

IMDRF GMTA/DITTA 합동워크숍 참가경험



IMDRF
International Medical Device
Regulators Forum

EU2023
EUROPEAN UNION
Chair



European
Commission



European
Union

Healthcare professional engagement in Post-market surveillance of Korea

You Kyoung Lee,

Dept. of Laboratory Medicine & Medical Device Clinical Research Center (MDRC),

SoonChunHyang University Bucheon Hospital

2023-03-27

순천향대학교부속 부천병원 이유경

The 21 hexagonal blocks represent APEC economies, with whom we, SCH pilot CoE, endeavor to share the benefits from the development of medical devices and healthcare.



1. 발표 내용

Day 1 - Joint IMDRF / Stakeholder (DITTA-GMTA) Workshop - 27 March 2023

The life cycle of medical devices: the importance of post-market-related activities

09:30 - 09:50

Post-market surveillance and RWE

Lifecycle approach to medical devices

Philippe Auclair, Matthias Neumann

[Presentations are available here](#)

09:50 - 11:10

Session 1 : Safety notices and Vigilance

This is a session to discuss how we can improve "Safety Notice & Vigilance" to be more efficient and effective for manufacturers, regulators and healthcare providers. Each stakeholder will present concerns and propose ideas to improve current situation and discuss at the panel session.

- Opportunities and challenges: Regulator's perspective - [Melissa Torres](#) and [Christophe Driesmans](#)
- Opportunities and challenges: Industry perspective - [Nicole Smith](#) and [Miang Tanakasemsub](#)
- Opportunities and challenges: Healthcare professional perspective - [Youkyoung Lee](#) and [Timothy Wilton](#)
- Panel discussion: Opportunities for improvement - moderated by [Paul Piscoi](#)

[The presentations are available here](#)

OVERVIEW

MDSIM consortium in Korea	3
MDAE & reportable MDAE	4
MDAE reporting in Korea	5
MDSIM; Healthcare professional engagement	6
What challenges we recognized	8
Perspective diversity	9
Business-cultural aspect	11
What efforts are we making	12
Engage in MDAE reporting, Why?	13
Tasks in MDAE reporting; health profession's viewpoint	14
What efforts are we making	15

MDSIM: Healthcare professional engagement

- Medical Device Safety Information Monitoring Center (MDSIM) Pilot (2010)
 - Two general hospitals
 - 60 (include 27 serious) cases collected through a medical record review
 - Lessons learned
 - Need to collect all MDAEs from serious to mild
 - Need to improve awareness to the MDAE and AER in the healthcare practice field
- The settle-down period (2012-2017)
 - Establishing MDSIM consortium
 - 6 designated certified tertiary hospitals (regional center)
 - Implement 'AE Review Committee' in each regional center
 - Implement 'adverse event terminology system'
- The challenge period (2018-present)
 - Expanding MDSIM
 - 17 regional centers & 123 affiliated healthcare institutions
 - MFDS established 'AE expert committee' (2018)

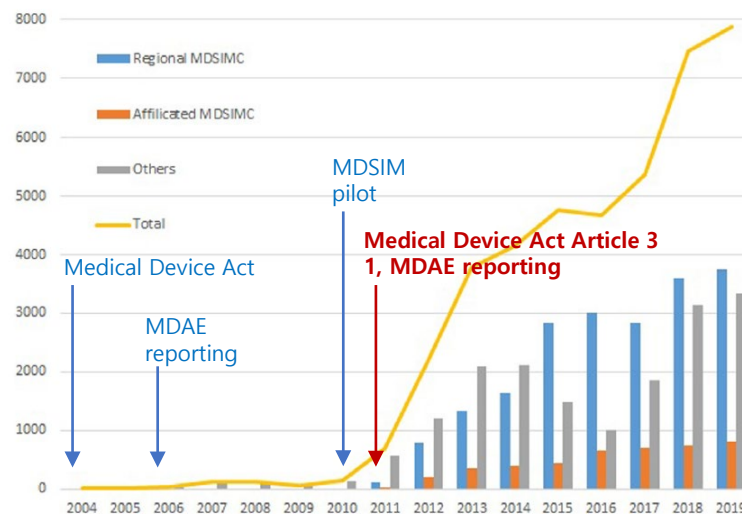
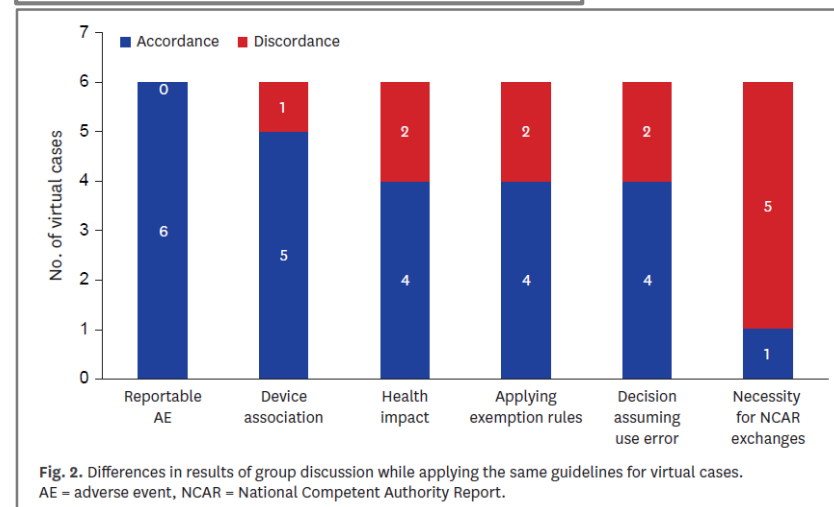
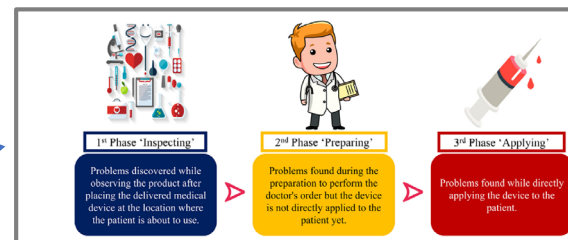
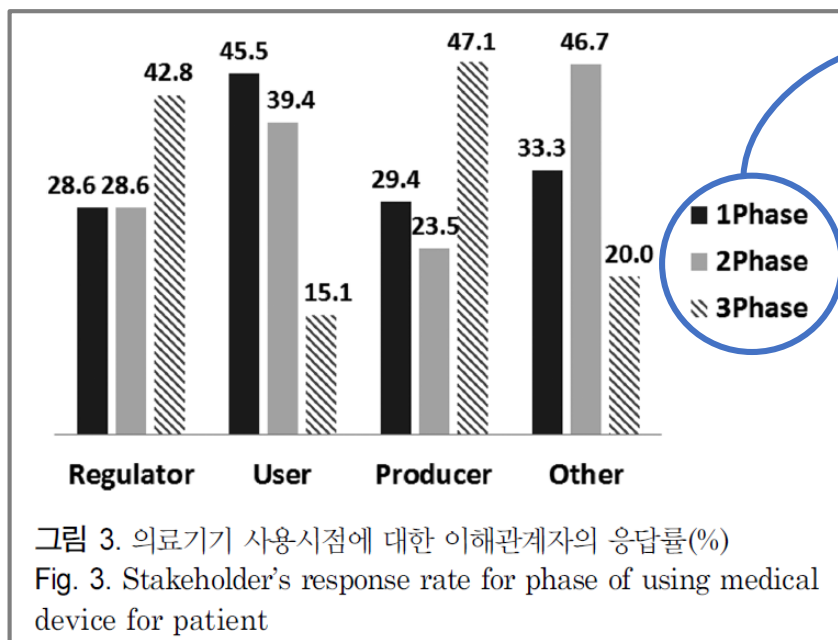


Fig. 1. Numbers of medical device adverse event reports by reporting year and source in Korea.
Note: MDSIMC = Medical Device Safety Information Monitoring Center.

S Choi et al. *The establishment of the Korean medical device safety information monitoring center: Reviewing ten years of experience*. Health policy 125 (2021) 941

Abbreviations: AER; Adverse Event Reporting, MDAE; Medical Device Adverse Event, MDSIM; Medical Device Safety Information Monitoring Center

Challenges; Perspective diversity



Lee YJ, et al. Perspective Diversity of Domestic Stakeholders on Medical Device Adverse Event Reporting. *Journal of Biomedical Engineering Research* 40:171;2019

C Yoon et al. Differences in Perspectives of Medical Device Adverse Events: Observational Results in Training Program Using Virtual Cases. *J Korean Med Sci*. 34(39):e255;2019

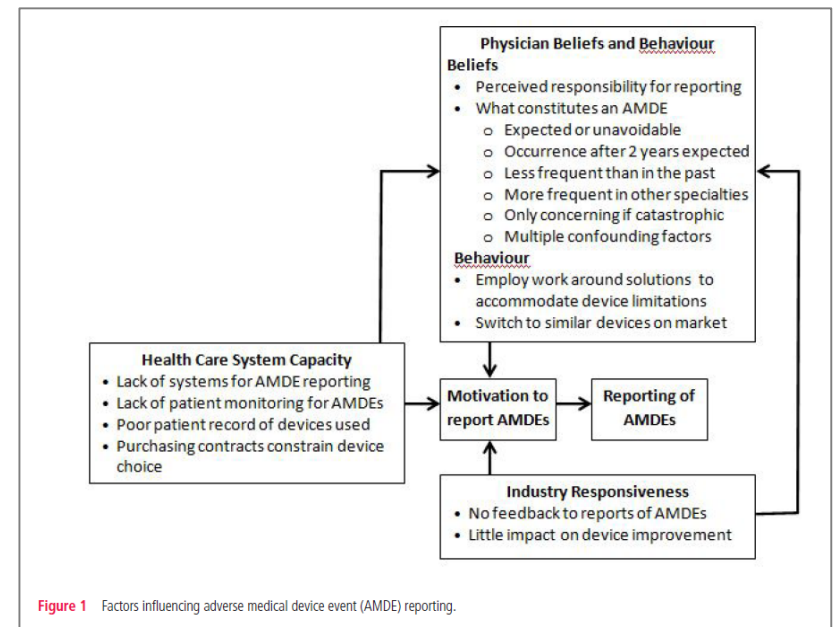
Challenges; Business-cultural aspect

• Lack of awareness

- It happens frequently and quite natural!
- Necessary to report?

• Cultural immaturity

- Fear of blame
- Too busy! Why me?



Gagliardi AR, et al. Factors influencing the reporting of adverse medical device events: qualitative interviews with physicians about higher risk implantable devices. *BMJ Qual Saf* 27:190–198;2018

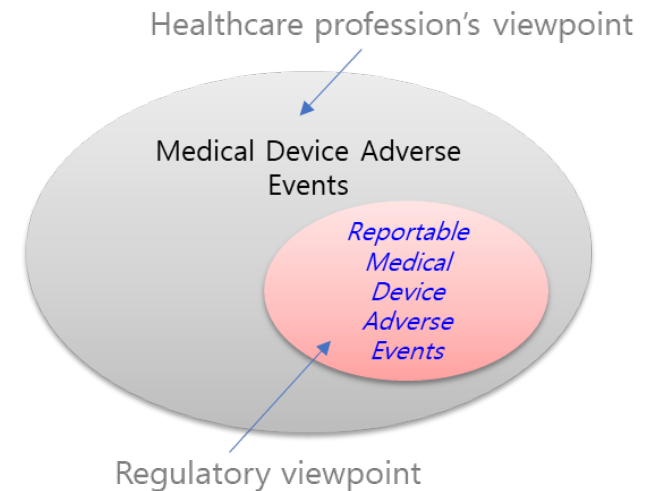
Engage in MDAE reporting, Why?

Why

- Quality improvement in healthcare practice
 - Improve patient outcome
 - Information fed into the quality management system of a healthcare institution
- Contribute to upgrading medical device
 - Identify clinical unmet needs
 - Risk management by manufacturer

Tasks & Health profession's viewpoint

- Implement 'Just Culture'
- Collecting MDAEs
 - Should not be limited to the reportable MDAEs
- Know the approximate event rate?
 - Need to build a system that can identify MDAEs against usage in healthcare practice (real-world data)



What efforts are we making

Education & training program

- MDSIM consortium
- Regular case review meetings with IMDRF code application training
- APEC Center of Excellence programs

Research activities

- Feasibility study to construct a big-data system for MDV
- Pilot study to capture UDI from MD during the healthcare procedure

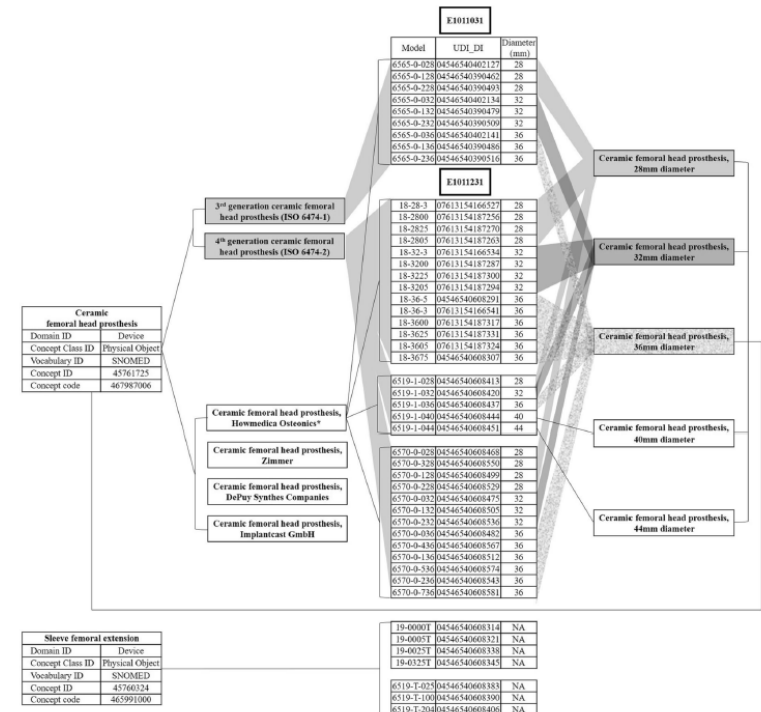


Figure 6. Ceramic femoral head hierarchy was applied to Stryker's products registered with national insurance EDI codes E1011031 and E1011231. EDI electronic data interchange, SNOMED systematized nomenclature of medicine clinical terms, UDI unique device identifier, DI device identifier.

S Choi, et al. Preliminary feasibility assessment of CDM-based active surveillance using current status of medical device data in medical records and OMOP-CDM. *Sci Rep* 11:24070;2021

Abbreviations: MDAE; Medical Device Adverse Event, MDSIM; Medical Device Safety Information Monitoring Center, MDV; Medical Device Vigilance, UDI; Unique Device Identifier

The 21 hexagonal blocks represent APEC economies, with whom we, SCH pilot CoE, endeavor to share the benefits from the development of medical devices and healthcare.

2. What's more



Sally S. • 팔로우 중
Medical Director RQM+ (freelancer)
5개월 • 수정됨 •

#IMDRF2023 kicked off in sunny Brussels this morning on #pms #rwe #samd #aimd with a poignant patient testimony; our 'why' Succinct summaries of the value of PMS data and RWE followed. The what's and the why's are well understood.

Some of the keys to implementation are:

1. Common language – IMDRF AE codes are available. The sooner they are adopted by all stakeholders the better,
2. Overcoming HCP reticence to report – Some great work in Korea on HCP education on a national scale [이유경You Kyoung Lee](#)
3. Turning #rwd into #rwe – there is no shortage of data related to SaMDs and AI but the challenge is providing the context and meaning. Entertainingly illustrated by [Pat Baird](#)
4. Fuel for the safari bus. IYKYK!

There was plenty more, what did I miss?

번역 보기



Result of voting

Consultation Information:

Consultation reference:	TS 16766
Consultation title:	Manufacturers' considerations for in vitro diagnostic medical devices in a public health emergency
Opening date:	2023-02-11
Closing date:	2023-03-10
Note:	

• Working group consultation

- 2023/02/11-2023/03/10
- 총 투표 26개국
- WD 승인; 찬성 21, 반대 1, 기권 4 (반대: BSI)
- Collated comments; 3개국(BSI, DIN, JISC) 39개

경청해 주셔서 감사합니다.



Auto-World, Brussels, Mar. 27, 2023