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 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**
- Diseases
- Diagnoses
- Signs
- Symptoms
- Therapeutic indications
- Investigation names & qualitative results
- Medical & surgical procedures
- Medical, social, family history
- Medication errors
- Product quality, device issues
- Terms from other terminologies

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

- System Organ Class (SOC) (26)
- High Level Group Term (HLGT) (335)
- High Level Term (HLT) (1,713)
- Preferred Term (PT) (19,550)
- Lowest Level Term (LLT) (70,177)

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 = Dysrhythmias

LLT (Non-current) = Other specified cardiac dysrhythmias

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 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)

- 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:
  - 1st: *Congenital, familial and genetic disorders*
  - 2nd: *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*
  - 3rd: *Infections and infestations*
# Conditions vs. Investigations

<table>
<thead>
<tr>
<th>PT</th>
<th>HLT</th>
<th>HLGT</th>
<th>SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy test positive</td>
<td>Reproductive hormone analyses</td>
<td>Endocrine investigations (incl sex hormones)</td>
<td>Investigations</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>Normal pregnancy, labour and delivery</td>
<td>Pregnancy, labour, delivery and postpartum conditions</td>
<td>Pregnancy, puerperium and perinatal conditions</td>
</tr>
</tbody>
</table>

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)
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

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

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

<table>
<thead>
<tr>
<th>SINGLE DIAGNOSIS</th>
<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>
<td></td>
</tr>
<tr>
<td>• Diagnosis (only possible option)</td>
<td>• Provisional diagnosis (only possible option)</td>
<td></td>
</tr>
<tr>
<td>Example: &quot;Myocardial infarction&quot; → select &quot;Myocardial infarction&quot;</td>
<td>Example: &quot;Possible myocardial infarction&quot; → select &quot;Myocardial infarction&quot; (select term as if definitive diagnosis)</td>
<td></td>
</tr>
</tbody>
</table>

Similar principles apply for multiple diagnoses

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### 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>Single diagnosis with signs/symptoms</td>
<td>Single provisional diagnosis with signs/symptoms</td>
<td></td>
</tr>
<tr>
<td>• Preferred: Diagnosis only</td>
<td>• Preferred: Provisional diagnosis and signs/symptoms</td>
<td></td>
</tr>
<tr>
<td>Example: &quot;Anaphylactic reaction with rash, dyspnea, hypotension, and laryngospasm&quot; → select &quot;Anaphylactic reaction&quot;</td>
<td>Example: &quot;Possible myocardial infarction with chest pain, dyspnea, diaphoresis&quot; → select &quot;Myocardial infarction&quot; &quot;Chest pain&quot;, &quot;Dyspnea&quot;, and &quot;Diaphoresis&quot;</td>
<td></td>
</tr>
</tbody>
</table>
Diagnoses and Provisional Diagnoses (cont)

<table>
<thead>
<tr>
<th>SINGLE DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITIVE DIAGNOSIS</td>
</tr>
<tr>
<td>Single diagnosis with signs/symptoms</td>
</tr>
<tr>
<td>• Alternate: Diagnosis and signs/symptoms</td>
</tr>
<tr>
<td>Example: &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>
</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/Vague Information

- First, attempt 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 Serum potassium abnormal 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”. Since “pain” is definite, select LLT Pain</td>
</tr>
<tr>
<td>Congestion</td>
<td>Unevaluable event</td>
<td>“Congestion” reported alone is vague; this can refer to multiple organs and physiologic processes</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</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
</tr>
<tr>
<td>Wrist fracture due to fall</td>
<td>Wrist fracture</td>
</tr>
<tr>
<td></td>
<td>Fall</td>
</tr>
</tbody>
</table>

Medication Errors

See Appendix B of MedDRA Introductory Guide for Concept Descriptions

- 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>
<tbody>
<tr>
<td>Medication was given intravenously instead of intramuscularly without sequelae</td>
<td>Intramuscular formulation administered by other route No adverse effect</td>
<td>If specifically reported that there is no adverse effect, acceptable to select LLT No adverse effect</td>
</tr>
<tr>
<td>Pharmacist notices that the names of two drugs are similar and is concerned that this may result in a medication error</td>
<td>Circumstance or information capable of leading to medication error</td>
<td>LLT Drug name confusion could be an optional additional term to select. Note: this example is a potential medication error.</td>
</tr>
</tbody>
</table>

Product Quality Issues

See Appendix B of MedDRA Introductory Guide

“Top-down” navigation in HLGT Product quality issues is optimal approach for term selection

- Product quality issue with clinical consequences

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>New bottle of drug tablets have unusual chemical smell that made me nauseous</td>
<td>Product odor abnormal Nauseous</td>
</tr>
<tr>
<td>I switched from one brand to another of my blood pressure medication, and I developed smelly breath</td>
<td>Product substitution issue brand to brand Smelly breath</td>
</tr>
</tbody>
</table>
Product Quality Issues (cont)

- Product quality issue without clinical consequences

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile lumbar puncture kit received in broken packaging (sterility compromised)</td>
<td>Product sterile packaging disrupted</td>
</tr>
</tbody>
</table>

Product Quality Issue vs. Medication Error

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

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>The mother administered insufficient amount of prescribed antibiotic because the lines on the dropper were hard to read</td>
<td>Product dropper calibration unreadable</td>
<td>Insufficient dosage</td>
</tr>
<tr>
<td></td>
<td>Insufficient dosage</td>
<td>Product quality issue and medication error</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

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

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 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