Adverse Event Terminology and Coding Working Group

March 2018

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

NWIP

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.
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  Sheila Martins Cordovil
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  Mary Raphael
  Richard McAteer
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  Tsutomu Makino
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  Toru Takahashi
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  Akimasa Takeuchi
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  Lailing Liew
AHWP: Sasikala Devi Thangavelu
  Azat Iskaliyev
  Dinara Esbolatova
  Gulnar Berkimbayeva
Recent Meetings

• Oct. 11th, 2017
  18th Teleconference
• Nov. 28th – Dec. 1st, 2017
  5th Face to Face meeting in Moscow, Russia
• Feb. 7th, 2018
  19th Teleconference

Coming Meetings

• April 16th – 20th, 2018
  6th Face to Face meeting in Canberra, Australia
What was the problem at device level?

Which components were involved

What were the probable causes of the problem

What adverse events happened at patient level

Adverse Event Reporting

DEVICE/COMPONENTS

Medical Device Problem (Annex A)

Component (Annex G)

Cause Investigation (Annex B-D)

PATIENT

Health Effects (Annex E, F) (Previously Patient Problem)
**Title:** IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes

Main Body: published on April 10\(^{th}\) in 2017 revised with the addition of Annexes B, C and D and published as Edition2 on Sep. 21\(^{st}\) in 2017.

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

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

Annex E, F (Health Effects): under discussion

Annex G (Component): to be discussed after Annexes E, F take shape
Annex E and F: Health Effects Terms and Codes

• Based on FDA terms and refers to MedDRA
• Consists of IMDRF codes, terms and definitions
• 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, wrong intervention due to incorrect diagnosis)
Annex E and F: Health Effects Terms and Codes

Injury and illness
- Serious, might lead serious
- Non-serious
- Events or No Health impact

Treatments
- Many types of Surgery
- Hospitalization
- Additional treatments
- No treatments

Status
- Death
- Not Recover
- Improve
- Recover
- No Patient Involved

Annex E
- Clinical Signs, Symptoms and Conditions

Annex F
- Health Impact
## Annex E: Clinical Signs, Symptoms and Conditions

<table>
<thead>
<tr>
<th>No./ Category (Organs, Systems, Disorders, Concepts)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nervous system: central</td>
</tr>
<tr>
<td>2. Nervous system: peripheral merged with No. 1</td>
</tr>
<tr>
<td>3. Mental, emotional and behavioural disorders</td>
</tr>
<tr>
<td>4. Blood and lymphatic system</td>
</tr>
<tr>
<td>5. Immune system</td>
</tr>
<tr>
<td>6. Vascular system</td>
</tr>
<tr>
<td>7. Heart</td>
</tr>
<tr>
<td>8. Respiratory system</td>
</tr>
<tr>
<td>9. Eye</td>
</tr>
<tr>
<td>10. Ear and labyrinth</td>
</tr>
<tr>
<td>11. Gastrointestinal system</td>
</tr>
<tr>
<td>12. Hepatic and biliary system</td>
</tr>
<tr>
<td>13. Metabolism and nutrition</td>
</tr>
<tr>
<td>14. Endocrine system</td>
</tr>
<tr>
<td>15. Kidney and urinary tract</td>
</tr>
<tr>
<td>16. Reproductive system</td>
</tr>
<tr>
<td>17. Breast moved to other section</td>
</tr>
<tr>
<td>18. Pregnancy, childbirth and the puerperium</td>
</tr>
<tr>
<td>19. Musculoskeletal system and connective tissue</td>
</tr>
<tr>
<td>20. Skin and subcutaneous tissue</td>
</tr>
<tr>
<td>21. Neoplasms benign, malignant and unspecified</td>
</tr>
<tr>
<td>(incl cysts polyps)</td>
</tr>
<tr>
<td>22. Infections</td>
</tr>
<tr>
<td>23. Injury</td>
</tr>
<tr>
<td>24. Toxicity moved to other section</td>
</tr>
<tr>
<td>25. Procedures and procedural complications</td>
</tr>
<tr>
<td>26. Investigations and diagnostic tests</td>
</tr>
<tr>
<td>27. General disorders</td>
</tr>
</tbody>
</table>
Annex E: Basic concept

◆ Terms belonging to categories below are commonly names of organ. Those terms may also exist in the suitable organ categories.

<table>
<thead>
<tr>
<th>No.</th>
<th>Category Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>Neoplasms benign, malignant and unspecified (incl. cysts and polyps)</td>
</tr>
<tr>
<td>22</td>
<td>Injury</td>
</tr>
<tr>
<td>23</td>
<td>Infection</td>
</tr>
<tr>
<td>25</td>
<td>Procedural complications</td>
</tr>
<tr>
<td>26</td>
<td>Investigations and diagnostic tests</td>
</tr>
<tr>
<td>27</td>
<td>Generalized disorders</td>
</tr>
</tbody>
</table>

◆ If a same term exist in more than two categories, the code for the term in the organ category will take a priority.

e.g. 9. Eye

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Code</th>
<th>Level 2</th>
<th>Code</th>
<th>Level 3</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye</td>
<td>E090000</td>
<td>Burn, corneal</td>
<td>E091500</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

23. Injury

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Code</th>
<th>Level 2</th>
<th>Code</th>
<th>Level 3</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injury</td>
<td>E230000</td>
<td>Burn</td>
<td>E232100</td>
<td>Burn, corneal</td>
<td>E091500</td>
</tr>
</tbody>
</table>
# Annex F: Health Impact

## Level 1 terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Change in Therapeutic Response</td>
</tr>
<tr>
<td>Serious Injury/ Illness/ Impairment</td>
<td>Delay to Diagnosis</td>
</tr>
<tr>
<td>Minor Injury/ Illness / Impairment</td>
<td>Delay to Treatment/ Therapy</td>
</tr>
<tr>
<td>Serious public health threat</td>
<td>Hospitalisation or Prolonged Hospitalisation</td>
</tr>
<tr>
<td>Reduction in life expectancy</td>
<td>Rehabilitation</td>
</tr>
<tr>
<td>Misdiagnosis</td>
<td>Surgical Intervention</td>
</tr>
<tr>
<td>Misclassification</td>
<td>Unexpected deterioration</td>
</tr>
<tr>
<td>Recognised procedural complication</td>
<td>Sedation</td>
</tr>
<tr>
<td>Inadequate/inappropriate treatment</td>
<td>Insufficient Information</td>
</tr>
<tr>
<td>Prolonged episode of care</td>
<td>Newly Identified Complication</td>
</tr>
<tr>
<td>Unexpected medical intervention</td>
<td>No Health Consequences Or Impact</td>
</tr>
<tr>
<td>Unexpected diagnostic intervention</td>
<td>No Patient Involvement</td>
</tr>
<tr>
<td>No code available</td>
<td>No Code Available</td>
</tr>
</tbody>
</table>
AE terminology Working Plan (as of Dec 2017)

- **Health Effect**
  - Initial target
  - 3 month Public Consultation
  - FD Published

- **Components**
  - WG f2f Moscow
  - WG f2f Canberra
  - WG f2f

- **Maintenance Pilot**
  - Full Maintenance Phase by AETM

- **Medical Device Problem**
  - April 2017

- **Cause Investigation**
  - September 2017
Thank you!