IMDRF
International Medical Device Regulators Forum

EU2023
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09:50 – 11:10

Session 1:
Safety notices and Vigilance

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09:50 – 10:10

Opportunities and challenges – Industry perspective

Miang Tanakasemsub

Regional Regulatory Affairs head, Asia Pacific, Johnson & Johnson

Nicole Taylor Smith

Head of Regulatory Science and Policy, Philips

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Safety notices and Vigilance

Opportunities and challenges – Industry perspective

Miang Tanakasemsub

Regional Regulatory Affairs Head, Johnson & Johnson Vision Asia Pacific

GHWP TC Vice Chair

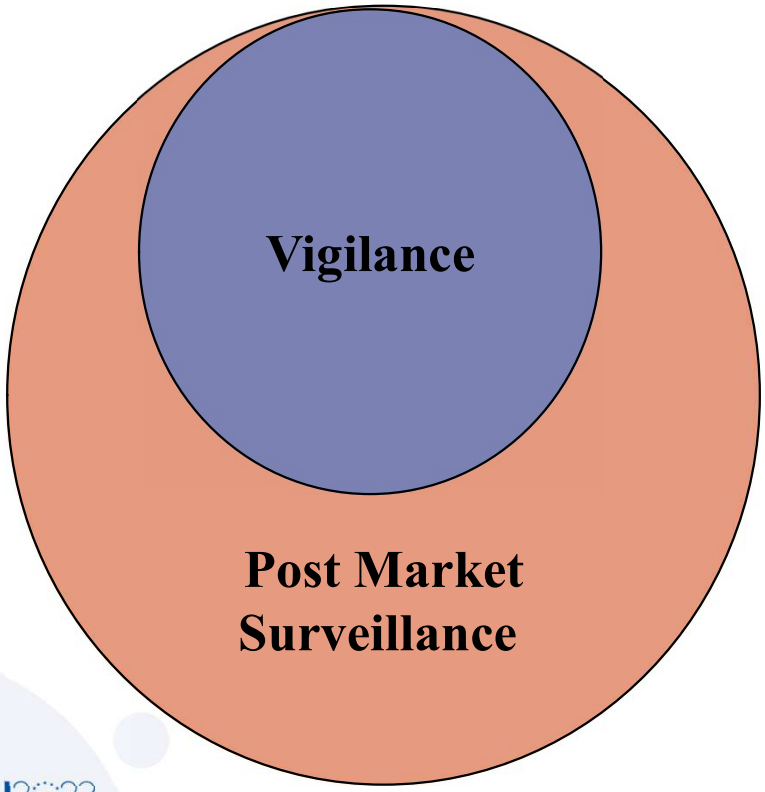
APACMED RA committee Chair

27 March 2023

OVERVIEW

- Postmarket Surveillance/ Vigilance
- Summary PMS activities & Links to International Standards
- Regional/Markets Key challenges
- Key Opportunities

Postmarket surveillance/ Vigilance



Vigilance:
<u>reacting</u> to adverse event

Post Market surveillance:
<u>proactive</u> collection of information

Vigilance:

The reporting and investigation of adverse events. Both the manufacturer and the Regulatory Authority play major roles.

Post market surveillance:

Post market collection of info on the quality, safety and performance of a MD by Regulatory Authorities or Manufacturers.

→ Injury prevention, Product improvement, Regulatory measures, ….

Summary PMS activities & Links to International Standards (*)

(*) Reference: section 9.2 of GHWG-GRM/N1R13 (2011)

Regional/Markets Key challenges

- Different Definitions
  - Adverse Events
  - FSCA
- Different AE reporting criteria
- Foreign AE report requirements
- No common AE/FSCA reporting forms
- Different reporting timelines
- Different Annual/PSUR reports requirements
- Multiple UDIs systems

Example SAE Reporting Timelines

China

- Not later than 7 days for events that led to death or serious deterioration in state of health,
- Not later than 20 days for events that led to serious injury that happen in China.
- Not later than 30 days for events that led to serious injury that happen overseas

Japan

- Unlabeled serious incidents or near incidents – 15 days
- Labeled serious incidents or near incidents – 30 days
- Unlabeled medium level incidents or near incidence – 30 days
- Serious incidents by infectious diseases that could be caused by using medical devices – 15 days.

Australia

- Death or serious deterioration in health: 10 days

Hong Kong SAR

- Deaths, serious injuries, or events of serious public health concern: 10 elapsed calendar days

Singapore

- Not later than 10 days for events that led to death or serious deterioration in state of health,

Example Not reportable Criteria

China

- There are no definite provisions for "Not Reportable Events"

Australia

- Events occurred outside Australia.
- by the user prior to its use
- Adverse incident caused solely by patient conditions
- Use of a medical device beyond its service life
- Protection against a fault functioned correctly
- Remove likelihood of occurrence of death or serious injury
- Expected and foreseeable side effects that are documented in manufacturer's instructions for use or labelling
- Adverse events described in an advisory notice
- Reporting exemptions granted by the Therapeutic Goods Administration

Hong Kong SAR

- Incidents occurred outside of Hong Kong
- Deficiency of a new device found by the user prior to its use
- Adverse incident caused by patient conditions
- Use of a medical device beyond its service life
- Protection against a fault functioned correctly and where no death or serious injury occurs
- Remote likelihood of occurrence of death or serious injury
- Expected and foreseeable side effects
- Adverse incidents described in an advisory notice previously sent to users
- Use errors
- Adverse incidents cause by abnormal use

Singapore

- Events occurred outside Singapore.

Japan

- There are no definite provisions for "Not Reportable Events" except for mishandling or user error.

Key Opportunities

- Harmonization definition/criteria/timelines/reporting forms
- Consider annual safety report requirements over foreign AE reporting requirements
- Consider Post Market requirements to be part of Renewal/ Recertification/ New medical device regulation requirements

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THANK YOU

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Postmarket Vigilance Industry Perspectives

Nicole Taylor Smith, DITTA

27 March 2023

Overview

- Post-market surveillance is **essential** to **ensure that medical devices continue to be safe, perform as intended, and remedial actions and improvements are undertaken**, as necessary
- Critical **need to harmonize** across regulatory jurisdictions
  - Implement IMDRF harmonized **coding system** for **adverse events**
  - Harmonized **terminology** and **definitions** for **corrective actions**
  - Propose **updates to outstanding GHTF Study Group 2 PMS documents** and adoption as IMDRF documents

Post Market Data

- Reactive information
- Proactive information
- Surveillance Management - Process/systems to collect, analyze, study, act, report, take action, etc.
- Master data to study, detect, evaluate, report, track, understand and innovate and develop

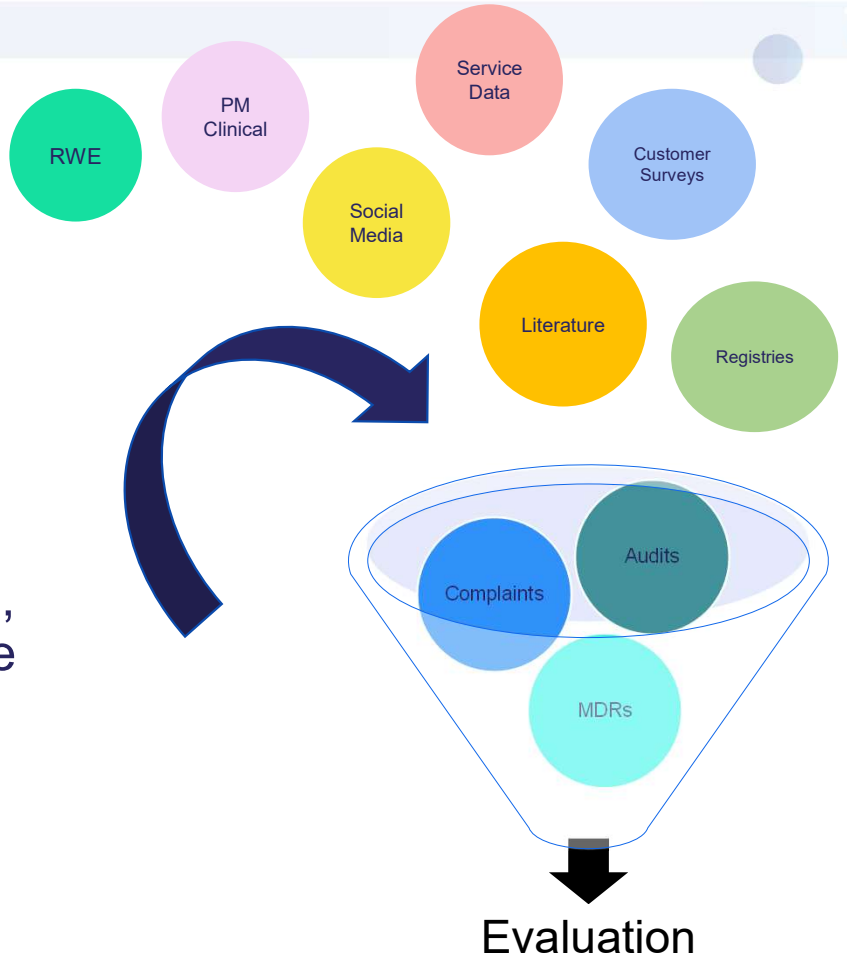
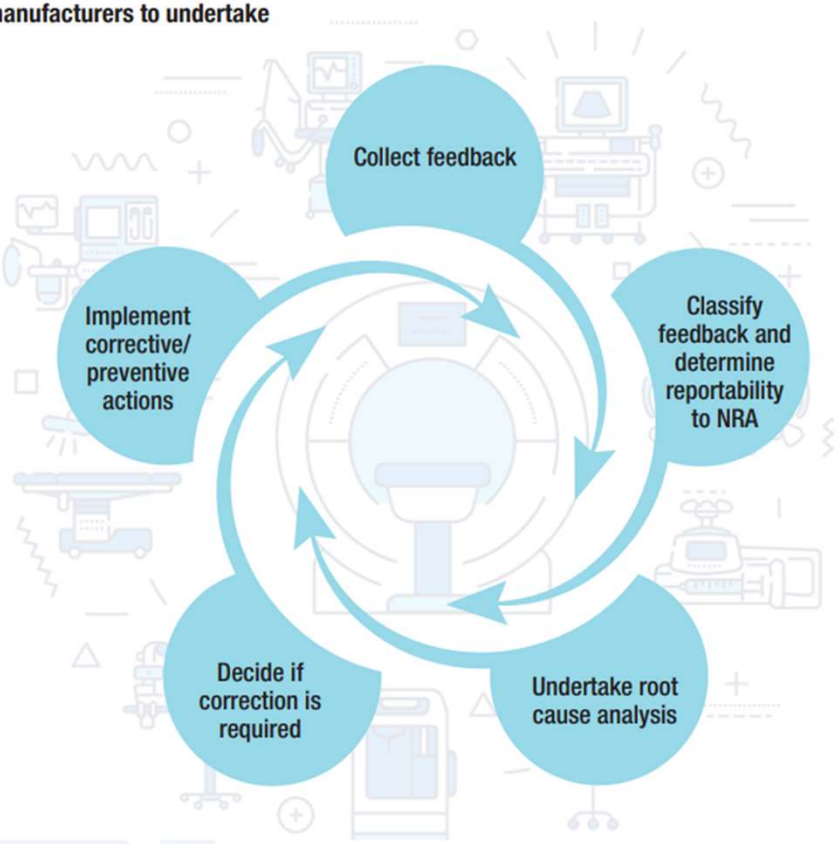


Fig. 3.
Actions for manufacturers to undertake
Page 25



Feedback

- Variations **challenge** our ability to collate and compare and **track data across the world**
- Difficult **to study global data** and accurately **predict and prevent patient harm**
- Impair ability to clearly **communicate** information and **understand impact**
- Less likely to **collaborate** and **rely** on another analysis
- Lack of clarity on how to interpret data due to **unharmonized adverse event codes** and **field corrective action terminology**
- Need for **harmonized reporting/notification template**

Importance of Harmonized Approaches

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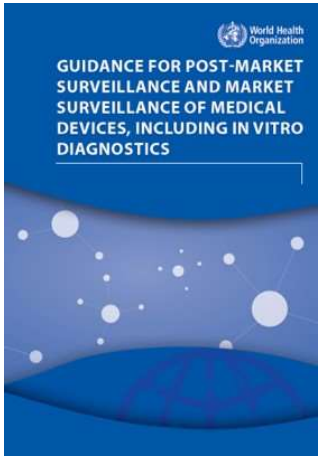

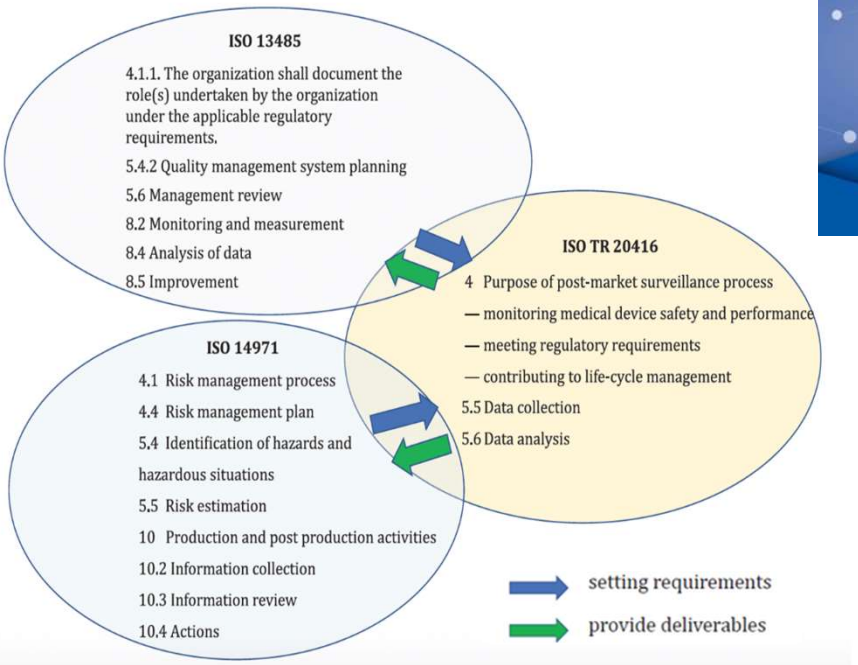

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Proposed Solutions

Harmonized Terminology for Reporting Adverse Events - **IMDRF AE Codes**

- Improve signal detection by adverse event management systems enabling a faster response by both industry and regulatory authorities
- Improves accuracy of capturing and reporting device related adverse events
- Reduces ambiguity which increases effectiveness of the evaluation process
- Readily usable (vs. narrative text) by management systems.

Proposed Solutions

- Additional jurisdictions join **IMDRF MDSAP** as member or affiliate

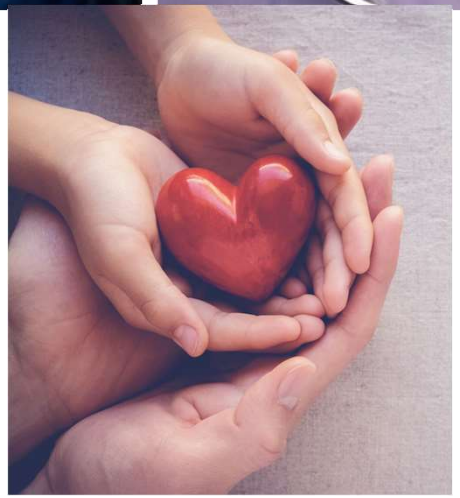
- Propose IMDRF to update/adopt **outstanding GHTF Study Group 2 PMS documents**
  - N79: Medical Devices Post Market Surveillance
  - N57: Content of Field Safety Notices
  - Harmonization of terminology across jurisdictions
  - Harmonized template for safety reporting

- Support for **new work item related to QMS** – joint work group for IMDRF, GHWP, and ISO

Proposed Solutions

- **Harmonized Unique Device Identifier (UDI)** for post-market surveillance
- *WHO Guidance for Post-Market Surveillance:*
  - **Implementation** of International Medical Device Regulators Forum **(IMDRF) guidance on unique device identification (UDI)** systems for medical devices will **aid documenting user feedback**, and onward **reporting to NRAs** by manufacturers
  - IMDRF's UDI is intended to "**facilitate unambiguous identification** of the medical device… used to **link and integrate existing government, clinical, hospital, and industry databases**"
  - UDI allows more **rapidly identify medical devices** implicated by user feedback.
  - UDI allows **traceability of the medical device throughout distribution and use**

Connected by our common goal… Patients



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THANK YOU / QUESTIONS

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10:10 – 10:30

Opportunities and challenges – Healthcare professional perspective

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Soon Chun Hyang University Hospital

Timothy Wilton

Medical Director, the National Joint Registry

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Healthcare professional engagement in Post-market surveillance of Korea

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

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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

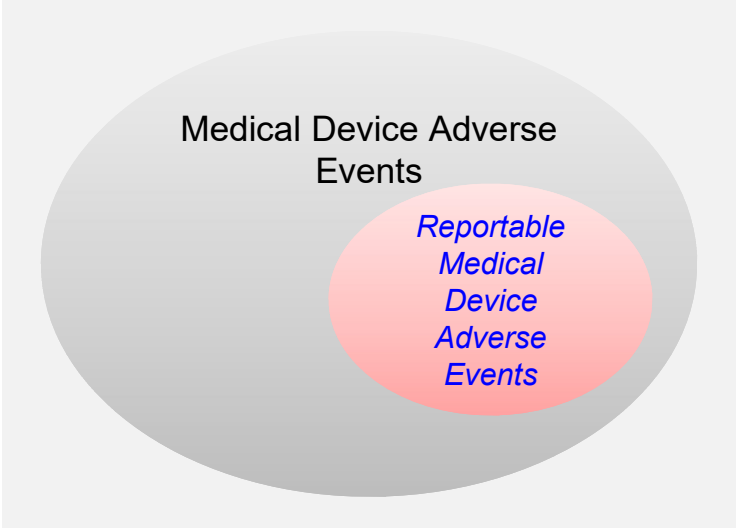
MDAE vs reportable MDAE

Medical Device Adverse Event (MDAE)[1]

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

Reportable MDAE[2]

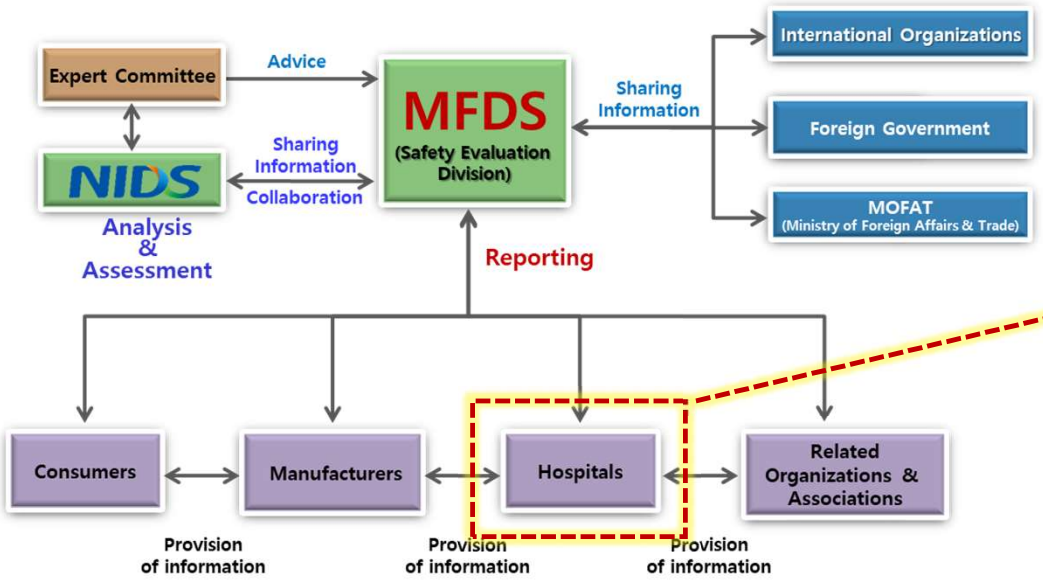
- An event has occurred
- The device is associated with the event
- The event led to one of the following outcomes
  - Death or Serious injury of a patient, user or other person
  - No death or serious injury occurred but the event might lead to death or serious injury

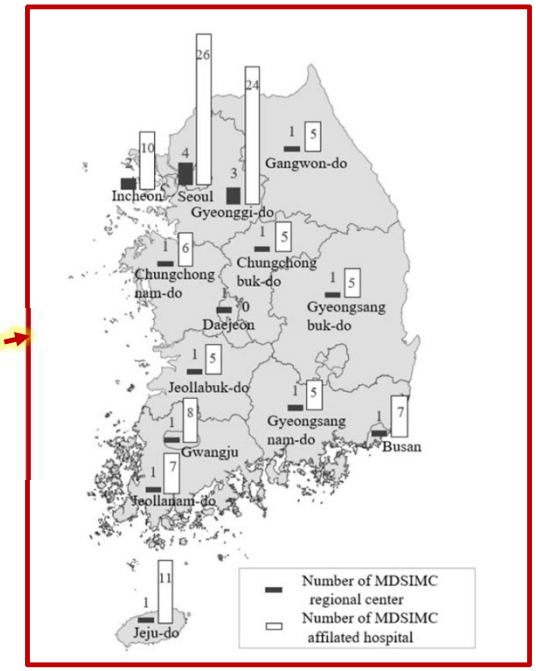


References:

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

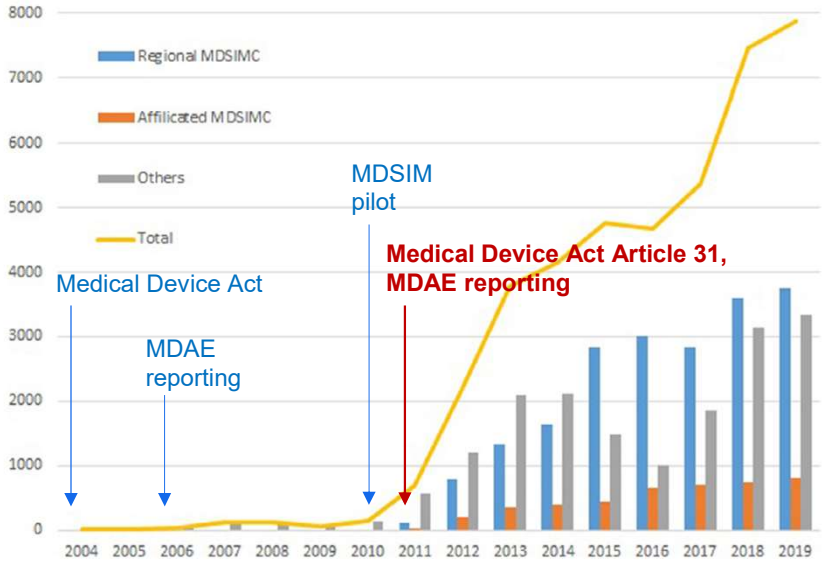


Fig. 1. Numbers of medical device adverse event reports by reporting year and source in Korea.
Note: MDSIMC = Medical Device Safety Information Monitoring Center.

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

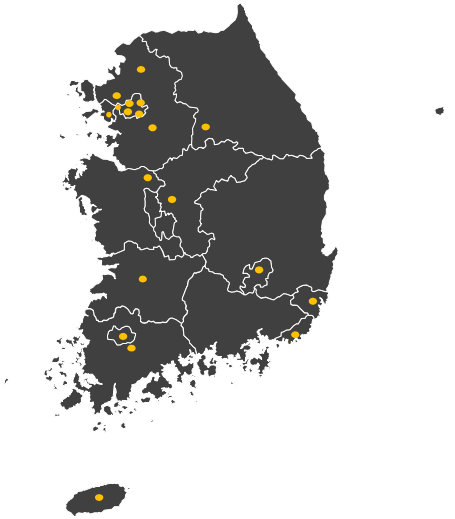
MDSIM; Brief history

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
  - 20 regional centers & 124 affiliated healthcare institutions
- MFDS established ‘AE expert committee’ (2018)



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

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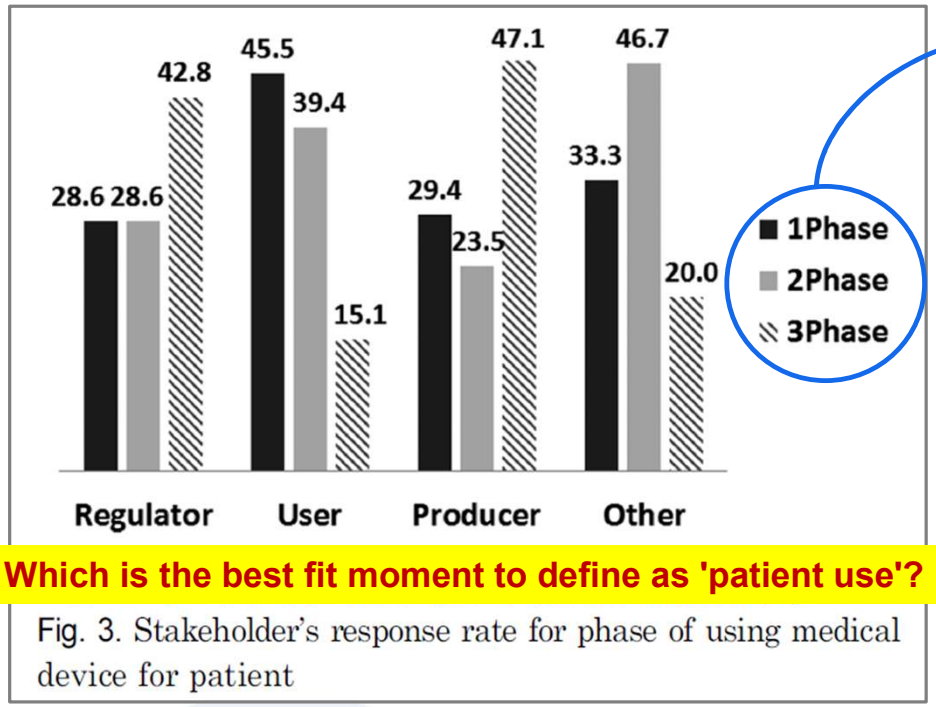
What challenges we recognized

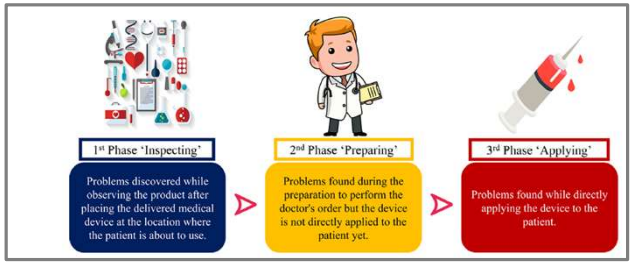
Perspective diversity



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



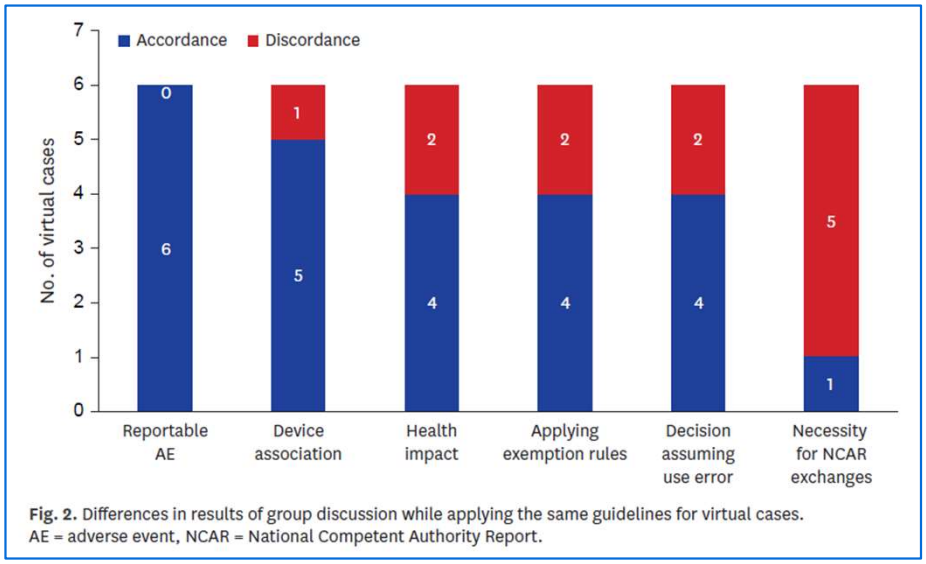


Fig. 2. Differences in results of group discussion while applying the same guidelines for virtual cases.
AE = adverse event, NCAR = National Competent Authority Report.

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?

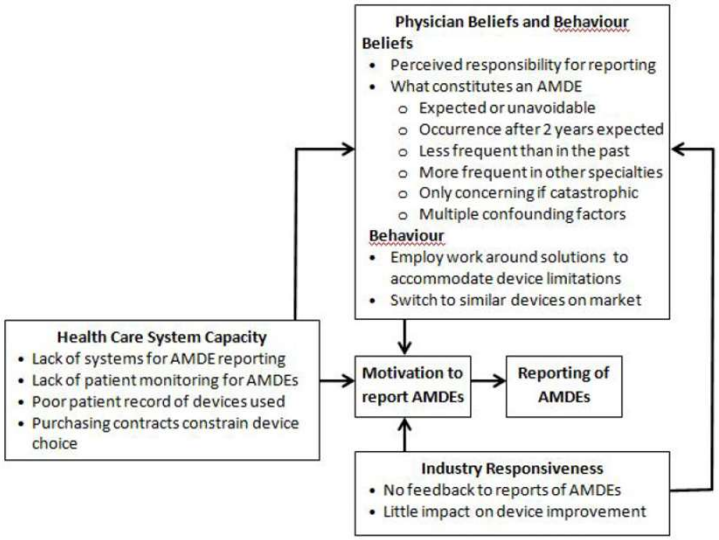


Figure 1 Factors influencing adverse medical device event (AMDE) reporting.

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

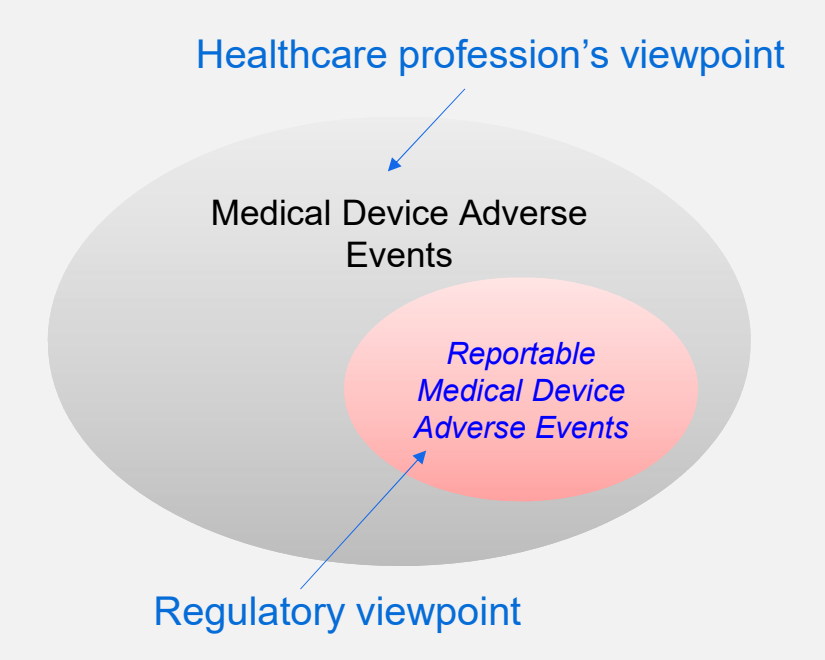
Contribute to upgrading medical device

- 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

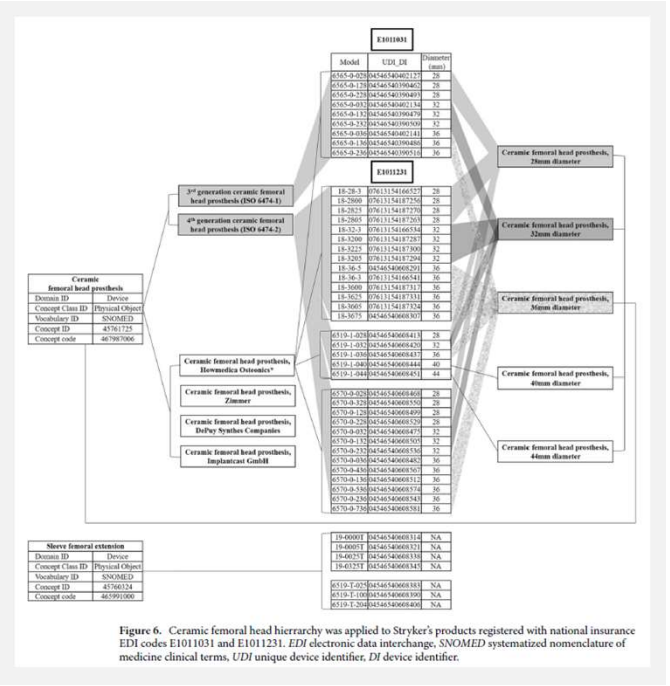


Figure 6. Ceramic femoral head hierrarchy was applied to Stryker's products registered with national insurance EDI codes E1011031 and E1011231. *EDI* electronic data interchange, *SNOMED* systematized nomenclature of medicine clinical terms, *UDI* unique device identifier, *DI* device identifier.

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

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THANK YOU / QUESTIONS

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Safety Notices and Vigilance - a Healthcare Professional's view - Opportunities and Challenges

Mr Tim Wilton MA FRCS Medical Director National Joint Registry (UK)

National Joint Registry
www.njrcentre.org.uk
Working for patients, driving forward quality

Conflict of Interest Statement

- Medical Director National Joint Registry
- Previously Chairman and Council member of Bone and Joint Journal
- President British Orthopaedic Association 2016
- President BASK 2010-2012
- Member of Orthopaedic Data Evaluation Panel (ODEP)
- Design Consultant Smith and Nephew 2003-2009
- No royalties at any time
- No shares or financial interests in any related company
- No financial support for Unit or Research from Industry

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Post Market Vigilance

- Can be by 'after event' reporting eg 'yellow card' system in UK
- Can be by routine collection of data eg in Registries
- Registries rely on pre-determined outcome collection (eg Revision)
- Registries have the capacity to link to other databases (eg Mortality)
- Registries are more likely to capture all cases and all specified failures
- Registries can't identify outcomes where the data are not either collected in the registry OR a linked database

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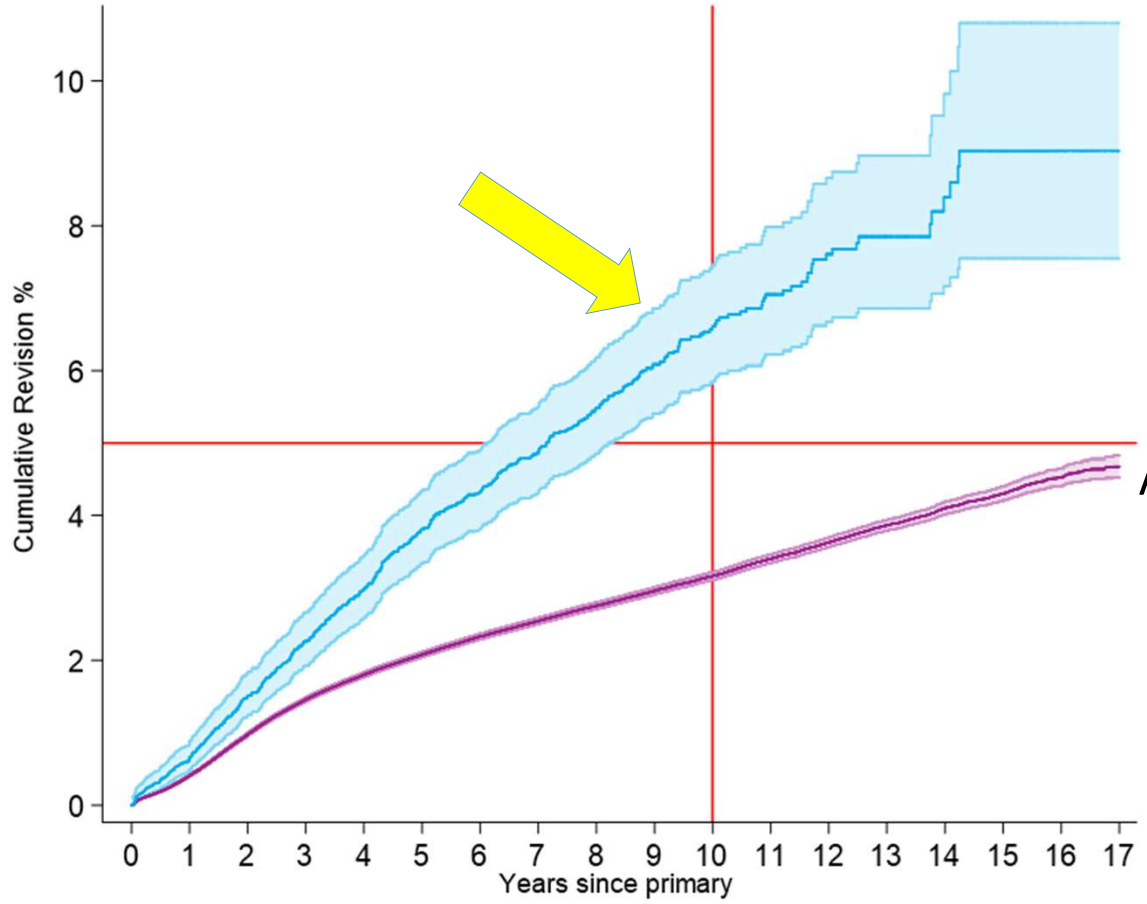
If an Implant had this revision rate would you want to know / do something about it?



Average Condylar TKR

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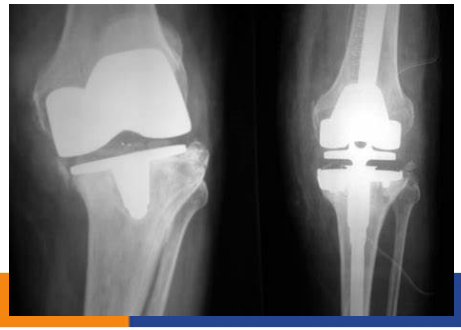
HOW BEST TO DETECT FAILED DEVICES?

- Any MISSED complication delays or prevents detection
- Reporting systems for ‘Failure’ are not usually robust
- Reports to MHRA about devices numbered about 15000 per year in 2012
- The same year there were 15000 revision hip and knee replacements
- About 2% of these were reported to the MHRA



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Registry Background

- NJR usual analysis has been on the basis of 'whole brand' with REVISION operation as the outcome measure

- In recent years this has been subdivided for knees according to Cruciate Retaining or Posterior Stabilised knees and also separated by patella resurfacing/not resurfacing (ie 4 groups)
- Statistically significant differences between large cohorts are common (?important)
- 'Outlier' implants are defined as showing 50% (Alert) or 100% (Alarm) higher than expected revision rate compared to the Combined CR/PS average

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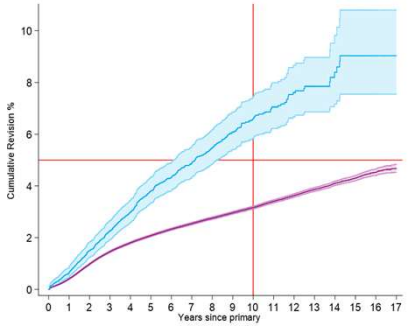
That device happens to be part of the Nexgen family



- Overall performance one of the more satisfactory knees

NJR Annual Report Data 2022

Brand[1]	N	Median (IQR) age at primary	Male (%)	Time since primary					
				1 year	3 years	5 years	10 years	15 years	18 years
Nexgen Hinge Type[Fem:Tib]	1,056	73 (64 to 80)	26	1.19 (0.68-2.09)	2.67 (1.79-3.97)	3.88 (2.72-5.54)	*7.47 (5.11-10.84)*	*9.36 (6.22-13.95)*	
Nexgen LCCK[Fem] Nexgen[Tib]	1,181	71 (64 to 79)	36	1.22 (0.72-2.04)	2.67 (1.85-3.85)	3.26 (2.30-4.62)	*4.85 (3.29-7.11)*	*8.20 (4.17-15.76)*	
Nexgen[Fem:Tib]	183,105	70 (64 to 76)	42	0.38 (0.35-0.41)	1.26 (1.20-1.31)	1.97 (1.90-2.04)	3.38 (3.27-3.49)	4.52 (4.33-4.71)	5.32 (4.80-5.90)
Nexgen[Fem] LPS (Legacy Posterior Stabilised ZimmerBiomet)[Tib]	3,319	67 (59 to 75)	46	0.46 (0.28-0.76)	1.84 (1.43-2.37)	2.56 (2.06-3.18)	4.20 (3.49-5.04)	5.90 (4.84-7.17)	*7.11 (5.51-9.14)*
Nexgen[Fem] TM Monoblock[Tib]	4,286	64 (58 to 71)	57	0.61 (0.42-0.90)	2.60 (2.16-3.13)	3.28 (2.78-3.87)	4.35 (3.76-5.05)	5.24 (4.[illegible]-6.08)	*5.62 (4.75-6.64)*
Optetrak CR[Fem] Optetrak[Tib]	1,641	70 (63 to 76)	43	0.86 (0.51-1.45)	3.44 (2.65-4.46)	4.89 (3.93-6.08)	8.17 (6.84-9.74)	*10.72 (8.75-13.10)*	

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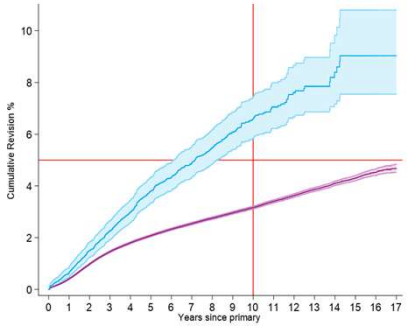
Nexgen Knee Family (Brand)



- Many surgeons have reported good outcomes
- *Keohane et al 2020* and *Brown et al 2021* expressed concern over high failure rate in some variants
- In 2016 the Sub-Brand Nexgen LPS was highlighted by NJR Implant Scrutiny Committee as having a high Revision Rate and referred to MHRA

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Further Process

- What happens after reporting an implant?
- Discussions between Regulator and Manufacturer?
- Discussions with Clinical organisations?
- Requests for Independent study results?

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Nexgen is a Complex Family

- There are similar designs which have different surface treatment
- The bearings can be mobile or fixed
- The ligaments can be retained or removed
- The Kneecap can be resurfaced or not
- Two different polyethylene materials can be used
- Most of these combinations are permitted

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Detailed Nexgen Analysis

88 Variants

CR Constructs Tibial - Bearing	All CR Nexgen Femoral Components	CR Option	CR Precoat	CR Porous	CR Flex Precoat	CR Flex GSF Precoat	CR Flex Porous
Stemmed Cemented Option - CR Flex Std	**82,684**	62,190	848	561	12,807	6,276	2
Stemmed Cemented Option - CR Flex Prolong	**1,605**	[illegible]	0	2	986	344	5
Stemmed Precoat - CR Flex Std	**8,203**	2,305	138	49	4,409	1,299	3
Stemmed Precoat - CR Flex Prolong	**2,090**	9	3	0	1,443	628	7
TM Tray - CR Flex Std	**219**	4	0	147	2	1	65
TM Tray - CR Flex Prolong	**91**	0	0	7	0	1	83
TM CR Monoblock	**4,264**	140	6	3,676	74	52	316
All Poly Tibia	**952**	803	1	0	39	109	0
All Tibial Components	**100,108**	**66,339**	**998**	**4,594**	**19,773**	**8,715**	**481**

PS Constructs Tibial - Bearing	All LPS Nexgen Femoral Components	LPS Option	LPS Porous	LPS Flex Option	LPS Flex GSF Option	LPS Flex Tivanium
Stemmed Cemented Option - LPS Flex Std	**69,372**	58,779	86	6,859	3,571	77
Stemmed Cemented Option - LPS Flex Prolong	**696**	76	0	345	74	201
Stemmed Precoat - LPS Flex Std	**9,184**	6,041	4	2,610	488	41
Stemmed Precoat - LPS Flex Prolong	**881**	8	0	248	168	457
LPS Fluted Precoat - LPS Std Mobile	**501**	0	0	345	156	0
TM Tray - LPS Flex Std	**370**	10	359	1	0	0
TM Tray - LPS Flex Prolong	**4**	0	3	0	0	1
TM LPS Monoblock	**1,888**	74	1,796	7	4	7
All Tibial Components	**82,896**	**70,704**	**2,263**	**11,458**	**4,652**	**785**

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Large numbers so Statistical significance quite likely

NEXGEN VARIANTS

Revised / Expected vs. all other NJR TKR: Comparison with average

Revision rate vs. all other bicondylar knees	All CR Nexgen Femoral Components	CR Option	CR Precoat	CR Porous	CR Flex Precoat	CR Flex GSF Precoat	CR Flex Porous
Stemmed Cemented Option - CR Flex Std	**0.76 (0.72 - 0.81)**	0.75 (0.71 - 0.80)	0.84 (0.44 - 1.48)	0.47 (0.22 - 0.86)	0.80 (0.70 - 0.91)	0.81 (0.66 - 0.98)	0.00 (0.00 - 50.76)
Stemmed Cemented Option - CR Flex Prolong	**0.51 (0.27 - 0.87)**	0.37 (0.01 - 2.06)		0.00 (0.00 - 67.38)	0.61 (0.29 - 1.12)	0.32 (0.04 - 1.15)	0.00 (0.00 - 30.86)
Stemmed Precoat - CR Flex Std	**0.72 (0.61 - 0.84)**	0.79 (0.57 - 1.08)	0.58 (0.07 - 2.11)	0.00 (0.00 - 2.06)	0.63 (0.50 - 0.78)	1.00 (0.68 - 1.41)	0.00 (0.00 - 62.37)
Stemmed Precoat - CR Flex Prolong	**1.13 (0.85 - 1.48)**	0.00 (0.00 - 10.78)	0.00 (0.00 - 59.00)		1.01 (0.70 - 1.42)	1.45 (0.91 - 2.20)	0.00 (0.00 - 9.50)
TM Tray - CR Flex Std	**0.58 (0.16 - 1.50)**	0.00 (0.00 - 44.06)		0.66 (0.14 - 1.93)	0.00 (0.00 - 109.05)	0.00 (0.00 - 133.71)	0.46 (0.01 - 2.58)
TM Tray - CR Flex Prolong	**0.71 (0.09 - 2.58)**			0.00 (0.00 - 11.82)		0.00 (0.00 - 41.63)	0.83 (0.10 - 3.01)
TM CR Monoblock	**1.00 (0.86 - 1.16)**	0.60 (0.16 - 1.54)	0.00 (0.00 - 14.98)	0.99 (0.84 - 1.15)	0.81 (0.22 - 2.07)	1.64 (0.45 - 4.19)	1.42 (0.81 - 2.31)
All Poly Tibia	**0.67 (0.34 - 1.16)**	0.64 (0.31 - 1.18)	0.00 (0.00 - 137.10)		3.27 (0.40 - 11.81)	0.00 (0.00 - 2.12)	
All Tibial Components	**0.79 (0.75 - 0.82)**	**0.76 (0.71 - 0.80)**	**0.78 (0.42 - 1.30)**	**0.89 (0.77 - 1.04)**	**0.77 (0.70 - 0.86)**	**0.88 (0.75 - 1.03)**	**1.16 (0.70 - 1.80)**

Revision rate vs. all other bicondylar knees	All LPS Nexgen Femoral Components	LPS Option	LPS Porous	LPS Flex Option	LPS Flex GSF Option	LPS Flex Tivanium
Stemmed Cemented Option - LPS Flex Std	**1.35 (1.30 - 1.41)**	1.24 (1.18 - 1.30)	1.[illegible] (0.28 - 2.6[illegible]	2.04 (1.83 - 2.26)	1.85 (1.58 - 2.16)	2.34 (0.64 - 6.00)
Stemmed Cemented Option - LPS Flex Prolong	**1.55 (1.01 - 2.29)**	2.02 (0.65 - 4.71)		1.45 (0.72 - [illegible]	[illegible] (0.01 - 3.17)	1.88 (0.81 - 3.70)
Stemmed Precoat - LPS Flex Std	**0.93 (0.82 - 1.06)**	0.72 (0.59 - 0.87)	0.00 (0.00 - 18.89)	1.32 (1.08 - 1.61)	1.07 (0.55 - 1.87)	2.62 (0.32 - 9.47)
Stemmed Precoat - LPS Flex Prolong	**1.63 (1.10 - 2.33)**	0.00 (0.00 - 25.74)		1.69 (0.81 - 3.10)	1.29 (0.42 - 3.02)	1.78 (1.00 - 2.93)
LPS Fluted Precoat - LPS Std Mobile	**1.18 (0.54 - 2.24)**			1.17 (0.43 - 2.54)	1.21 (0.25 - 3.54)	
TM Tray - LPS Flex Std	**1.26 (0.71 - 2.08)**	0.00 (0.00 - 13.93)	1.29 (0.72 - 2.13)	0.00 (0.00 - 293.12)		
TM Tray - LPS Flex Prolong	**5.01 (0.13 - 27.91)**		0.00 (0.00 - 19.98)			66.53 (1.68 - 370.70)
TM LPS Monoblock	**0.83 (0.64 - 1.06)**	0.90 (0.25 - 2.31)	0.79 (0.60 - 1.02)	1.87 (0.05 - 10.44)	8.74 (1.06 - 31.56)	2.30 (0.06 - 12.80)
All Tibial Components	**1.27 (1.22 - 1.32)**	**1.17 (1.12 - 1.22)**	**0.87 (0.69 - 1.09)**	**1.76 (1.61 - 1.91)**	**1.65 (1.42 - 1.90)**	**1.98 (1.34 - 2.81)**

Revised / Expected (95% CI)
Adjusted for patient age and gender

p < 0.001	p < 0.001
p < 0.05	p < 0.05

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Outlier status requires 50% or 100% increase compared to class average

NEXGEN VARIANTS

Potential Outlier status vs. all other NJR TKR

Potential outlier status cf. all other bicondlyar knees	All CR Nexgen Femoral Components	CR Option	CR Precoat	CR Porous	CR Flex Precoat	CR Flex GSF Precoat	CR Flex Porous
Stemmed Cemented Option - CR Flex Std	**0.76 (0.72 - 0.81)**	0.75 (0.71 - 0.80)	0.84 (0.44 - 1.48)	0.47 (0.22 - 0.86)	0.80 (0.70 - 0.91)	0.81 (0.66 - 0.98)	0.00 (0.00 - 50.76)
Stemmed Cemented Option - CR Flex Prolong	**0.51 (0.27 - 0.87)**	0.37 (0.01 - 2.06)		0.00 (0.00 - 67.38)	0.61 (0.29 - 1.12)	0.32 (0.04 - 1.15)	0.00 (0.00 - 30.86)
Stemmed Precoat - CR Flex Std	**0.72 (0.61 - 0.84)**	0.79 (0.57 - 1.08)	0.58 (0.07 - 2.11)	0.00 (0.00 - 2.06)	0.63 (0.50 - 0.78)	1.00 (0.68 - 1.41)	0.00 (0.00 - 62.37)
Stemmed Precoat - CR Flex Prolong	**1.13 (0.85 - 1.48)**	0.00 (0.00 - 10.78)	0.00 (0.00 - 59.00)		1.01 (0.70 - 1.42)	1.45 (0.91 - 2.20)	0.00 (0.00 - 9.50)
TM Tray - CR Flex Std	**0.58 (0.16 - 1.50)**	0.00 (0.00 - 44.06)		0.66 (0.14 - 1.93)	0.00 (0.00 - 109.05)	0.00 (0.00 - 133.71)	0.46 (0.01 - 2.58)
TM Tray - CR Flex Prolong	**0.71 (0.09 - 2.58)**			0.00 (0.00 - 11.82)		0.00 (0.00 - 41.63)	0.83 (0.10 - 3.01)
TM CR Monoblock	**1.00 (0.86 - 1.16)**	0.60 (0.16 - 1.54)	0.00 (0.00 - 14.98)	0.99 (0.84 - 1.15)	0.81 (0.22 - 2.07)	1.64 (0.45 - 4.19)	1.42 (0.81 - 2.31)
All Poly Tibia	**0.67 (0.34 - 1.16)**	0.64 (0.31 - 1.18)	0.00 (0.00 - 137.10)		3.27 (0.40 - 11.81)	0.00 (0.00 - 2.12)	
All Tibial Components	**0.79 (0.75 - 0.82)**	**0.76 (0.71 - 0.80)**	**0.78 (0.42 - 1.30)**	**0.89 (0.77 - 1.04)**	**0.77 (0.70 - 0.86)**	**0.88 (0.75 - 1.03)**	**1.16 (0.70 - 1.80)**

Potential outlier status cf. all other bicondlyar knees	All LPS Nexgen Femoral Components	LPS Option	LPS Porous	LPS Flex Option	LPS Flex GSF Option	LPS Flex Tivanium
Stemmed Cemented Option - LPS Flex Std	**1.35 (1.30 - 1.41)**	1.24 (1.18 - 1.30)	1.02 (0.28 - 2.6[illegible])	2.04 (1.83 - 2.26)	1.85 (1.58 - 2.16)	2.34 (0.64 - 6.00)
Stemmed Cemented Option - LPS Flex Prolong	**1.55 (1.01 - 2.29)**	2.02 (0.65 - 4.71)		[illegible] 2.59)	0.57 (0.01 - 3.17)	1.88 (0.81 - 3.70)
Stemmed Precoat - LPS Flex Std	**0.93 (0.82 - 1.06)**	0.72 (0.59 - 0.87)	0.00 (0.00 - 18.89)	1.32 (1.08 - 1.61)	1.07 (0.55 - 1.87)	2.62 (0.32 - 9.47)
Stemmed Precoat - LPS Flex Prolong	**1.63 (1.10 - 2.33)**	0.00 (0.00 - 25.74)		1.69 (0.81 - 3.10)	1.29 (0.42 - 3.02)	1.78 (1.00 - 2.93)
LPS Fluted Precoat - LPS Std Mobile	**1.18 (0.54 - 2.24)**			1.17 (0.43 - 2.54)	1.21 (0.25 - 3.54)	
TM Tray - LPS Flex Std	**1.26 (0.71 - 2.08)**	0.00 (0.00 - 13.93)	1.29 (0.72 - 2.13)	0.00 (0.00 - 293.12)		
TM Tray - LPS Flex Prolong	**5.01 (0.13 - 27.91)**		0.00 (0.00 - 19.98)			66.53 (1.68 - 370.70)
TM LPS Monoblock	**0.83 (0.64 - 1.06)**	0.90 (0.25 - 2.31)	0.79 (0.60 - 1.02)	1.87 (0.05 - 10.44)	8.74 (1.06 - 31.56)	2.30 (0.06 - 12.80)
All Tibial Components	**1.27 (1.22 - 1.32)**	**1.17 (1.12 - 1.22)**	**0.87 (0.69 - 1.09)**	**1.76 (1.61 - 1.91)**	**1.65 (1.42 - 1.90)**	**1.98 (1.34 - 2.81)**

Revised / Expected (95% CI)
Adjusted for patient age and gender

LCI > 2x expected	UCI < 1/2 expected
LCI > 1.5x expected	UCI < 2/3 expected
LCI > 1.2x expected	UCI < 5/6 expected

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Potential Outlier Status just for Tibial Loosening

NEXGEN VARIANTS

Potential Outlier Status - Aseptic Tibial Loosening	All CR Nexgen Femoral Components	CR Option	CR Precoat	CR Porous	CR Flex Precoat	CR Flex GSF Precoat	CR Flex Porous
Stemmed Cemented Option - CR Flex Std	**1.14 (1.02 - 1.27)**	1.13 (0.99 - 1.28)	2.13 (0.58 - 5.46)	0.20 (0.01 - 1.14)	1.13 (0.85 - 1.48)	1.43 (0.98 - 2.02)	0.00 (0.00 - 308.32)
Stemmed Cemented Option - CR Flex Prolong	**1.20 (0.33 - 3.08)**	0.00 (0.00 - 10.16)		0.00 (0.00 - 441.81)	2.01 (0.55 - 5.15)	0.00 (0.00 - 3.91)	0.00 (0.00 - 158.23)
Stemmed Precoat - CR Flex Std	**0.89 (0.63 - 1.22)**	1.20 (0.60 - 2.14)	0.00 (0.00 - 6.05)	0.00 (0.00 - 8.19)	0.64 (0.37 - 1.02)	1.72 (0.82 - 3.16)	0.00 (0.00 - 494.07)
Stemmed Precoat - CR Flex Prolong	**0.80 (0.29 - 1.74)**	0.00 (0.00 - 70.77)	0.00 (0.00 - 549.99)		0.62 (0.13 - 1.81)	1.18 (0.24 - 3.46)	0.00 (0.00 - 43.97)
TM Tray - CR Flex Std	**0.00 (0.00 - 3.05)**	0.00 (0.00 - 202.73)		0.00 (0.00 - 4.60)	0.00 (0.00 - 674.89)	0.00 (0.00 - 758.69)	0.00 (0.00 - 9.72)
TM Tray - CR Flex Prolong	**0.00 (0.00 - 7.65)**			0.00 (0.00 - 63.55)		0.00 (0.00 - 139.27)	0.00 (0.00 - 9.28)
TM CR Monoblock	0.36 (0.21 - 0.59)	0.00 (0.00 - 2.53)	0.00 (0.00 - 73.58)	0.39 (0.22 - 0.64)	0.00 (0.00 - 3.29)	0.00 (0.00 - 6.93)	0.49 (0.01 - 2.75)
All Poly Tibia	**0.00 (0.00 - 1.66)**	0.00 (0.00 - 1.92)	0.00 (0.00 - 1077.67)		0.00 (0.00 - 46.28)	0.00 (0.00 - 16.80)	
All Tibial Components	**1.01 (0.91 - 1.11)**	**1.11 (0.97 - 1.25)**	**1.56 (0.43 - 4.00)**	**0.36 (0.21 - 0.58)**	**0.94 (0.74 - 1.18)**	**1.41 (1.03 - 1.88)**	**0.34 (0.01 - 1.90)**

Potential Outlier Status - Aseptic Tibial Loosening	All LPS Nexgen Femoral Components	LPS Option	LPS Porous	LPS Flex Option	LPS Flex GSF Option	LPS Flex Tivanium
Stemmed Cemented Option - LPS Flex Std	**2.92 (2.74 - 3.12)**	2.52 (2.33 - 2.72)	3.31 (0.68 - 9.6	5.41 (4.64 - 6.28)	4.49 (3.55 - 5.62)	0 (0.00 - 11.13)
Stemmed Cemented Option - LPS Flex Prolong	**3.21 (1.47 - 6.09)**	3.97 (0.48 - 14.33)		4.28 (1.39 - 9.98)	0.00 (0.00 - 12.13)	2.42 (0.29 - 8.75)
Stemmed Precoat - LPS Flex Std	**1.33 (1.03 - 1.70)**	0.77 (0.49 - 1.16)	0.00 (0.00 - 91.24)	2.27 (1.61 - 3.12)	1.88 (0.51 - 4.80)	0.00 (0.00 - 26.35)
Stemmed Precoat - LPS Flex Prolong	**2.14 (0.86 - 4.42)**	0.00 (0.00 - 345.54)		0.97 (0.02 - 5.43)	0.00 (0.00 - 5.40)	3.88 (1.42 - 8.45)
LPS Fluted Precoat - LPS Std Mobile	**0.91 (0.02 - 5.07)**			0.00 (0.00 - 5.18)	2. (0.07 - 14.42)	
TM Tray - LPS Flex Std	**0.44 (0.01 - 2.42)**	0.00 (0.00 - 73.50)	0.45 (0.01 - 2.48)	0.00 (0.00 - 3449.84)		
TM Tray - LPS Flex Prolong	**0.00 (0.00 - 95.59)**		0.00 (0.00 - 98.95)			0.00 (0.00 - 2813.41)
TM LPS Monoblock	**0.27 (0.09 - 0.62)**	0.00 (0.00 - 3.34)	0.29 (0.09 - 0.67)	0.00 (0.00 - 26.30)	0.00 (0.00 - 72.67)	0.00 (0.00 - 33.53)
All Tibial Components	**2.41 (2.27 - 2.55)**	**2.20 (2.05 - 2.35)**	**0.43 (0.20 - 0.82)**	**3.76 (3.30 - 4.26)**	**3.67 (2.92 - 4.55)**	**2.70 (1.16 - 5.31)**

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Worst outcomes for Tibial Loosening

- Combination of THREE associated factors-

- Flex Femoral Component
- LPS Components
- Absence of PMMA Precoat on Tibial Baseplate

- It does NOT appear to be simply the Non-Precoat Tibia so removing that from the market is likely to address only part of the issue

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Formal Notification to MHRA

- Early 2022 these problematic combinations were reported
- Further discussion occurred with manufacturer and MHRA then FDA
- Manufacturer noted that these UK findings were not identified globally
- They suggested ‘rationalisation’ of the implant portfolio without safety concerns being raised
- Pressure applied by MHRA and FDA to issue a Safety Notice

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FSN Issued and 'Option' Tibia withdrawn

- December 2022 Field Safety Notice issued identifying the 'Option' Tibial component as having a high revision rate
- 'Option' tibial implant withdrawn from market and limited follow-up advice given
- Concerns expressed by many surgeons that they should notify all existing patients with affected devices and consider follow-up examination
- Urgent consultation required with professional organisations, surgeons and registry about how much intervention is required and from whom

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Registry Actions

- The Registry can identify the problem – IF the correct analysis is done
- The Registry can identify every case with the affected device
- The Registry can inform each hospital which of their patients is affected
- Clinical advice with full information about the devices concerned is essential to giving the appropriate plan for further action
- This must be available at the time the FSN is issued to avoid confusion

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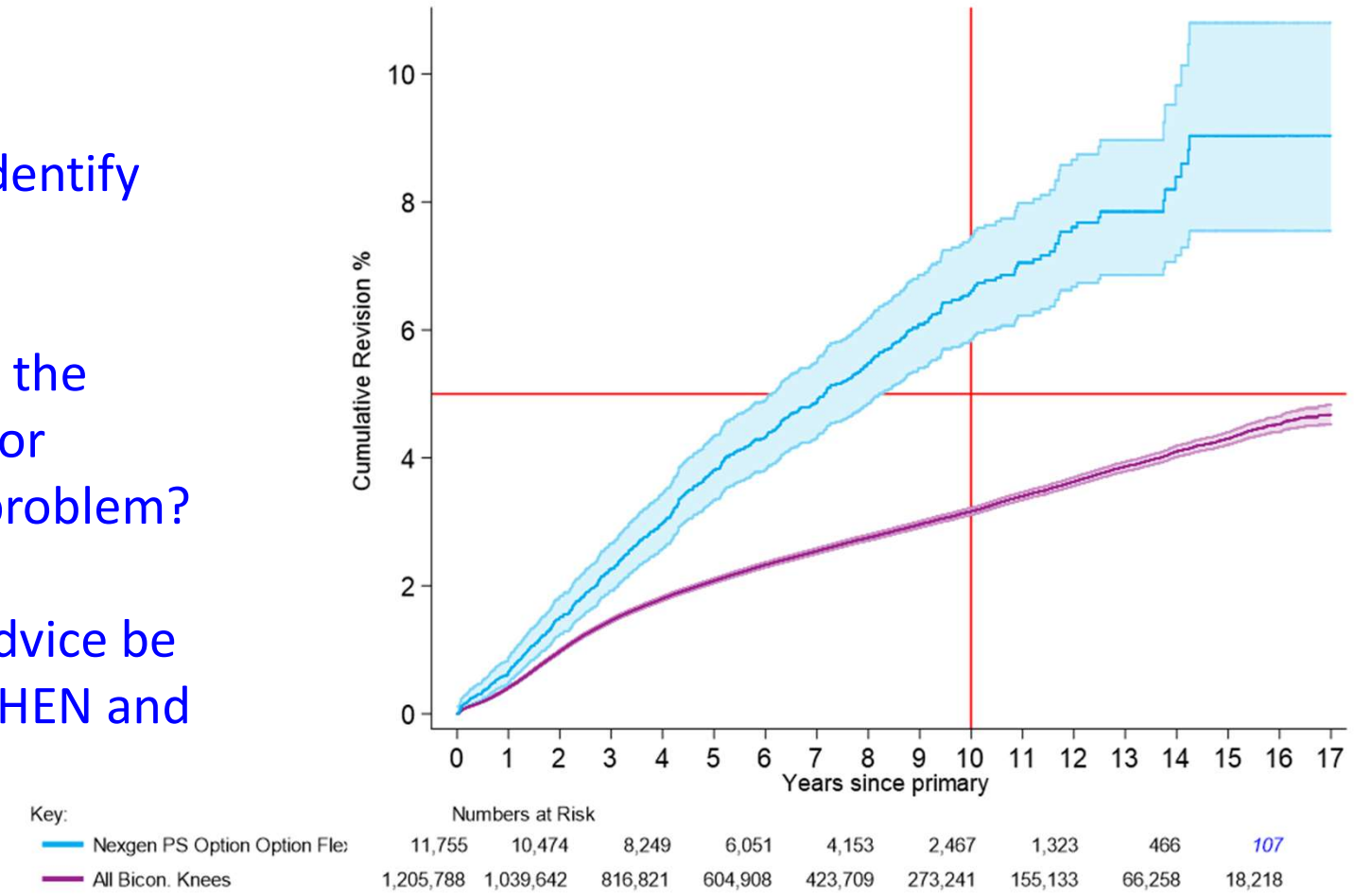
PS Meniscal: Option:Option: Femoral Flex vs All bicondylar knees

How best to identify this variant?

Where should the threshold be for identifying a problem?

How should advice be developed, WHEN and by whom?



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Conclusions

- Identifying a problem implant is difficult but requires comprehensive data
- Once identified should the device be formally withdrawn?
- Is it enough to allow the manufacturer to remove the device from the market?
- Many devices with much worse revision rates have been withdrawn for ‘commercial reasons’ and not for SAFETY reasons

IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

THANK YOU / QUESTIONS

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European Commission | European Union

IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

10:30 – 10:50

Opportunities and challenges – Regulator's perspective

Christophe Driesmans

Head of the Materiovigilance Entity, Federal Agency for Medicines and Health Products

Melissa Torres

Associate Director for International Affairs, Center for Devices and Radiological Health, FDA

European Commission | European Union

Safety notices and vigilance
A regulator's perspective

IMDRF 2023

BRUSSELS

27 March 2023

Christophe Driesmans

famhp
federal agency for medicines and health products

.be

Purpose of post-market surveillance, vigilance & safety notices

- Continuously verify/monitor the benefit/risk profile of medical devices in the real world compared to pre-market phase

- Take the appropriate measures to reduce/eliminate the risks and the harms of medical devices in the market

- Inform the (end-)users of the medical devices affected, the risks associated and the measures they can take to lower the risk + action the manufacturer will take

➢ **Increased safety of all medical devices in the market**
➢ **Increased patient safety and public health**

European context

New regulation + incorporation of IMDRF work

EUDAMED: European database on medical devices (manufacturers, devices, vigilance, pre-market data, market surveillance,…)

- ➢ including UDI database

- 1 vigilance database, instead of 31 separated vigilance databases

	Population	Incidents/year	Safety Notices/year
BELGIUM	11.5 million	4,500	600
EEA+TR+XI	+500 million	+100,000	~2,000

- Inclusion of IMDRF adverse event terminology to all vigilance reports
- Signal detection foreseen on vigilance data
- Transparency to the public (devices, vigilance data, safety notices,…)

Opportunities

Triumvirate of UDI, IMDRF adverse event terminology and device nomenclature (GMDN/EMDN/…)

- Deeper understanding of vigilance data within a jurisdiction

- Allows to incorporate other data sources in a more straightforward way:
  - Device registries
  - Implant registries
  - Other data sources (e.g. reimbursement data)

- Easier way of combining data from other jurisdictions (using one or multiple coding systems)

➢ **Truly play our role as regulators and give meaningful insights to manufacturers, healthcare professionals and patients**

Challenges/opportunities

- Standardization/covergence of data fields/requirements
- Collaboration/sharing of experiences on signal detection in medical devices
- Increased patient self-care/self-monitoring/self-diagnostic
- Medical APPs, software, personalised medical devices
- Vigilance data is limited/biased
- The flow POST-market => PRE-market

Contact

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Postmarket Surveillance: A Regulator's Perspective

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Overview

- Postmarket surveillance is a set of activities to collect and evaluate experience gained from medical devices that have been placed on the market, and to identify the need to take any action.
- Ensuring the safety of medical devices on an ongoing basis is far more complex than having a vigilant postmarket surveillance system for quick identification of new or increased safety concerns, timely public communication about them, and effective interventions.
- It is also important to foster innovation that spurs the development of safer, more effective technologies and assures timely patient access and ultimately improves patient safety.
- Postmarket surveillance and fostering innovation are key objectives and priority areas of the IMDRF Strategic Plan
- Postmarket surveillance and medical device safety have been long standing priorities at US FDA

Key Aspects of a Postmarket Surveillance System

- Communicates timely, accurate, systematic, and prioritized assessments of the benefits and risks of medical devices throughout their marketed life using high quality, standardized, structured, electronic health-related data

- Ensures that medical devices continue to be safe and well performing, and ensures that actions are undertaken if the risk of the use of a particular medical device outweighs the benefit

- Identifies potential safety signals in near real-time from a variety of data sources

- Can facilitate the approval of new devices, or new uses of existing devices

Challenges

- Medical device postmarket surveillance presents unique challenges compared to drugs and biologics due to the
  - greater diversity and complexity of medical devices,
  - iterative nature of medical product development,
  - learning curve associated with technology adoption, and
  - relatively short product life cycle.
- Lack of alignment in terminology globally
  - Adverse Event Reporting
  - Safety Notices/Recalls
- Multiple/complex data sources
  - Global
  - Reactive and proactive
- Reliance on traditional surveillance studies can take a long time before you can characterize any risks and determine whether a signal represents a true safety concern

Postmarket Surveillance: An International Perspective

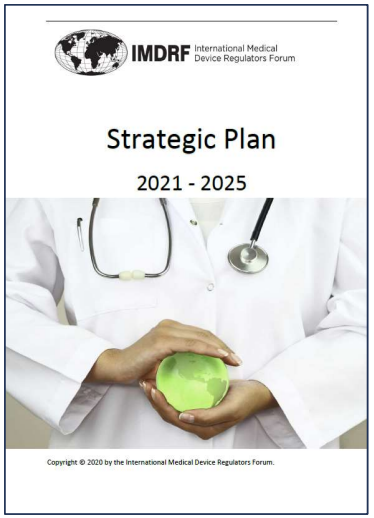
IMDRF Strategic Plan

Key Objectives

1. Strengthen postmarket surveillance for medical devices and implement regulatory life cycle processes.
2. Manage regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance.

Priority Areas

- Premarket: Develop a risk calibrated regulatory approach for innovations and promote harmonized pre-market review requirements for medical devices.
- Postmarket: Leverage post-market monitoring and surveillance to ensure accessibility to safe and effective innovations for patients.



IMDRF Adverse Event Terminology Working Group

The purpose of the IMDRF AE WG is to provide a comprehensive, improved terminology and coding system for adverse events. This

- Helps regulatory agencies by
  - enabling them to analyze safety information about medical devices with higher accuracy and reliability;
  - facilitating communication about medical device adverse events between regulatory agencies.
- Helps regulated industry by
  - reducing the burden of managing safety information on medical device products
  - reducing the burden of preparing multiple adverse event reports to regulatory agencies.
- Widespread use of an improved coding system will improve signal detection by adverse event management systems enabling a faster response by both manufacturers and regulatory authorities.

IMDRF/AE WG/N43FINAL:2020 (Edition 4)

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes

Authoring Group: IMDRF Adverse Event Terminology Working Group

Date: 18 March 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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IMDRF Annexes and Alignment with FDA Coding

The FDA is fully harmonized with IMDRF AE Codes, so each FDA code is mapped to a single corresponding IMDRF code.

Annex A – Device Problem	= FDA Device Problem Codes
Annex B – Type of Investigation	= FDA Evaluation Method Code
Annex C – Investigation Findings	= FDA Evaluation Results Code
Annex D – Investigation Conclusion Code	= FDA Evaluation Conclusions
Annex E – Health Effects Clinical Signs, Symptoms & Conditions	= FDA Patient Problem Code
Annex F- Health Effects Health Impact	= FDA Patient Problem Code
Annex G – Components	= FDA Component Code

IMDRF Adverse Event Terminology Working Group

Current Work Item

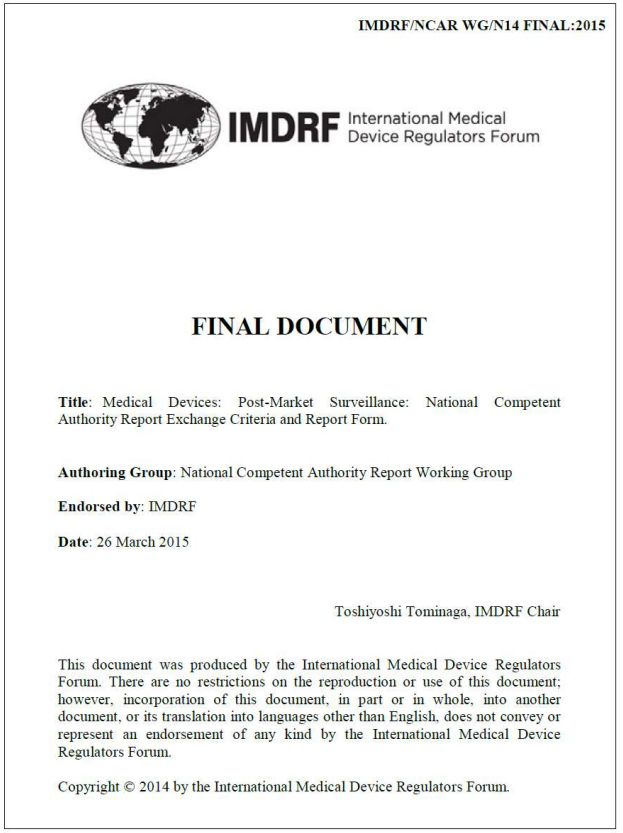
- Expanding the harmonization of adverse event terminology, and standardising data fields across jurisdictions in view of fully exploiting adverse event reporting for signal detection.
- This will allow standardization of the data fields and requirements used in forms and templates of the different jurisdictions (e.g., adverse event / incident reporting, FSCA, trend reporting, NCAR exchange).
- This work item will enable improved information sharing across jurisdictions to facilitate subsequent collaborative analysis of trending and signal detection

National Competent Authority Report (NCAR)

Program established in IMDRF to facilitate the exchange of relevant post market safety information on medical devices with global distribution in order to trigger rapid adoption of field safety corrective actions in all concerned geographies to avoid death or serious deterioration of health, when relevant.

IMDRF/NCAR WG/N14 FINAL:2015 ***Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form***

- Full Implementation: April 2016 – Present
- NCAR is used to send information that another regulator may not already be aware of and is used to gather information from multiple regulators



IMDRF/NCAR WG/N14 FINAL:2015

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form.

Authoring Group: National Competent Authority Report Working Group

Endorsed by: IMDRF

Date: 26 March 2015

Toshiyoshi Tominaga, IMDRF Chair

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International Medical Device Safety Meetings

Goal

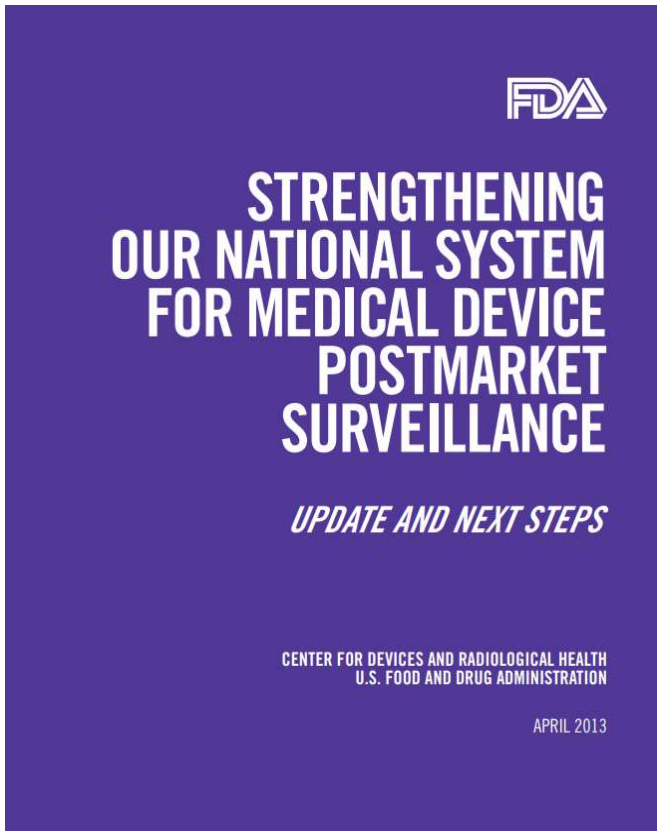
To combine and improve upon regulatory intelligence from multiple regulatory authorities (who have confidentiality commitments with each other) in order to identify and act as quickly as possible on proactive risk reduction and post market medical device safety issues.

Objectives

- share up to date information related to post market safety performance of medical devices;
- notify of pending or complete regulatory/compliance actions, including communications;
- share approaches to collection, analysis, and benefit-risk decision-making regarding post market medical device performance;
- share and collaborate on pro-active risk reduction activities;
- share / develop strategic approaches to the post market regulation of medical devices and
- identify potential actions and projects for future collaboration.

Postmarket Surveillance: A US FDA Perspective

US FDA
Postmarket Surveillance and Medical Device Safety



Key Accomplishments

- Established a Unique Device Identification System
- Improved regulatory clarity regarding use of real world evidence
- Developed the National Evaluation System for health Technology (NEST) - an active surveillance and evaluation system
- Established a signal management program
- Recalibrated the benefit-risk framework for device oversight in the pre- and post-market settings
  - Issued several benefit-risk guidance documents
- Established the Case for Quality Program
- Continued to fostered innovation towards safer medical devices
- Continued to modernize our adverse event reporting system

Summary

- Opportunities for greater global alignment
  - Build upon the IMDRF Adverse Event work
  - Greater global adoption of the IMDRF Adverse Event codes
  - Harmonization/convergence of terminology and requirements for safety notices/recalls
  - Update existing GHTF Study Group 2 documents on Postmarket Surveillance/Vigilance

- Optimize postmarket data collection, quality, completeness, and analysis

Thank you/Questions?

IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

10:50 – 11:10

Panel discussion

Opportunities for improvement

Paul Piscoi

Administrator, DG Santé, European Commission (Moderator)

European Commission | European Union