Adverse Event Terminology and Coding Working Group

March 2019

Working Group Chair:
H. Ishikawa
Office of Standards and Compliance for Medical Devices 
Pharmaceuticals and Medical Devices Agency
Overview of IMDRF AE WG

Initial submission: September 2014
Not adopted
Followed by discussions in the small expert WG
Adoption: March 2015

Mission;
Development of a harmonized terminology for reporting adverse events related to medical devices including in-vitro diagnostics (IVDs).

Purpose;
To improve the efficiency of the adverse event management systems for faster response by both industry and regulatory agencies, with the use of a single, appropriate adverse event terminology and coding system.
Benefits:

- Improved accuracy of capturing and reporting of medical device related adverse events,
- Reduced ambiguity, hence increased effectiveness of the evaluation process, and
- Better usability, in contrast to narrative text;

for

- More sophisticated signal detection (i.e. the identification of potential novel risks), and
- Trending analysis by incident management systems including advanced querying functions and data visualization.

Thus enabling a faster response by both regulatory agencies and device manufacturers.
Member list

Australia: TGA
- Pamela Carter
- Jorge Garcia

Brazil: ANVISA
- Maria Gloria Vicente
- Adriana Moufarrege
- Sheila Martins Cordovil
- Carla Cruz

Canada: Health Canada
- Richard McAteer
- Tanya Hiebert
- Leanne Moore

European Union:
- Jean-François Roche (EC)
- Tony Sant (UK, MHRA)
- Claudius Griesinger (EC/JRC)
- Graham Nash (UK, MHRA)
- Tim Raemaekers (EC/JRC)
- Juan Antonio Blasco Amaro (EC/JRC)
- Dimitrios Panidis (EC/JRC)
- Robin Seidel (BfArM- Germany)

Russia: Roszdravnadzor
- Aysylu Valeeva
- Elena Astapenko
- Yaroslav Kurtkov

WHO: Anita Sands

Japan: PMDA
- Hiroshi Ishikawa (Chair)
- Mari Shirotani
- Madoka Murakami
- Miho Sato
- Tsutomu Makino
- Takako Niwa
- Toru Takahashi
- Kaori Ogawa
- Yukari Namba
- MHLW Ryo Iwase
- Akimasa Takeuchi

US: FDA
- Nancy Pressly
- Evan Jacobs

Singapore: HSA
- Woei Jiuang Wong
- Lailing Liew

South Korea: MFDS
- Hyeonho Kim

AHWP:
- Sasikala Devi Thangavelu
- Azat Iskaliyev
- Dinara Esbolatova
- Gulnar Berkimbayeva
Recent Meetings

• April 16th – 20th, 2018
  6th Face to Face meeting in Canberra, Australia
• Nov 14th, 2018
  21st Teleconference
• Nov 26th – 30th, 2018
  7th Face to Face meeting in Singapore
• Feb 20th, 2019
  22nd Teleconference

Coming Meetings

• March 26th- 29th, 2019
  8th Face to Face meeting in Brazil
Adverse Event Reporting

DEVICE/COMPONENTS

Medical Device Problem (Annex A)

What was the problem at device level?

Component (Annex G)

Which components were involved

Cause Investigation (Annex B-D)

What were the probable causes of the problem

PATIENT

Health Effects (Annex E, F)
(Previously “Patient Problem”)

What adverse events happened at patient level
Title: IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes


Annex A (Medical Device Problem): published with mapping on April 10th in 2017; Sep. 21st in 2017 (Edition2)

Annex B – D (Cause Investigation): published with mapping on Sep. 21st in 2017

Annex E, F (Health Effects): submitted for approval as Final Document

Annex G (Component): Under discussion
Annex E and F: Health Effects Terms and Codes

- Based on FDA terms and refers to MedDRA
  
  As a response to some public comments, the WG has decided to provide mapping information with MedDRA terms/codes, cooperating with MedDRA.

- 2 annexes

  Annex E: Clinical Signs, Symptoms and Conditions (3 levels)
  (Structured according to Organ / Physiological system)

  Annex F: Health Impact (3 levels)
  (e.g., death, hospitalization, unexpected medical intervention)

- Consists of IMDRF codes, terms and definitions
- Coding principles are the same as Annex A-D.
Annex E and F: Health Effects Terms and Codes

**Annex E**  Clinical Signs, Symptoms and Conditions

- e.g. Paralysis
- Keratitis
- Burn
- Fracture

Category (Level 1)
(Organs, Systems, Disorders, Concepts)

**Annex F**  Health Impact

- e.g. Death
- Delay to Diagnosis/Treatment/Therapy
- Hospitalisation or Prolonged Hospitalisation
- Inadequate/Inappropriate Treatment
- Minor Injury/ Illness/Impairment
- Serious Public Health Treat/Injury/Illness/Impairment
- Misdiagnosis/Misclassification
- Intervention/Medical Intervention
## Annex E: Clinical Signs, Symptoms and Conditions

### No./ Category (Level 1) (Organs, Systems, Disorders, Concepts)

<table>
<thead>
<tr>
<th>No.</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Nervous System</td>
</tr>
<tr>
<td>2.</td>
<td>Mental, Emotional and Behavioural Disorders</td>
</tr>
<tr>
<td>3.</td>
<td>Blood and Lymphatic System</td>
</tr>
<tr>
<td>4.</td>
<td>Immune System</td>
</tr>
<tr>
<td>5.</td>
<td>Vascular System</td>
</tr>
<tr>
<td>6.</td>
<td>Heart</td>
</tr>
<tr>
<td>7.</td>
<td>Respiratory System</td>
</tr>
<tr>
<td>8.</td>
<td>Eye</td>
</tr>
<tr>
<td>9.</td>
<td>Ear and Labyrinth</td>
</tr>
<tr>
<td>10.</td>
<td>Gastrointestinal System</td>
</tr>
<tr>
<td>11.</td>
<td>Hepatic and Biliary System</td>
</tr>
<tr>
<td>12.</td>
<td>Metabolism and Nutrition</td>
</tr>
<tr>
<td>13.</td>
<td>Kidney and Urinary Tract</td>
</tr>
<tr>
<td>14.</td>
<td>Reproductive System and Breast</td>
</tr>
<tr>
<td>15.</td>
<td>Pregnancy, Childbirth and the Puerperium</td>
</tr>
<tr>
<td>16.</td>
<td>Musculoskeletal System</td>
</tr>
<tr>
<td>17.</td>
<td>Skin and Subcutaneous Tissue</td>
</tr>
<tr>
<td>18.</td>
<td>Neoplasms Benign, Malignant and Unspecified</td>
</tr>
<tr>
<td>19.</td>
<td>Infections</td>
</tr>
<tr>
<td>20.</td>
<td>Injury</td>
</tr>
<tr>
<td>21.</td>
<td>Procedural Complications</td>
</tr>
<tr>
<td>22.</td>
<td>Investigations and Diagnostic Tests</td>
</tr>
<tr>
<td>23.</td>
<td>General Disorders</td>
</tr>
<tr>
<td>24.</td>
<td>Others</td>
</tr>
</tbody>
</table>

LIST (all terms in one sheet)
• Categories are treated as Level 1 with codes but not used for reporting. Categories do not have definitions.
• Basic coding principle is the same as other Annexes.

E XX XX XX

• The Annex E excel file has a tab with all terms (LIST) and tabs for each category.
• For term which exists in a secondary place, its code is linked to the primary code.
## Annex F: Health Impact

<table>
<thead>
<tr>
<th>Level 1 terms</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in Therapeutic Response</td>
<td>Recognised Device or Procedural Complication</td>
</tr>
<tr>
<td>Death</td>
<td>Reduction in Life Expectancy</td>
</tr>
<tr>
<td>Brain Death</td>
<td>Sedation</td>
</tr>
<tr>
<td>Delay to Diagnosis</td>
<td>Rehabilitation</td>
</tr>
<tr>
<td>Delay to Treatment/ Therapy</td>
<td>Surgical Intervention</td>
</tr>
<tr>
<td>Disruption of Subsequent Medical Procedure</td>
<td>Serious Public Health Threat</td>
</tr>
<tr>
<td>Exacerbation of Existing Condition</td>
<td>Unexpected Deterioration</td>
</tr>
<tr>
<td>Hospitalization or Prolonged Hospitalization</td>
<td>Unexpected Diagnostic Intervention</td>
</tr>
<tr>
<td>Fetal Harm</td>
<td>Unexpected Medical Intervention</td>
</tr>
<tr>
<td>Inadequate/Inappropriate Treatment or Diagnostic Exposure</td>
<td>Insufficient Information</td>
</tr>
<tr>
<td>Minor Injury/ Illness / Impairment</td>
<td>Unanticipated Adverse Device Effect</td>
</tr>
<tr>
<td>Serious Injury/ Illness/ Impairment</td>
<td>No Health Consequences or Impact</td>
</tr>
<tr>
<td>Misdiagnosis/ Misclassification</td>
<td>No Patient Involvement</td>
</tr>
<tr>
<td>Prolonged Episode of Care</td>
<td>Appropriate Term/Code Not Available</td>
</tr>
</tbody>
</table>
Annex G: Parts and Components

- Based on FDA terms
- Reviewed the terms based on practical usage
- Proposed WD to be submitted for the MC September meeting in 2019
- After 2 month consultation, proposed final document will be submitted to the MC early 2020
AE terminology Working Plan (as of Mar 2019)

2018

- Q4: MC TC
- Q1: MC f2f

2019

- Q1: MC TC
- Q2: MC f2f
- Q3: MC f2f
- Q4: MC TC

2020

- Q1: MC f2f
- Q2: MC TC
- Q3: MC f2f
- Q4: MC TC

FD Published

- Q4: FD Published

2 month?

Public Consultation

Health Effect

Components

- Health Effect
  - Singapore
  - FD Published

- Components
  - WG f2f
  - Brazil
  - Canada?

Maintenance Pilot

- Maintenance Pilot
  - Full Maintenance Phase by AETM

Medical Device Problem

Cause Investigation

Health Effect
Thank you!