

Summary of Changes to

**MedDRA[®] TERM SELECTION:
POINTS TO CONSIDER**

ICH-Endorsed Guide for MedDRA Users

***Release 4.9
Based on MedDRA Version 18.0***

1 March 2015

The following is a listing of changes made between releases 4.8 and 4.9 of the *MedDRA Term Selection: Points to Consider* document:

Throughout document

- 1) Correction of general spelling, punctuation, spacing, and format errors
- 2) Replacement of references to MedDRA Version 17.1 to Version 18.0
- 3) Update of examples based on MedDRA version changes

2.4 – Always Select a Lowest Level Term

The Example table:

Example

Reported	LLT Selected
Lip sore	Lip sore (PT Lip pain)
Lip sores	Sores lip (PT Cheilitis)
Sore gums	Sore gums (PT Gingival pain)
Sores gum	Sores gum (PT Gingival inflammation)

Was changed as follows (note the change of PT *Gingival inflammation* to PT *Noninfective gingivitis*, related to MedDRA version changes):

Example

Reported	LLT Selected
Lip sore	Lip sore (PT <i>Lip pain</i>)
Lip sores	Sores lip (PT <i>Cheilitis</i>)
Sore gums	Sore gums (PT <i>Gingival pain</i>)
Sores gum	Sores gum (PT <i>Noninfective gingivitis</i>)

3.3.2 If self-injury is reported

The Example table:

Example

Reported	LLT Selected	Comment
Self slashing	Self inflicted laceration	LLT <i>Self inflicted laceration</i> is linked to PT <i>Intentional self-injury</i>
Cut her own wrists		
Cut wrists in a suicide attempt	Suicide attempt	In addition, LLT <i>Self inflicted laceration</i> can be selected
Took an overdose in an attempt to commit suicide	Intentional overdose Suicide attempt	If overdose is reported in the context of suicide or a suicide attempt, the more specific LLT <i>Intentional overdose</i> can be selected (see also Section 3.18)

Was changed as follows (note that Self inflicted laceration has been moved from the Comment column to the LLT Selected column for the second example):

Example

Reported	LLT Selected	Comment
Self slashing	Self inflicted laceration	LLT <i>Self inflicted laceration</i> is linked to PT <i>Intentional self-injury</i>
Cut her own wrists		
Cut wrists in a suicide attempt	Self inflicted laceration Suicide attempt	.
Took an overdose in an attempt to commit suicide	Intentional overdose Suicide attempt	If overdose is reported in the context of suicide or a suicide attempt, the more specific LLT <i>Intentional overdose</i> can be selected (see also Section 3.18)

3.10.1 Events in the mother

There were several changes made to this section of the document to provide examples of term selection and to identify a preferred option for exposures without clinical consequences.

The wording and examples in this section were replaced with the following:

3.10.1 Events in the mother

3.10.1.1. Pregnant patient exposed to medication with clinical consequences

If a pregnancy exposure is reported with clinical consequences, select terms for both the pregnancy exposure and the clinical consequences.

Example

Reported	LLT Selected
Pregnant patient receiving drug X experienced a pruritic rash	Maternal exposure during pregnancy Pruritic rash

3.10.1.2 Pregnant patient exposed to medication without clinical consequences

If a pregnancy exposure report specifically states that there were no clinical consequences, the **preferred option** is to select only a term for the pregnancy exposure. Alternatively, a term for the pregnancy exposure and the additional LLT *No adverse effect* can be selected (see Section 3.21).

Example

Reported	LLT Selected	Preferred Option
Patient received drug X while pregnant (no adverse effect)	Maternal exposure during pregnancy	✓
	Maternal exposure during pregnancy No adverse effect	

3.15 – Medication Errors, Accidental Exposures and Occupational Exposures

There were several changes made to this section of the document to provide examples of term selection and to identify a preferred option for medication errors and potential medication errors without clinical consequences.

First, the section name:

3.15 – Medication Errors/Administration Errors, Accidental Exposures and Occupational Exposures

Was changed as follows:

3.15 – Medication Errors, Accidental Exposures and Occupational Exposures

Second, the section name:

3.15.1 Medication/administration errors

Was changed as follows:

3.15.1 Medication errors

3.15.1.1 Medication errors reported with clinical consequences

The Example table:

Example

Reported	LLT Selected	Comment
Patient was administered wrong drug and experienced hypotension	Wrong drug administered Hypotension	
Because of similar sounding drug names, the patient took the wrong drug and experienced a rash	Drug name confusion Wrong drug administered Rash	
Insulin was given using the wrong syringe resulting in the administration of an overdose. The patient developed hypoglycaemia.	Wrong device used Accidental overdose Hypoglycaemia	If an overdose is reported in the context of a medication error, the more specific term <i>LLT Accidental overdose</i> can be selected (see also Section 3.18)

Was changed as follows (note the changes and the addition of a comment to the second example):

Example

Reported	LLT Selected	Comment
Patient was administered wrong drug and experienced hypotension	Wrong drug administered Hypotension	
Because of similar sounding drug names, the wrong drug was dispensed; as a result, the patient took the wrong drug and experienced a rash	Drug name confusion Wrong drug dispensed Wrong drug administered Rash	It is important to select terms for all medication error concepts, i.e., do not subtract information
Insulin was given using the wrong syringe resulting in the administration of an overdose. The patient developed hypoglycaemia.	Wrong device used Accidental overdose Hypoglycaemia	If an overdose is reported in the context of a medication error, the more specific term <i>LLT Accidental overdose</i> can be selected (see also Section 3.18)

3.15.1.2 Medication errors and potential medication errors reported without clinical consequences

The wording and Example tables in this section:

Medication errors without clinical consequences are not ARs/AEs. However, it is important to record the occurrence or **potential** occurrence of a medication error. Select a term that is closest to the description of medication error reported.

Also, if specifically reported that no adverse effect has occurred, it is acceptable to select LLT *No adverse effect*.

In instances where the medication did not reach the patient, it is acceptable to select LLT *Drug not taken in context of intercepted medication error*.

Example

Reported	LLT Selected	Comment
Medication was given intravenously instead of intramuscularly	Intramuscular formulation administered by other route	
Medication was given intravenously instead of intramuscularly without sequelae	Intramuscular formulation administered by other route No adverse effect	See Section 3.21

The pharmacist selected the wrong drug strength but the error was detected prior to dispensing to the patient	Intercepted wrong drug strength selected	LLT <i>Intercepted wrong drug strength selected</i> links to PT <i>Intercepted drug dispensing error</i>
Pharmacist notices that the names of two drugs are similar and is concerned that this may result in a medication error	Drug name confusion Circumstance or information capable of leading to medication error	Note: this example is a potential medication error and LLT <i>Drug name confusion</i> provides additional information about the nature of the potential medication error
Drug inadvertently administered. The error was noticed soon afterwards.	Drug administration error	

Were changed as follows (note that a preferred option – to select only a term for the medication error – is now identified and examples of intercepted medication errors have been deleted):

Medication errors without clinical consequences are not ARs/AEs. However, it is important to record the occurrence or **potential** occurrence of a medication error. Select a term that is closest to the description of medication error reported.

If a medication error report specifically states that there were no clinical consequences, the **preferred option** is to select only a term for the medication error. Alternatively, a term for the medication error and the additional LLT *No adverse effect* can be selected (see Section 3.21).

Example

Reported	LLT Selected	Preferred Option
Medication was given intravenously instead of intramuscularly without sequelae	Intramuscular formulation administered by other route	✓
	Intramuscular formulation administered by other route No adverse effect	

Example

Reported	LLT Selected	Comment
Pharmacist notices that the names of two drugs are similar and is concerned that this may result in a medication error	Drug name confusion Circumstance or information capable of leading to medication error	Note: this example is a potential medication error and LLT <i>Drug name confusion</i> provides additional information about the nature of the potential medication error
Drug inadvertently administered. The error was noticed soon afterwards.	Drug administration error	

3.15.1.3 Medication monitoring errors

The concept description for medication monitoring error:

For the purposes of term selection and analysis of MedDRA-coded data, a medication monitoring error is an error that occurs in the process of monitoring the effect of the medication through clinical assessment and/or laboratory data. It can also refer to errors in following instructions or information pertinent to the safe use of the medication.

Was changed as follows (note the addition of the word “monitoring” in the second sentence. This concept description has also been updated in the MedDRA Introductory Guide and the Web-Based Browser):

For the purposes of term selection and analysis of MedDRA-coded data, a medication monitoring error is an error that occurs in the process of monitoring the effect of the medication through clinical assessment and/or laboratory data. It can also refer to monitoring errors in following instructions or information pertinent to the safe use of the medication.

The wording and term examples for medication errors in the context of labelled interactions:

If the label describes **known effects** when the product is co-administered with specific drugs, with specific foods, or to patients with specific disease states, then select a medication error term for the type of interaction, such as those listed below:

Medication Error Terms – Labelled Interactions
Labelled drug-drug interaction medication error Labelled drug-food interaction medication error Labelled drug-disease interaction medication error Documented hypersensitivity to administered drug

Were changed as follows (note the change of Documented hypersensitivity to administered drug to Documented hypersensitivity to administered product – a new term added in MedDRA Version 18.0):

If the label describes **known effects** when the product is co-administered with specific drugs, with specific foods, or to patients with specific disease states, and if the report does not indicate that this is intentional misuse or intentional off label use, then select a medication error term for the type of interaction, such as those listed below:

Medication Error Terms – Labelled Interactions
Labelled drug-drug interaction medication error Labelled drug-food interaction medication error Labelled drug-disease interaction medication error Documented hypersensitivity to administered product

3.15.1.4 Do not infer a medication error

The Example table:

Reported	LLT Selected	Comment
Antibiotic was prescribed for a week, and the patient stopped treatment after 2 days because of bitter taste	Prescribed dosing duration not completed Taste bitter	LLT <i>Taste bitter</i> represents a sensory perception issue. LLT <i>Medication after taste</i> refers to a product quality issue
Incorrect dosing by patient	Incorrect dose administered	Do not select <i>Extra dose administered</i> or <i>Overdose</i> based on this information alone
Patient took only half the prescribed dose	Underdose	

Was changed as follows (note the deletion of the first two examples and the addition of a comment to the underdose example):

Example

Reported	LLT Selected	Comment
Patient took only half the prescribed dose	Underdose	Based on this report, it is not known whether the underdose is intentional or accidental. If information is available, select the more specific LLT <i>Accidental underdose</i> or LLT <i>Intentional underdose</i> as appropriate.

3.16 – Misuse, Abuse and Addiction

The table and wording in this section:

Concept	Intentional?	By Whom?	Therapeutic Use?	Additional Sections in this Document
Misuse	Yes	Patient/consumer	Yes	3.16.1
Abuse	Yes	Patient/consumer	No	3.16.2
Addiction	Yes	Patient/consumer	No	3.16.3
Medication error	No	Patient/consumer or healthcare provider	Yes	3.15
Off label use	Yes	Healthcare provider	Yes	3.27

Was changed as follows (note the addition of a footnote regarding the definitions of misuse and additional wording regarding term selection):

Concept	Intentional?	By Whom?	Therapeutic Use?	Additional Sections in this Document
Misuse	Yes	Patient/consumer	Yes*	3.16.1
Abuse	Yes	Patient/consumer	No	3.16.2
Addiction	Yes	Patient/consumer	No	3.16.3
Medication error	No	Patient/consumer or healthcare provider	Yes	3.15
Off label use	Yes	Healthcare provider	Yes	3.27

* Definitions of misuse may not always include the concept of therapeutic use; misuse may be similar to the concept of abuse in some regions.

Select the most specific term available and always check the MedDRA hierarchy above the selected term to be sure it is appropriate for the reported information. In some cases, it may be appropriate to select more than one MedDRA LLT to represent the reported information.

3.16.1 Misuse

The Example table:

Example

Reported	LLT Selected
Patient deliberately ingested the topical medication	Intentional use by incorrect route
Patient deliberately took the medication for two days longer than instructed on the product label	Intentional use beyond labelled duration

Was changed as follows (note the deletion of the first example and change to the second example):

Example

Reported	LLT Selected
Patient deliberately took the medication twice daily instead of once daily	Intentional misuse in dosing frequency

3.18 – Overdose, Toxicity and Poisoning

The Example table:

Example

Reported	LLT Selected	Comment
Overdose of pills	Overdose	
A child was accidentally poisoned when she ingested a chemical cleaning product	Accidental poisoning Chemical poisoning	
Patient deliberately took an overdose of analgesic pills to treat his worsening arthritis	Intentional overdose	LLT <i>Arthritis aggravated</i> can be selected as the indication for treatment
The dose of drug X taken was above the recommended maximum dose in the label	Drug overdose	
Nurse inadvertently administered an additional vaccine dose to an already vaccinated child	Inappropriate dose of vaccine administered	Please note that LLT <i>Inappropriate dose of vaccine administered</i> is a maladministration term, not specifically an overdose term

Was changed as follows (note the changes to the first and fourth examples):

Example

Reported	LLT Selected	Comment
Patient took an overdose	Overdose	Based on this report, it is not known whether the overdose is intentional or accidental. If information is available, select the more specific LLT <i>Accidental overdose</i> or LLT <i>Intentional overdose</i> as appropriate.

Reported	LLT Selected	Comment
A child was accidentally poisoned when she ingested a chemical cleaning product	Accidental poisoning Chemical poisoning	
Patient deliberately took an overdose of analgesic pills to treat his worsening arthritis	Intentional overdose	LLT <i>Arthritis aggravated</i> can be selected as the indication for treatment
The dose taken was above the recommended maximum dose in the label	Overdose	Based on this report, it is not known whether the overdose is intentional or accidental. If information is available, select the more specific LLT <i>Accidental overdose</i> or LLT <i>Intentional overdose</i> as appropriate.
Nurse inadvertently administered an additional vaccine dose to an already vaccinated child	Inappropriate dose of vaccine administered	Please note that LLT <i>Inappropriate dose of vaccine administered</i> is a maladministration term, not specifically an overdose term

3.19.2 Device-related event reported without clinical consequences

The Example table:

Example

Reported	LLT Selected
Medical device breakage	Device breakage
My patch is leaking on my arm	Leaking patch
My patch is not sticking to my skin	Medicinal patch adhesion issue

Was changed as follows (note the deletion of the third example):

Example

Reported	LLT Selected
Medical device breakage	Device breakage
My patch is leaking on my arm	Leaking patch

3.27 – Off Label Use

The wording in this section:

The concept of “off label use” relates to situations where the product is intentionally used for a medical purpose not in accordance with the authorised product information.

Was changed as follows (note the addition of a second sentence):

The concept of “off label use” relates to situations where the product is intentionally used for a medical purpose not in accordance with the authorised product information. When recording off label use, consider that product information and/or regulations/requirements may differ between regulatory regions.

3.27.1 Off label use when reported as an indication

The wording in this section:

If a medical condition is reported as an indication **along with “off label use”**, the **preferred option** is to select terms for the medical condition and LLT *Off label use* or other appropriate LLTs linked to PT *Off label use*. Alternatively, select a term for the medical condition/indication alone. Select LLT *Off label use* alone **only** if it is the only information available.

Was changed as follows (note the use of “medical condition/indication” to indicate that these are the same concept):

If a medical condition/indication is reported **along with “off label use”**, the **preferred option** is to select terms for the medical condition/indication and off label use. Alternatively, select a term for the medical condition/indication alone. Select LLT *Off label use* alone **only** if it is the only information available.

The Example table:

Example

Reported	LLT Selected	Comment
Used off label	Off label use	
Off label use in paediatric patients	Drug use in unapproved population	Refers to a population of patients
Drug X given to a 10 year old boy; the drug is not indicated for use below 18 years	Adult product administered to child	LLT <i>Adult product administered to child</i> is linked to PT <i>Off label use</i>

Was changed as follows (note the deletion of the second and third examples):

Example

Reported	LLT Selected
Used off label	Off label use

3.27.2 Off label use when reported with an AR/AE

The wording in this section:

If an AR/AE occurs in the setting of off label use for a medical condition, the **preferred option** is to select LLT *Off label use*, or other appropriate LLTs linked to PT *Off label use*, and a term for the medical condition in addition to a term for the AR/AE. Alternatively, select a term for the medical condition and a term for the AR/AE.

Was changed as follows (note the use of “medical condition/indication” to indicate that these are the same concept):

If an AR/AE occurs in the setting of off label use for a medical condition/indication, the **preferred option** is to select LLT *Off label use*, or other appropriate LLTs linked to PT *Off label use*, and a term for the medical condition/indication in addition to a term for the AR/AE. Alternatively, select a term for the medical condition/indication and a term for the AR/AE.

3.28.1 Product quality Issue reported with clinical consequences

The Example table:

Example

Reported	LLT Selected
New bottle of drug tablets have unusual chemical smell that made me nauseous	Product odour abnormal Nauseous
I switched from one brand to another of my blood pressure medication, and I developed smelly breath	Product substitution issue brand to brand Smelly breath
Consumer noted that the toothpaste they had purchased did not taste like normal. Subsequent investigation of the product lot number revealed that the toothpaste was a counterfeit product.	Product counterfeit Product taste abnormal

Was changed as follows (note change to the third example):

Example

Reported	LLT Selected
New bottle of drug tablets have unusual chemical smell that made me nauseous	Product odour abnormal Nauseous
I switched from one brand to another of my blood pressure medication, and I developed smelly breath	Product substitution issue brand to brand Smelly breath
Consumer noted that the toothpaste they had purchased caused a stinging sensation in the mouth. Subsequent investigation of the product lot number revealed that the toothpaste was a counterfeit product.	Product counterfeit Stinging mouth

3.28.3 Product quality issue vs. medication error

The Example table:

Example

Reported	LLT Selected	Comment
Pharmacist dispensing Drug A inadvertently attached a product label for Drug B	Wrong label placed on medication during dispensing	Medication error
The drug store clerk noted that the wrong product label was attached to some bottles in a shipment of mouthwash	Product label on wrong product	Product quality issue
The mother administered insufficient amount of prescribed antibiotic because the lines on the dropper were hard to read	Product dropper calibration unreadable Insufficient dosage	Product quality issue and medication error

Was changed as follows (note change to the third example):

Example

Reported	LLT Selected	Comment
Pharmacist dispensing Drug A inadvertently attached a product label for Drug B	Wrong label placed on medication during dispensing	Medication error
The drug store clerk noted that the wrong product label was attached to some bottles in a shipment of mouthwash	Product label on wrong product	Product quality issue
The mother administered an underdose of antibiotic because the lines on the dropper were hard to read	Product dropper calibration unreadable Accidental underdose	Product quality issue and medication error. If underdose is reported in the context of a medication error, the more specific LLT <i>Accidental underdose</i> can be selected.

4.3.1 Current members of the ICH Points to Consider Working Group

The table of current members was replaced and updated as follows:

Affiliation	Member
Commission of the European Communities	Maria Luisa Casini
	Kavita Chadda
European Federation of Pharmaceutical Industries and Associations	Hilary Vass*
	Christina Winter [†]
Health Canada	Alison Bennett
	Polina Ostrovsky
	Lynn Macdonald
Japanese Maintenance Organization	Yutaka Nagao
	Kazuyuki Sekiguchi
	Mitsuru Takano
	Reiji Tezuka
Japan Pharmaceutical Manufacturers Association	Yo Tanaka
	Hitomi Takeshita
MedDRA MSSO	Judy Harrison
Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency	Yuhei Fukuta
	Miki Ohta
	Daisuke Sato
	Makiko Isozaki
	Kiyomi Ueno
Pharmaceutical Research and Manufacturers of America	Milbhor D'Silva
	JoAnn Medbery
US Food and Drug Administration	Sonja Brajovic [#]
	Christopher Breder
Ministry of Food and Drug Safety, Korea	YuBin Lee
	Kyung-Eun Yoon
World Health Organization	Daisuke Tanaka

* Current Rapporteur

Regulatory Chair

[†] Former Rapporteur

4.3.2 Former members of the ICH Points to Consider Working Group

The table of former members was replaced and updated as follows:

Affiliation	Member
Commission of the European Communities	Dolores Montero; Carmen Kreft-Jais; Morell David; Sarah Vaughan
European Federation of Pharmaceutical Industries and Associations	Barry Hammond [†] ; Reinhard Fescharek [†]
Health Canada	Heather Morrison; Michelle Séguin; Heather Sutcliffe; Bill Wilson
Japanese Maintenance Organization	Osamu Handa; Akemi Ishikawa; Yasuo Sakurai; Yuki Tada
Japan Pharmaceutical Manufacturers Association	Takayoshi Ichikawa; Akemi Ishikawa; Satoru Mori; Yasuo Sakurai; Kunikazu Yokoi
MedDRA MSSO	JoAnn Medbery; Patricia Mozzicato
Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency	Tamaki Fushimi; Wakako Horiki; Sonoko Ishihara; Kazuhiro Kemmotsu; Tatsuo Kishi; Chie Kojima; Emiko Kondo; Hideyuki Kondou; Kemji Kuramochi; Tetsuya Kusakabe; Kaori Nomura; Izumi Oba; Shinichi Okamura; Yoshihiko Sano; Nogusa Takahara; Kenichi Tamiya; Daisuke Tanaka; Shinichi Watanabe; Takashi Yasukawa; Go Yamamoto; Manabu Yamamoto; Nobuhiro Yamamoto
Pharmaceutical Research and Manufacturers of America	David Goldsmith; Sidney Kahn; Anna-Lisa Kleckner; Susan M. Lorenski; Margaret M. Westland [†]
US Food and Drug Administration	Miles Braun; Andrea Feight; John (Jake) Kelsey [†] ; Brad Leissa; Toni Piazza-Hepp

[†] Former Rapporteur