Coding with Confidence

Judy E. Harrison, MD
Senior Medical Officer
MedDRA MSSO

Jean D. Cole, PharmD, CMC
Associate Director
Gilead Sciences, Inc.
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Disclosure

• Judy Harrison, M.D. is a consultant to Northrop Grumman Information Systems/MedDRA MSSO

• MedDRA MSSO provides MedDRA via subscription to its users and provides training and other MedDRA-related services
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

IN

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

OUT

Not a drug dictionary
Frequency qualifiers
Numerical values for results
Severity descriptors
Not an equipment, device, diagnostic product dictionary

Patient demographic terms
Clinical trial study design terms
MedDRA Structure

System Organ Class (SOC) (26)

High Level Group Term (HLGT) (334)

High Level Term (HLT) (1,717)

Preferred Term (PT) (20,057)

Lowest Level Term (LLT) (71,326)

MedDRA Version 16.0
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

SOC = Cardiac disorders

HLGT = Cardiac arrhythmias

HLT = Rate and rhythm disorders NEC

PT = Arrhythmia

LLT (Non-current) Other specified cardiac dysrhythmias

LLT Dysrhythmias

LLT Arrhythmia NOS
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 has an 8-digit code
- Codes used for electronic submissions

(Diagram of MedDRA codes for ear and labyrinth disorders)
Language Translations

- Chinese
- Czech
- Dutch
- English
- French
- German
- Hungarian
- Italian
- Japanese
- Portuguese
- Spanish
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

• 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)

SOC = Respiratory, thoracic and mediastinal disorders

HLGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

PT = Influenza

SOC = Infections and infestations

HLGT = Viral infectious disorders

HLT = Influenza viral infections
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
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\textsuperscript{st}: Congenital, familial and genetic disorders

  2\textsuperscript{nd}: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

  3\textsuperscript{rd}: Infections and infestations
DIRECTIVE 2010/84/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 December 2010
amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use
(Text with EEA relevance)
Member States should operate a pharmacovigilance system to collect information that is useful for the monitoring of medicinal products, including information on suspected adverse reactions arising from use of a medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, including overdose, misuse, abuse and medication errors, and suspected adverse reactions associated with occupational exposure.
Revisions Related to New EU PV Legislation

• Significant revisions to MedDRA Term Selection: Points to Consider for Release 4.5, based on MedDRA v16.0 (1 April 2013)
  – Definitions added (consistent with international regulatory authorities’ definitions)
  – Examples added
  – New section on Misuse, Abuse and Addiction

• MedDRA Introductory Guide v16.0 (1 March 2013)
  – Definitions added (consistent with MTS:PTC definitions)

• MedDRA v16.0 (1 March 2013)
  – Added new HLT Occupational exposures
“MedDRA Term Selection: Points to Consider” Document
MedDRA Term Selection: Points to Consider (MTS:PTC)

- An ICH-endorsed guide for MedDRA users
- 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 the basis for individual organizations’ coding conventions
MedDRA Term Selection: PTC (cont)

- Developed by a working group of the ICH Steering Committee
  - Regulators and industry representatives
  - EU, Japan, USA
  - Canadian observer, MSSO, JMO
- Updated twice yearly with each MedDRA release
- Available on MSSO, JMO, and ICH Web sites
  - English and Japanese
  - Variety of file formats for ease of viewing and editing
  - Summary of Changes document
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
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
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
- Investigations
Term Selection Points (cont)

• Medication/Administration 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
## Diagnoses and Provisional Diagnoses

### SINGLE DIAGNOSIS

<table>
<thead>
<tr>
<th>DEFINITIVE DIAGNOSIS</th>
<th>PROVISIONAL DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single diagnosis without signs and symptoms</td>
<td>Single provisional diagnosis without signs and symptoms</td>
</tr>
<tr>
<td>• Diagnosis (only possible option)</td>
<td>• Provisional diagnosis (only possible option)</td>
</tr>
</tbody>
</table>

**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)

<table>
<thead>
<tr>
<th>SINGLE DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DEFINITIVE DIAGNOSIS</strong></td>
</tr>
<tr>
<td>Single diagnosis with signs/symptoms</td>
</tr>
<tr>
<td>•Preferred: Diagnosis only</td>
</tr>
</tbody>
</table>

**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)

<table>
<thead>
<tr>
<th>SINGLE DIAGNOSIS</th>
<th>DEFINITIVE DIAGNOSIS</th>
<th>PROVISIONAL DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Single diagnosis with signs/symptoms</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Alternate: Diagnosis and signs/symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Example:</strong> &quot;Anaphylactic reaction with rash, dyspnea, hypotension, and laryngospasm&quot; → select &quot;Anaphylactic reaction&quot;, &quot;Rash&quot;, &quot;Dyspnea&quot;, &quot;Hypotension&quot;, and &quot;Laryngospasm&quot;</td>
<td><strong>Single provisional diagnosis with signs/symptoms</strong></td>
<td><strong>Alternate: Signs/symptoms only (as provisional diagnosis may change)</strong></td>
</tr>
<tr>
<td><strong>Example:</strong> “Possible myocardial infarction with chest pain, dyspnea, diaphoresis&quot; → select “Chest pain”, “Dyspnea”, and “Diaphoresis&quot;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Diagnoses and Provisional Diagnoses (cont)

- Always include signs/symptoms not associated with diagnosis

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial infarction, chest pain, dyspnea, diaphoresis, ECG changes and jaundice</td>
<td>Myocardial infarction Jaundice (note that jaundice is not typically associated with myocardial infarction)</td>
</tr>
</tbody>
</table>
Conflicting/Ambiguous Information

- First, try to obtain more specific information

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperkalemia with a serum potassium of 1.6 mEq/L</td>
<td>Serum potassium abnormal</td>
<td>LLT <em>Serum potassium abnormal</em> covers both of the reported concepts (note: serum potassium of 1.6 mEq/L is a low result, not high)</td>
</tr>
<tr>
<td>GU pain</td>
<td>Pain</td>
<td>“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 <em>Pain</em></td>
</tr>
</tbody>
</table>
Vague Information

- First, try to obtain more specific information

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turned green</td>
<td>Unevaluable event</td>
<td>“Turned green” reported alone is vague; this could refer to a patient condition or even to a product (e.g., pills)</td>
</tr>
<tr>
<td>Patient had a medical problem of unclear type</td>
<td>Ill-defined disorder</td>
<td>Since it is known that there is some form of a medical disorder, LLT Ill-defined disorder can be selected</td>
</tr>
</tbody>
</table>
Combination Terms

• One condition is more specific than the other

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrhythmia due to atrial fibrillation</td>
<td>Atrial fibrillation</td>
</tr>
</tbody>
</table>

• A MedDRA combination term is available

<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>
</tbody>
</table>
Combination Terms (cont)

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

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

See Appendix B of MedDRA Introductory Guide for Concept Descriptions

“Top-down” navigation in HLGT Medication errors is best approach for term selection

- Medication error with clinical consequences

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient was administered wrong drug and experienced hypotension</td>
<td>Wrong drug administered Hypotension</td>
</tr>
<tr>
<td>Because of similar sounding drug names, the patient took the wrong drug and experienced a rash</td>
<td>Drug name confusion Wrong drug administered Rash</td>
</tr>
</tbody>
</table>
Medication Errors (cont)

Important to record occurrence or potential occurrence of medication error

- Medication error without clinical consequences

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
</table>
| 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 No adverse effect |
| 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 Drug name confusion could be an optional additional term to select. Note: this example is a potential medication error. |
3.16 – Misuse, Abuse and Addiction

The concepts of misuse, abuse and addiction are closely related and can pose challenges for term selection since the terms may overlap to some extent; the specific circumstances of each case/reported event may help in consideration for term selection of these concepts. Medical judgment and regional regulatory considerations need to be applied.

It may also be useful to consider these concepts as shown in the table below.

<table>
<thead>
<tr>
<th>Concept</th>
<th>Intentional?</th>
<th>By Whom?</th>
<th>Therapeutic Use?</th>
<th>Additional Sections in this Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misuse</td>
<td>Yes</td>
<td>Patient/consumer</td>
<td>Yes</td>
<td>3.16.1</td>
</tr>
<tr>
<td>Abuse</td>
<td>Yes</td>
<td>Patient/consumer</td>
<td>No</td>
<td>3.16.2</td>
</tr>
<tr>
<td>Addiction</td>
<td>Yes</td>
<td>Patient/consumer</td>
<td>No</td>
<td>3.16.3</td>
</tr>
<tr>
<td>Medication error</td>
<td>No</td>
<td>Patient/consumer or healthcare provider</td>
<td>Yes</td>
<td>3.15</td>
</tr>
<tr>
<td>Off label use</td>
<td>Yes</td>
<td>Healthcare provider</td>
<td>Yes</td>
<td>3.27</td>
</tr>
</tbody>
</table>
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
• “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
Practical Experience Applying Coding Principles and Conventions

Jean D. Cole, PharmD, CMC
Assoc. Dir., Drug Safety & Public Health
Gilead Sciences, Inc.
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 particular 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 Information

- Consider what is being reported. Is it a:
  - Clinical condition - Diagnosis, sign or symptom?
  - Indication?
  - Test result?
  - Injury?
  - Procedure?
  - Medication error?
  - 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”
• Check the hierarchy
• 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)
Example 1:
Diagnoses, Signs, and Symptoms

• “Altered mental status and arm weakness – cerebrovascular accident versus postictal state”
Example 1: Assessing the Verbatim

- “Altered mental status and arm weakness – cerebrovascular accident versus postictal state”
- Altered mental status = sign/symptom
- Arm weakness = sign/symptom
- Cerebrovascular accident = one provisional diagnosis
- Postictal state = another provisional diagnosis
Example 1: Term Selection

• “Altered mental status and arm weakness
  – cerebrovascular accident versus postictal state”
  – Consult PTC 3.1
  – Preferred option is to code signs, symptoms, and all provisional diagnoses
  – S/Sx: LLT Mental status changes, LLT Weakness of arms
  – Provisional Dx: LLT Cerebrovascular accident, LLT Postictal state
Example 2: Combination Concepts and Complications

• “Hypersensitivity reaction manifesting as interstitial nephritis, complicated by hyperkalemia”
Example 2: Assessing the Verbatim

• “Hypersensitivity reaction manifesting as interstitial nephritis, complicated by hyperkalemia”
Example 2: Term Selection

• “Hypersensitivity reaction manifesting as interstitial nephritis, complicated by hyperkalemia”

• Check for applicable combination terms:
  – LLT Nephritis allergic found
  – Better than coding to both LLT Nephritis interstitial and LLT Hypersensitivity reaction (preserves relationship between mechanism and manifestation; loss of “interstitial” is acceptable based on medical judgment)

• Code the complication:
  – LLT Hyperkalemia (not adequately expressed in LLT Nephritis allergic)
Exercise 1: Complications
Which term(s) would you choose?

- “Hypertensive crisis resulting in organ failure (multiple): encephalopathy, acute renal failure and oliguria”
  a) LLT Hypertensive crisis
  b) LLT Organ failure
  c) LLT Multiple organ failure
  d) LLT Encephalopathy
  e) LLT Hypertensive encephalopathy
  f) LLT Hypertensive nephropathy
  g) LLT Acute oliguric renal failure
Exercise 1: Suggested Terms

- “Hypertensive crisis resulting in organ failure (multiple): encephalopathy, acute renal failure and oliguria”
  a) LLT Hypertensive crisis (exact match)
  b) LLT Organ failure
  c) LLT Multiple organ failure (more specific)
  d) LLT Encephalopathy
  e) LLT Hypertensive encephalopathy (good combination term; captures causal relationship)
  f) LLT Hypertensive nephropathy
  g) LLT Acute oliguric renal failure (good combination term; captures reporter’s words and severity of event)
Exercise 2: Investigation Terms - PTC 3.14

- “Routine labs showed marked elevations in ALT, alkaline phosphatase, and bilirubin.”
  
a) LLT Hepatobiliary disease
b) LLT ALT increased, LLT Alkaline phosphatase increased, LLT Bilirubin elevated
c) LLT Raised liver function tests
d) LLT Elevated liver enzymes, LLT Bilirubin elevated
Exercise 2: Investigation Terms

• “Routine labs showed marked elevations in ALT, alkaline phosphatase, and bilirubin.”

a) LLT Hepatobiliary disease (disorder term)

b) LLT ALT increased, LLT Alkaline phosphatase increased, LLT Bilirubin elevated (specificity preserved)

c) LLT Raised liver function tests (specificity lost)

d) LLT Elevated liver enzymes, LLT Bilirubin elevated (specificity lost)
Pitfalls and Solutions, 1

• Do not subtract information (code all relevant information)

• 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

• In selecting an LLT for a result of an investigation, parent PT of the selected LLT should contain a qualifier/adjective
  – E.g., “present/absent”, “increased/decreased”, etc.

• If parent PT of selected LLT does not contain a qualifier/adjective, you may have inadvertently selected an LLT for the test name, not a result
  – E.g., “Blood found in urine”, select LLT Blood in urine (PT Blood urine present). Do not select LLT Blood urine (PT Blood urine has no qualifier/adjective and thus represents the test name only)
Pitfalls and Solutions, 3

• Not finding the most specific term → Combine bottom-up and top-down searches
  – For “rheumatoid arthritis in a 6-year old”, select LLT *Juvenile rheumatoid arthritis*, not LLT *Rheumatoid arthritis*

• 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*
Pitfalls and Solutions, 4

- Inappropriate terms selected by autocoder
  - Review all weight-based autocoding carefully, apply medical judgment
    - “Allergic to CAT scan” autocoded as LLT *Allergic to cats*
    - “Myocardial infarction in the fall of 2000” autocoded as LLT *Myocardial infarction* and LLT *Fall*
Tips for Coding Medication Errors and Product Quality Issues

• See Appendix B of MedDRA Introductory Guide for Concept Descriptions

• “Top-down” navigation in HLGT Medication errors and HLGT Product quality issues is best approach for term selection

• 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 and Tablet crushed incorrectly
  – Code all elements, including associated AEs
Exercise 3: Product Quality Issue

• “A patient who had been receiving epidural injections of a compounded, preservative-free corticosteroid for severe back pain presented to the ER with chest pain, headache, and a fever. He was diagnosed with fungal meningitis due to *Exserohilum rostratum*, which was attributed to the use of a contaminated lot of the corticosteroid. Unfortunately, the event was fatal.”
Exercise 3: Assessing the Verbatim

• “A patient who had been receiving epidural injections of a compounded, preservative-free corticosteroid for severe back pain presented to the ER with chest pain, headache, and a fever. He was diagnosed with fungal meningitis due to *Exserohilum rostratum*, which was attributed to the use of a contaminated lot of the corticosteroid. Unfortunately, the event was fatal.”
Exercise 3: Signs, Symptoms & Diagnosis – PTC 3.1

• “...chest pain, headache, and a fever. He was diagnosed with fungal meningitis due to *Exserohilum rostratum*.”

  a) LLT *Fungal meningitis*, LLT *Chest pain*, LLT *Headache*, and LLT *Fever*
  
  b) LLT *Exserohilum infection*, LLT *Chest pain*

  c) LLT *Meningitis exserohilum*

  d) LLT *Meningitis exserohilum*, LLT *Chest pain*
Exercise 3: Signs, Symptoms & Diagnosis – PTC 3.1

• “…chest pain, headache, and a fever. He was diagnosed with fungal meningitis due to *Exserohilum rostratum.*”

  a) LLT *Fungal meningitis*, LLT *Chest pain*, LLT *Headache*, and LLT *Fever*
  b) LLT *Exserohilum infection*, LLT *Chest pain*
  c) LLT *Meningitis exserohilum*
  d) LLT *Meningitis exserohilum*, LLT *Chest pain*

- “…fungal meningitis due to *Exserohilum rostratum*, which was attributed to the use of a contaminated lot of the corticosteroid.”
  - a) LLT *Transmission of an infectious agent via a medicinal product*, LLT *Product quality issue*
  - b) LLT *Pharmaceutical product contamination*
  - c) LLT *Transmission of an infectious agent via a medicinal product*, LLT *Product contamination fungal*
  - d) LLT *Product packaging issue*

- “…fungal meningitis due to Exserohilum rostratum, which was attributed to the use of a contaminated lot of the corticosteroid.”
  
  a) LLT Transmission of an infectious agent via a medicinal product, LLT Product quality issue
  
  b) LLT Pharmaceutical product contamination
  
  c) LLT Transmission of an infectious agent via a medicinal product, LLT Product contamination fungal
  
  d) LLT Product packaging issue
Exercise 3: Other Codeable Concepts

• “A patient who had been receiving epidural injections of a compounded, preservative-free corticosteroid for severe back pain…”
  – Select LLT Back pain for indication term “severe back pain”

• “Unfortunately, the event was fatal.”
  – Per PTC 3.2.1, do not select LLT Death, as it is the outcome of a reported adverse event
Exercise 4: Medication Errors

“A junior staff member started to give a patient an IV injection of an antipsychotic intended for IM use, but a senior staff member intervened before hardly any had been given. There were no adverse effects from this incident; however, the patient has refused any further injections.
Exercise 4: Medication Errors

“A junior staff member started to give a patient an IV injection of an antipsychotic intended for IM use, but a senior staff member intervened before hardly any had been given. There were no adverse effects from this incident; however, the patient has refused any further injections.
Exercise 4: Medication Errors

• “A junior staff member started to give a patient an IV injection of an antipsychotic intended for IM use…”
  – a) LLT Wrong injection technique
  – b) LLT Intramuscular formulation administered by other route
  – c) LLT Intercepted medication error
  – d) LLT Drug maladministration
Exercise 4: Medication Errors

• “A junior staff member started to give a patient an IV injection of an antipsychotic intended for IM use…”

  a) LLT *Wrong injection technique* (more an error of route than of technique)

  b) LLT *Intramuscular formulation administered by other route* (best specificity)

  c) LLT *Intercepted medication error* (use when the drug did not reach the patient)

  d) LLT *Drug maladministration* (too general)
Exercise 4: Medication Errors

• “There were no adverse effects from this incident…”
  a) Would not select any code
  b) LLT No toxic effect
  c) LLT No adverse effect
Exercise 4: Medication Errors

• “There were **no adverse effects** from this incident…”
  
a) Would not select any code (acceptable per PTC 3.15.1.2)
  
b) LLT *No toxic effect*
  
c) LLT *No adverse effect* (also acceptable per PTC 3.15.1.2)
Exercise 4: Medication Errors

• “However, the patient has refused any further injections.”
  a) LLT Treatment noncompliance
  b) LLT Refusal of treatment by patient
  c) LLT Drug dose omission
  d) LLT Contraindication to medical treatment
Exercise 4: Medication Errors

“However, the patient has refused any further injections.”

a) LLT *Treatment noncompliance*

b) LLT *Refusal of treatment by patient* (most specific; note this term is in SOC *Social circumstances*)

c) LLT *Drug dose omission*

d) LLT *Contraindication to medical treatment*
Tips for Handling Abbreviations

- Train investigators to avoid reporting abbreviations.
- Consider context in the verbatim that might clarify the abbreviation.
- Consider specifying that a certain medical acronym dictionary will be used (>1 meaning → query).
- Consider developing an in-house list of acceptable abbreviations.
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