IMDRF International Medical Device Regulators Forum

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

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.

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 Kurtukov

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

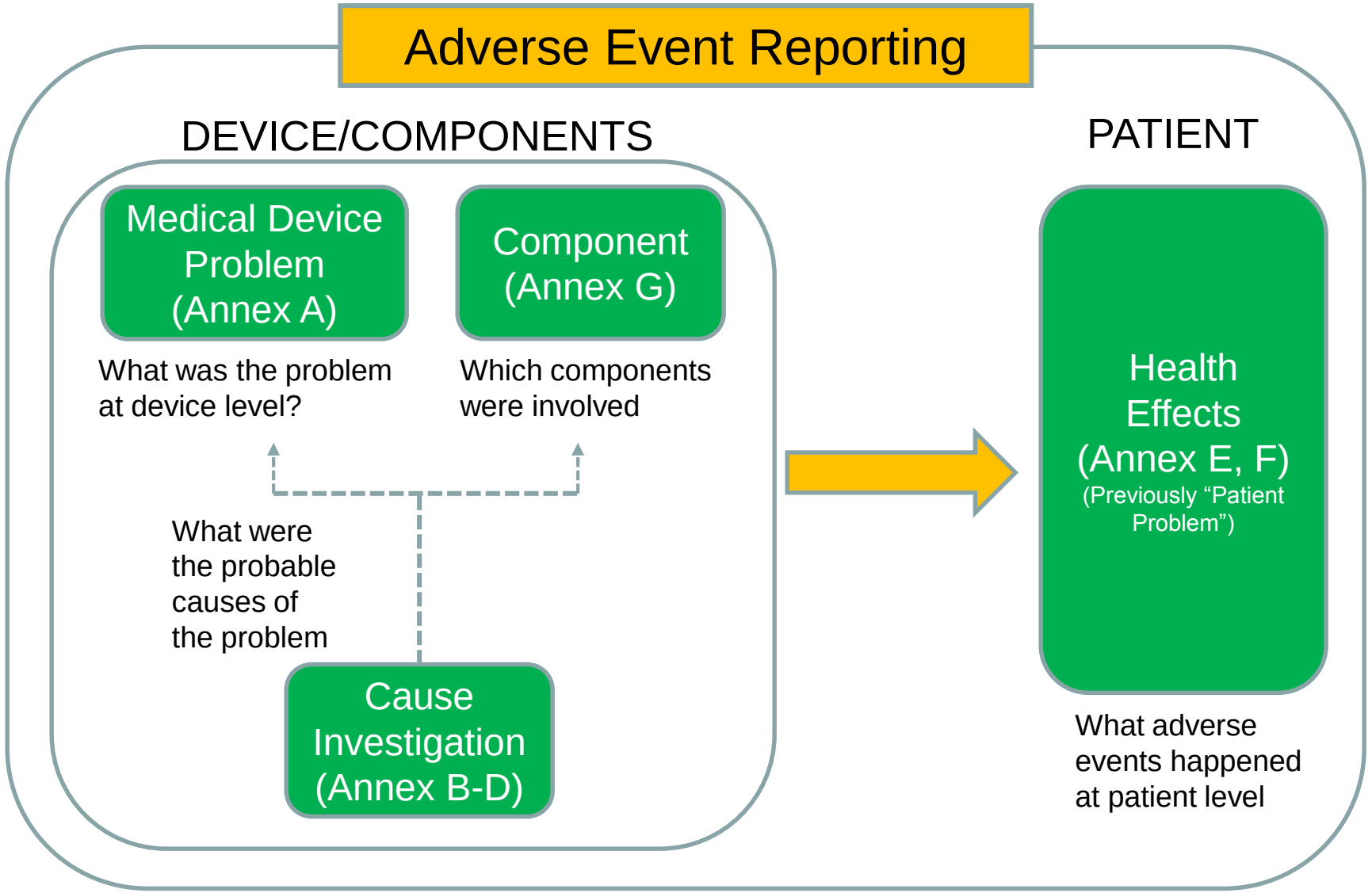
AHWP:
- Sasikala Devi Thangavelu
- Azat Iskaliyev
- Dinara Esbolatova
- Gulnar Berkimbayeva

Recent Meetings

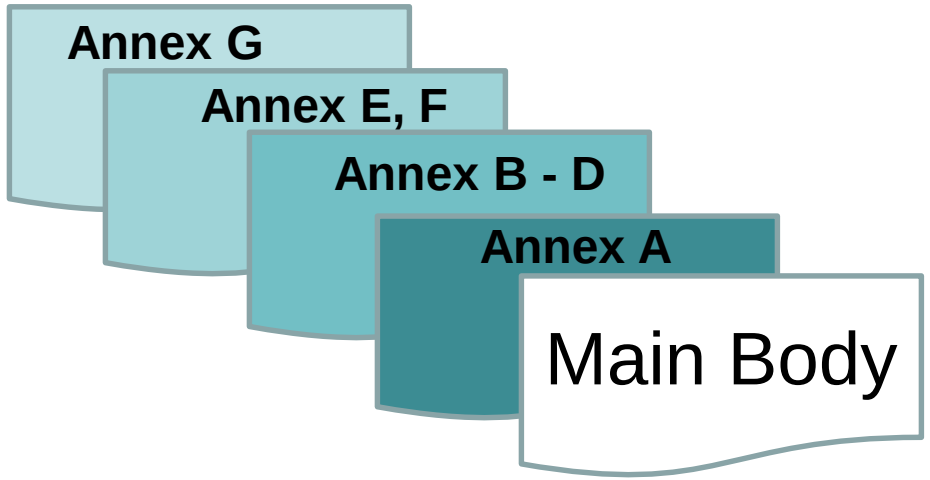
- April 16th – 20th, 2018
  6th Face to Face meeting in Canberra, Australia
- Nov 14th, 2018
  21st Teleconference
- Nov 26th – 30th, 2018
  7th Face to Face meeting in Singapore
- Feb 20th, 2019
  22nd Teleconference

Coming Meetings

- March 26th- 29th, 2019
  8th Face to Face meeting in Brazil


Adverse Event Reporting
DEVICE/COMPONENTS
PATIENT
Medical Device Problem (Annex A)
Component (Annex G)
What was the problem at device level?
Which components were involved
What were the probable causes of the problem
Cause Investigation (Annex B-D)
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



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

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

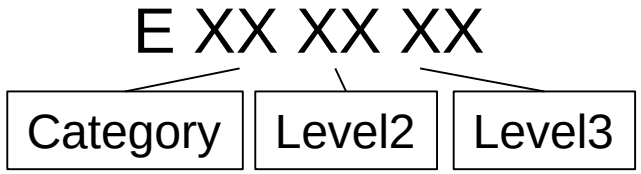
e.g. Death
Delay to Diagnosis/Treatment/Therapy
Hospitalisation or Prolonged Hospitalisation
Inadequate/Inappropriate Treatment
Minor Injury/ Illness/Impairment
Serious Public Health Treat/Injury/Illness/Impariment
Misdiagnosis/Misclassification
Intervention/Medical Intervention

Annex E: Clinical Signs, Symptoms and Conditions

No./ Category (Level 1) (Organs, Systems, Disorders, Concepts)	
1. Nervous System	14. Reproductive System and Breast
2. Mental, Emotional and Behavioural Disorders	15. Pregnancy, Childbirth and the Puerperium
3. Blood and Lymphatic System	16. Musculoskeletal System
4. Immune System	17. Skin and Subcutaneous Tissue
5. Vascular System	18. Neoplasms Benign, Malignant and Unspecified
6. Heart	19. Infections
7. Respiratory System	20. Injury
8. Eye	21. Procedural Complications
9. Ear and Labyrinth	22. Investigations and Diagnostic Tests
10. Gastrointestinal System	23. General Disorders
11. Hepatic and Biliary System	24. Others
12. Metabolism and Nutrition	LIST (all terms in one sheet)
13. Kidney and Urinary Tract	

Annex E Coding system

- 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.



- 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.

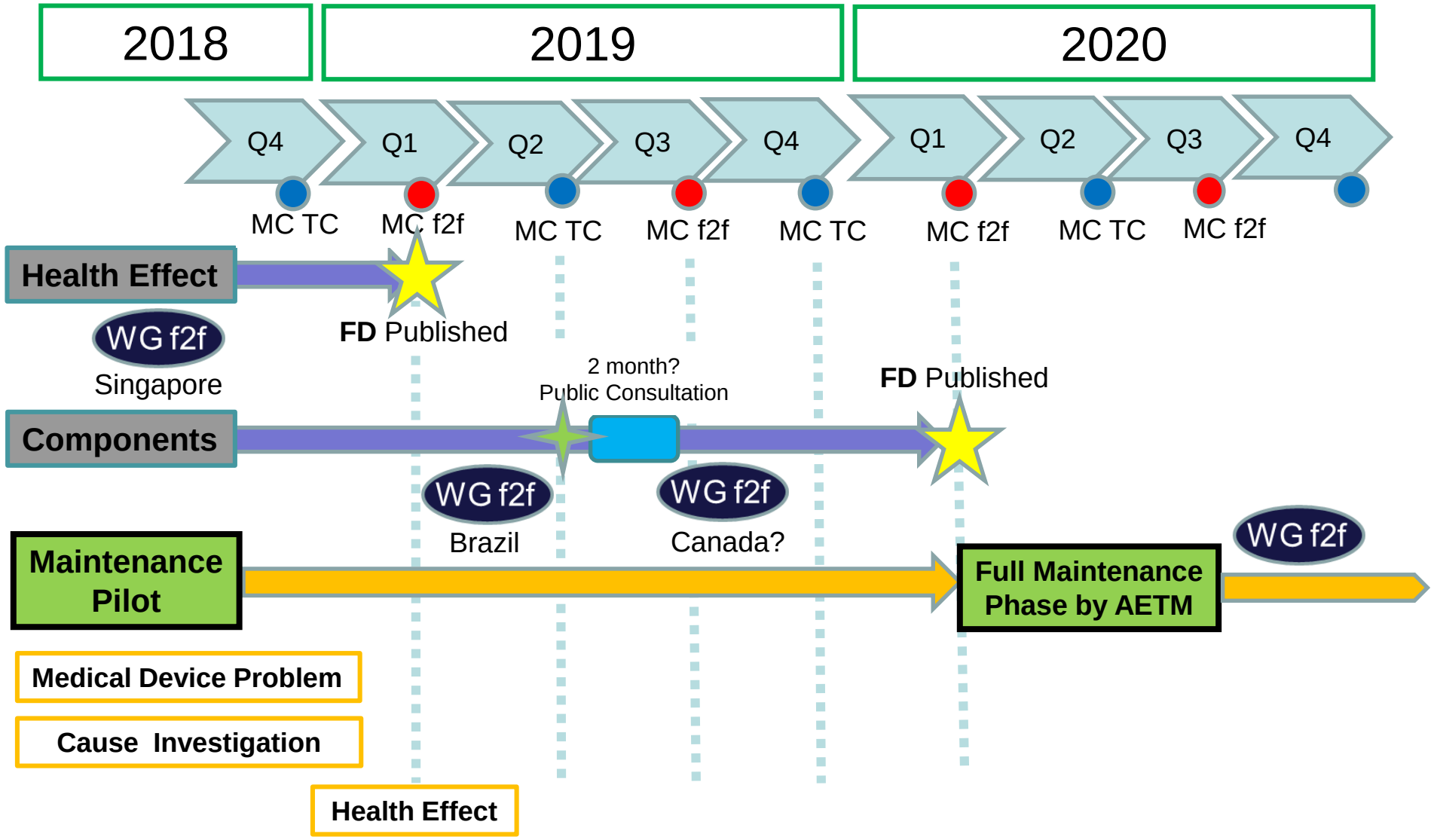
Annex F: Health Impact

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

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)



Thank you!