Introduction to MedDRA: Coding and Data Analysis

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42nd European Cystic Fibrosis Conference
5th June 2019
Preparatory Learning

What do we already know about MedDRA?

1.
2.
3.
4.
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9.
10.
What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities
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.
MedDRA’s Purpose

• Facilitate the exchange of clinical information through standardization

• Important tool for product evaluation, monitoring, communication, electronic records exchange, and oversight

• Supports coding (data entry) and retrieval and analysis of clinical information about human medical products including pharmaceuticals, biologics, vaccines, and drug-device combination products
• As of January 2019
  – 5,700 Subscribing organizations (MSSO+J MO)
  – 122 Countries

• Graph shows types of subscribing organizations
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
- Product use 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) (27)

High Level Group Term (HLGT) (337)

High Level Term (HLT) (1,737)

Preferred Term (PT) (23,708)

Lowest Level Term (LLT) (80,262)
Examples of Cystic Fibrosis Terms

- Other CF terms include
  - Gastrointestinal
  - Hepatic
  - Pancreatic
  - CF gene carrier
Codes and Languages

Cefaleia
Portuguese

Kopfschmerz
German

Hoofdpijn
Dutch

Headache
English

Céphalée
French

Bolest hlavy
Czech

Fejfájás
 Hungarian

Cefalea
Italian

日本頭痛
Japanese

Cefalea
Spanish

Electronic Submission

头痛
Chinese

Головная боль
Russian
• Multi-axial = the representation of a medical concept in multiple SOCs
  – Allows grouping by different classifications
  – Allows retrieval and presentation via different data sets
• All PTs assigned a primary SOC
  – Determines which SOC will represent a PT during cumulative data outputs
  – Prevents “double counting”
  – Supports standardized data presentation
  – Pre-defined allocations should not be changed by users
A Multi-Axial Terminology (cont)

SOC = Respiratory, thoracic and mediastinal disorders (Secondary SOC)

HLGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

PT = Influenza

SOC = Infections and infestations (Primary SOC)

HLGT = Viral infectious disorders

HLT = Influenza viral infections
Rules for Primary SOC Allocation

- PTs represented in only one SOC are automatically assigned that SOC as primary
- 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
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
## Can You Select the Primary SOC for This PT?

<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</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congenital neonatal</td>
<td>Neonatal and perinatal conditions</td>
<td></td>
<td>Pregnancy, puerperium and perinatal conditions</td>
</tr>
<tr>
<td>infections</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retroviral infections</td>
<td>Viral infectious disorders</td>
<td></td>
<td>Infections and infestations</td>
</tr>
<tr>
<td>Acquired immunodeficiency</td>
<td>Immunodeficiency syndromes</td>
<td></td>
<td>Immune system disorders</td>
</tr>
<tr>
<td>syndromes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MSSO’s MedDRA Browsers

• MedDRA Desktop Browser (MDB)
  – Download MDB and release files from MedDRA website

• MedDRA Web-Based Browser (WBB)
  – [https://tools.meddra.org/wbb/](https://tools.meddra.org/wbb/)

• Features
  – Both require MedDRA ID and password
  – View/search MedDRA and SMQs
  – Support for all MedDRA languages
  – Language specific interface
  – Ability to export search results and Research Bin to local file system
MedDRA users have access, as part of their subscription, to a range of powerful computer tools which help to get the most out of the database in addition to the different guides and training available which support implementation and use of MedDRA.

Help Yourself
Get answers to some of your immediate questions via the MedDRA Self-Service Application

Related Documents:
Facilitating MedDRA Use
Related Links:
- Download the Desktop Browsers (MSSO and JMO)
- Open the Web-Based Browser
- Open the MVAT
- Training Materials
- Submit Change (WebCR)
• MedDRA Mobile Browser for use on phones and tablets

• Accessed at: mmb.meddra.org

• Requires your organisation’s MedDRA ID and Password
Coding in everyday life?
Coding in everyday life?
Coding in everyday life?
Coding in everyday life?
<table>
<thead>
<tr>
<th>PtC Category</th>
<th>PtC Document</th>
<th>Purpose</th>
<th>Languages</th>
<th>Release Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Term Selection</td>
<td>MedDRA Term Selection: Points to Consider</td>
<td>Promote accurate and consistent coding with MedDRA</td>
<td>English and Japanese</td>
<td>Updated with each MedDRA release</td>
</tr>
<tr>
<td></td>
<td>MedDRA Term Selection: Points to Consider Condensed Version</td>
<td>Shorter version focusing on general coding principles to promote accurate and consistent use of MedDRA worldwide</td>
<td>All MedDRA languages (except English and Japanese)</td>
<td>Update as needed</td>
</tr>
<tr>
<td>Data Retrieval and Presentation</td>
<td>MedDRA Data Retrieval and Presentation: Points to Consider</td>
<td>Demonstrate how data retrieval options impact the accuracy and consistency of data output</td>
<td>English and Japanese</td>
<td>Updated with each MedDRA release</td>
</tr>
<tr>
<td></td>
<td>MedDRA Data Retrieval and Presentation: Points to Consider Condensed Version</td>
<td>Shorter version focusing on general retrieval and analysis principles to promote accurate and consistent use of MedDRA worldwide</td>
<td>All MedDRA languages (except English and Japanese)</td>
<td>Update as needed</td>
</tr>
<tr>
<td>General</td>
<td>MedDRA Points to Consider Companion Document</td>
<td>More detailed information, examples, and guidance on specific topics of regulatory importance. Intended as a “living” document with frequent updates based on users’ needs. First edition covers data quality and medication errors.</td>
<td>English and Japanese</td>
<td>Updated as needed</td>
</tr>
</tbody>
</table>
MedDRA® TERM SELECTION: POINTS TO CONSIDER
ICH-Endorsed Guide for MedDRA Users

Release 4.17
Based on MedDRA Version 22.0

1 March 2019

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• 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 basis for individual organization’s own coding conventions
• 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
- 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>
Assessing the Reported Information

• Consider what is being reported. Is it a:
  – Clinical condition - Diagnosis, sign or symptom?
  – Indication?
  – Test result?
  – Injury?
  – Procedure?
  – Medication error?
  – Product use issue?
  – Product quality issue?
  – Social circumstance?
  – Device issue?
  – Procedural complication?

  – Is it a combination of these?

The type of report will influence the way you search for a suitable LLT. It may indicate in which SOC you expect to find the closest match.
Narrative vignette

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

The patient suffered from an *allergic reaction to an antibiotic*
Symptoms

The patient states she has been experiencing increasingly frequent episodes of coughing.
Lung function tests indicate a decrease in FEV1 and FVC.
Medication errors

Patient accidentally took drug Y instead of drug X and became short of breath
Patient demographics

A 2 day old baby was noted to have a mild fever
Indications

The patient was prescribed Drug X to prevent *Mycobacterium avium complex lung infection*
Specificity

Following the procedure, the patient experienced several days of constipation
Surgical and medical procedures

His breathing improved markedly with more regular chest physical therapy
Social circumstances

The patient was confined to a wheelchair
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 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)

#### 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>•Preferred: Diagnosis only</td>
<td>•Preferred: Provisional diagnosis and signs/symptoms</td>
</tr>
<tr>
<td>Example: “Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm”</td>
<td>Example: “Possible myocardial infarction with chest pain, dyspnoea, diaphoresis” → select “Myocardial infarction” “Chest pain”, “Dyspnoea”, and “Diaphoresis”</td>
</tr>
</tbody>
</table>

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

Similar principles apply for multiple diagnoses
Diagnoses and Provisional Diagnoses (cont)

- Always include signs/symptoms not associated with diagnosis

<table>
<thead>
<tr>
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<th>LLT Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial infarction, chest pain, dyspnoea, diaphoresis, ECG changes and jaundice</td>
<td>Myocardial infarction Jaundice (note that jaundice is not typically associated with myocardial infarction)</td>
</tr>
</tbody>
</table>
Micro-organism Specific Infection

- Select term to capture infecting micro-organism at specified site

<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>
Micro-organism Specific Infection

- If no appropriate combination term exists, the preferred approach is to select two LLTs for both pathogen and site.
- The alternate approach is to choose to select only one term.

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Preferred Option</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemophilus respiratory</td>
<td>Haemophilus infection</td>
<td>✓</td>
<td>Represents both microorganism-specific infection</td>
</tr>
<tr>
<td></td>
<td>Respiratory infection</td>
<td></td>
<td><em>and</em> anatomic location</td>
</tr>
<tr>
<td></td>
<td>Respiratory infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Haemophilus infection</td>
<td></td>
<td>Represents location-specific infection</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></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>Hyperkalaemia 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>
First, try to obtain more specific information.

<table>
<thead>
<tr>
<th>Reported</th>
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<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 <em>Ill-defined disorder</em> 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>
<tr>
<td>Hepatic function disorder (acute hepatitis)</td>
<td>Hepatitis acute</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>
<tr>
<td>Rash with itching</td>
<td>Itchy rash</td>
</tr>
</tbody>
</table>
• 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>Diarrhoea and vomiting</td>
<td>Diarrhoea Vomiting</td>
</tr>
<tr>
<td>Wrist fracture due to fall</td>
<td>Wrist fracture Fall</td>
</tr>
</tbody>
</table>
• Medical condition vs. investigation result

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypoglycaemia</td>
<td>Hypoglycaemia</td>
<td>LLT <em>Hypoglycaemia</em> links to SOC <em>Metabolism and nutrition disorders</em></td>
</tr>
<tr>
<td>Decreased glucose</td>
<td>Glucose decreased</td>
<td>LLT <em>Glucose decreased</em> links to SOC <em>Investigations</em></td>
</tr>
</tbody>
</table>
### 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>
• 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 hyperkalaemia</td>
<td>Hyperkalaemia</td>
<td>It is not necessary to select LLT <em>Potassium increased</em></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 <em>Liver function tests abnormal</em> should not be selected.</td>
</tr>
</tbody>
</table>
MedDRA Coding Exercise
Which LLT Would You Select?

Verbatim: “Became color blind in adolescence”

A. Color blindness
B. Blindness color
C. Colour blindness acquired
D. Color blindness acquired
Which LLT Would You Select?

Verbatim: “Turned very greasy”

A. Ill-defined disorder
B. Unevaluable event
C. Skin greasy
D. Unevaluable reaction
Which LLT Would You Select?

Verbatim: “Deliberately took an overdose”

A. Intentional overdose
B. Overdose NOS
C. Deliberate overdose
D. Overdose
Which LLT Would You Select?

Verbatim: “Four-year old accidentally took his mother’s medication”

A. Accidental overdose
B. Accidental exposure to product by child
C. Accidental drug intake by child
D. Accidental ingestion
Which LLT Would You Select?

Verbatim: “Infection after surgery”

A. Infection
B. Postoperative wound infection
C. Surgical wound infection
D. Postoperative infection
Which LLT Would You Select?

**Verbatim:** “Had GU”

A. Gastric ulcer
B. Ill-defined disorder
C. GU
D. Unevaluable event
E. Genitourinary tract infection
Which LLT Would You Select?

Verbatim:
“Hypernatraemia (Serum sodium = 115 mEq/L)”

A. Serum sodium abnormal
B. Hypernatraemia
C. Hyponatraemia
D. Serum sodium decreased
Which LLT Would You Select?

Verbatim: “Death from multiple organ failure following haemorrhage post lung transplant”

A. Sudden death
B. Death
C. Multiple organ failure
D. Lung transplant
Which LLT Would You Select?

Verbatim: “Patient was found dead”

A. Death from natural causes
B. Death
C. Died in sleep
D. Found dead
Which LLT Would You Select?

Verbatim: “The hospital diagnosed a perinephric abscess due to Proteus spp.”

A. Proteus infection
B. Perinephric abscess
C. Proteus infection AND Perinephric abscess
D. Abscess bacterial
Which LLT Would You Select?

Verbatim: “Died as a result of a suicide attempt”

A. Suicide gesture
B. Attempted suicide
C. Completed suicide
D. Death
Which LLT Would You Select?

Verbatim: “Abused by her father”

A. Physical abuse
B. Child sexual abuse
C. Child neglect
D. Child abuse
Which LLT Would You Select?

Verbatim: “After taking OTC NSAIDs, along with his prescribed antibiotic, he developed pain in her kidneys.”

A. Adverse reaction to antibiotics
B. Nephrotoxicity
C. Kidney pain
D. Drug interaction
MedDRA Data Retrieval and Presentation: Points to Consider (DRP:PTC)

- Provides data retrieval and presentation options for industry or regulatory purposes
- Most effective when used in conjunction with MedDRA Term Selection: PTC document
- Recommended to be used as basis for individual organization’s own data retrieval conventions

MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER
ICH-Endorsed Guide for MedDRA Users on Data Output

Release 3.17
Based on MedDRA Version 22.0

1 March 2019

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What is a Query?

Patient Registry
Clinical Trial Database
Safety Database

Case
LLT1
LLT2
LLT3

Query
SMQ
PT
LLT
LLT
LLT 1
PT
LLT
LLT
LLT

"Hit"
Query Strategy Tips

- Define the condition
- Develop inclusion/exclusion criteria
- Good browser is key component
- Search “non multi-axial” and “other/support” SOCs
- Search a term’s “neighbors”, including secondary locations
- Use grouping terms where applicable
- Avoid using LLTs (Exception: species information at LLT level in SOC *Infections and infestations*)
- Store for future use
- Review for impact of new MedDRA versions
Complete the Circle
(Connect the DOTSSS!)

- **Diagnosis/disease terms**
- **Operations** (Surgical and medical procedures)
- **Tests** (Investigations)
- **Support SOC's (Other...)**
- **Signs & symptoms**
- **Social circumstances**
Standardised MedDRA Queries (SMQs)

- Collaboration between CIOMS (Council for International Organizations of Medical Sciences) and ICH (MSSO)
- Groupings of terms from one or more MedDRA SOCs related to medical condition or area of interest
- Terms relate to signs/symptoms, diagnoses, syndromes, physical findings, laboratory and other test data, etc.
- Intended to aid in case identification
SMQ Benefits and Limitations

• Benefits
  – Application across multiple therapeutic areas
  – Validated reusable search logic
  – Standardized communication of safety information
  – Consistent data retrieval
  – Maintenance by MSSO/J MO

• Limitations
  – Do not cover all medical topics or safety issues
  – Will evolve and undergo further refinement even though they have been tested during development
SMQ in Production - Examples

• As of Version 22.0, a total of 104 level 1 SMQs in production

  • Agranulocytosis
  • Anaphylactic reaction
  • Cerebrovascular disorders
  • Convulsions
  • Depression and suicide/self-injury
  • Hepatic disorders
  • Hypersensitivity
  • Ischaemic heart disease
  • Lack of efficacy/effect

  • Medication errors
  • Osteonecrosis
  • Peripheral neuropathy
  • Pregnancy and neonatal topics
  • Pseudomembranous colitis
  • Rhabdomyolysis/myopathy
  • Severe cutaneous adverse reactions
  • Systemic lupus erythematosus
MedDRA Term Inclusion

• SMQs are constructed at MedDRA PT level
• LLTs that are subordinate to an included PT are also included
Narrow and Broad Searches

- “Narrow” scope – specificity (cases highly likely to be condition of interest)
- “Broad” scope – sensitivity (all possible cases)
- “Broad search” = All broad + all narrow terms
Narrow vs. Broad Example

SMQ Lactic acidosis

Definition
Lactic acidosis is a form of high anion gap metabolic acidosis. Intrinsic cardiac contractility may be depressed, but inotropic function can be normal because of catecholamine release. Peripheral arterial vasodilatation and central vasoconstriction can be present. Central nervous system function is depressed, with headache, lethargy, stupor, and, in some cases, even coma. Glucose intolerance may occur. Characterized by an increase in plasma L-lactate. Acidosis is seldom significant unless blood lactate exceeds 5 mmol/l. Clinical presentation in type B lactic acidosis: symptoms: hyperventilation or dyspnea, stupor or coma, vomiting, drowsiness, and abdominal pain. Onset of symptoms and signs is usually rapid accompanied by deterioration in the level of consciousness.

Source

Note
Testing in two regulatory databases confirmed that the term list is adequate; in one regulatory database, the term “acidosis” identified cases, but this may be a phenomenon of the database characteristics (coding of verbatims to terms of an older terminology or other coding conventions).
Some SMQs are designed to utilize algorithms

Better case identification among broad search terms may result if cases are selected by a defined combination of selected terms
Algorithmic SMQ Example

- **Anaphylactic reaction (SMQ):**
  - A case with any of the following PTs:
    - Anaphylactic reaction
    - Anaphylactic shock
    - Anaphylactic transfusion reaction
    - Anaphylactoid reaction
    - Anaphylactoid shock
    - Circulatory collapse
    - Dialysis membrane reaction
    - Kounis syndrome
    - Procedural shock
    - Shock
    - Shock symptom
    - Type I hypersensitivity

(Narrow search terms = Category A)
Algorithmic SMQ Example (cont)

<table>
<thead>
<tr>
<th>Category B - Upper airway/ Respiratory</th>
<th>Category C - Angioedema/ Urticaria, etc.</th>
<th>Category D - Cardiovascular/ Hypotension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute respiratory failure</td>
<td>Allergic oedema</td>
<td>Blood pressure decreased</td>
</tr>
<tr>
<td>Asthma</td>
<td>Angioedema</td>
<td>Blood pressure diastolic decreased</td>
</tr>
<tr>
<td>Bronchial oedema</td>
<td>Erythema</td>
<td>Blood pressure systolic decreased</td>
</tr>
</tbody>
</table>

- Case = A (Narrow terms)
- Or Term from Category B and term from Category C
- Or Term from either Category B or Category C plus Term from Category D
Hierarchical SMQs

- Some SMQs may develop as a set of queries related to one another in a hierarchical relationship.
- Not related to MedDRA standard hierarchy.
- One or more subordinate SMQs combined to create a superordinate, more inclusive SMQ.
Hierarchical SMQ Example

- Haematopoietic cytopenias
  - Haematopoietic cytopenias affecting more than one type of blood cell
  - Haematopoietic erythronopenia
  - Haematopoietic leukopenia
  - Haematopoietic thrombocytopenia
Browser Demonstration SMQ View
MedDRA Training Opportunities
– Available for Users

• Free Face-to-Face (F2F) training
  – Coding with MedDRA
  – Safety Data Analysis and Standardised MedDRA Queries
  – Getting Started with MedDRA

• Free webinars
  – Getting Started with MedDRA
  – MedDRA Overview
  – MedDRA Coding Basics
  – Advanced MedDRA Coding
  – Data Analysis and Query Building with MedDRA
  – Standardised MedDRA Queries
  – What’s New with MedDRA (with each MedDRA release)
Registration for Training

MedDRA
Medical Dictionary for Regulatory Activities

Schedule

The description, training materials and online registration form for each training event are available from the schedule below by clicking on the convenient event.

Note: Face-to-Face classes are posted under the Face-to-Face training tab. Webinars are posted under the Webinars tab.

MSSO Cancellation Policies:

Courses: The MSSO reserves the right to cancel any scheduled training event. The MSSO is not responsible for expenditures made for travel arrangements. It is recommended that travel arrangements not be made prior to two weeks before the scheduled event.

Registration: If an individual's cancellation notification is not received in advance, the MSSO will consider revoking an individual's access to future face training sessions.

For comprehensive training in MedDRA application in coding and analysis, we recommend users attend both the Coding with MedDRA and MedDRA: Safety Data Analysis and SMQs courses.

Waiting List Status for MedDRA Training Events:

If you register for a MedDRA training course and are placed on the waiting list for that course, you will be contacted if space becomes available. If space is not available, your registration will not roll over to a future course. You must re-register for each subsequent course.

Training Certificates:

Attendees of the face-to-face training sessions receive a certificate of course completion. This certificate can be downloaded and printed from the MedDRA Self-Service Application. Certificates are not provided for participation in MedDRA training webinars.

MedDRA Training

<table>
<thead>
<tr>
<th>MAY 22/2019</th>
<th>Face-to-Face Training - Coding with MedDRA</th>
<th>MAY 23/2019</th>
<th>Face-to-Face Training - MedDRA: Safety Data Analysis and SMQs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 left</td>
<td>Sunnyvale, California, USA</td>
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<td>Sunnyvale, California, USA</td>
</tr>
<tr>
<td>MAY 28/2019</td>
<td>Face-to-Face Training - Coding with MedDRA</td>
<td>MAY 29/2019</td>
<td>Face-to-Face Training - Coding with MedDRA</td>
</tr>
<tr>
<td>0 left</td>
<td>Chaozhou District, Beijing, China</td>
<td>0 left</td>
<td>Chaozhou District, Beijing, China</td>
</tr>
</tbody>
</table>

Training Statistics for 2018:
71 face-to-face classes attended by 2,753 attendees from 10 countries. 25 webinars with 2,584 connections from 57 countries.

Help Yourself
Get answers to some of your immediate questions via the MedDRA Self-Service Application

User Comments on MedDRA Training:

"I thoroughly enjoyed the coding course and having both lectures and hands-on exercises was a fantastic way to learn."

"A really informative course, presented in an accessible and cogent way. I would highly recommend both the course and the instructor."
MedDRA Training Opportunities
– Available to All

• Free resources on MedDRA website
  – Slides for all F2F courses and webinars
  – Short videocasts on MedDRA-related topics
    • Available in several languages
    • Can be downloaded or viewed directly on website
    • Help trainees prepare for F2F courses
• Webinars and videocasts available on new MedDRA MSSO YouTube Channel
More Resources for MedDRA Users

- MedDRA website
  - Help Desk
  - Subscriptions
  - News and Events
  - MedDRA Best Practices document
  - Points to Consider documents
  - Terminology downloads
  - Training
  - Tools
  - MedDRA publications
  - User group meetings
  - Expert meetings
MSSO Contacts

• Website
  – www.meddra.org

• Email
  – mssohelp@meddra.org

• Frequently Asked Questions
  – www.meddra.org/faq