Impact of Adverse Event Reporting and Learning System and Case-Oriented Compensation/Investigation and Prevention System on Enhancing Patient Safety Culture and Mitigating Conflict in Japan

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Japan Council for Quality Health Care (JQ)

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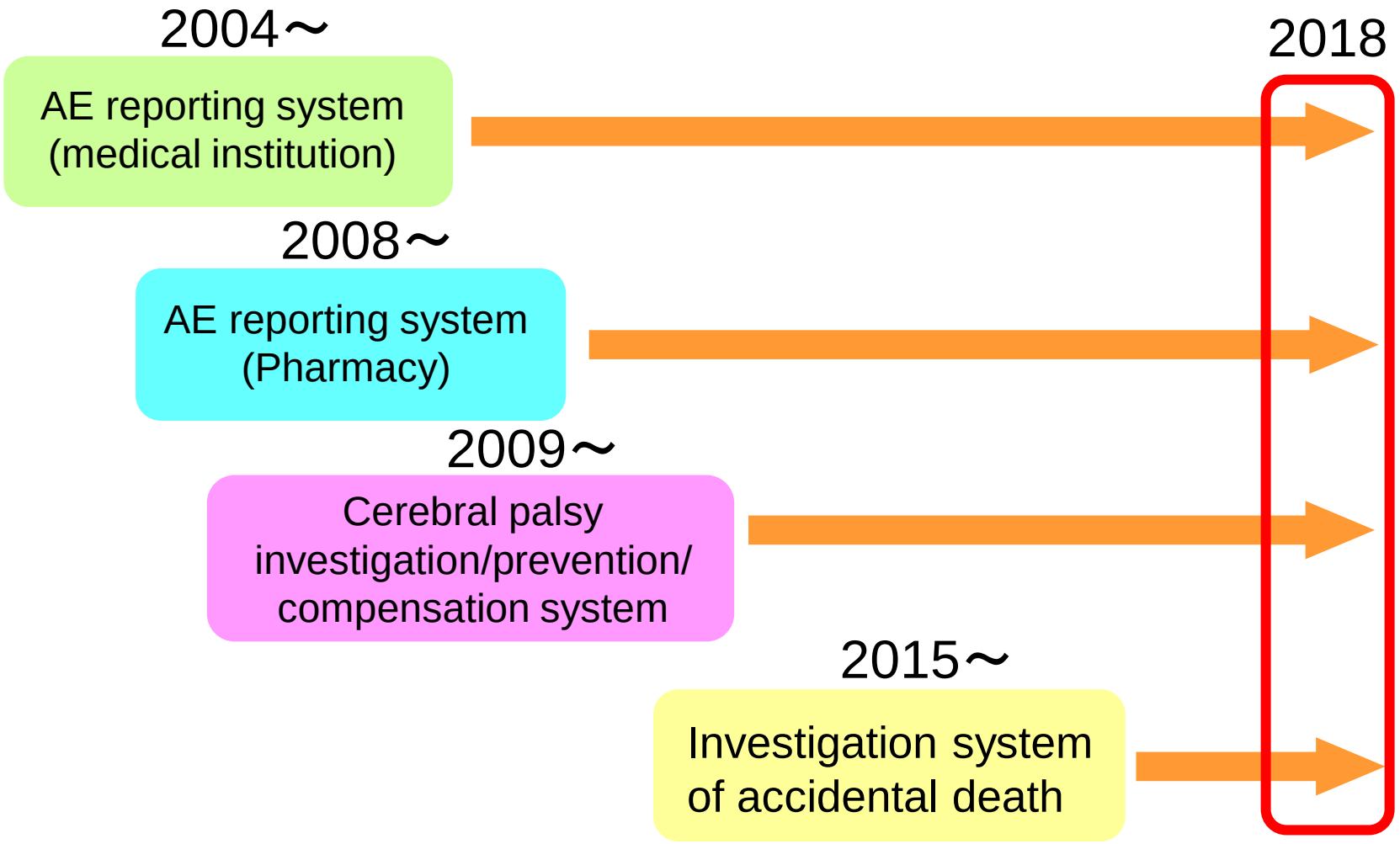
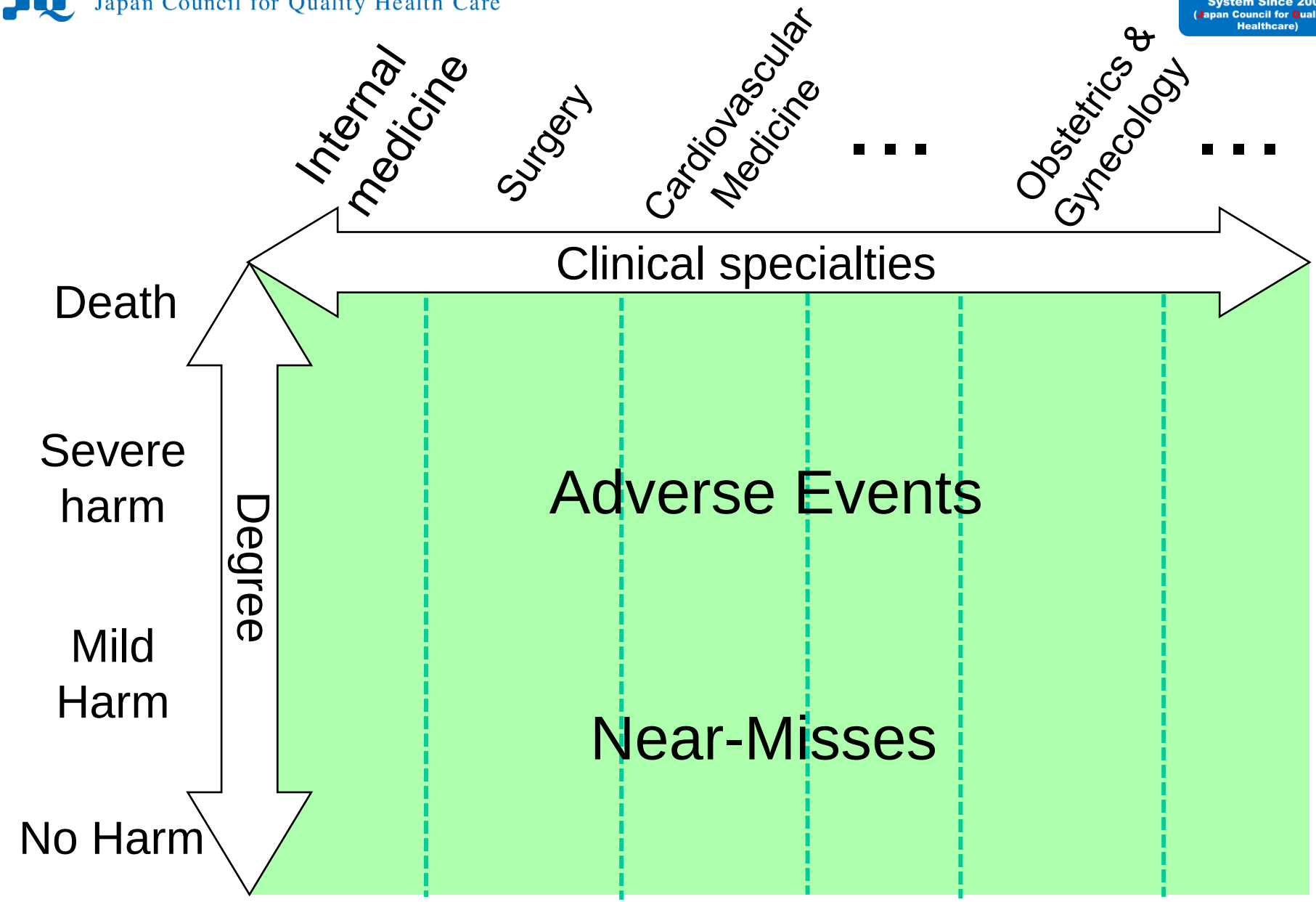
"To err is human to cover up is unforgivable, to fail to learn is inexcusable."

Sir Liam Donaldson, Envoy for Patient Safety

Nationwide reporting/investigation/learning system with public or quasi public nature




Internal medicine
Surgery
Cardiovascular Medicine
. . .
Obstetrics & Gynecology
. . .
Clinical specialties
Death
Severe harm
Mild Harm
No Harm
Degree
Adverse Events
Near-Misses

Adverse Event Reporting System Since 2004 (Japan Council for Quality in Healthcare)

Overview of the nationwide adverse event reporting/learning system (2004~)

Adverse event

Hospitals (Mandatory)

-**University Hospitals**
-National Hospitals
etc.

Hospitals (Voluntary)

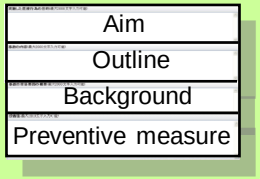
Near-miss

Hospitals (Voluntary)

Web reporting

①Cord-choice

②Description



On-site visit
（Voluntary survey）

Japan Council for Quality Health Care

Aim
Patient safety and prevention of medical accident
（No blame）

Steering Committee
(Experts, Patient representative)

Secretariat

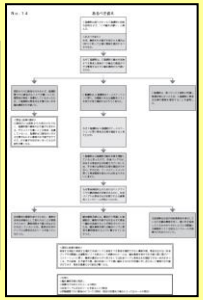
Expert Panel

Annual/ Quarterly report

Medical safety information

Database

Training program (RCA)

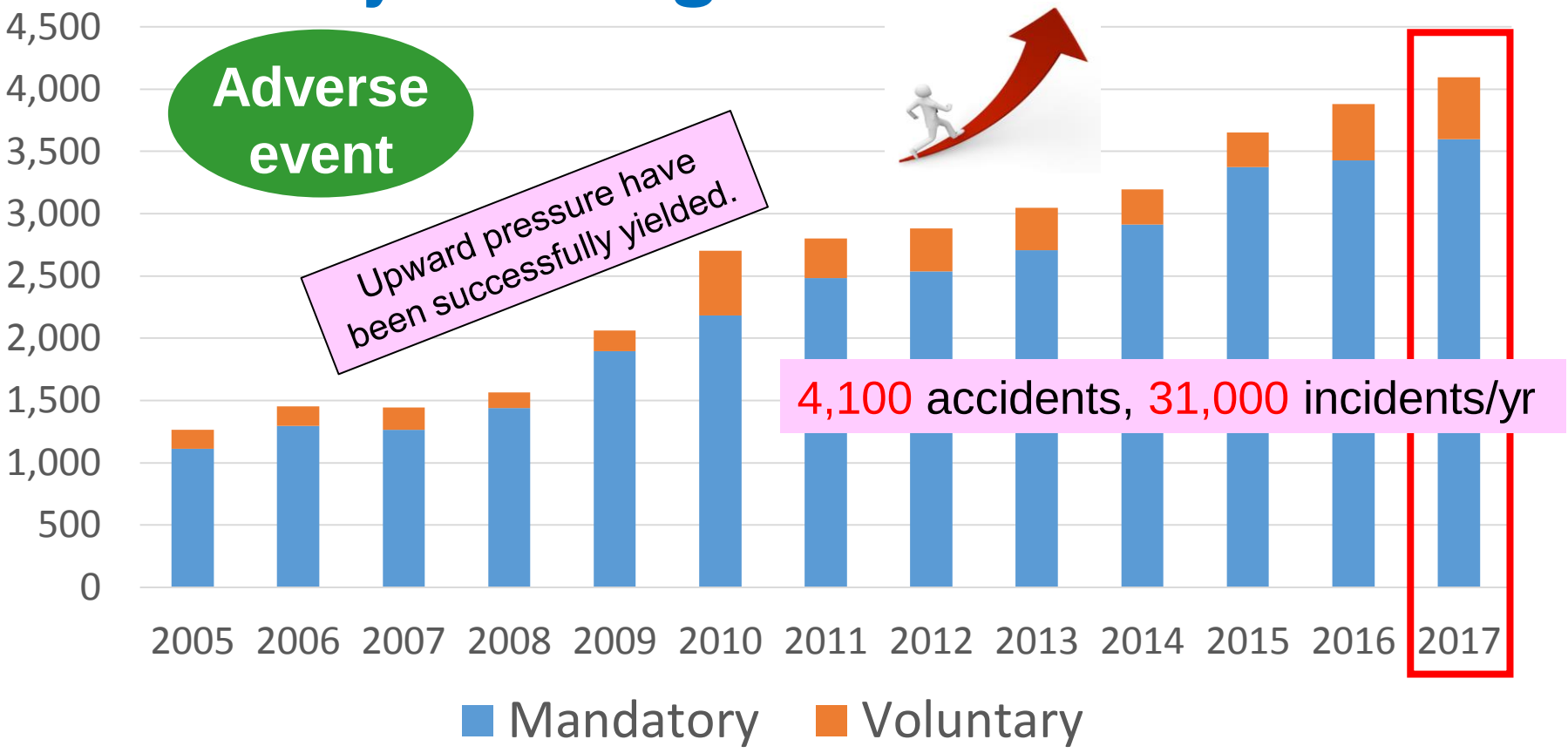


General public

Health care professionals/ facilities

Government

Year-to-year change in the number of AEs



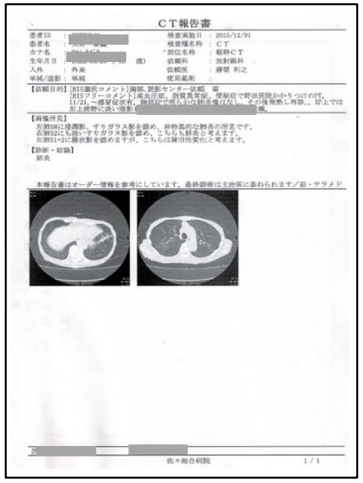
Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Mandatory	1,114	1,296	1,266	1,440	1,895	2,182	2,483	2,535	2,708	2,911	3,374	3,428	3,598
Voluntary	151	155	179	123	169	521	316	347	341	283	280	454	497

Thematic analysis (~200 themes since 2004)

- Wrong Administration of Antineoplastic Agents, Anti-Coagulants etc.
- **Failure to Confirm CT, MRI Imaging Report**
- Patient's Falls From a Pediatric Bed
- Drug Mix-up Due to Similar Appearance
- Tubing Disconnection of Ventilator Circuit
- Double Dosing of Medicines Brought in at Hospitalization and Drugs Prescribed in Hospital
- Accidentally Ingestion or Aspiration of a Foreign Body During Dental Treatment
- Film Dressing Worngly Affixed to a Permanent Tracheostomy
- "Nor-Adrenalin Administeration" Instead of "Adrenaline" During Resuscitation

"Failure to Confirm CT, MRI etc. Imaging Report"

- *The patient diagnosed as "**Abdominal Aortic Aneurysm**" **underwent CT scanning** for following up the possible growth of it. Vascular physician in charge recorded the finding of the CT image in the medical chart.*



- ***One year after**, nephrologist, another physician in charge of the patient, learned from other hospital that the patient developed **lung cancer**.*
- *Reviewing the **CT examination report issued by radiologist** one year ago, it described as "**There is a lesion highly suspicious of lung cancer**".*

Preventative action by a hospital group in 2017

- Japanese National University Hospital Alliance (JANUHA, 45 National University Hospitals) participated in a program to survey and enhance prophylactic measures to the failure of radiological imaging report by on-site visit and appraisal in 2017 .

"Medical Safety Information" (Monthly alert)

Medical Safety Information, Project to Collect Medical Near-Miss/Adverse Event Information; No.99, February 2015

Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information
Medical Safety Information

Logo

Title

No.99, February 2015

Left-Right Mix-Up When Inserting a Thoracostomy Tube

Eight cases have been reported involving left-right mix-up du
position or orientation when inserting a thoracostomy tube o
(information collection period: from January 1, 2011 to Decemb
is compiled based on "Individual Theme Analysis" (p.174) in the

Key statement

Cases of left-right mix-up when inserting a thoracostomy tube or performing a thoracentesis have been reported. In all of these cases, the medical staff failed to check the site immediately before the procedure.

Image of case 1

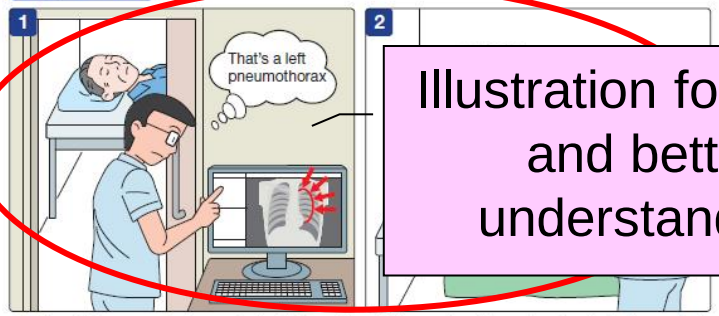


Illustration for quick and better understanding

◆ Of the eight cases reported, seven involved the insertion of a thoracostomy tube and one involved a thoracentesis.

Project to Collect Medical Near-Miss/ Adverse Event Information
Medical Safety Information
No.99, February 2015

Left-Right Mix-Up When Inserting a Thoracostomy Tube

Case 1

A patient with left pneumothorax was to have a thoracostomy tube inserted. Usually, the patient waits in a sitting position and is placed in the position required immediately before the procedure. However, in this case, when t eady lying on the bed in a supine po ocedure from the right-hand side. As marked the right thoracic area and as no air leaking from the tub and re

Case summary

Case 2

Outpatient Department Physician A and Ward Physician B checked the planned site of tube insertion on an image taken from a patient admitted with a diagnosis of left pneumothorax. Two hours later, they decided to carry out the procedure in the patient's room, because the treatment room was unavailable. To make it easier to carry out the procedure, the positions of the patient's head and feet were reversed. In doing so, the physicians got their left and right the wrong way around and placed the patient in the left lateral decubitus position before marking the 2nd right intercostal space, into which they inserted the tube. When a chest X-ray was taken to check the site of the tip of the tube, they discovered that they had erroneously inserted it into the right-hand side.

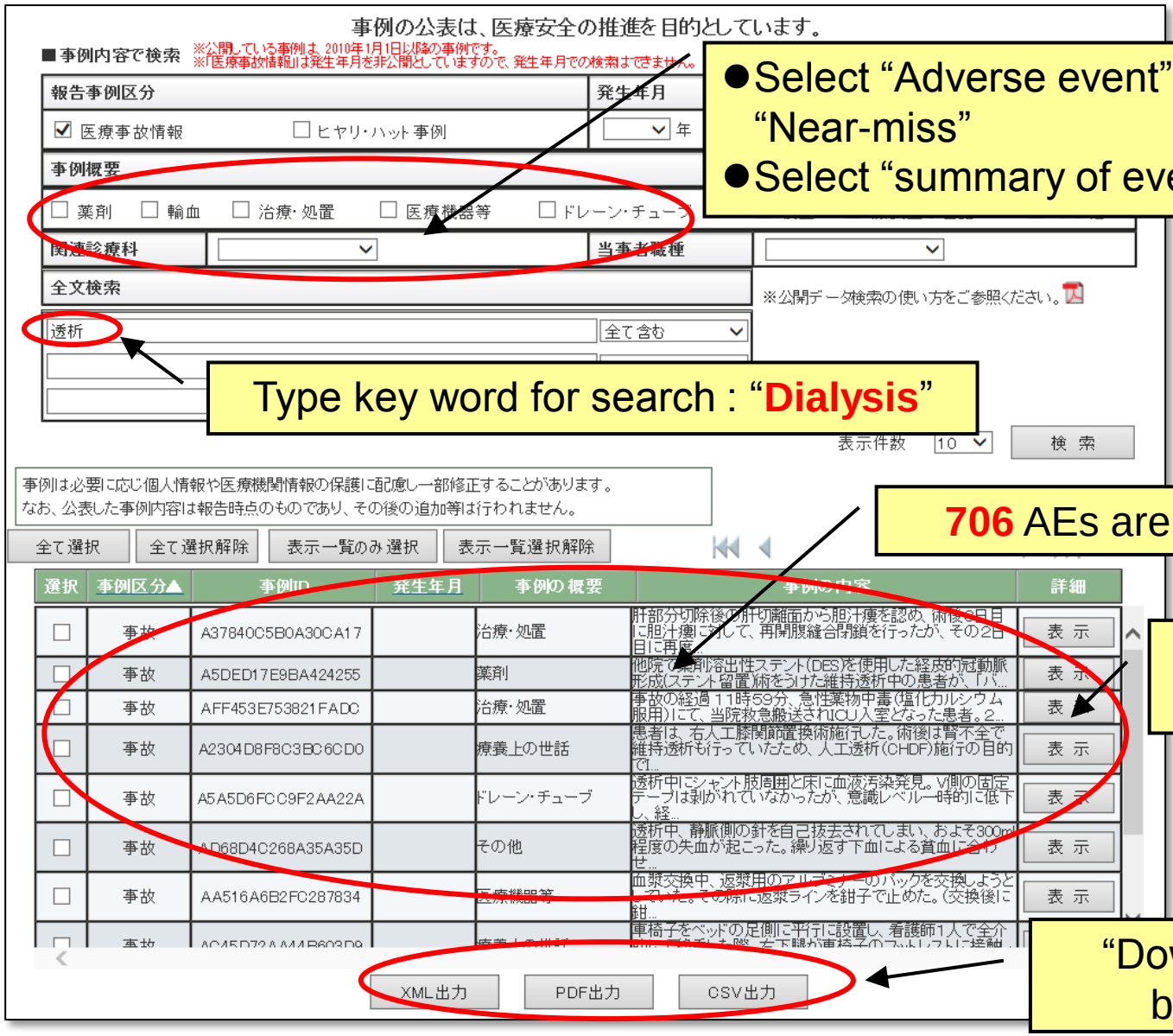
Preventative measures

Prevent curred.
- The ph d/or the consen ure site, and the es.
- The ph fore the proced .

rt of the Project to Collect Medical Near-Miss/Adverse Event Information (a Ministry of Health, Labour and Welfare grant project), this al safety information was prepared based on the cases collected in the Project as well as on opinions of the "Comprehensive Evaluation " to prevent the occurrence and recurrence of medical adverse events. See quarterly reports and annual reports posted on the Japan cil for Quality Health Care website for details of the Project.
/www.med-safe.jp/
racy of information was ensured at the time of preparation but cannot be guaranteed in the future.
information is intended neither to limit the discretion of healthcare providers nor to impose certain obligations or responsibilities on them.

Department of Adverse Event Prevention
Japan Council for Quality Health Care
1-4-17 Misakicho, Chiyoda-ku, Tokyo 101-0061 JAPAN
Direct Tel: +81-3-5217-0252 Direct Fax: +81-3-5217-0253
http://www.jcqhc.or.jp/

Web-based search system on AE / Near-miss



- Select “Adverse event” or “Near-miss”
- Select “summary of events”

Type key word for search : “**Dialysis**”

706 AEs are matched.

“Browse” button

“Download” button

Sound-alike drugs

"*Almarl*" vs "*Amaryl*"

"*Almarl*"

The brand was relinquished and replaced with generic name in **2012** by the manufacturer for patient safety reason.

Disclosure and publicity

Project to Collect Medical Near-miss/
Adverse Event Information
2016 Annual Report

August 28, 2017

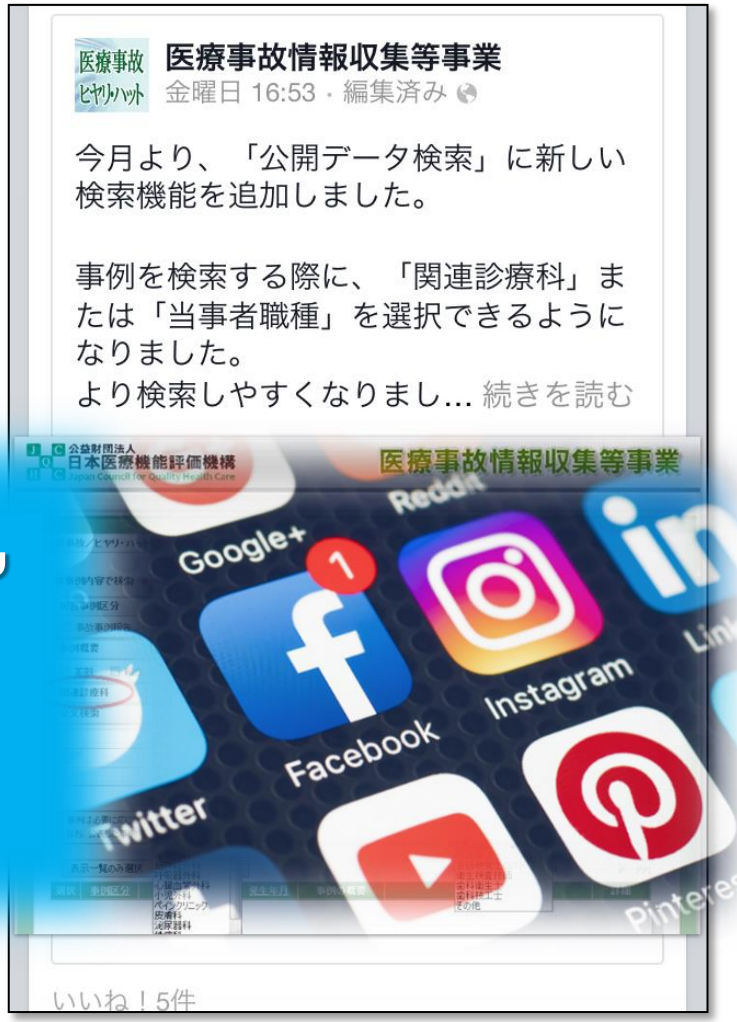
公益財団法人 日本医療機能評価機構
Japan Council for Quality Health Care
Division of Adverse Event Prevention

The current status of the project can be browsed at:
Website: http://www.med-safe.jp/
English page: http://www.med-safe.jp/contents/english/index.html

- Quarterly report No. 1-52
- Annual report 2005-2016
- Reports are Released **at press conference**

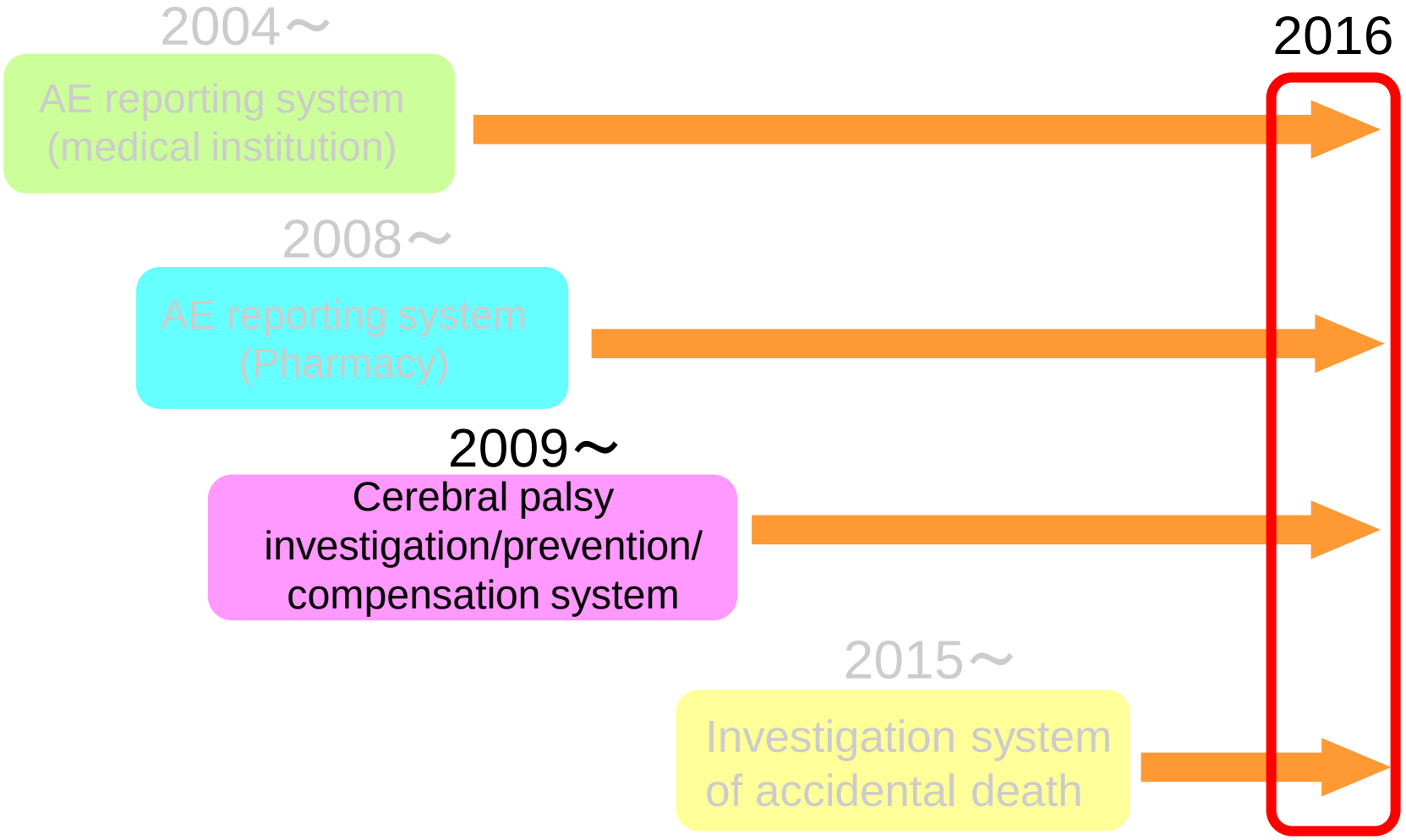
NHK News (TV News), August 29, 2016

Distribution of knowledge through SNS（Facebook）(2014~)

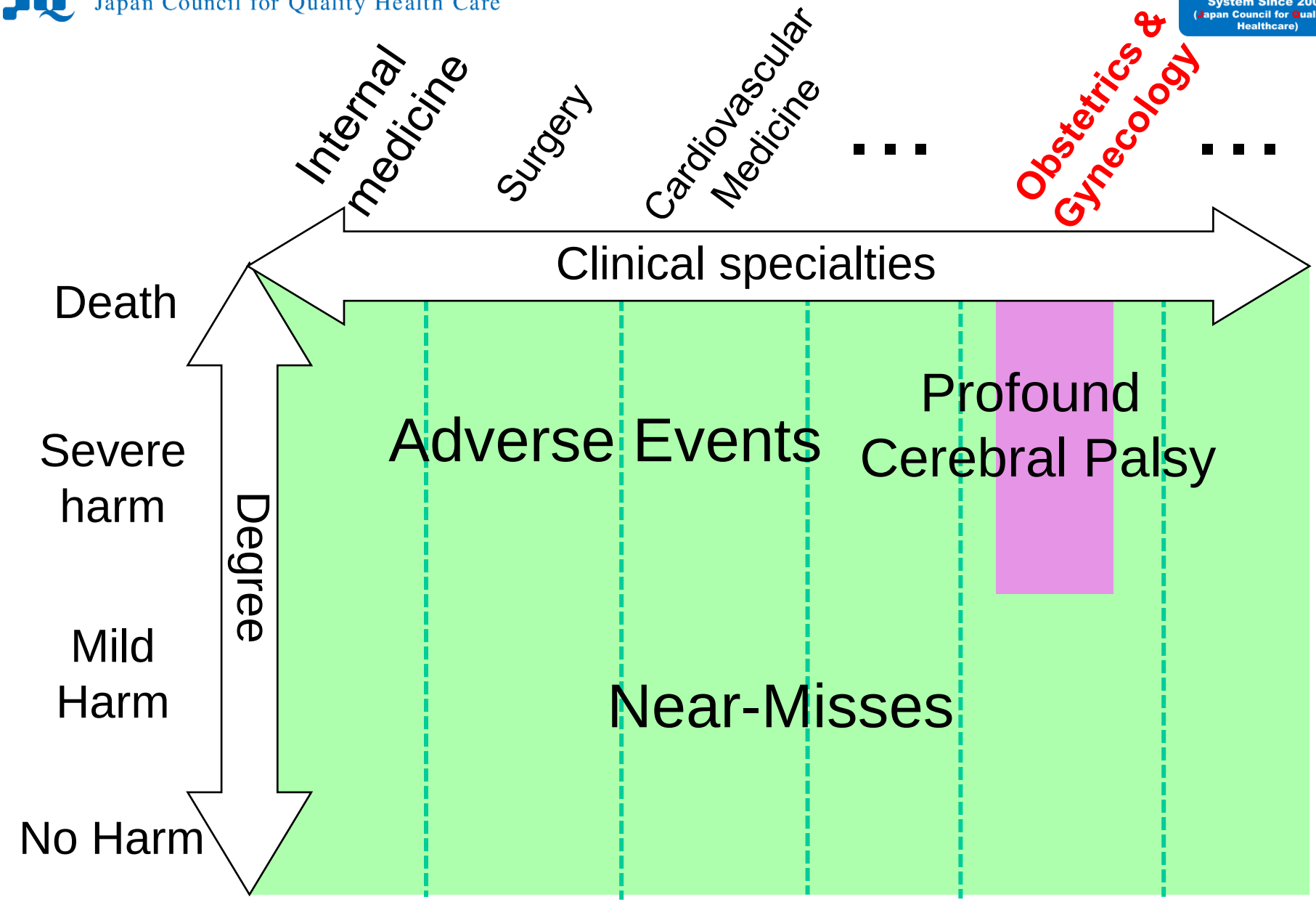


Quarterly/Annual report,
Thematic analysis
Monthly alert,
etc.

Nationwide reporting/investigation/learning system with public or quasi public nature



Adverse Event Reporting System Since 2004 (Japan Council for Quality in Healthcare)



Background

In order to secure safe and trustworthy perinatal care which benefit not only obstetricians but guardians , A)-C) should be put into effect.

Liberal Democratic Party, Study Committee on Mitigation of Conflict in Medicine（Nov. 29, 2006）

A) **Compensate patients** who developed disability possibly due to obstetric adverse events

B) **Bring conflict to settlement** as early as possible,

C) **Establish a mechanism that improves quality of obstetric care** by investigating causes of cerebral palsy.

No-fault compensation/investigation/prevention system for cerebral palsy

~ the Japan Obstetric Compensation System (2009～)~

No-fault compensation

Petition (Report of CP) → Review → Payment

Examined irrespective of negligence

Investigation/Prevention

Childbirth facilities
Medical chart,
Birthcare record,
laboratory data, etc.

Families
Descriptive questions

20-30 pages

Prevention, early settlement of conflicts and Improvement of quality

Monetary Compensation
(30 million JPY = 291,300 USD)

Lump-sum payment

To compensate for expenses on nursing case facilities

6 million yen (58,250 USD)

+

Annual installments

To compensate for annual nursing care expenses

total **24 million yen (233,050 USD)**

6 million JPY

Annual payment of 1.2 million JPY

× **20 years**

+

Statistics of eligible case by birth year

(As of Dec 31, 2016)

Birth year	No. case reviewed	No. case by eligibility			
		Eligible	Not Eligible	Preliminary to review	In process
2009	561	**419**	142	0	0
2010	423	**382**	141	0	0
2011	496	**355**	143	0	0
2012	358	278	60	19	1
2013	264	211	23	28	2
2014	194	163	23	8	0
2015	68	62	2	3	1
Total	**2,504**	**1,893**	544	61	6

Compilation of standardized investigation report

Childbirth facility

Records, Laboratory data, etc.

Data on resources of the childbirth facility, etc.

Guardian

Question on the delivery, CP etc.

Clarify clinical course or document basis

JQ

Productivity: 416 reports /2017

Investigation Committee

7 Sub-committees

A B C D E F G

Final Report

Draft Report

Committee

Final Report

Final Report

- **Delivery** to childbirth facility and family
- **Disclosure** on HP on condition of **anonymity**

Technical assistance

Secretariat (Midwife, Obstetrician, Technical staff)

Dr Takashi Okai（1947-2017）

http://www.showa-u.ac.jp/topics/2012/20120523_000.html

- Professor Emeritus of Showa University
- Chair of investigational committee of JOCS-CP
- Former Vice President of Japan Association of Obstetricians and Gynecologists

JQ appreciate his dedication to the system and tireless work on ***reviewing over 1,600 investigational reports*** *even during his last days in hospital.*

Compiling and distributing prevention report to exhibit impact on quality of care

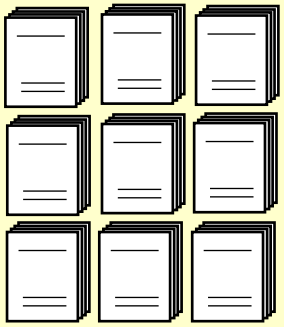
Investigation committee

Report of "Individual case"

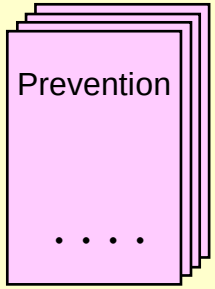
- Cause
- Appraisal
- Preventive measures

Prevention committee

Report of "Aggregated reports of individual case"



- Quantitative, Epidemiological analysis
- Thematic analysis
- Recommendation of preventive measure, etc.

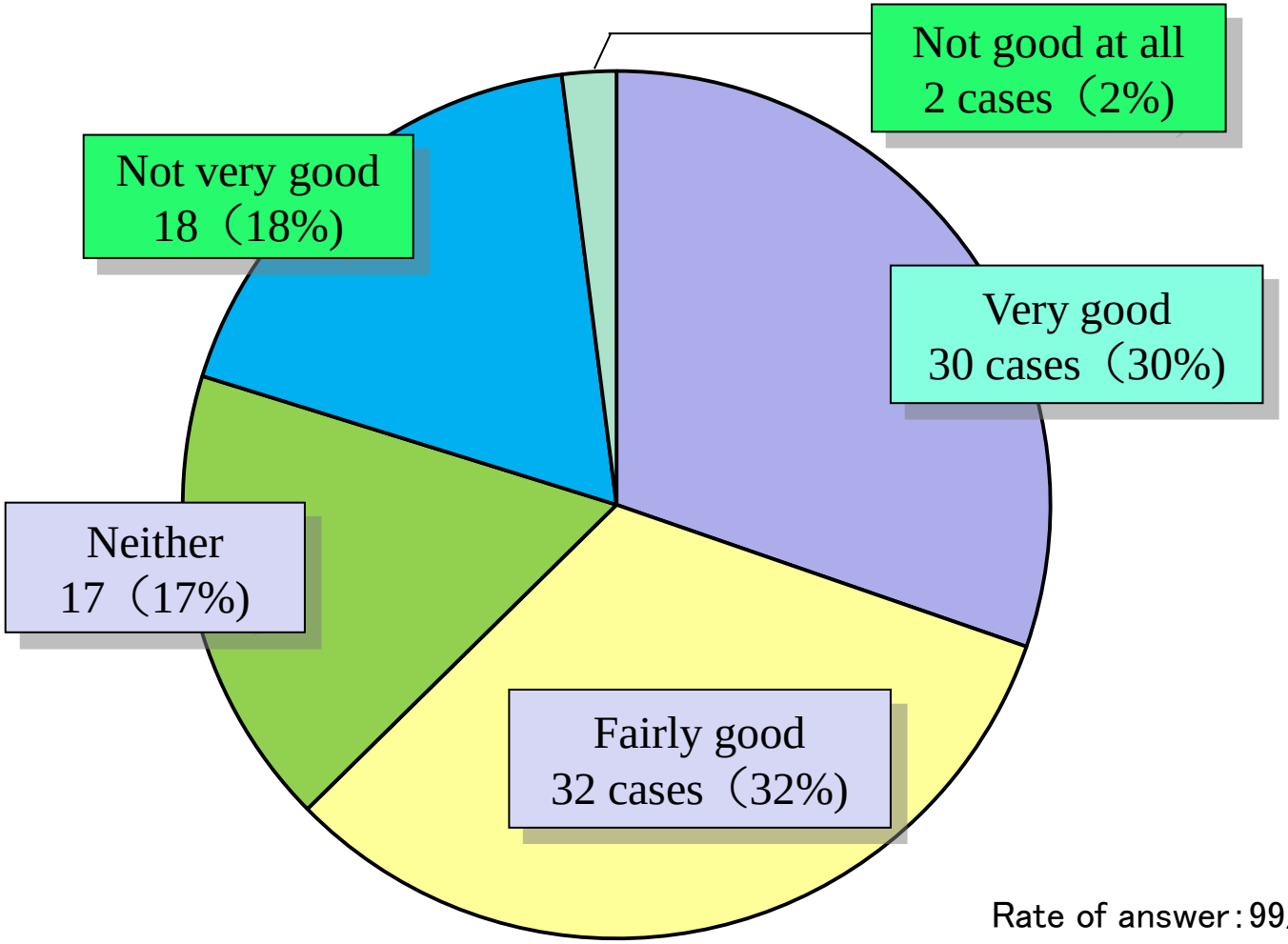


A) Report; Delivered both to family and childbirth facility
B) Summarized report; Posted on the web
C) Report with identifiers deleted; Available only for research use through internal process

A) Delivered to **Childbirth facility, Scientific society**, Government, etc.
B) Posted on the web to be open to the public

Survey on investigational report （for guardians）

Q4: “Did the investigation report works good for you?”



Rate of answer：99/195（=50.7%）

Survey on investigational report （for guardians）

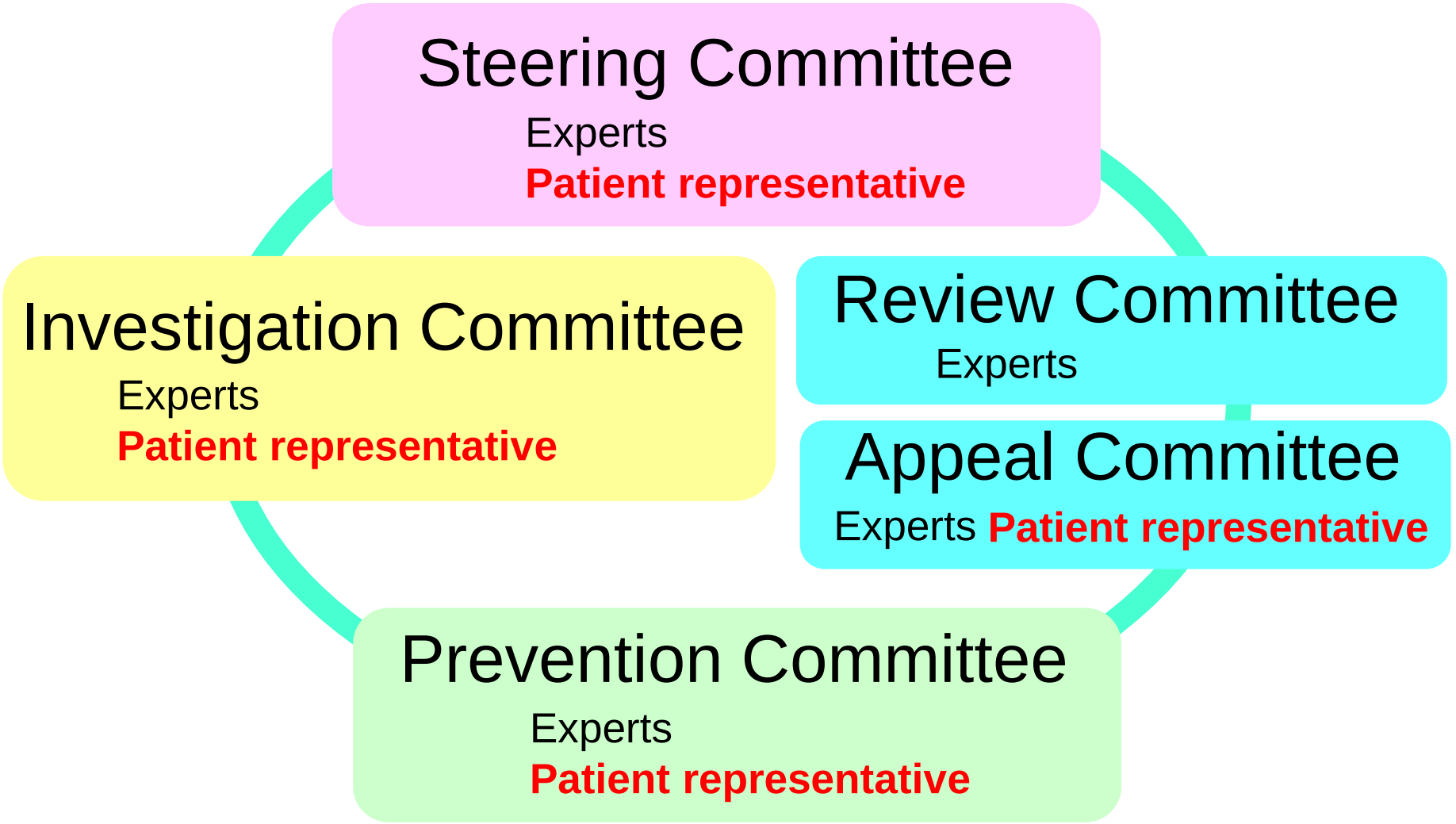
Q4: “Did the investigation report works good for you?”

Reasons for “Very good” and “Fairly good” groups		62
1	Investigation was done by a third body	49
2	Supposedly, lead to improvement of obstetric care	33
3	Cause was identified	27
4	Sense of distrust was mitigated against childbirth facilitiy and physicians	9
5	Others	10

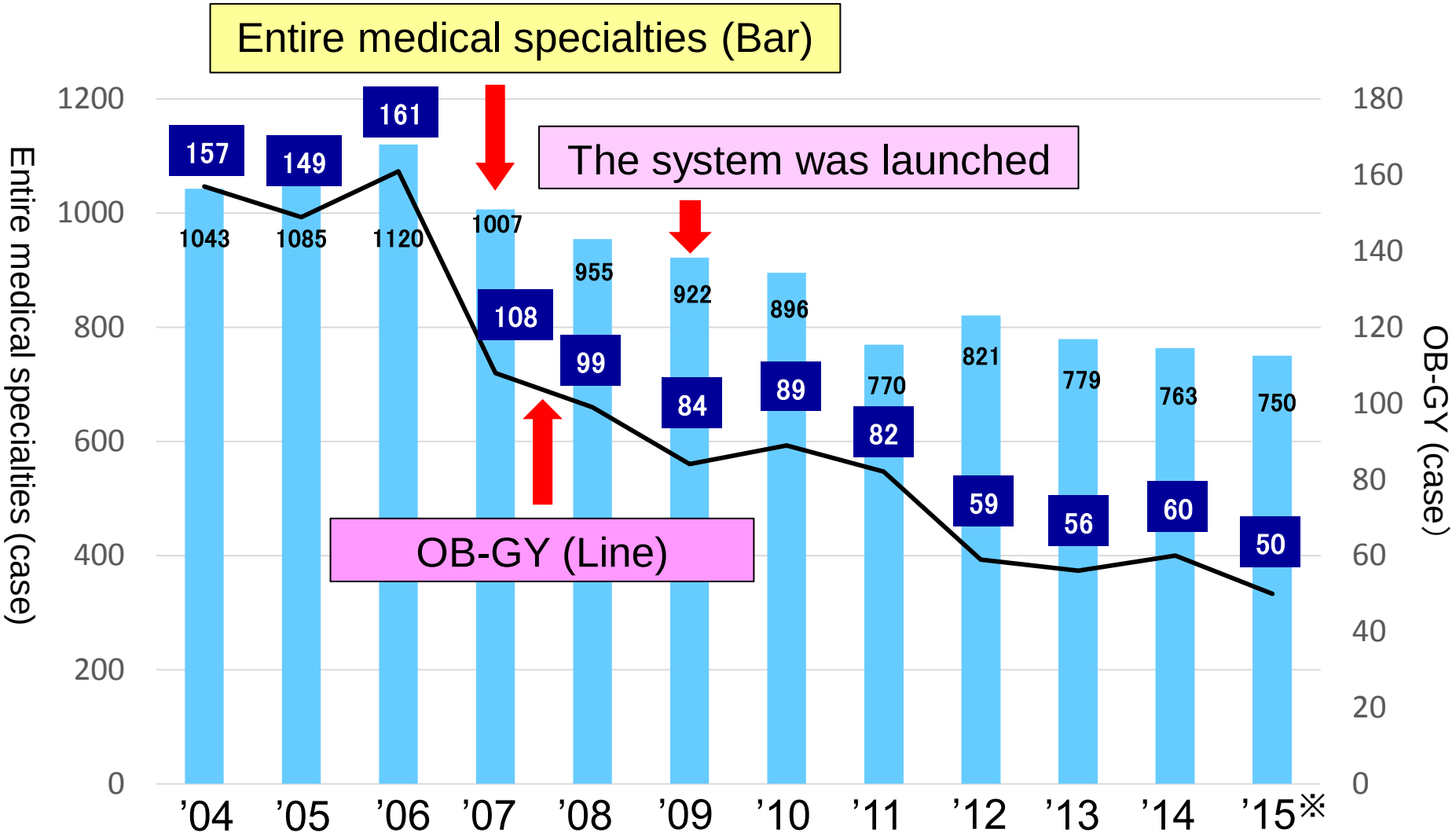
Reasons for “Not very good” and “Not good at all” groups		20
1	Cause was not eventually identified	16
2	Sense of distrust grew against childbirth facility and physicians	10
3	Supposedly, never lead to improvement of obstetric care	8
4	Sleptical about fairness and/or neutrality in investigation	7
5	Others	5

Rate of answer：99/195（=50.7%）

Patient involvement in operating JOCS-CP



Possible impact on lawsuit case



Statistics of lawsuit trend by medical specialties by the Supreme Court

※Preliminary figure

Contribution to Global PS Community

- ✓ *18th **Healthcare Accreditation Thai** National Forum*
- ✓ ***2nd Ministerial Summit** on Patient Safety*
- ✓ *5th Anniversary Meeting of the **Taiwan Patient Safety Culture Club (TPSCC)***
- ✓ ***34rth ISQua Conference***
- ✓ ***WHO/OECD** 6th Meeting on Health Care Quality Improvement in the Asia-Pacific Region.*
- ✓ *2017 **WHO** Experts Meeting for the Collaborative Design of the Global Knowledge sharing platform for Patient Safety (GKPS).*
- ✓ *12th **Italian Risk Management Forum** in Healthcare*

Thank you for your attention

”Ari-Ga-To-Go-Zai-Ma-Shita”

3rd Ministerial Summit on Patient Safety, 13-14 Apr 2018, Tokyo