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# Healthcare professional engagement in Post-market surveillance of Korea


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# OVERVIEW

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# Healthcare professional engagement in Post-market surveillance of Korea

**Medical device adverse event reporting by healthcare institutions in Korea, 12 years experience**

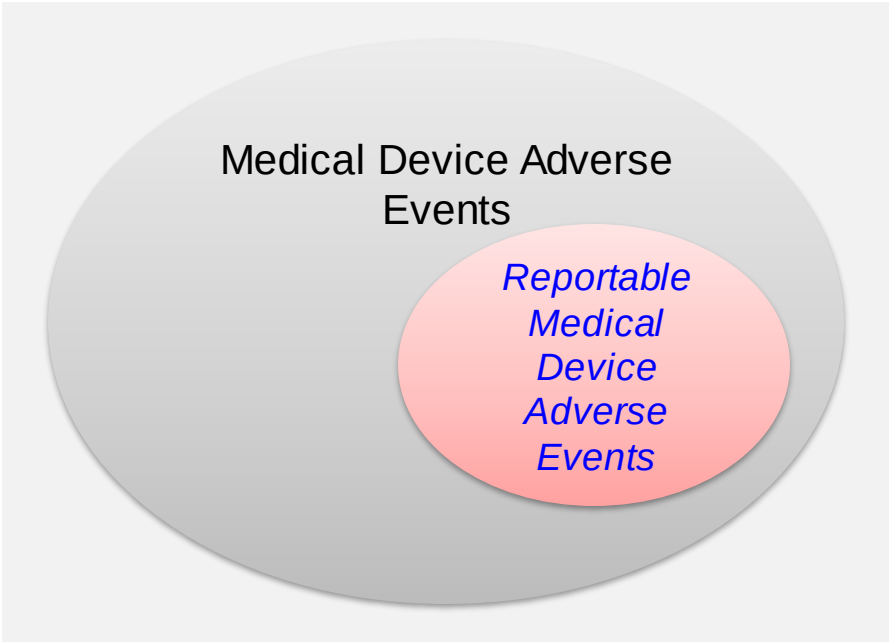
# MDAE vs reportable MDAE

## Medical Device Adverse Event (MDAE)[1]

- an unexpected event that occurs during or result from 'patient use' of a medical device

## Reportable MDAE[2]

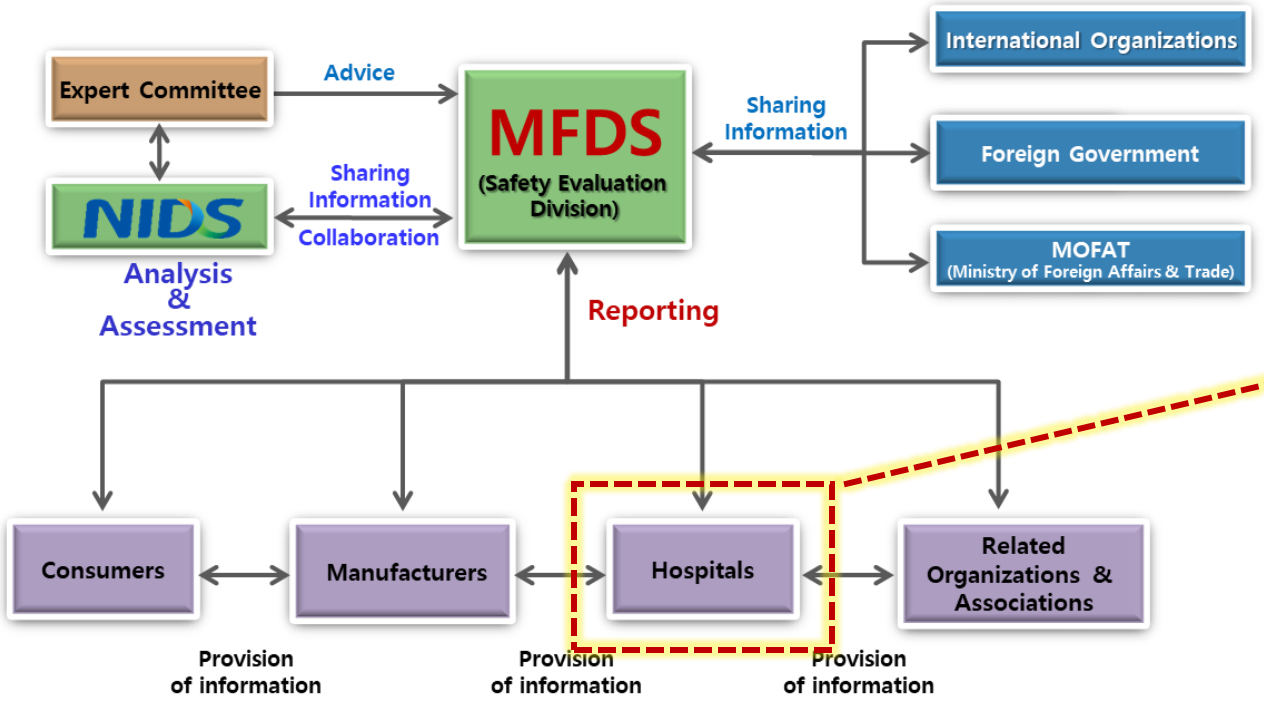
- An event has occurred
- The device is associated with the event
- The event led to one of the following outcomes
  - Death or Serious injury of a patient, user or other person
  - No death or serious injury occurred but the event might lead to death or serious injury

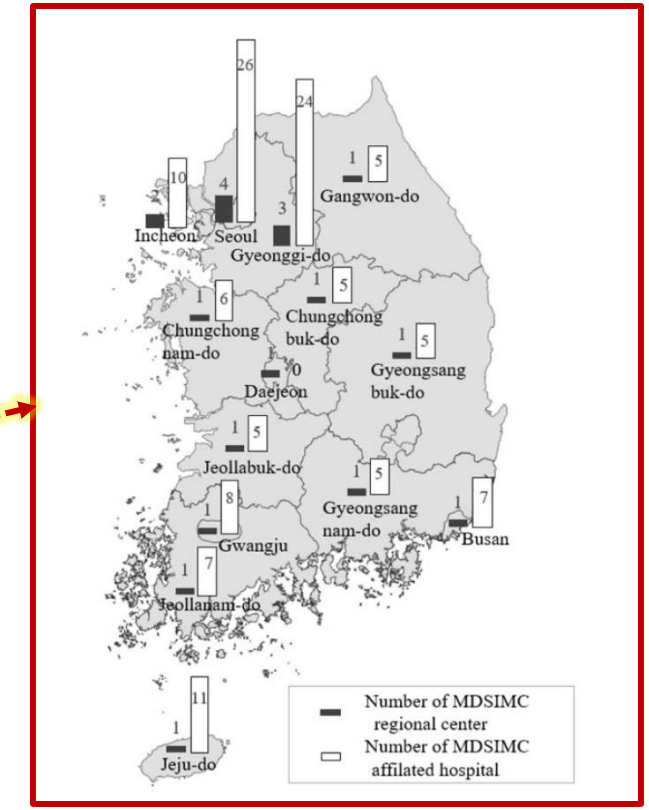



References:

1. C Yoon et al. *Differences in Perspectives of Medical Device Adverse Events: Observational Results in Training Program Using Virtual Cases.* J Korean Med Sci. 2019 Oct 14;34(39):e255
2. GHTF/SG2/N21R8:1999 (GHTF/FD:99-7)

# MDAE reporting in Korea




S Choi et al. *The establishment of the Korean medical device safety information monitoring center: Reviewing ten years of experience*. Health policy 125 (2021) 941-946

Abbreviations: AER; Adverse Event Reporting, MFDS; Ministry of Food and Drug Safety, NIDS; National Institute of Medical Device Safety Information

# 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 <u>all MDAEs</u> from serious to mild
  - Need to <u>improve awareness</u> to the MDAE and AER in the healthcare practice field

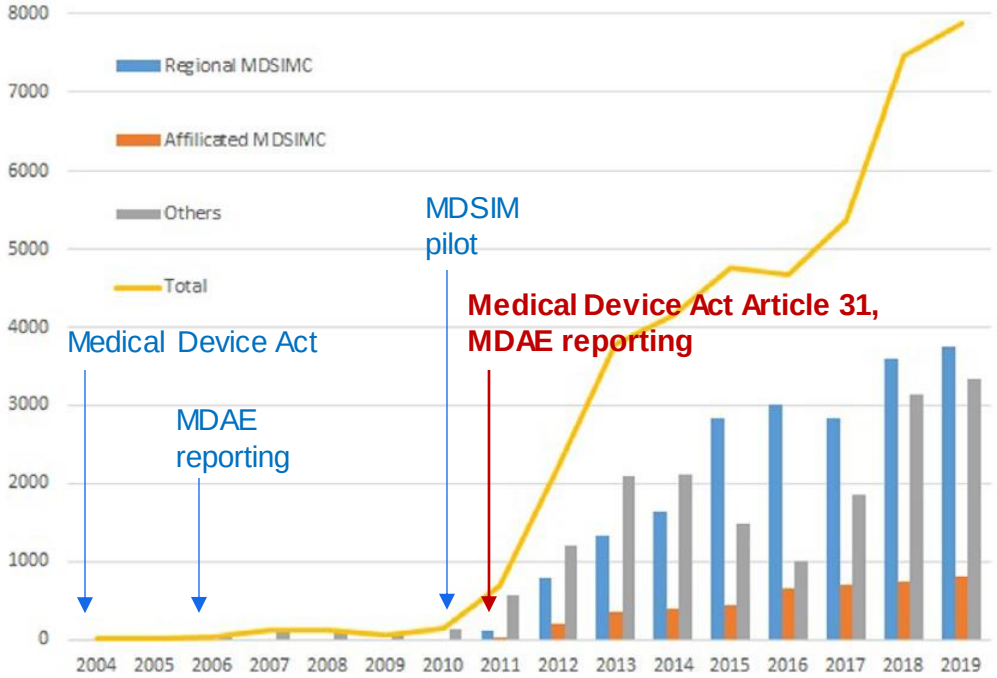



**Fig. 1.** Numbers of medical device adverse event reports by reporting year and source in Korea.
*Note:* MDSIMC = Medical Device Safety Information Monitoring Center.

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

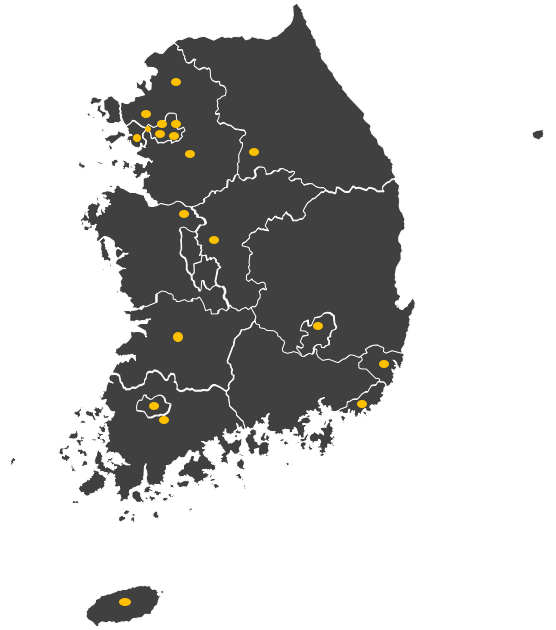
# MDSIM; Brief history

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)



Abbreviations: AE; Adverse Event, MDSIM; Medical Device Safety Information Monitoring Center

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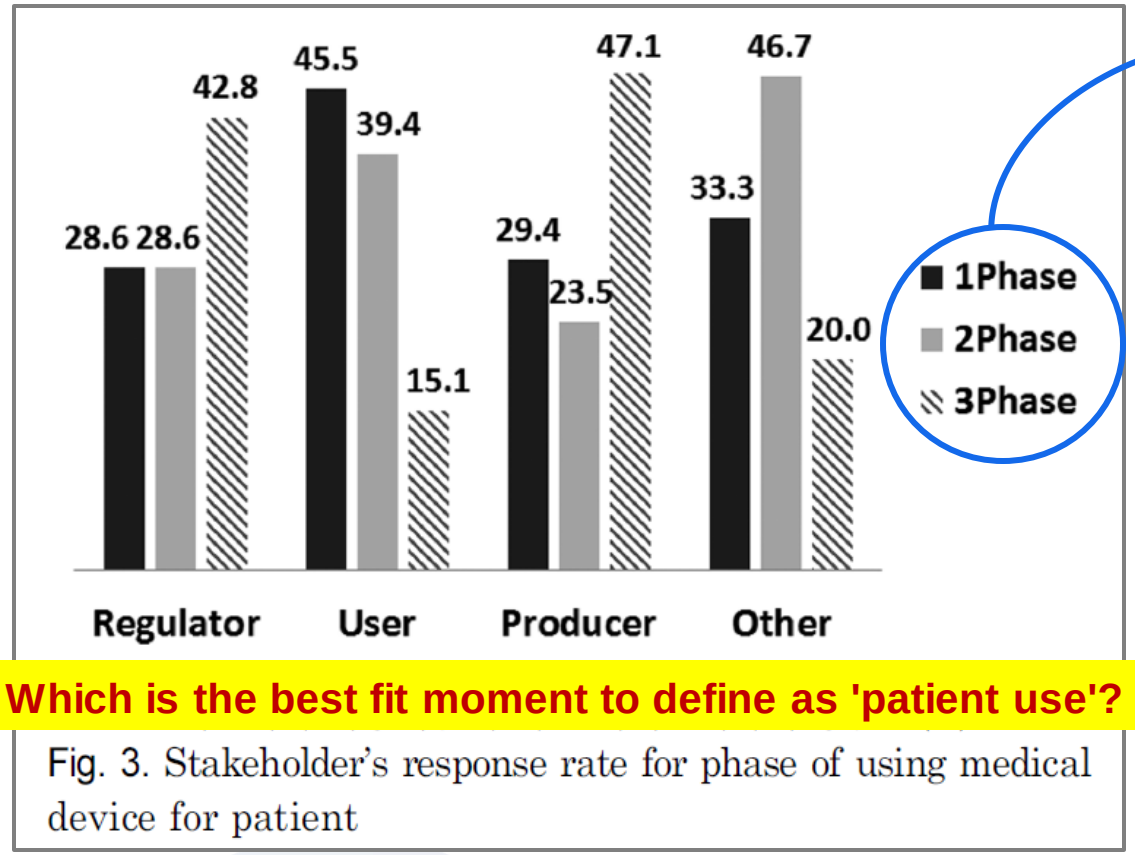
## What challenges we recognized

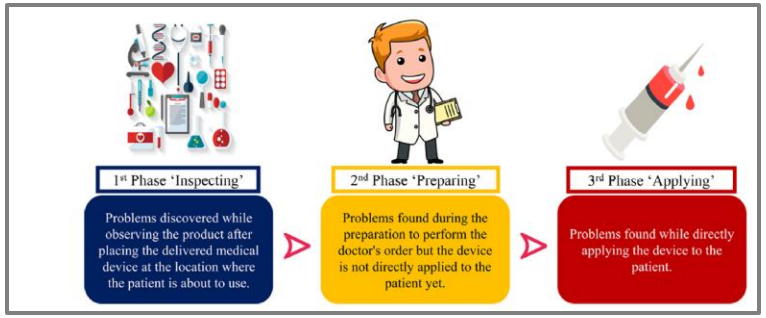
# Perspective diversity




**Which is the best fit moment to define as 'patient use'?**

Fig. 3. Stakeholder's response rate for phase of using medical device for patient

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



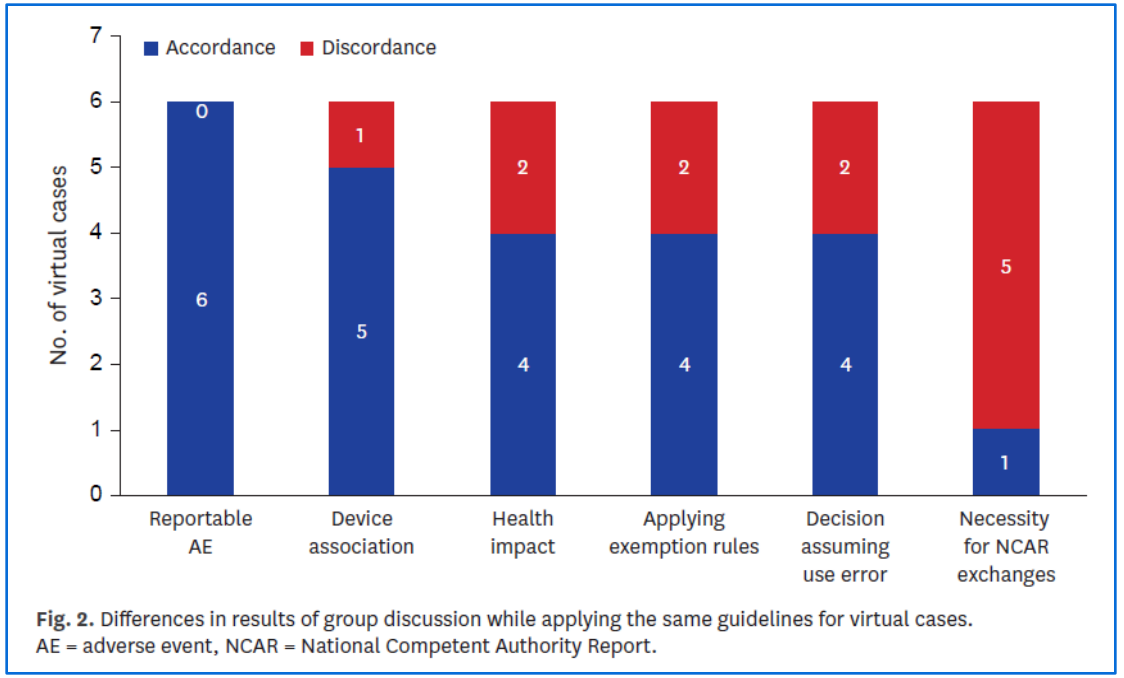




**Fig. 2.** Differences in results of group discussion while applying the same guidelines for virtual cases.
AE = adverse event, NCAR = National Competent Authority Report.

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

# Business-cultural aspect

## Lack of awareness

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

## Cultural immaturity

- Fear of blame
- Too busy! Why me?

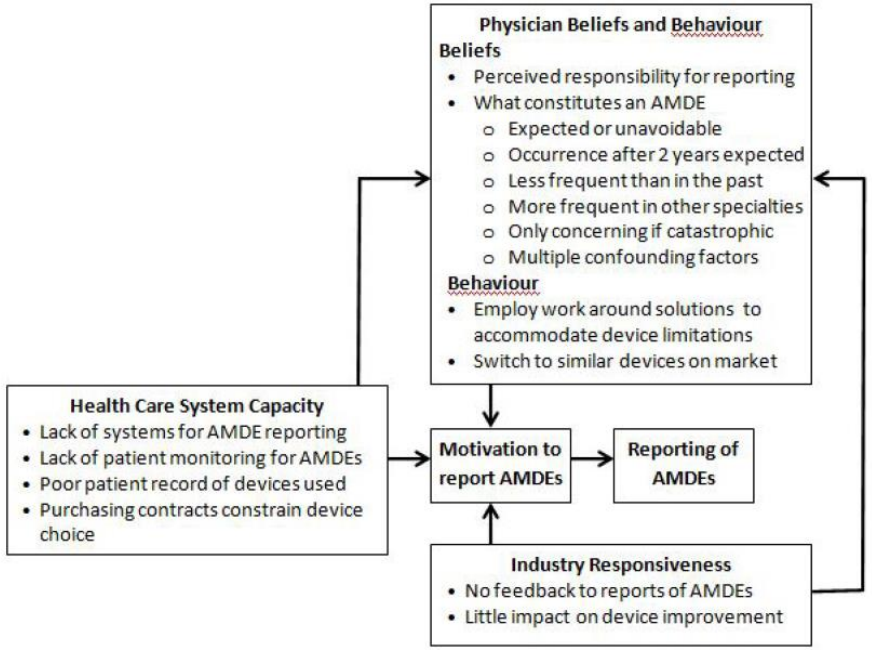



Figure 1 Factors influencing adverse medical device event (AMDE) reporting.

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

Abbreviations: MDAE; Medical Device Adverse Event

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## What efforts are we making

# Engage in MDAE reporting, Why?

## Quality improvement in healthcare practice

- Improve patient outcome
- Information fed into the quality management system of a healthcare institution

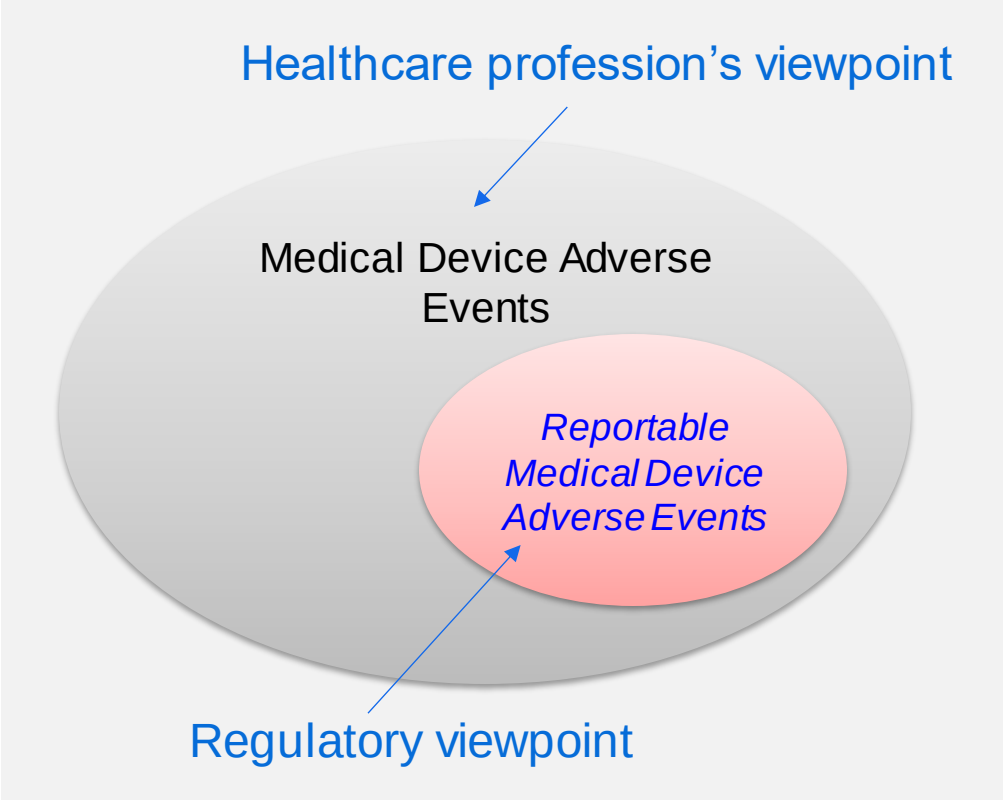
## Contribute to upgrading medical device

- Identify clinical unmet needs
- Risk management by manufacturer

Abbreviations: MDAE; Medical Device Adverse Event

# Tasks in MDAE reporting; 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)




Abbreviations: MDAE; Medical Device Adverse Event

# 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

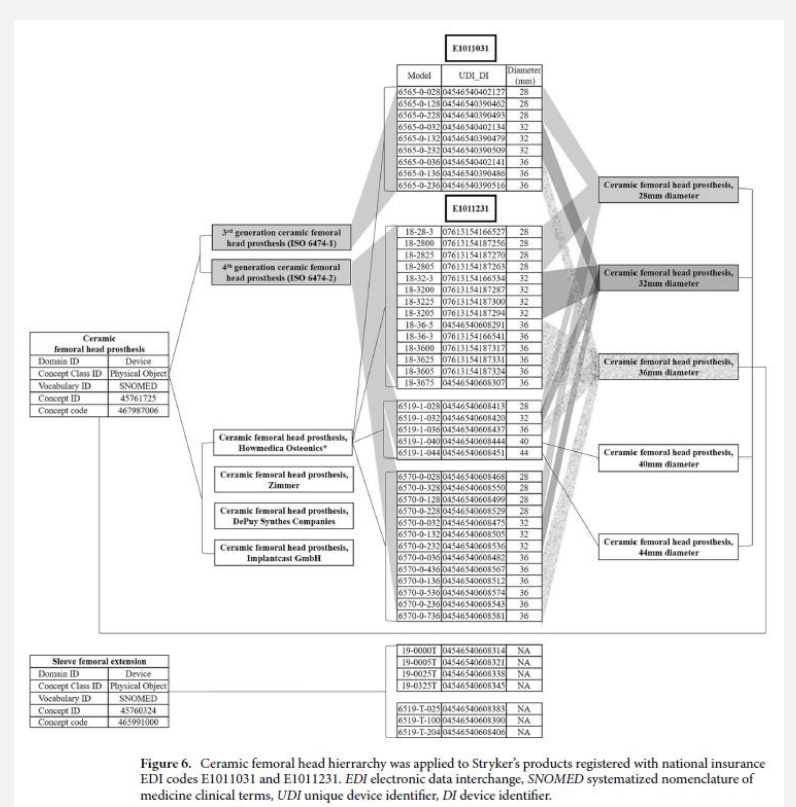



Figure 6. Ceramic femoral head hierrarchy was applied to Stryker's products registered with national insurance EDI codes E1011031 and E1011231. *EDI* electronic data interchange, *SNOMED* systematized nomenclature of medicine clinical terms, *UDI* unique device identifier, *DI* device identifier.

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 Vigillance, UDI; Unique Device Identifier

# THANK YOU / QUESTIONS

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