MedDRA was developed under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Board, which is composed of the six ICH parties (EU, EFPIA, MHLW, JPMA, FDA, PhRMA), the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, the Health Canada, and the WHO (as Observer).
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Course Overview

- MedDRA background
- MedDRA’s structure, scope, and characteristics
- MedDRA maintenance
- Coding conventions
- Synonym lists
- QA of coding
- *MedDRA Term Selection: Points to Consider* document
- Hands-on coding exercises
MedDRA Background
What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities
Objectives for MedDRA Development

Result of an ICH initiative (M1)

To provide:

- An international multi-lingual terminology
- Standardized communication between industry and regulators
- Support of electronic submissions
- Application through all phases of the development cycle
Objectives for MedDRA Development (cont)

To provide (cont):

• Classification for a wide range of clinical information
• Support for multiple medical product areas
• A terminology that saves time, resources, and money
MedDRA and the MSSO

• International support and development of terminology
• Foster use of MedDRA through communications and educational offerings
• “Custodians”, not owners, of the terminology
• JMO (partner organization for Japanese-language MedDRA)
• Governed by a Management Board (industry, regulators, multi-national, other interested parties)
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.
Regulatory Status of Mandate

• US FDA
  – Used in several FDA databases (AERS, VAERS, and CAERS)

• Japanese Ministry of Health, Labour and Welfare
  – Mandatory use for electronic reports
  – Used in Periodic Infection and Safety Reports
  – For medical devices with biological components, infections to be described with MedDRA terms
Regulatory Status of Mandate (cont)

- European Union
  - EudraVigilance database
    - Clinical trial SUSARs (Suspected Unexpected Serious Adverse Reactions) and post-authorization Individual Case Safety Reports (ICSRs) – use MedDRA LLTs (current version or the one previous to it)
  - Volume 9A (To be retired in 2012)
    - MedDRA required for adverse reactions in Periodic Safety Update Report
    - Standardised MedDRA Queries (SMQs) recommended for signal detection
Regulatory Status of Mandate (cont)

- European Union (cont)
  - New PV legislation (Directive and Regulation) effective July 2012 broadens AR definition:
    - Occurring in context of medication errors
    - With uses outside terms of marketing authorization
    - Misuse and abuse
    - In context of occupational exposures
  - Implementing measures include use of international terminologies, standards, and formats (MedDRA specifically mentioned)
Regulatory Status of Mandate (cont)

• European Union (cont)
  – Interface between EudraVigilance and EU Risk Management Plan
    • To code indications, risks, interactions (potential and identified)
  – Summary of Product Characteristics guideline
    • MedDRA to be used throughout; in particular for Contraindications, Special warnings and precautions for use, and Undesirable effects sections
Regulatory Status of Mandate (cont)

• ICH M4E Guideline on Common Technical Document
  – Recommended in adverse event summary tables

• Canada
  – Guidance Document for Industry - Reporting Adverse Reactions to Marketed Health Products
    • Recommended as standard for adverse reaction reports
  – Guidance for Industry - Product Monograph (labeling)
    • Preferred terminology for adverse drug reactions
MedDRA Overview
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 an equipment, device, diagnostic product dictionary
- Patient demographic terms
- Clinical trial study design terms
- Not a drug 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)

MedDRA Version 15.0
MedDRA Term Level Definitions

- **SOC** - Highest level of the terminology, and distinguished by anatomical or physiological system, etiology, or purpose
- **HLGT** - Subordinate to SOC, superordinate descriptor for one or more HLTs
- **HLT** - Subordinate to HLGT, superordinate descriptor for one or more PTs
- **PT** - Represents a single medical concept
- **LLT** - Lowest level of the terminology, related to a single PT as a synonym, lexical variant, or quasi-synonym (Note: All PTs have an identical LLT)
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
High Level Group Term

Subordinate only to SOCs and superordinate descriptor for one or more HLTs

SOC
Cardiac disorders

HLGT
Coronary artery disorders

HLGT
Cardiac arrhythmias

HLGT
Cardiac valve disorders
High Level Term

Subordinate to HLGTs and superordinate descriptor for the PTs linked to it

- SOC
  - Cardiac disorders

- HLGT
  - Cardiac arrhythmias

- HLT
  - Cardiac conduction disorders
  - Rate and rhythm disorders NEC
  - Supraventricular arrhythmias
Examples of PTs

SOC = Cardiac disorders

HLGT = Cardiac arrhythmias

HLT = Rate and rhythm disorders NEC

PT Arrhythmia
PT Bradycardia
PT Tachyarrhythmia
Examples of LLTs

SOC = Cardiac disorders

HLGT = Cardiac arrhythmias

HLT = Rate and rhythm disorders NEC

PT = Arrhythmia

LLT Arrhythmia

LLT Arrhythmia NOS

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)

**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
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
### Cardiac disorders vs. Vascular disorders

<table>
<thead>
<tr>
<th>PT</th>
<th>HLT</th>
<th>HLGT</th>
<th>SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arteritis coronary</td>
<td>Coronary artery disorders NEC</td>
<td>Coronary artery disorders</td>
<td>Cardiac disorders (P)</td>
</tr>
<tr>
<td>Arterial inflammations</td>
<td>Vascular inflammations</td>
<td>Vascular inflammations</td>
<td>Vascular disorders</td>
</tr>
</tbody>
</table>
## SOC Congenital, familial and genetic disorders - Example

<table>
<thead>
<tr>
<th>PT</th>
<th>HLT</th>
<th>HLGT</th>
<th>SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital HIV infection</td>
<td>Viral infections congenital</td>
<td>Infections and infestations congenital</td>
<td>Congenital, familial and genetic disorders  (P)</td>
</tr>
<tr>
<td>Congenital neonatal infections</td>
<td>Neonatal and perinatal conditions</td>
<td></td>
<td>Pregnancy, puerperium and perinatal conditions</td>
</tr>
<tr>
<td>Retroviral infections</td>
<td>Viral infectious disorders</td>
<td></td>
<td>Infections and infestations</td>
</tr>
<tr>
<td>Acquired immunodeficiency syndromes</td>
<td>Immunodeficiency syndromes</td>
<td></td>
<td>Immune system disorders</td>
</tr>
</tbody>
</table>
# 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.
Standardised MedDRA Queries (SMQs)
Definition of SMQ

- Result of cooperative effort between CIOMS and ICH (MSSO)
- Groupings of terms from one or more MedDRA System Organ Classes (SOCs) related to defined medical condition or area of interest
- Included terms may relate to signs, symptoms, diagnoses, syndromes, physical findings, laboratory and other physiologic test data, etc., related to medical condition or area of interest
- Intended to aid in case identification
SMQs in Production - Examples

- As of Version 15.0, a total of 86 in production

- Agranulocytosis
- Anaphylactic reaction
- Cerebrovascular disorders
- Convulsions
- Depression and suicide/self-injury
- Hepatic disorders
- Ischaemic heart disease
- Lack of efficacy/effect
- Peripheral neuropathy
- Pregnancy and neonatal topics
- Pseudomembranous colitis
- Rhabdomyolysis/myopathy
- Severe cutaneous adverse reactions
- Systemic lupus erythematosus
SMQ Applications

• Clinical trials
  - Where safety profile is not fully established, use multiple SMQs on routine basis as screening tool
  - Selected SMQs to evaluate previously identified issue (pre-clinical data or class effect)

• Postmarketing
  - Selected SMQs to retrieve cases for suspected or known safety issue
  - Signal detection (multiple SMQs employed)
  - Single case alerts
  - Periodic reporting (aggregate cases for safety and other issues, e.g., lack of efficacy)
SMQ Resources

- Refer to MSSO Web site for information on SMQs

http://www.meddramsso.com/subscriber_smq.asp
MedDRA Maintenance

• MedDRA is a user responsive terminology
• Subscribers may submit change requests to the MSSO for consideration
  – Core and basic subscribers: 100 change requests (CRs) per month
  – For simple changes (PT and LLT levels), notification of supplemental change within 7-10 working days
  – Weekly supplemental changes posted on MSSO Web site
  – Complex changes above PT level received all year round. Posted for subscribers’ comments mid-year.
MedDRA Maintenance (cont)

- Twice yearly official updates
  - 1 September X.1 release (Simple changes only)
  - 1 March X.0 release (Complex and simple changes)
MedDRA Version Analysis Tool (MVAT)

- Web-based (https://mssotools.com/mvat)
- Free to all subscribers
- Allows for comparison of any two versions
- Features
  - Version Report Generator (produces exportable report comparing any two versions)
  - Data Impact Report (identifies changes to a specific set of MedDRA terms or codes uploaded to MVAT)
  - Search Term Change (identifies changes to a single MedDRA term or code)
WebCR

- Web-based tool for Change Requests (CR)
  - URL: https://mssotools.com/webcr/
  - Via the Change Request Information page
- Ability to submit CRs online
- Immediate confirmation
- Review unsubmitted CRs online
- Ability to query CR history back to v5.1
Change Request Justification Statements

• Justification statement always required
• Inadequate justification – “Term does not exist in MedDRA”
• Adequate justification – statement of need
• Support with definitions and references (PDFs preferred)
• Examples of need:
  – Term needed to code an indication
  – Concept is being reported in a clinical trial
Proactive MedDRA Maintenance

• What is the proactive approach?
  - Corrections/improvements made internally by the MSSO
  - General changes suggested by users

• Submitting ideas
  - Send to MSSO Help Desk. Justification is helpful.
  - Example: Consider consolidation of HLTs with only one PT

• Evaluation of proposals
  - MSSO is not obligated to respond
  - Proactive approach does not replace usual CR process
MSSO’s MedDRA Browsers

• MedDRA Desktop Browser
  – Download from MSSO Web site
  – View/search MedDRA and SMQs
  – Export functionality

• MedDRA Web-Based Browser
  – https://www.meddrabrowser.org/dsnavigator/
  – Requires specific user ID and password
  – Access to all MedDRA versions in English and available EU languages (and Chinese, if subscribed)
  – View/search MedDRA and SMQs
  – Export functionality
MedDRA Browser Demonstration and Instruction
Coding Exercises
Exercise 1

The patient states she has been experiencing headaches, dizziness and vertigo.

____________________  LLT →  ______________________  PT
____________________  LLT →  ______________________  PT
____________________  LLT →  ______________________  PT
Exercise 2

Lab results indicate an increase in erythrocytes.

__________________ LLT → __________________ PT
Exercise 3

LJ, a 55 year old female, is a heavy smoker and suffers from alcohol abuse.

__________ LLT → ___________ PT

__________ LLT → ___________ PT
Exercise 4

Drug was contaminated with Staphylococcus.

____________________ LLT → ______________________ PT
Exercise 5

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

__________ LLT → _____________ PT

__________ LLT → _____________ PT
Exercise 6

A 32 year old female had a contraceptive implant in her left arm. On a follow-up visit, the insertion site was noted to be infected.

___________________ LLT → ___________________ PT
Exercise 7

The patient’s insulin pump was noted to be broken.

______________________ LLT → ____________________ PT
Coding with MedDRA
What Is “Coding”? 

Code

1 : a systematic statement of a body of law; especially one given statutory force
2 : a system of principles or rules <moral code>
3 a : a system of signals or symbols for communication
   b : a system of symbols (as letters or numbers) used to represent assigned and often secret meanings
4 : genetic code
5 : a set of instructions for a computer
Why Do We Code?

- Retrieve
- Present
- Analyze
- Communicate
Role of a Terminology

• Provides a TOOL to represent data/concepts using “place-holder” terms
• Assists in retrieval, analysis, and comprehension of data
What Does MedDRA Offer?

• Size and specificity ("granularity")
• Hierarchy/grouping terms
• “Support” SOCs widen data collection/analysis options
• Up-to-date and medically rigorous
• User-responsive
• STANDARDIZATION
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, may still need manual coding
Can I Make Coding Conventions Specific to My Company/Product?

• MedDRA may reduce the need to do this because:
  – Increased size/granularity will result in better (i.e., more accurate) representation of data
  – Secondary SOC allocations allow for different “views” of the data

• This type of approach should be done cautiously
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 extremities</td>
<td>LLT <em>Myalgia of lower extremities</em> is a better choice than LLT <em>Muscular pain</em> since it captures both the event and body site</td>
</tr>
</tbody>
</table>

MSSO-DI-6017-15.0.5
Synonym List Maintenance

- For new MedDRA versions, run synonyms against new MedDRA LLTs
  - Identify new non-current LLTs that are on synonym list; flag for recoding
  - Identify possible new current direct matches

- Remaining challenge is to determine if “better medical matches” have been added
  (essentially, a manual process)

- Communicate results to users of synonym list
QA Reports

• Allows reviewers to check for consistency (both auto-encoded and human-coded terms)
• Check for adherence to/deviation from coding conventions
• Check for emerging drifts/biases
• Multiple data views (verbatims to coded terms; coded term to verbatims; by SOC, etc.)
### QA Sample Report

<table>
<thead>
<tr>
<th>SOC</th>
<th>HLT</th>
<th>PT</th>
<th>Verbatim</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bronchospasm and obstruction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wheezing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>WHEEZING</td>
<td></td>
<td></td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Wheeze</td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>INCREASED WHEEZING</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Breathing suppressed wheezing</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>HYPERREACTIVITY AND WHEEZING</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>wheeze in chest</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Laryngeal and adjacent sites disorders NEC (excl infections and neopla</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vocal cord disorder</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SPASTMODIC DYSTONIA OF THE VOCAL CORDS</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Newborn respiratory disorders NEC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Transient tachypnoea of the newborn</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Transient hazy vision</strong></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Transient tachypnea, neonatal</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Tachypnea of the newborn, transient</td>
<td></td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>
# QA Sample Report

## Metabolism and nutrition disorders

### Potassium imbalance

<table>
<thead>
<tr>
<th>SOC</th>
<th>HLT</th>
<th>PT</th>
<th>Verbatim</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Hyperkalaemia]</td>
<td></td>
<td></td>
<td>Hyperkalaemia</td>
<td>58</td>
</tr>
<tr>
<td>[HYPERKALAEMIA]</td>
<td></td>
<td></td>
<td>Hyperkalaemia</td>
<td>9</td>
</tr>
<tr>
<td>[Rebound perioperative hyperkalemia]</td>
<td></td>
<td></td>
<td>Hyperkalaemia</td>
<td>6</td>
</tr>
<tr>
<td>[HYPERPOTASSEMIA]</td>
<td></td>
<td></td>
<td>Hyperkalaemia</td>
<td>4</td>
</tr>
<tr>
<td><strong>Increased Potassium</strong></td>
<td></td>
<td></td>
<td>Increased serum potassium/Hyperkalemia</td>
<td>1</td>
</tr>
<tr>
<td>[Hypokalaemia]</td>
<td></td>
<td></td>
<td>Hypokalaemia</td>
<td>164</td>
</tr>
<tr>
<td>[Hypokalaemia]</td>
<td></td>
<td></td>
<td>Hypokalaemia</td>
<td>49</td>
</tr>
<tr>
<td>[HYPOPOTASSEMIA]</td>
<td></td>
<td></td>
<td>Hypokalaemia</td>
<td>15</td>
</tr>
<tr>
<td>[SUPPLEMENTATION FOR RITODRINE-INDUCED HYPOKALEMIA]</td>
<td></td>
<td></td>
<td>Hyperkalaemia</td>
<td>6</td>
</tr>
<tr>
<td>[Present hypokalemia]</td>
<td></td>
<td></td>
<td>Hypokalemia trend</td>
<td>2</td>
</tr>
<tr>
<td>[Hypokalemia trend]</td>
<td></td>
<td></td>
<td>hypokalaemia</td>
<td>1</td>
</tr>
<tr>
<td>[hypokalaemia]</td>
<td></td>
<td></td>
<td>hypokalaemia</td>
<td>1</td>
</tr>
<tr>
<td>[TRANSIENT HYPOKALEMIA]</td>
<td></td>
<td></td>
<td>Hypokalemia trend</td>
<td>1</td>
</tr>
<tr>
<td>[HYPOKALEMIA SEVERE]</td>
<td></td>
<td></td>
<td>Hypokalemia trend</td>
<td>1</td>
</tr>
<tr>
<td>[HYPOKALEMIA PROPHYLAXIS]</td>
<td></td>
<td></td>
<td>Hypokalemia trend</td>
<td>1</td>
</tr>
</tbody>
</table>
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)

- Developed by a working group of the ICH Steering Committee
  - Regulators and industry representatives
  - EU, Japan, USA
  - Canadian observer, MSSO, JMO
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
Quality of Source Data

Quality Assurance

- Quality of original information impacts quality of output
- Obtain clarification of data
- Can be optimized by careful design of data collection forms and proper training of staff
- Organizations’ coding guidelines should be consistent with MTS:PTC
- Review of term selection by qualified individuals
- Human oversight of automated coding results
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
Select Only Current LLTs

- 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”

- Select current LLTs only
  - Non-current terms for legacy conversion/historical purposes
When to Request a Term
Use of Medical Judgment

- Avoid company-specific “work-arounds” for MedDRA deficiencies. If concept not adequately represented in MedDRA, submit Change Request to MSSO.
- If no exact match in MedDRA, use medical judgment to match to an existing term that adequately represents the concept.
Selecting More than One Term
Check the Hierarchy

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

• Check the hierarchy above a selected LLT (PT, HLT, HLGT, SOC) to ensure placement accurately reflects meaning of reported term
Select Terms for All Reported Information

• Select terms for every AR/AE reported, regardless of causal association
• Select terms for device-related events, product quality issues, medication errors, medical and social history, investigations and indications as appropriate
• If diagnosis reported with characteristic signs and symptoms, preferred option is to select term for diagnosis only
Do Not Add Information

• Do not make diagnosis if only signs/symptoms reported

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain, increased serum amylase, and increased serum lipase</td>
<td>Abdominal pain</td>
<td>It is inappropriate to assign an LLT for diagnosis of “pancreatitis”</td>
</tr>
<tr>
<td></td>
<td>Serum amylase increased</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lipase increased</td>
<td></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
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

<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>
<th>DEFINITIVE DIAGNOSIS</th>
<th>PROVISIONAL DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single diagnosis with signs/symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>•Preferred: Diagnosis only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Example: &quot;Anaphylactic reaction with rash, dyspnea, hypotension, and laryngospasm&quot;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>→ select “Anaphylactic reaction&quot;</td>
<td></td>
</tr>
<tr>
<td>Example: “Possible myocardial infarction with chest pain, dyspnea, diaphoresis&quot;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>→ select &quot;Myocardial infarction&quot; “Chest pain”, “Dyspned”, and &quot;Diaphoresis&quot;</td>
<td></td>
</tr>
</tbody>
</table>

Similar principles apply for multiple diagnoses
### SINGLE DIAGNOSIS

<table>
<thead>
<tr>
<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>
</tr>
<tr>
<td>• Alternate: Diagnosis and signs/symptoms</td>
<td>• Alternate: Signs/symptoms only (as provisional diagnosis may change)</td>
</tr>
</tbody>
</table>

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"

Similar principles apply for multiple diagnoses
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>
Death and Other Patient Outcomes

- Death is an outcome and is not usually considered an AR/AE

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death due to myocardial infarction</td>
<td>Myocardial infarction</td>
<td>Record death as an outcome in an appropriate data field</td>
</tr>
<tr>
<td>Constipation, ruptured bowel, peritonitis, sepsis; patient died</td>
<td>Constipation Perforated bowel Peritonitis Sepsis</td>
<td>-</td>
</tr>
</tbody>
</table>
Death and Other Patient Outcomes (cont)

- If only information reported is death, select most specific death term available

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient was found dead</td>
<td>Found dead</td>
</tr>
<tr>
<td>Patient died in childbirth</td>
<td>Maternal death during childbirth</td>
</tr>
</tbody>
</table>
Death and Other Patient Outcomes (cont)

- Hospitalization, disability and other patient outcomes are not generally considered ARs/AEs

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalisation due to congestive heart failure</td>
<td>Congestive heart failure</td>
<td>Record hospitalisation as an outcome</td>
</tr>
<tr>
<td>Patient was hospitalised</td>
<td>Hospitalisation</td>
<td>If only information reported is patient outcome, select most specific term available</td>
</tr>
</tbody>
</table>
Suicide and Self-Harm

- Accurate and consistent term selection for reports of suicide attempts, completed suicides, and self-harm is necessary for data retrieval and analysis.
- If suicide attempt is fatal, select term reflecting outcome instead of attempt only.

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suicide attempt resulted in death</td>
<td>Completed suicide</td>
<td>Record death as an outcome</td>
</tr>
</tbody>
</table>
### Conflicting/Ambiguous/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>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”. Since “pain” is definite, select LLT <em>Pain</em>.</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>
What Term to Select?

- Clinical complication of IUD
  IUD complication (PT Medical device complication)?
  Intra-uterine death (PT Intra-uterine death)?
  Unevaluable event?

- Hypoglycemia (blood glucose = 200 mg/dL)
  Blood glucose abnormal?
  Blood glucose increased?
  Hypoglycemia?
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>
What Term to Select?

• Unwitnessed sudden death; found pulseless and apneic
  Sudden death?
  Unattended death?
  Sudden death, cause unknown?
  Pulseless?
  Apnea?

• Stiff neck and shoulders
  Stiff neck? (PT *Musculoskeletal stiffness*)
  Stiffness shoulder? (PT *Musculoskeletal stiffness*)
  *Musculoskeletal stiffness*?
Body Site vs. Event Specificity

- MedDRA term includes body site and event information

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin rash on face</td>
<td>Rash on face</td>
</tr>
</tbody>
</table>

- No MedDRA term that includes body site and event. Event information has priority.

<table>
<thead>
<tr>
<th>Reported</th>
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<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin rash on chest</td>
<td>Skin rash</td>
<td>In this instance, there is no available term for a skin rash on the chest</td>
</tr>
</tbody>
</table>
Body Site vs. Event Specificity (cont)

- No MedDRA term that includes body site and event. Exercise judgment; body site may take priority.

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
</table>
| Cyanosis at injection site| Injection site reaction| Cyanosis implies a generalized disorder. In this example, selecting LLT Cyanosis would result in loss of important medical information and miscommunication.
Body Site vs. Event Specificity (cont)

- If event reported at multiple body sites and all LLTs link to same PT, select a single LLT; the event information has priority

<table>
<thead>
<tr>
<th>Reported</th>
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<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin rash on face and neck</td>
<td>Skin rash</td>
<td>LLT Rash on face and LLT Neck rash both link to PT Rash</td>
</tr>
</tbody>
</table>
Location Specific vs. Microorganism Specific Infection

- MedDRA term includes microorganism and anatomic location

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumococcal pneumonia</td>
<td>Pneumococcal pneumonia</td>
<td>In this example, the implied anatomic location is the lung</td>
</tr>
</tbody>
</table>
Location Specific vs. Microorganism Specific Infection (cont)

- If no MedDRA term includes both microorganism and anatomic location
- Preferred option: select terms for both microorganism specific infection and anatomic location

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory chlamydial infection</td>
<td>Chlamydial infection</td>
<td>Preferred option. Represents both microorganism specific infection and anatomic location</td>
</tr>
<tr>
<td></td>
<td>Respiratory infection</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Represents location-specific infection</td>
</tr>
<tr>
<td></td>
<td>Chlamydial infection</td>
<td>Represents microorganism specific infection</td>
</tr>
</tbody>
</table>
What Term to Select?

- Viral infection of vestibular apparatus
  Labyrinthitis?
  Viral infection?
  Viral labyrinthitis?

- Soft tissue mycosis
  Soft tissue infection?
  Infection mycotic?
  Both terms?
Medical and Surgical Procedures

- Only the procedure is reported

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient had tonsillectomy in childhood</td>
<td>Tonsillectomy</td>
</tr>
</tbody>
</table>

- Procedure and diagnosis are reported

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver transplantation due to liver injury</td>
<td>Liver injury</td>
<td>Preferred Option. Selecting term for the procedure may indicate severity of the condition.</td>
</tr>
<tr>
<td>Liver transplantation</td>
<td>Liver transplantation</td>
<td></td>
</tr>
<tr>
<td>Liver injury</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver injury</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Investigations

- Medical condition vs. investigation result

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypoglycemia</td>
<td>Hypoglycemia</td>
<td>LLT Hypoglycemia links to SOC Metabolism and nutrition disorders</td>
</tr>
<tr>
<td>Decreased glucose</td>
<td>Glucose decreased</td>
<td>LLT Glucose decreased links to SOC Investigations</td>
</tr>
</tbody>
</table>
Investigations (cont)

• Unambiguous investigation result

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose 40 mg/dL</td>
<td>Glucose low</td>
<td>Glucose is clearly below the reference range</td>
</tr>
</tbody>
</table>

• Ambiguous investigation result

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>His glucose was 40</td>
<td>Glucose abnormal</td>
<td>No units have been reported. Select LLT Glucose abnormal if clarification cannot be obtained.</td>
</tr>
</tbody>
</table>
Investigations (cont)

• Investigation results consistent with diagnosis

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elevated potassium, K 7.0 mmol/L, and hyperkalemia</td>
<td>Hyperkalemia</td>
<td>It is not necessary to select LLT Potassium increased</td>
</tr>
</tbody>
</table>

• Grouped investigation result terms

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased alkaline phosphatase, increased SGPT, increased SGOT and elevated LDH</td>
<td>Alkaline phosphatase increased SGPT increased SGOT increased LDH increased</td>
<td>Select four individual terms. A single term such as LLT Liver function tests abnormal should not be selected.</td>
</tr>
</tbody>
</table>
What Term to Select?

- WBCs markedly increased
  WBC increased?
  Leukocytosis?
  Both terms?

- CSF was positive for Candida spp.
  Candidal meningitis?
  Candida test positive?
What Term to Select?

- Sudden onset of fevers up to 105 F
  Temperature elevation?
  Fever?
  Fever of unknown origin?

- Low hemoglobin and hematocrit
  Anemia?
  Hemoglobin low?
  Hematocrit low?
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</td>
<td>Intramuscular formulation administered by other route</td>
<td>If specifically reported that there is no adverse effect, acceptable to</td>
</tr>
<tr>
<td>sequelae</td>
<td>No adverse effect</td>
<td>select LLT <em>No adverse effect</em></td>
</tr>
<tr>
<td>Pharmacist notices that the names of two drugs are similar and is</td>
<td></td>
<td></td>
</tr>
<tr>
<td>concerned that this may result in a medication error</td>
<td><em>Circumstance or information capable of leading to medication error</em></td>
<td><em>LLT Drug name confusion could be an optional additional term to select.</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Note: this example is a potential medication error.</em></td>
</tr>
</tbody>
</table>
Transmission of Infectious Agent via Medicinal Product

- Select term for transmission and term for infection, if identified

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient received a nasal spray product and later developed a severe nasal infection with <em>Burkholderia cepacia</em>. Cultures of unopened containers of the nasal spray grew B. cepacia</td>
<td>Transmission of an infectious agent via a medicinal product <em>Burkholderia cepacia</em> infection</td>
</tr>
<tr>
<td>Patient received a blood transfusion and developed Hepatitis C</td>
<td>Transfusion-transmitted infectious disease Hepatitis C</td>
</tr>
</tbody>
</table>
Transmission of Infectious Agent via Medicinal Product (cont)

• Use medical judgment if reporter does not explicitly state transmission of infectious agent via medicinal product but this could be implied by other data within case

• Select LLT *Suspected transmission of an infectious agent via a medicinal product*

• Use same LLT in E2B field for sender’s diagnosis
Overdose, Toxicity and Poisoning

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

- **Overdose with clinical consequences**

<table>
<thead>
<tr>
<th>Reported</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Stomach upset from study drug overdose</td>
<td>Stomach upset</td>
</tr>
<tr>
<td></td>
<td>Overdose</td>
</tr>
</tbody>
</table>

- **Overdose without clinical consequences**

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient received an overdose of medicine</td>
<td>Overdose</td>
<td>LLT No adverse effect can also be selected</td>
</tr>
<tr>
<td>without any adverse consequences</td>
<td>No adverse effect</td>
<td></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 Insufficient dosage</td>
<td>Product quality issue and medication error</td>
</tr>
</tbody>
</table>
What Term to Select?

- Drug injected IM instead of SC; no sequelae
  Subcutaneous injection formulation administered by other route?
  Incorrect route of drug administration?
  No adverse effect?

- Unintended overdose, dispensing error
  Accidental overdose?
  Adverse event?
  Drug dispensing error?
  Medication error?
What Term to Select?

- Pills do not split correctly along score APACHE II score?
  Tablet issue?
  Scored tablet splitting issue?
- Hair was found inside drug blister pack
  Hair loss?
  Blister infected?
  Product blister packaging issue?
  Product contamination hair?
Points to Consider About MedDRA Term Selection: Points to Consider

• A “living document,” intended to grow and change as MedDRA advances from version to version

• A “companion document” to MedDRA

• Recommended to be used as the basis for individual organizations’ coding conventions
Course Summary

• In this course, we covered:
  - A review of MedDRA’s structure, including primary SOC allocation rules
  - Scope of MedDRA (with practice exercises)
  - Coding conventions, synonym lists, and coding QA
  - Introduction to the *MedDRA Term Selection: Points to Consider* document
  - Coding exercises
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