *Hepatitis B* → SOC *Infections and infestations*
  - Do not use non-current LLT *Hep B* (PTC 2.5)
  - Query if abbreviation is unacceptable
  - Would not need to code if patient known to have had Hep B at baseline (PTC 3.5.5)



## Example 1: Term Selection, cont.

- Liver cirrhosis, Liver failure: LLT *Liver cirrhosis* and LLT *Liver failure* both → SOC *Hepatobiliary disorders*
  - Neither term is adequately expressed by the other or by LLT *Hepatitis B*
- Death: outcome
  - Do not code (PTC 3.2.1)



## Example 2: Complications and Provisional Diagnoses

- “Sepsis leading to shock (from spontaneous bacterial peritonitis or bowel perforation)”



## Example 2: Assessing the Verbatim

- “Sepsis leading to shock (from spontaneous bacterial peritonitis or bowel perforation)”



## Example 2: Term Selection

- “Sepsis leading to shock (from spontaneous bacterial peritonitis or bowel perforation)”
- Check for applicable combination terms:
  - LLT/PT *Septic shock* found
  - Better than coding to both LLT/PT *Sepsis* and LLT/PT *Shock* (preserves relationship)
- SBP or bowel perforation:
  - Potential causes of the septic shock
  - Uncertain if both conditions were actually present (likely a differential diagnosis)



## Example 2: Term Selection, cont.

- Code both provisional diagnoses for best capture:
  - LLT *Spontaneous bacterial peritonitis*  
PT *Peritonitis bacterial*  
SOC *Infections and infestations*
  - LLT *Bowel perforation*  
PT *Intestinal perforation*  
SOC *Gastrointestinal disorders*



## Examples 1 & 2: Actual Verbatim

- “Death due to liver failure secondary to Hep B liver cirrhosis and sepsis from spontaneous bacterial peritonitis or bowel perforation”



## Exercise 1: Complications Which term(s) would you choose?

- “Retinal disease from HIV with near total blindness (R and L)”
  - LLT *Retinal damage*
  - LLT *Retinal disorder*
  - LLT *HIV disease*
  - LLT *Blindness*
  - LLT *HIV retinopathy*
  - LLT *Blindness, both eyes*



## Exercise 1: Suggested Terms

- “Retinal disease from HIV with near total blindness (R and L)”
  - LLT *Retinal damage* (goes to injury SOC)
  - LLT *Retinal disorder* (combo term available)
  - LLT *HIV disease* (combo term available)
  - LLT *Blindness* (not the most specific LLT)
  - LLT *HIV retinopathy* (good combo term)
  - LLT *Blindness, both eyes* (most specific term for this reported condition)



## Exercise 1: Why not also code the HIV?

- If patient known to have had HIV at baseline (can't tell here)
- Combination term was available
- Check hierarchy for PT *AIDS retinopathy*:
  - Primary SOC: *Infections and infestations, HLT Retroviral infections*
  - Secondary SOCs: *Eye disorders, Immune system disorders*
- Coded event will display in infections SOC



## Exercise 2: Lab Tests

### Which option would you choose?

- “Testing showed increased serum creatinine and BUN, with increased BUN/creatinine ratio.”
  - a) LLT *Increased serum creatinine, LLT BUN increased*
  - b) LLT *Increased serum creatinine, LLT BUN increased, LLT Blood urea nitrogen/creatinine ratio increased*
  - c) LLT *Renal function tests NOS abnormal*



## Exercise 2: Suggested Terms

- “Testing showed increased serum creatinine and BUN, with increased BUN/creatinine ratio.”
  - a) LLT *Increased serum creatinine, LLT BUN increased (does not capture the abnormal ratio)*
  - b) LLT *Increased serum creatinine, LLT BUN increased, LLT Blood urea nitrogen/creatinine ratio increased*
  - c) LLT *Renal function tests NOS abnormal (do not lump together per PTC 3.14.4; loss of specificity; also not NOS, as abnormalities were specified)*



## Pitfalls and Solutions, 1

- Do not lose information by lumping
- Do not add information by coding to a diagnosis that is not explicitly stated in the verbatim → Reread verbatim carefully, resist any internal or external pressure to code to unstated diagnoses
  - If the physician who actually saw the patient was not comfortable committing to a diagnosis, why should you be?



## Pitfalls and Solutions, 2

- Terms that sound like something they aren't (eg, LLT *Blood urine*) → Read through the other PTs under that HLT
  - LLT/PT *Blood urine* vs. LLT/PT *Blood urine present* (lab test name vs. lab test result)
- Not finding the most specific term → Combine bottom-up and top-down searches, use judicious translations
  - For “osteoporosis due to advanced age”, select LLT/PT *Senile osteoporosis*, not LLT/PT *Osteoporosis*



## Pitfalls and Solutions, 3

- “Autocoder specials” (ie, inappropriate terms selected by autocoder) → Review all weight-based autocoding carefully, apply medical judgment
- Inadvertently sacrificing detail at the PT level to capture detail in an LLT → Check hierarchy
  - For “intermittent migraine headaches”, use LLT *Migraine headache* → PT *Migraine*, not LLT *Intermittent headache* → PT *Headache*



## Exercise 3: Medication Errors and Product Quality Issues

- “Eye clinic nurse reported accidentally using a vial of an unpreserved injectable medication on more than one patient and complained that the warning on the label stating that it was for single use only was too small to read. One of the patients developed an injection site infection.”



## Tips for Coding Medication Errors and Product Quality Issues

- Spend some time reading through the available terms and hierarchies, for familiarity
- Read the LLTs to better understand the meaning of the PTs:
  - For example, PT *Wrong technique in drug usage process* includes LLTs like *Wrong injection technique*, *Tablet crushed incorrectly*, and *Inhalation not administered correctly*.
- Code all elements: medication errors, product quality issues, and associated adverse events



## Exercise 3: Assessing the Verbatim

- “Eye clinic nurse reported accidentally using a vial of an unpreserved injectable medication on more than one patient and complained that the warning on the label stating that it was for single use only was too small to read. One of the patients developed an injection site infection.”



### Exercise 3: Medication Error

#### Which option would you choose?

- “Eye clinic nurse reported accidentally using a vial of an unpreserved injectable medication on more than one patient.”
  - a) LLT *Medication error*
  - b) LLT *Circumstance or information capable of leading to a medication error*
  - c) LLT *Multiple use of single-use product*
  - d) LLT *Poor quality drug administered*



### Exercise 3: Medication Error

#### Suggested Term

- “Eye clinic nurse reported accidentally using a vial of an unpreserved injectable medication on more than one patient.”
  - a) LLT *Medication error* (not specific)
  - b) LLT *Circumstance or information capable of leading to a medication error* (error occurred)
  - c) LLT *Multiple use of single-use product*
  - d) LLT *Poor quality drug administered* (presumes poor quality)



### Exercise 3: Product Quality Issue Which option would you choose?

- “Eye clinic nurse complained that the warning on the label stating that it was for single use only was too small to read.”
  - a) LLT *Product label issue*
  - b) LLT *Product quality issue*
  - c) LLT *Product label missing text*



### Exercise 3: Product Quality Issue Suggested Term

- “Eye clinic nurse complained that the warning on the label...was too small to read.”
  - a) LLT *Product label issue* (note: label refers to the actual label on the product)
  - b) LLT *Product quality issue* (too general)
  - c) LLT *Product label missing text* (text was there, just too small)



### Exercise 3: Adverse Effect

#### Which option would you choose?

- “One of the patients developed an injection site infection.”
  - a) LLT *Infection*
  - b) LLT *Injection site infection*
  - c) LLT *Eye infection*



### Exercise 3: Adverse Effect

#### Suggested Term

- “One of the patients developed an injection site infection.”
  - a) LLT *Infection* (too general)
  - b) LLT *Injection site infection*
  - c) LLT *Eye infection* (presumes eye)



## Exercise 4: Overdose and Self-Harm

- “Patient with reactive depression due to the recent passing of his spouse attempted suicide by intentionally taking a handful of his diuretic tablets.”



## Exercise 4: Assessing the Verbatim

- “Patient with reactive depression due to the recent passing of his spouse attempted suicide by intentionally taking a handful of his diuretic tablets.”



## Exercise 4: Depression/Loss Which options would you choose?

- “Patient with reactive depression due to the recent passing of his spouse”
  - 1) LLT *Depression* or LLT *Reactive depression*?
  - 2) LLT *Death of spouse* or no code at all?  
SOC *Social circumstances*



## Exercise 4: Depression/Loss Suggested Terms

- “Patient with reactive depression due to the recent passing of his spouse”
  - 1) LLT *Depression* or LLT *Reactive depression*?  
*LLT Reactive depression (same PT, but more specific)*
  - 2) LLT *Death of spouse* or no code at all?  
SOC *Social circumstances*  
*See PTC 3.23 (generally do not enter as AE; could enter under medical/social history; consult local conventions)*



## Exercise 4: Overdose/Self-Harm

### Which options would you choose?

- “Patient attempted suicide by intentionally taking a handful of his diuretic tablets.”
  - 1) LLT *Attempted suicide* or  
LLT *Suicidal behavior*?
  - 2) LLT *Diuretic abuse* or  
LLT *Drug overdose deliberate self-inflicted* or  
LLT *Drug toxicity due to intentional overdose*?



## Exercise 4: Overdose/Self-Harm

### Suggested Terms

- “Patient attempted suicide by intentionally taking a handful of his diuretic tablets.”
  - 1) LLT *Attempted suicide* (exact match)  
LLT *Suicidal behavior* (different PT)
  - 2) LLT *Diuretic abuse* (refers to something else)  
LLT *Drug overdose deliberate self-inflicted*  
LLT *Drug toxicity due to intentional overdose*  
(no toxicity was reported)



## Tips for Handling Abbreviations

- Train investigators to avoid reporting abbreviations
- Consider context in the verbatim that might disambiguate the abbreviation
- Consider using the ARGH Biomedical Acronym Resolver to look up various meanings of acronyms and their frequency of use in Medline
  - Longer acronyms might be specific enough to code
- Consider specifying that a certain medical acronym dictionary will be used (>1 meaning → query)



## Funny Verbatims

- “Trauma of right knee during skiing in FRANCE”
- “Endorses smoking marijuana once per day”
- “Just her time to go”
- “Tongue stud”
- “Brain feels like a lava lamp”
- “Fungus left feet”
- “Feeling like Gumby”
- “Loss of sensibility in pubic area”



## Best Practices



## Summary

In this workshop we:

- Reviewed key principles in the “MedDRA Term Selection: Points to Consider” document
- Learned practical approaches to coding consistently, accurately, and with confidence
- Engaged in practical exercises and shared best practices

