2.1 To understand the existing environment for PSL RLS

Shin Ushiro M.D., PhD. [1-4]

1. Japan Council for Quality Health Care（JQ）
2. International Society for Quality Health Care (ISQua)
3. Kyushu University Hospital
4. Ministry of Health, Labour and Welfare, Japan

KYUSHU UNIVERSITY

Aim

To learn about;

- existing national adverse event systems: What are the target entities subject to reporting?
- how they are working with production of data, reports etc. to spread for patient safety across the country.
- compensation system as an incentive for reporting
- how the RLS effectively work in existing legal environment.

About JQ

Established July 27, 1995

Chair Hirobumi Kawakita

Major Shareholders

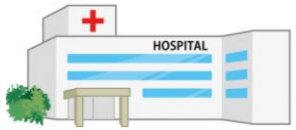
- **Japan Medical Association (JMA)**
- **Ministry of Health, Labor and Welfare (MHLW)**
- Japan Hospital Association
- Japan Dentist Association
- Japan Nursing Association
- Japan Pharmacist Association
- Japanese Federation of Health Insurance, etc.

JQ's Projects on Quality and Safety Improvement

- Hospital Accreditation
- Patient Safety Promotion Group of Among Accredited Hospitals
- Education and Training on Patient Safety
- EBM Medical Information Distribution Project (Minds)
- **Nationwide Adverse Events Reporting System of Medical Instutions**
- **Nationwide Near-miss Event Reporting System of Community Pharmacy**
- **The Japan Obstetric Compensation/Investigatiuon and Prevention System for Cerebral Palsy**
- National Quality Indicator (QI) Measurement Project

Patient representatives participate in the operation of most projects.

Reporting & Learning System institutionalized in healthcare system in Japan



Medical institution
(Hospital, Clinic)

Internal reporting system mandated by Health care act

Reporting of AEs, Near-miss

On-site survey
Accreditation

Regular inspection*

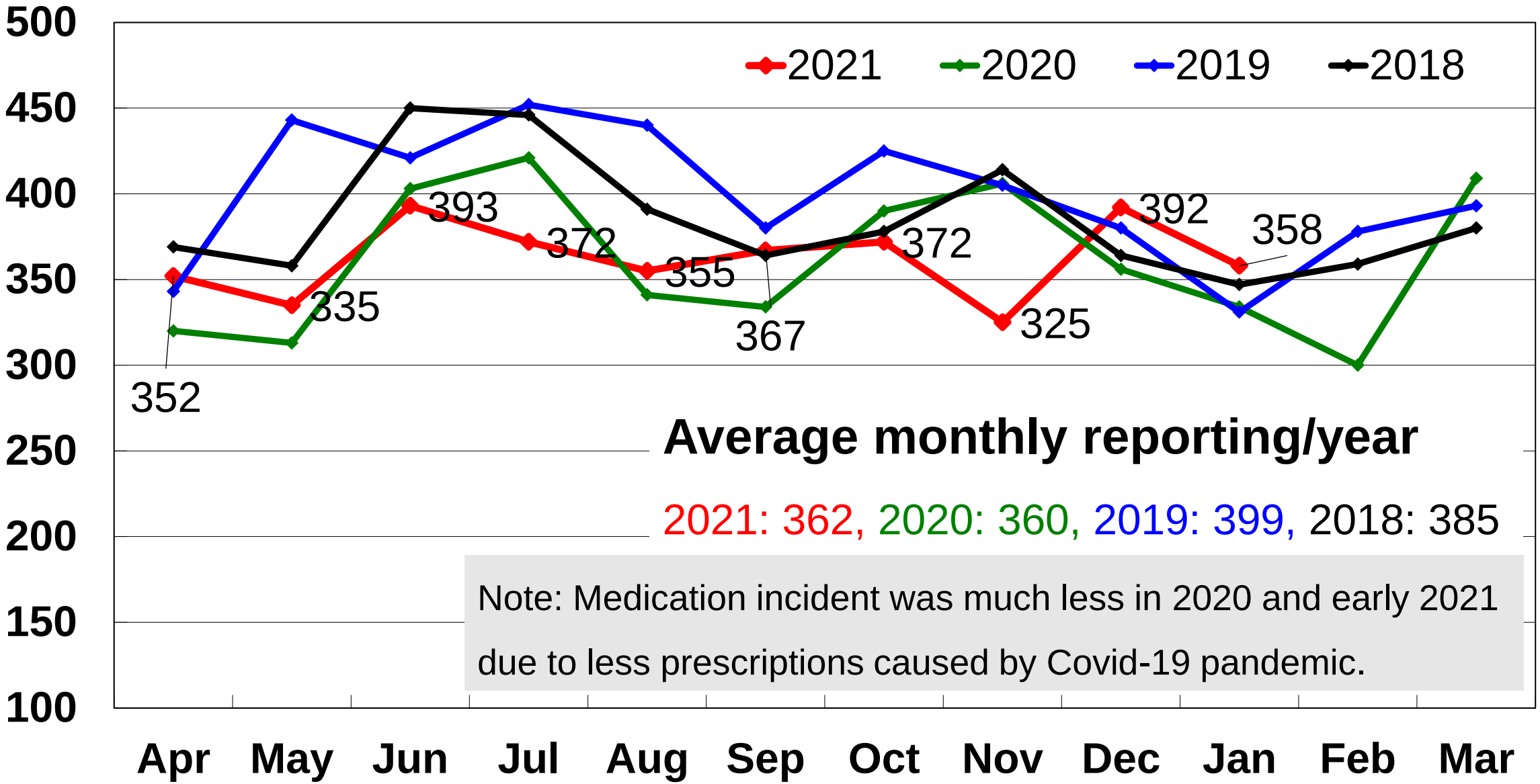
Central, Local governments

External reporting system participated by mandatory* and voluntary hospitals

* Hospitals mandated to report under the government ordinance
  - University hospitals
  - National Hospital Group, etc.

* Inspection under “Health Care Act”; Hospital-annually, Clinic-every 2-3 years

Monthly reporting statistics (Kyushu University Hospital)



Average monthly reporting/year

2021: 362, 2020: 360, 2019: 399, 2018: 385

Note: Medication incident was much less in 2020 and early 2021 due to less prescriptions caused by Covid-19 pandemic.

Patient incident reporting, analysis, sharing and learning

Staff involved

Patient incident reporting:350-400/month

Division of patient safety
(Full-time physician, nurse, pharmacist, part-time staff)

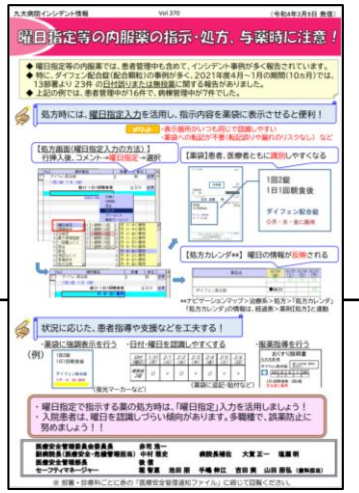
Interview analysis

Case with significant consequence:15-20/month

Director, Deputy director (Chief patient safety officer) etc.

Regular meetings (Monthly, Bi-weekly, Daily)

- Committee
- Division meeting: full members
- Division meeting: core members
- Daily staff meeting
- Risk manager meeting



Monthly alert

Ad-hoc meetings

- Investigation committee
- M&M conference

Ministerial ordinance for enforcement of the Health Care Act (Article 9.23), revised in 2003 for patient safety promotion

Safety management system to be installed in “Designated hospital for advanced treatment (University hospitals etc.)"

Article 16.3 (1.8) of the Health Care Act shall stipulate the following;

1. Securing the following system in place:
   a. Assignment of a staff on full-time basis for patient safety management and nosocomial infection control.
   b. Installment of a department in charge of patient safety.
   c. Launch of a section to provide consultation service to patient/family on patient safety issues.

Patient Safety in “Designated hospital for advanced treatment i.g. University Hospitals” (2016)

I. **Appointment of a deputy director** or official in an equivalent position to a chief officer in charge of patient safety

II. **Installation of an institutional reporting system of “fatal case”** in inpatient care.

III. **Deployment of a physician and a pharmacist in division of patient safety on full-time on full time basis** in addition to nurse that has already been in full-time position since 2003.

Patient Safety in “Designated hospital for advanced treatment i.g. University Hospitals” (2016) (cont’d)

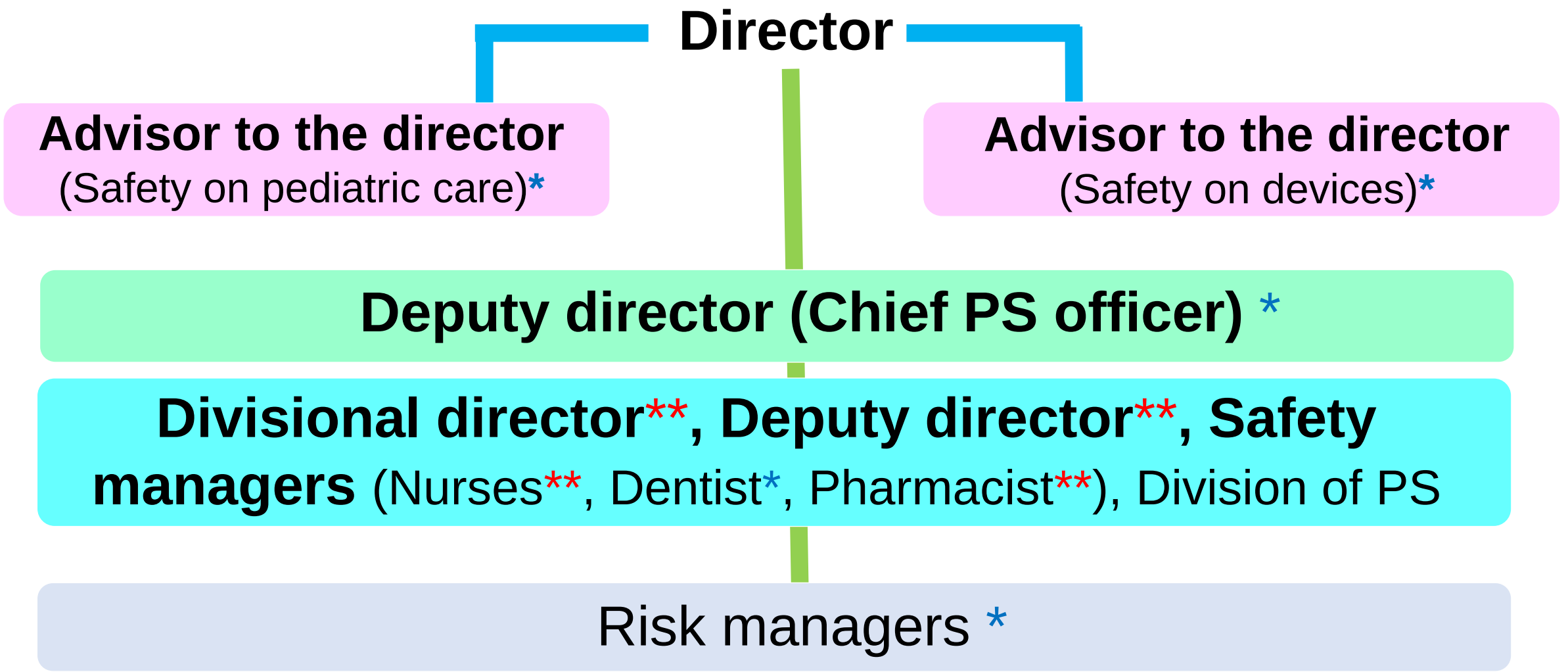
IV. **Installation of a “Patient Safety Audit Committee”** in the presence of external member i.g patient representative etc.

V. **Monitoring of quality and safety metr**ics.

VI. **Reinforcement of quality control of health record** under the guidance of an assigned person in charge.

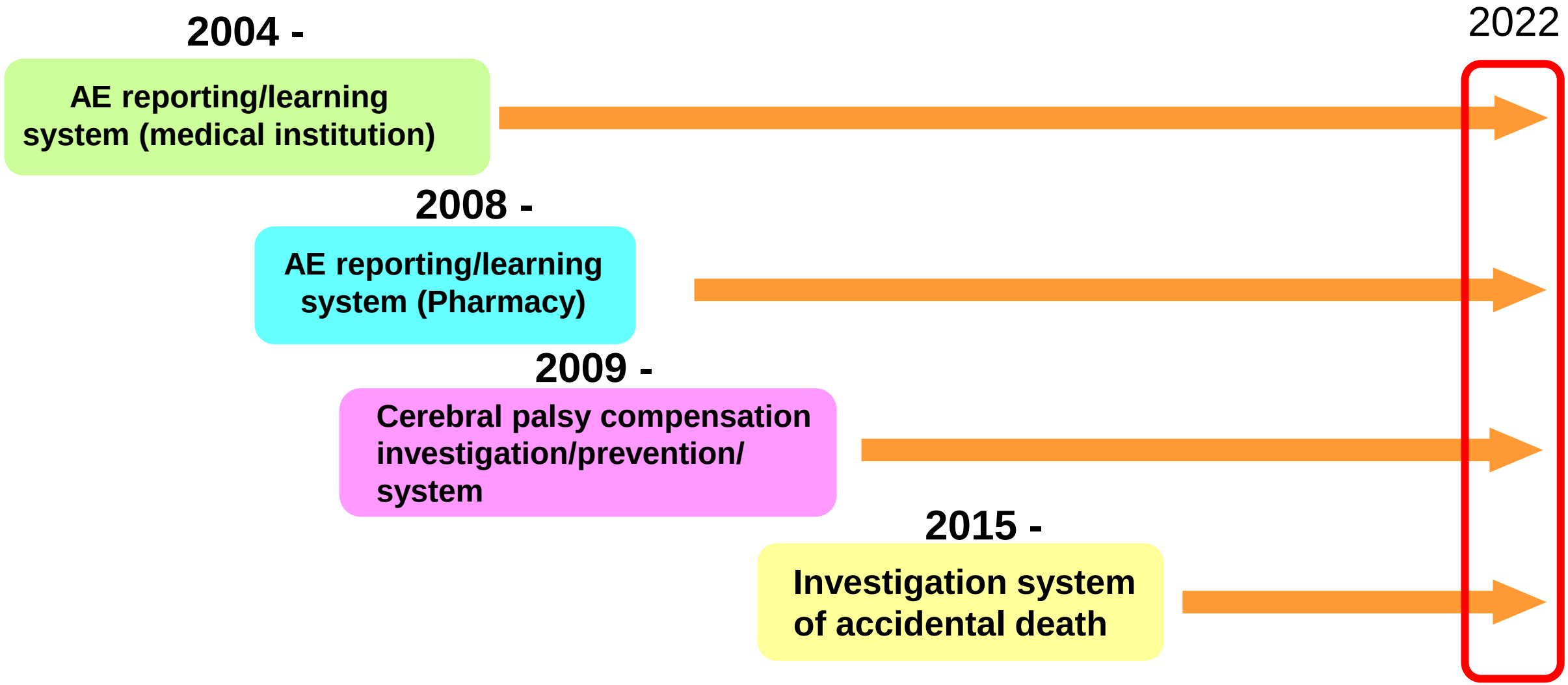
VII. **Reinforcement of a review process for introducing a novel and risky technology in surgery** or other procedures.

Staff Structure of Patient Safety Management

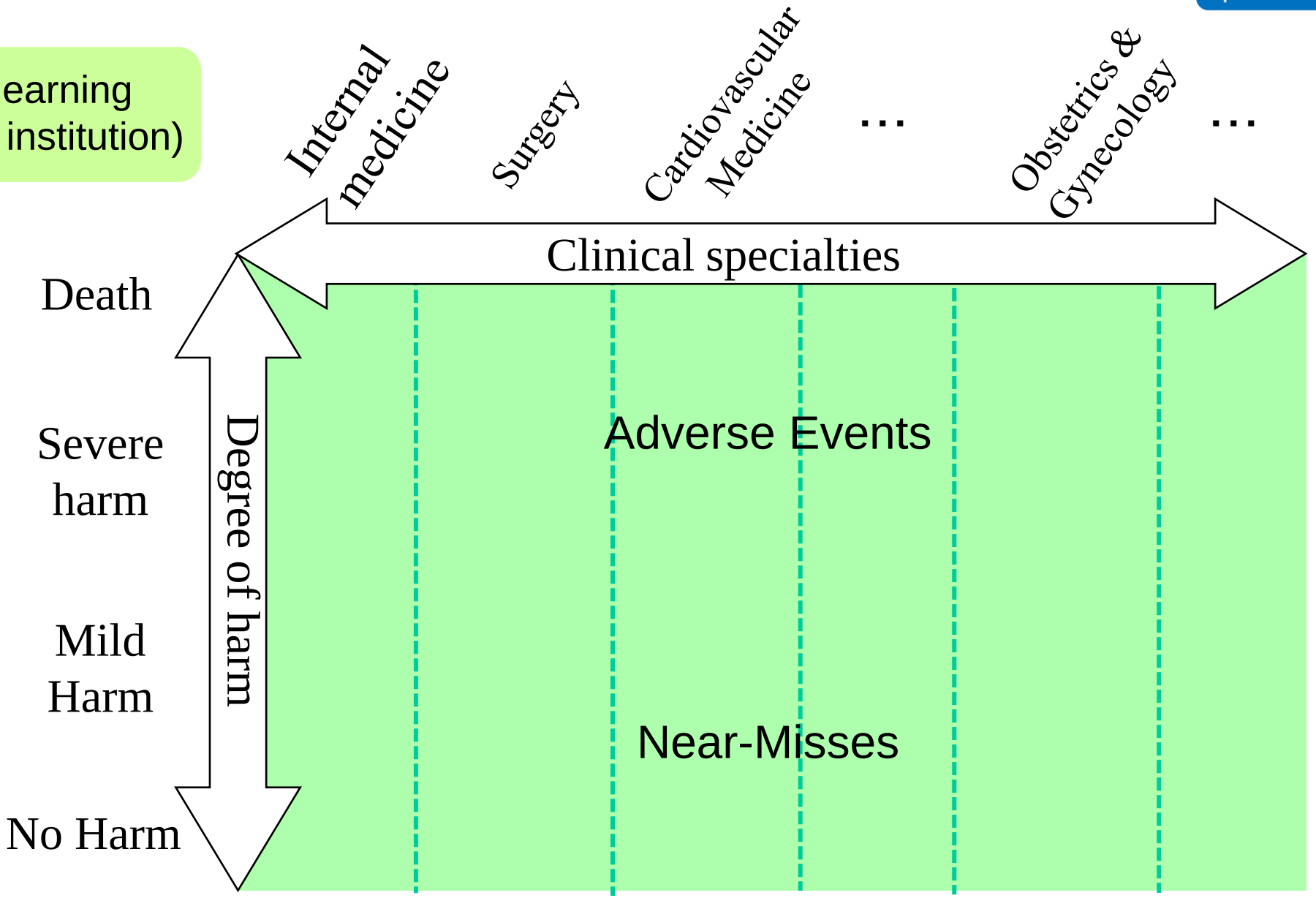


* Concurrent appointment, ** Full-time appointment

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



AE reporting/learning system (medical institution)



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

Adverse event Reporting / Learning System Since 2004
Japan Council for Quality Health Care

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-based reporting

①Cording

②Text

Aim
Outline
Background
Preventive measure

On-site visit
（Voluntary survey）

Japan Council for Quality Health Care

Aim
Patient safety and prevention of accident
（No blame）

Steering Committee
(Experts, **Patient representative**)

Expert Panel

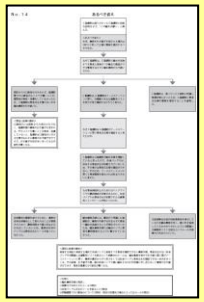
Secretariat

Annual/Quarterly report

Monthly alert

Database

Training program (RCA)



General public

Health care professionals/ facilities

Government

Number of institutions by registration type

Registration type; **(A)**, **(B)** or both			**(B) Near-miss reporting system**					
			Rgistered				Not-registered	Total
			Occurrense count and Case Report		**Occurrence count Report ONLY**			
(A) Adverse event reporting system	Rgistered	**Mandatory**	122	513	85	335	67 278	274 **1,127**
		Voluntary	391		250		212	853
	Not-registered		163		283			446
Total			676		618		279	**1,573**
			1,294					

Statistics as of Sep 30, 2021

Registered medical institutions with/without reporting obligation (Mandatory / Voluntary) of AE reporting

Mandatory	274
Voluntary	853
Total	1,127

Note; Statistics of Japanese hospital

i. No. Hospital 8,300

ii. No. Hospital Beds

A) Mandatory reporting hospital 139,485

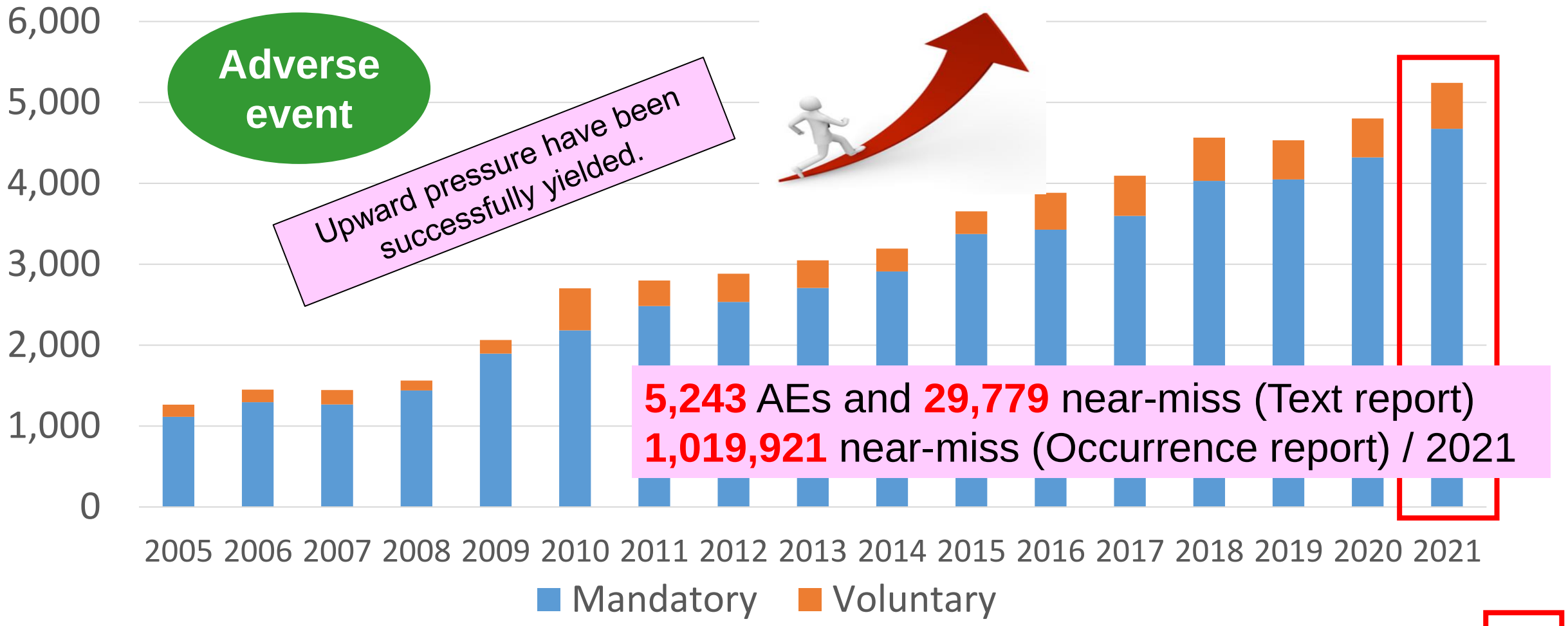
B) Entire hospital 1,529,215

Japan National University Hospital Alliance on Patient Safety (JANUHA-PS)

Chair; Tokyo Medical-Dental University Hospital

Vice-Chair; Kagoshima University Hospital

Trajectory of the AE reporting to JQ

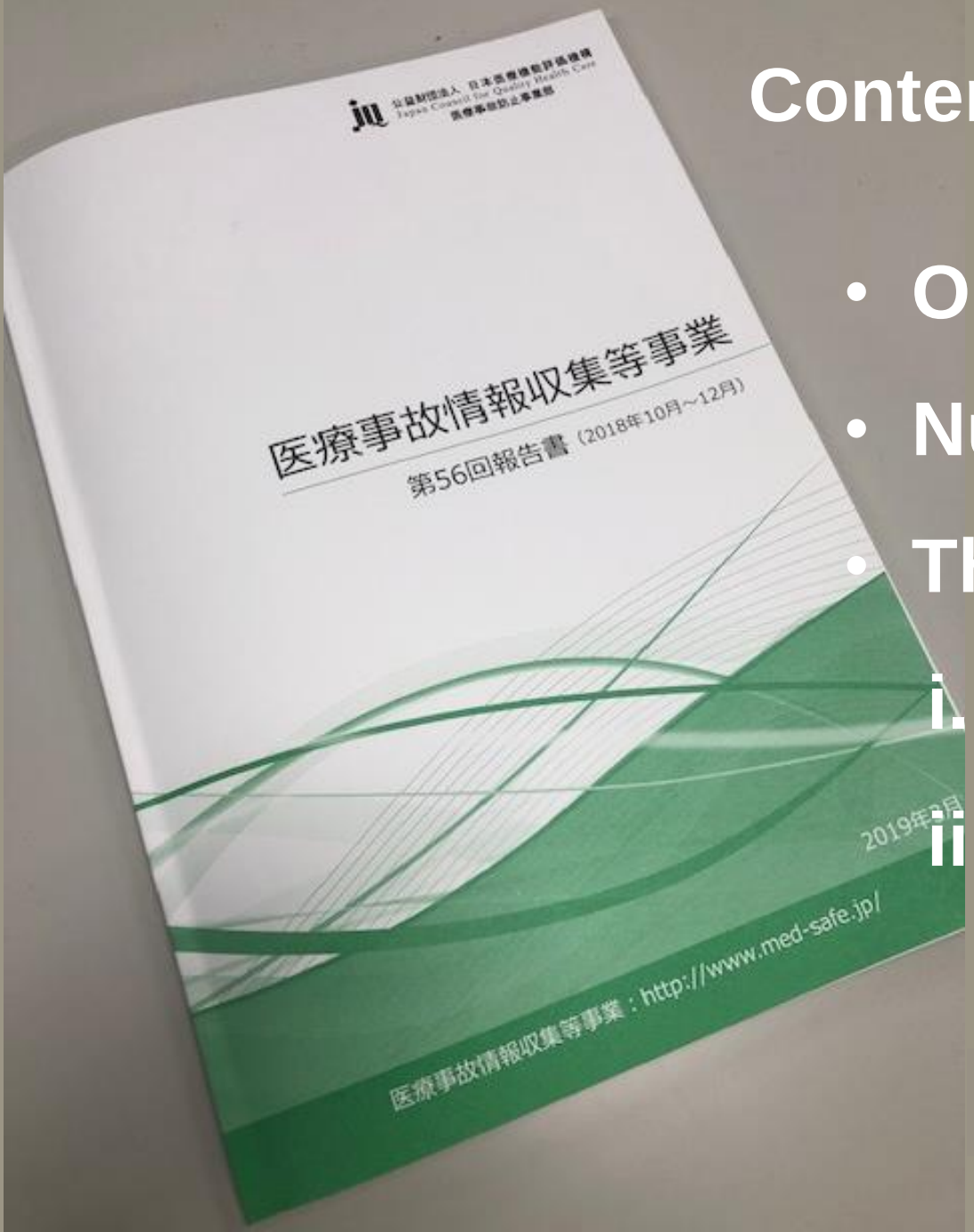


5,243 AEs and **29,779** near-miss (Text report)
1,019,921 near-miss (Occurrence report) / 2021

Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
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	4,030	4,049	4,321	4,674
Voluntary	151	155	179	123	169	521	316	347	341	283	280	454	497	535	483	481	569

Probable reason for “the steady rise” in external reporting

- Strict adherence to “**No-blame**” and “**Anonymity**” in operation **by JQ**
- **Repeated call for registration** through series of lectures across Japan (20-30 lectures annually)
- **Feedback** to medical professionals with helpful products i.g. Monthly alert, Database
- **Pressure** on medical institutions for registration by media and patient/family/lawyer
- **Guidance, instruction by the local government** through annual/regular inspection
- Enhanced **transparency** by providing data for practical and research use to the healthcare fronts and research institution, etc.

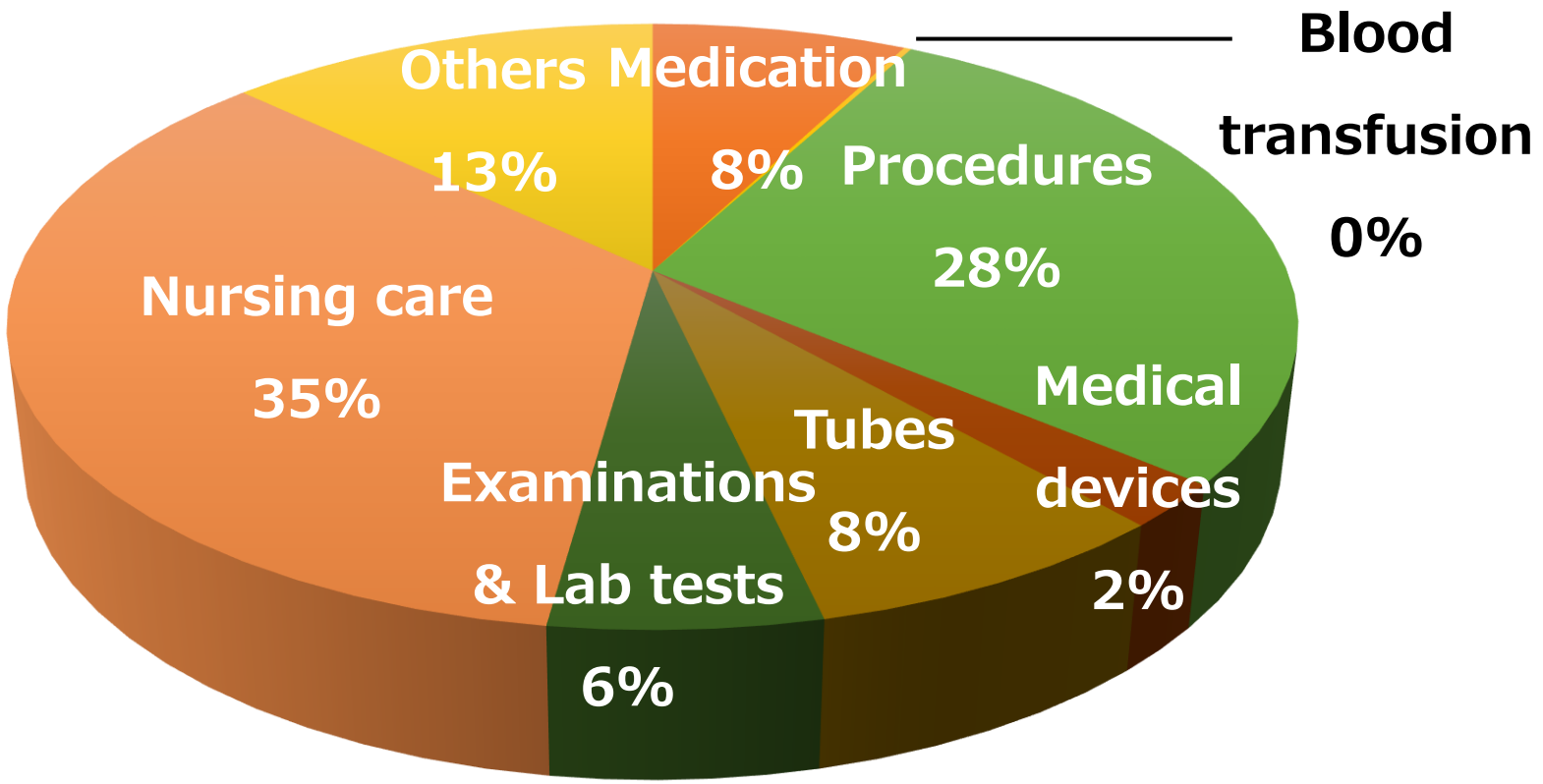


Contents of Annual/Quarterly report *

- Outline of the system
- Numerical analysis
- Thematic analysis
  i. “New themes; 240 themes
  ii. “Recurrent” themes; 127 themes

* 67 Quarterly reports & 16 Annual reports

Types of Adverse Event



2019 Annual Report of JQ's AE/Near-miss reporting system

Frequent AEs（10 cases or more / yr）

Summary	Total
Drug	
Overdose administration	54
Wrong drug	22
Overdose prescription	20
Wrong patient	19
Wrong drug dispesing	17
Faster setting of injection rate	17
Wrong method of administration (Wrong injection route, etc.)	12
Failure to prescribe	11
Administration of Contraindicated drug	11
Underdose administration	11
Failure to administer	11

（Annual report 2019）

Themes of analysis in past quarterly reports

67th report (2021-4)	Medication error related to chemotherapy for outpatient (series 2)
	Medication error related to chemotherapy for outpatient (series 1)
66th report (2021-3)	Discontinued injection of cathecolamine due to delayed exchange of prefilled syringe
	Error that residents are involved
65th report (2021-2)	Adverse event involving resident (series 2)
	Wrong injection through mix-up of "SILECE®" and "SERENACE®"
	Wrong injection through mix-up of "MEYLON®7%" and "MEYLON®8.4%"
	Wrong procedure to use tracheal tube with speaking valve
64th report (2021-1)	Adverse event involving resident (series 1)
	Adverse event involving Covid-19

Reporting and learning system of community pharmacy (2008~)

Community pharmacy
Voluntary-based

Near-miss

"Cases which toakes place or is identified in pharmacy"

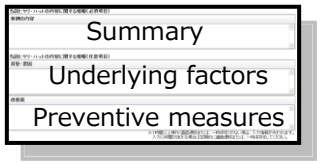
Categories

- ✓ Prescription
- ✓ Dispensing
- ✓ Designated insured materials
- ✓ OTC: Over The Counter Drug

Web-based reporting

i) Coding

ii) Text



Japan Council for Quality Health Care
Division of AE Prevention

Steering committee (Experts, Patient representative)

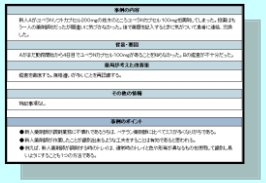
Secretariat

Technical panel (Drug, Device, Human error)

Aim : Prevention
Principles : No-blame, Anonymous

Annual/Half-yearly report

Sentinel case report



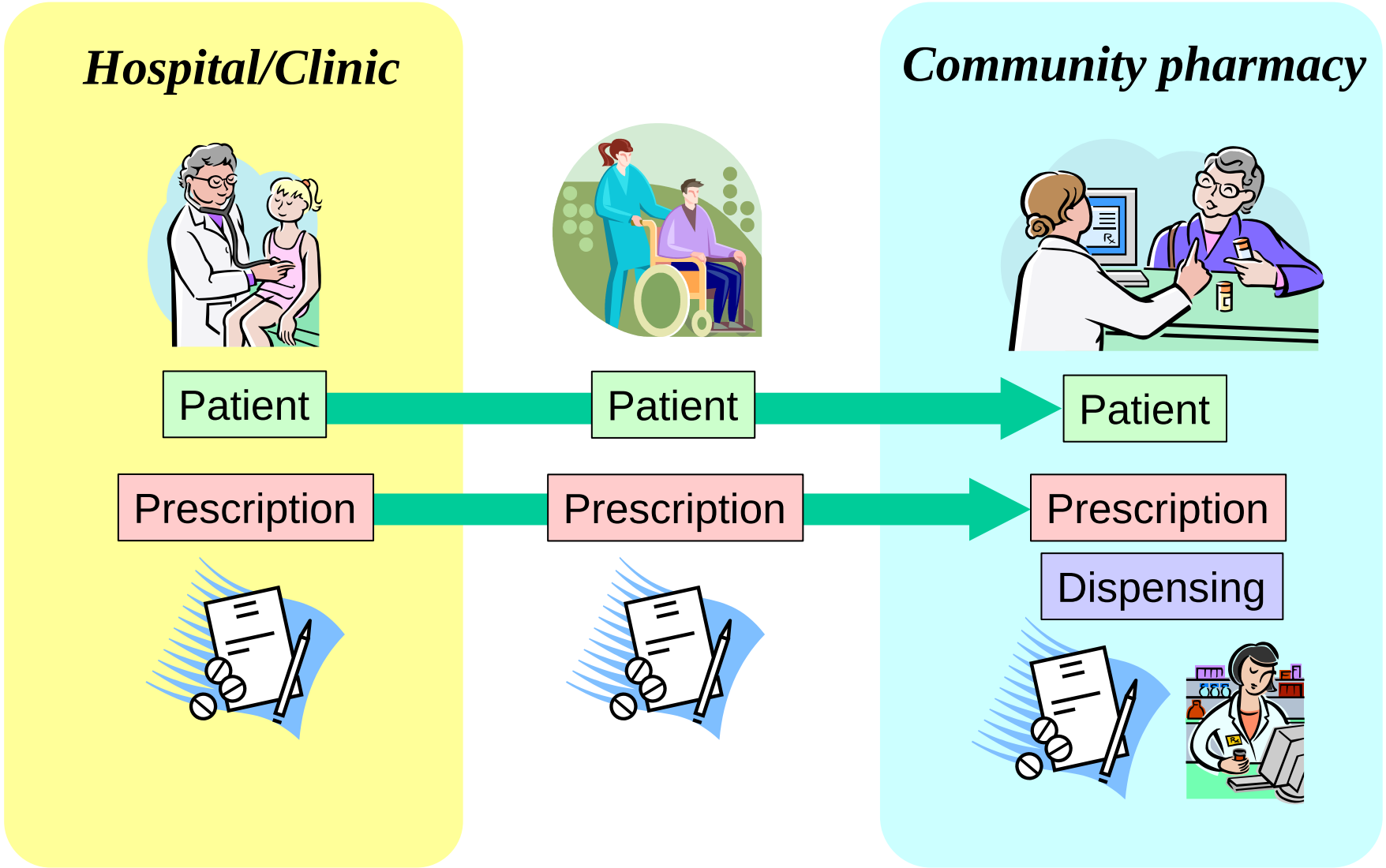
Iconic table

Iconic case

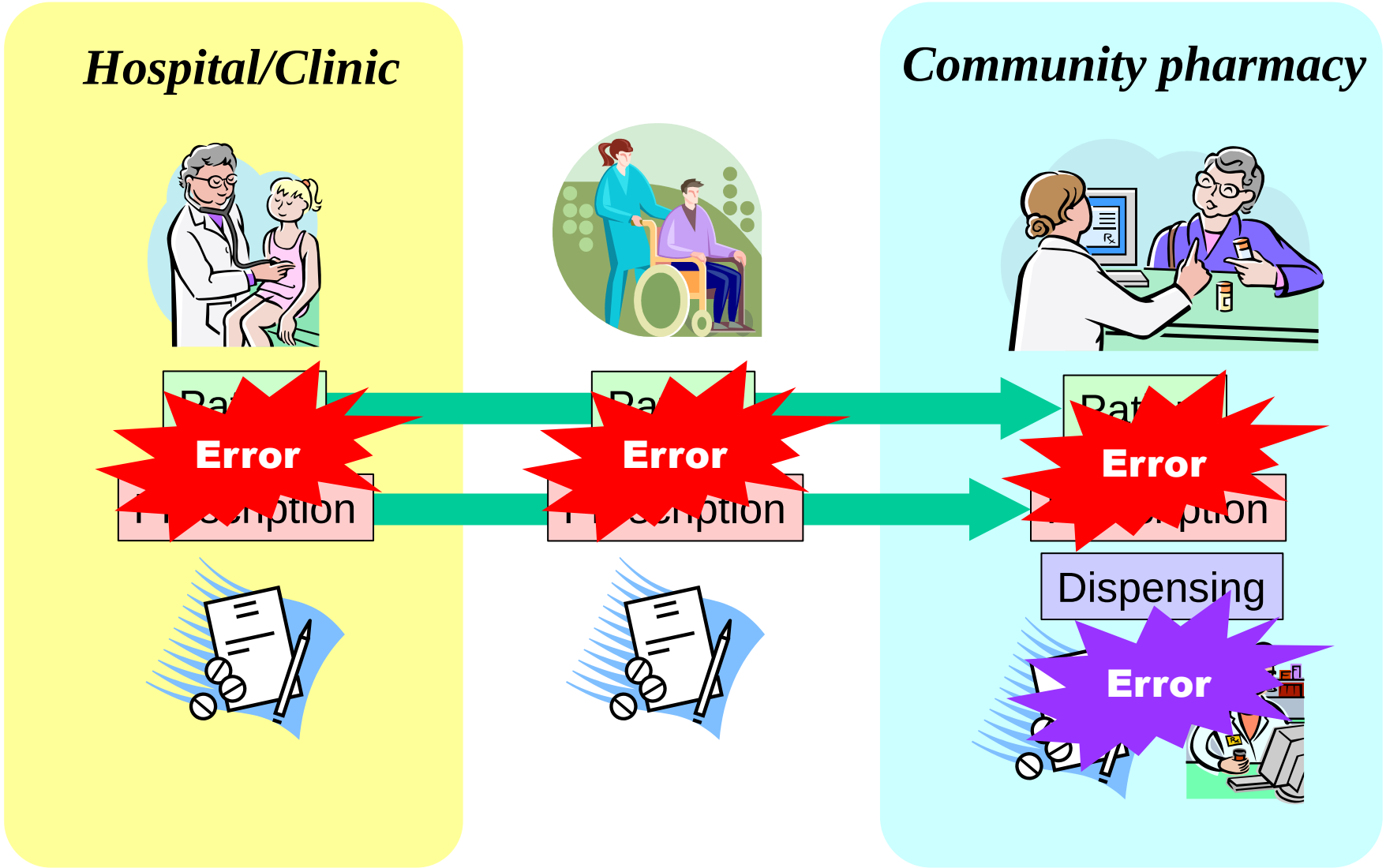
Database

- ✓ Nation
- ✓ Community Pharmacy
- ✓ Relevant Scientific Society/Organization
- ✓ Government etc.

Working flow of medication therapy: from prescription to administration

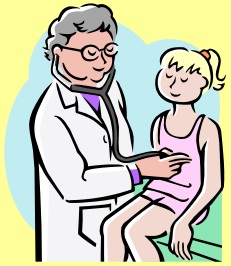


Working flow of medication therapy: from prescription to administration



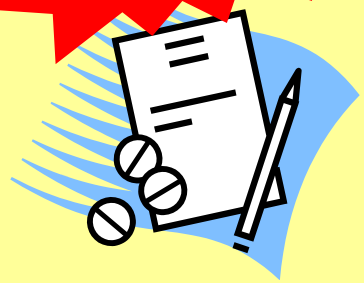
Two types of errors frequently identified in community pharmacy

Hospital/Clinic



Prescription error

Error

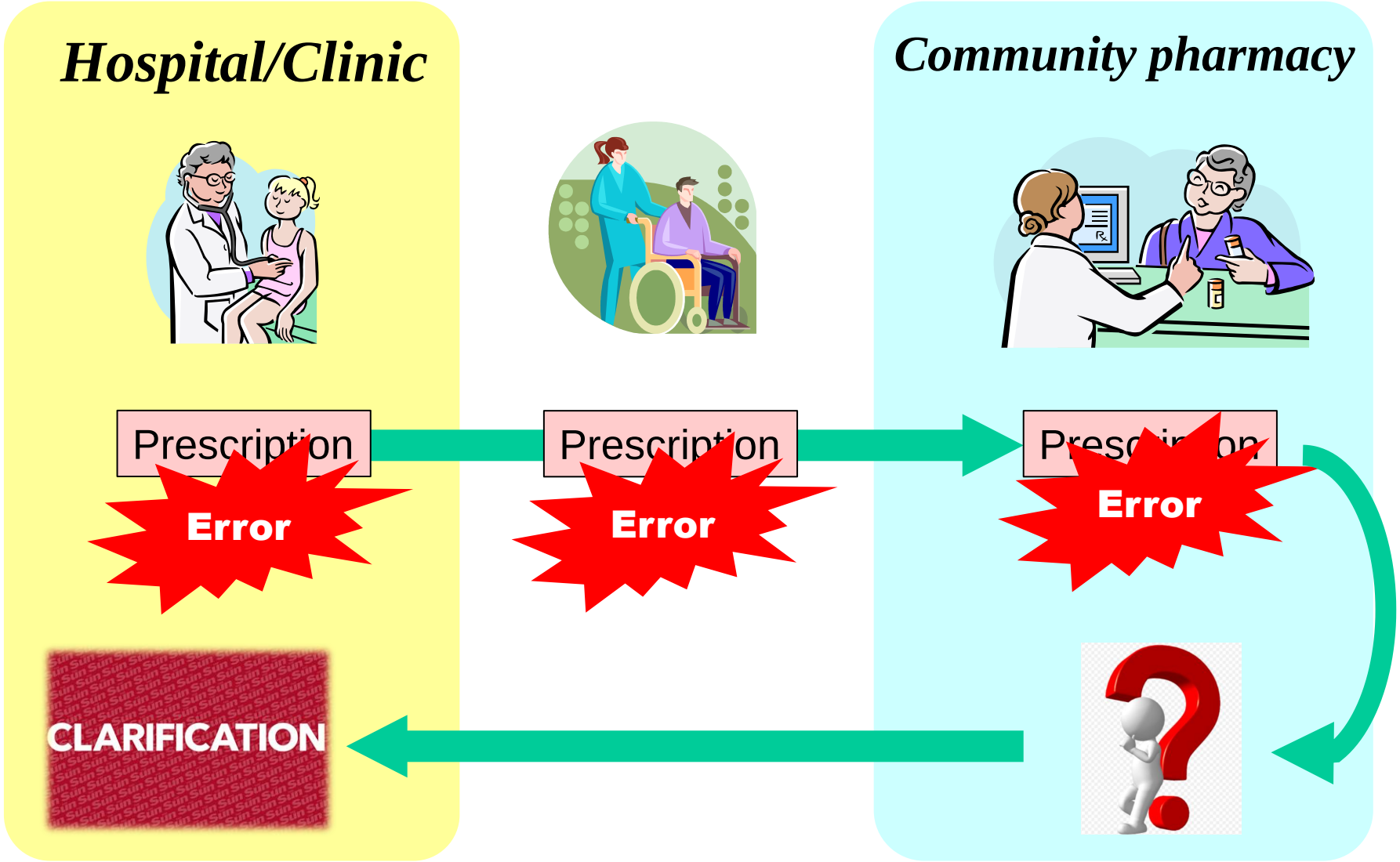


Community pharmacy

Dispensing error

Error

Clarification of questionable prescription by pharmacist



Clarification“ stipulated in Article 24” in “Pharmacists Act”

(Uncertainty in Prescription)

Article 24

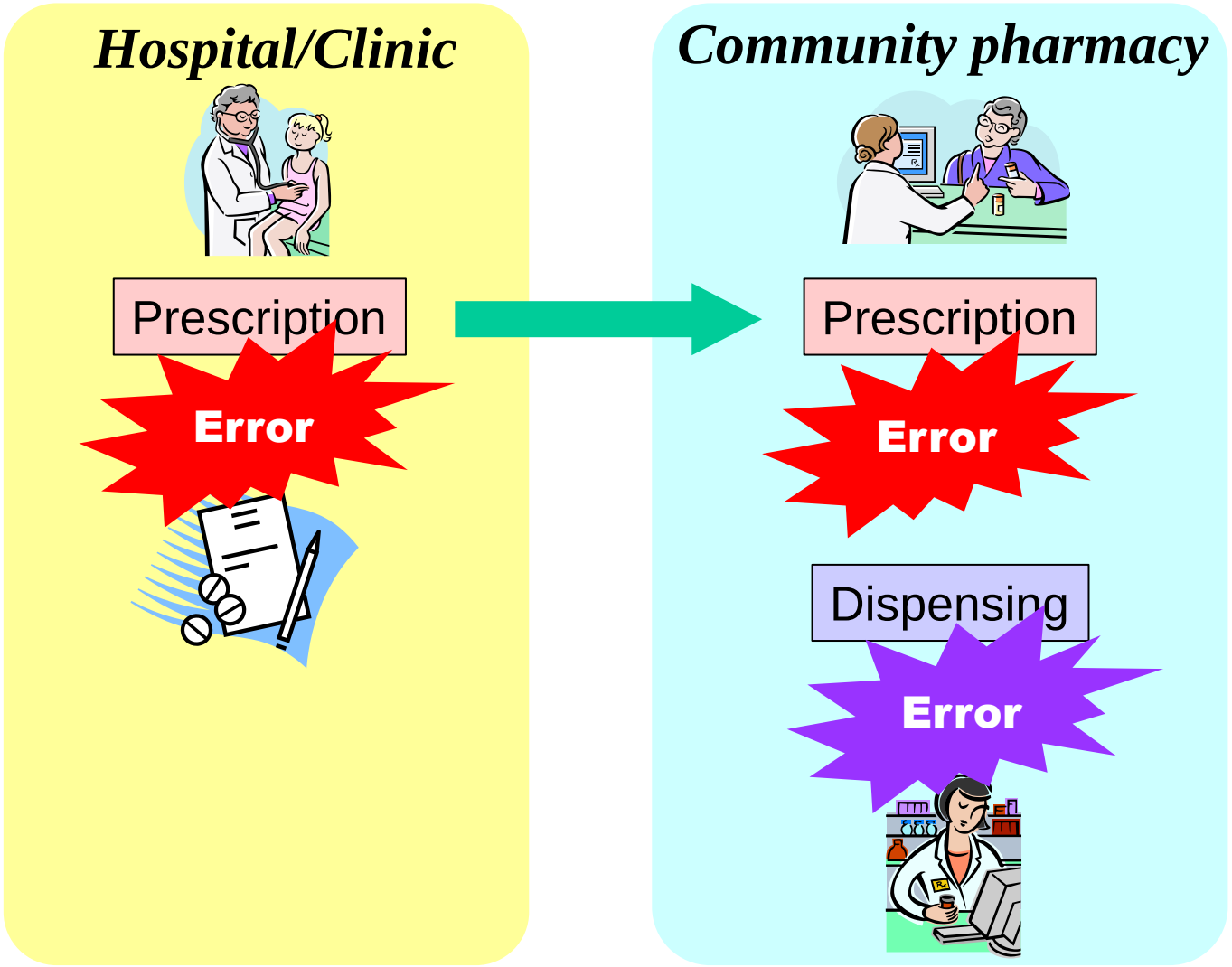
In case of any **uncertainty** in a prescription, a pharmacist may dispense medicine according thereto only after clarifying said uncertainty through communication with physician, dentist or veterinarian who issued the prescription and **resolving said uncertainty**.

Criteria for Near-miss reporting

1. Despite of errors in medication being made, it was **detected prior to provision to patients**.
2. Despite of errors in medication being **provided to patients**, there was either **little or no effect** on patients' condition with minimum treatment with medication such as disinfectant, poultice, and analgesics.
3. Despite of errors in medication being **provided to patients**, there is **no further information** on patients' condition.

Note; "Error in medication" encompasses those which take place not only in pharmacy but in hospital or clinic.

Two types of “Error in medication” to meet the criteria for reporting



Prescription error

Dispensing error

Report

Action as “Family pharmacist”, “Your pharmacist” - “Pharmacy Vision for Patient” by MoHLW

Transition from “work for products” to “work for patient”

Patient-centered jobs

Product-oriented jobs

- Reception and filing of prescription sheet
- Dispensing (Weighing, Mixing, Cutting)
- Recording of relevant data on medication envelope
- Issuance of invoice
- Inspection and release of products
- Inventory control

- Education & training by academic and professional societies for enhancing expertise
- Sharing patient’s data i.e. aliments, lab data etc. through digital prescription
- Collection of safety data on pharmaceutical products

Enhancement of expertise including communication skills

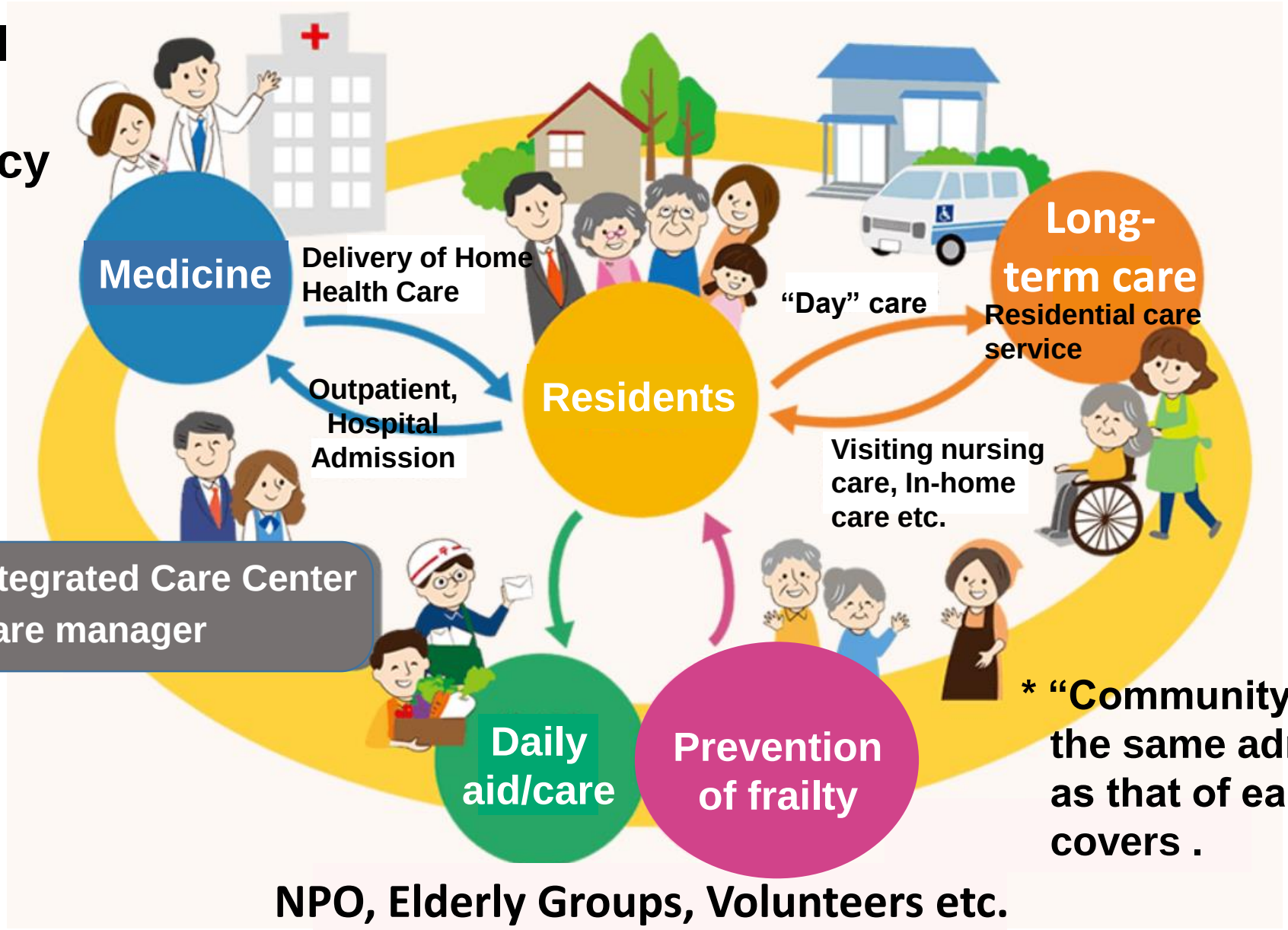
Patient-centered jobs

- Inspection of prescription i.g. duplication, contraindicated combination
- Clarification of prescription with physician
- Careful guidance of administration to a patient
- Home-visit management of medication therapy
- Feedback of side effects and compliance to a physician
- Proposal of preferred prescription
- Inventory control at individual level

Product-oriented jobs

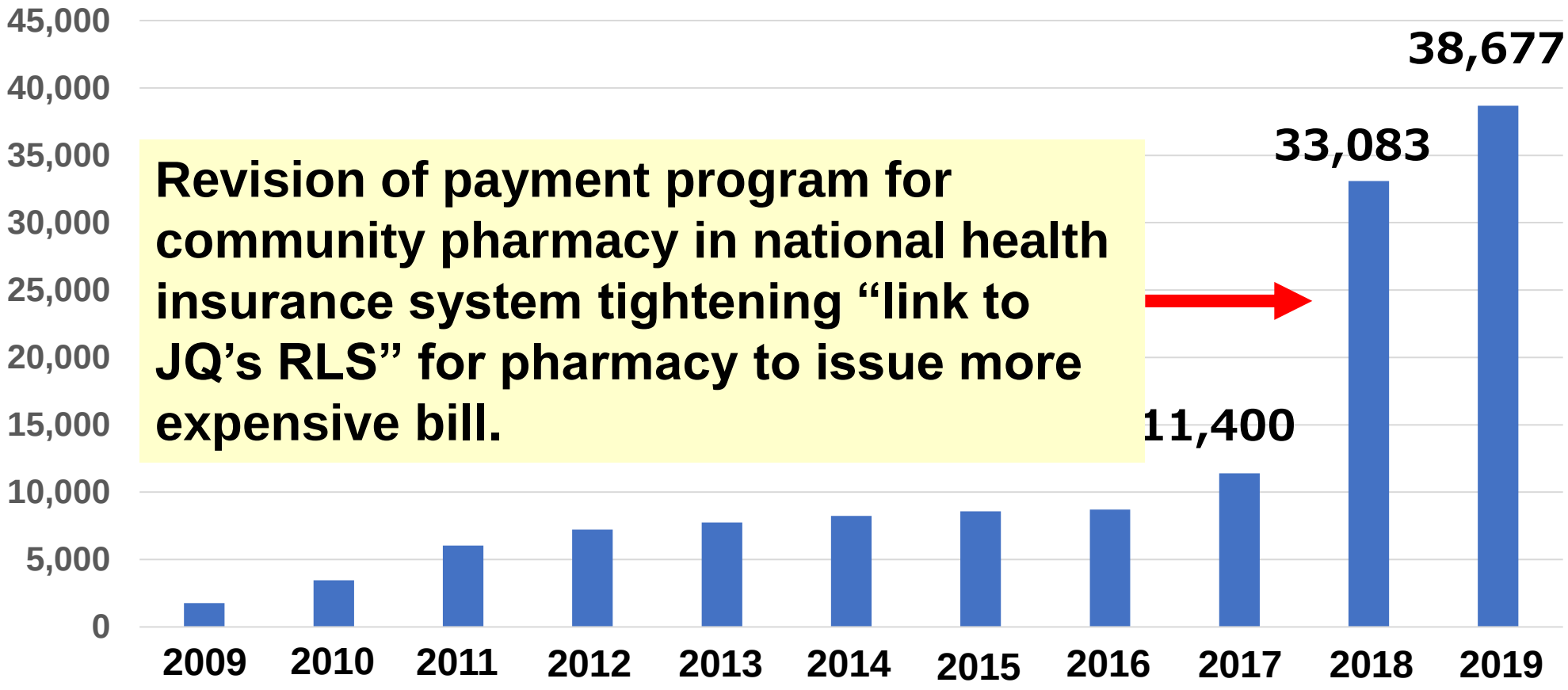
Envisioned “Community*-based Integrated Care” in Japan

- Hospital
- Clinic
- Pharmacy



* “Community” is defined as the same administrative area as that of each “mid-school” covers .

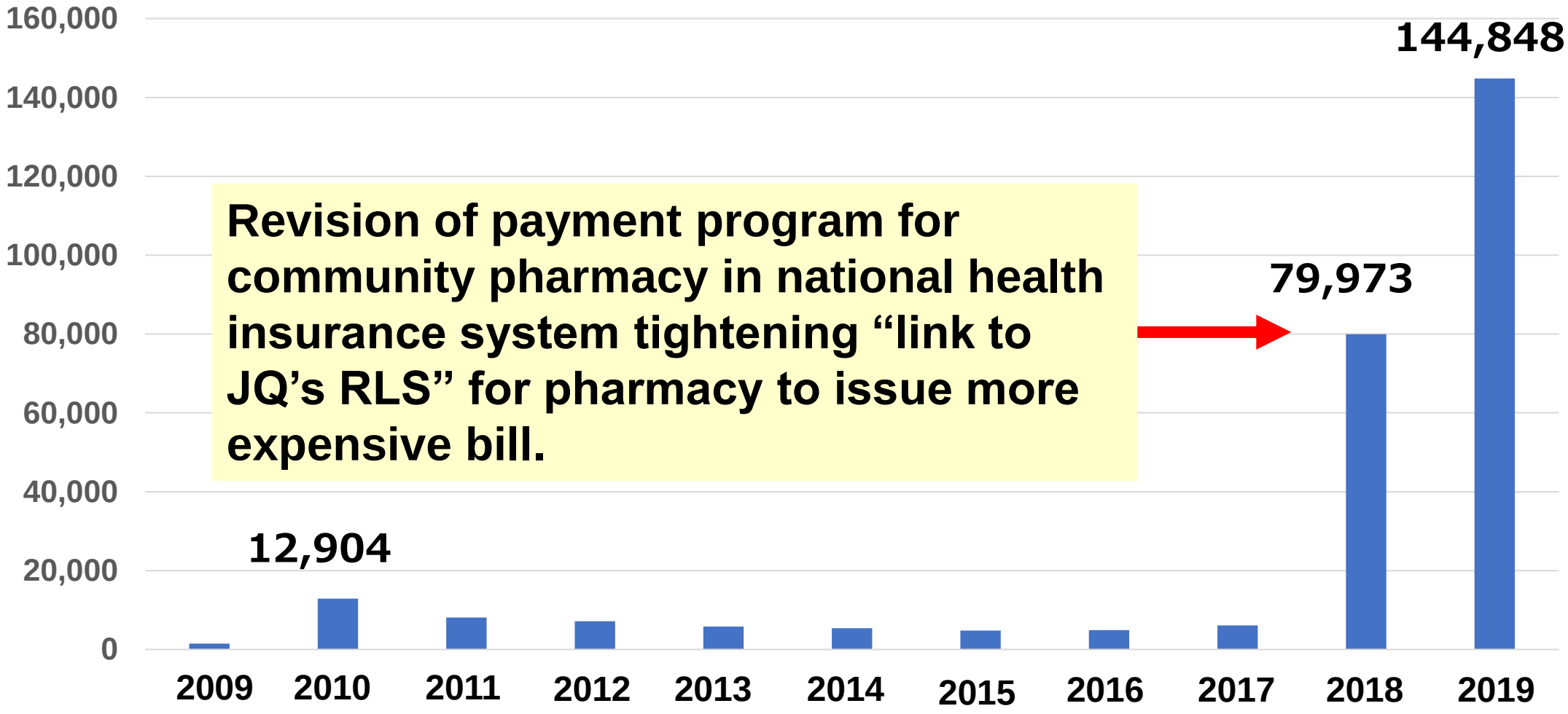
Trajectory of the number of registered pharmacies* (2009-2019)



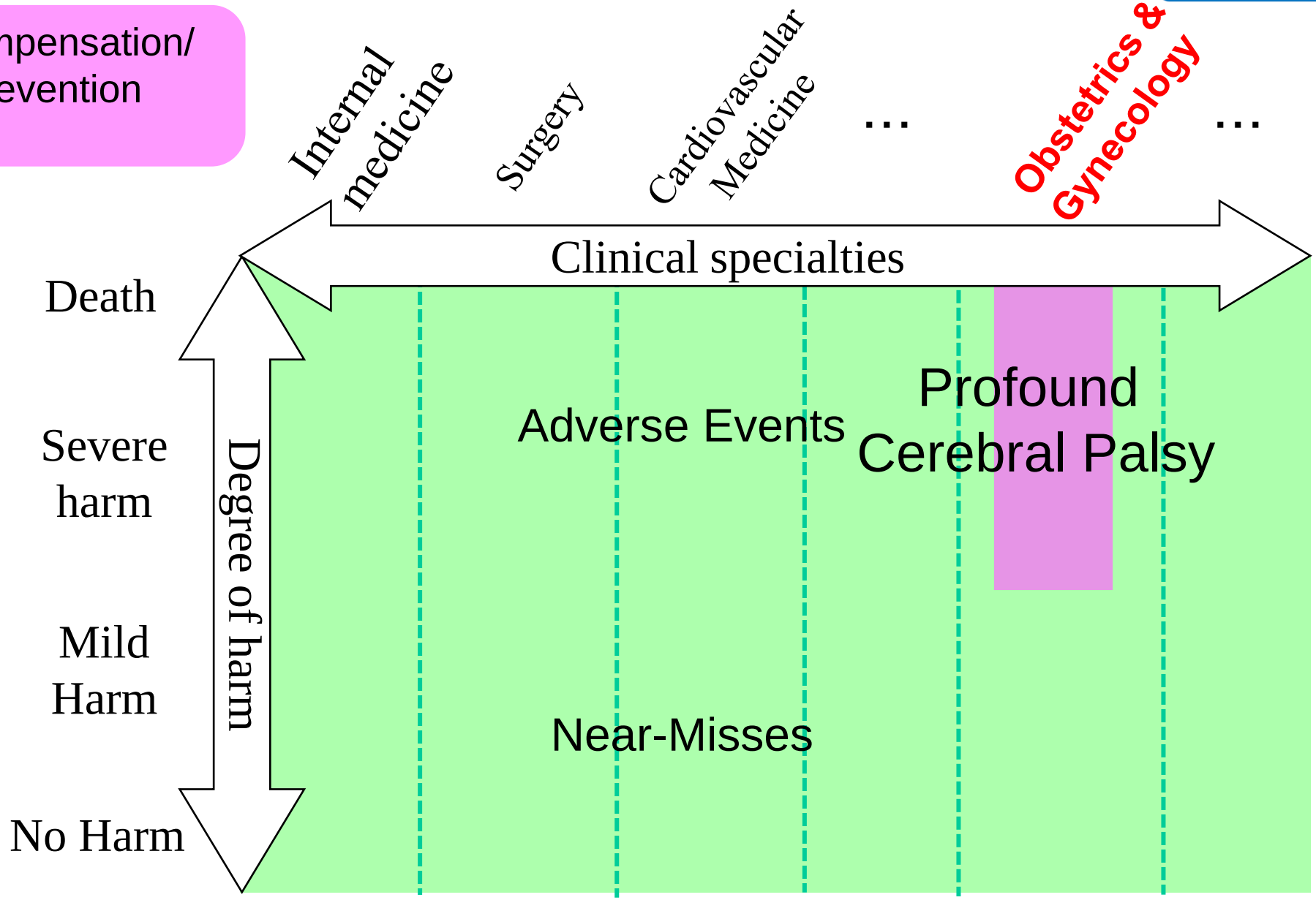
Revision of payment program for community pharmacy in national health insurance system tightening "link to JQ's RLS" for pharmacy to issue more expensive bill.

* The number of pharmacy : **59,613 institutions**
(Statistics by the Ministry of Health, Labour and Welfare, 2018)

Trajectory of the number of near-miss reports from pharmacies（2009-2019）



Cerebral palsy compensation/ investigation/prevention system



Why the compensation system for CP was called for?

- ✓ Shortage of obstetrician
- ✓ Long working hours, Burnout
- ✓ **Rising lawsuit cases** (e.g. **Cerebral palsy**)
- ✓ Low birth rate

Study committee installed in ad-hoc manner in the leading political party

It is normally difficult to figure out whether the delivery procedure is negligent, while cerebral palsy is frequently disputed in the court. The frequent dispute is one of the reasons for the current shortage of obstetricians.

Liberal Democratic Party, Review Meeting on How to Handle Healthcare Disputes（Nov. 29, 2006）

2006 Framework of no-fault compensation system by LDP *

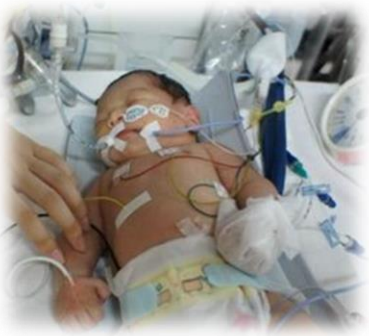
In order to secure safe and trustworthy perinatal care which benefit not only obstetricians but guardians , i)-iii) should be put into effect.

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

i. **Compensate patients** who developed disability possibly due to obstetric adverse events.
ii. **Bring conflict to settlement** as early as possible.
iii. **Establish a mechanism that improves quality of obstetric care** by investigating causes of cerebral palsy.

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

No-fault compensation/investigation/ prevention system for cerebral palsy , 2009～)



No-fault compensation (Insurance)

Petition (Report of CP) → Review → Payment

Proceeding irrespective of negligence

Investigation/Prevention with Patient Representatives

Medical chart, Birth care record, laboratory data, etc.

Family's Voices

20-30 pages

Prevention, early settlement of conflicts and Improvement of quality

What does “No-fault compensation” mean in JOCS-CP ?

“No-fault compensation”

Compensation INDEPENDENT from inquiry about negligence

~~Malpractice?~~

OR

~~Not malpractice?~~

Registration of childbirth facilities

As of Nov 30, 2021

	No. childbirth facilities	No. participating facilities	% Participation
Hospital	1,173	1,173	100.0
Clinic	1,557	1,555	99.9
Birth center	445	445	100.0 *
Total	3,175	3,173	99.9

* Institutions not registered: **2** clinics

Note; **No legislation** to mandate above facilities for registration.

Whole picture of proceedings in the system

A) Petition filed by childbirth facility — **Application**

B) Deliberation of eligibility — **Review 1**

B) Deliberation of eligibility on **appealed** case — **Review 2**

C) Payment of monetary compensation — **Compensation**

D) Investigation to issue report — **Investigation**

E) Prevention by distributing knowledge for improving quality & safety — **Prevention**

Patient participation in operating the JOCS-CP

Steering Committee
Experts
Patient representative

Review Committee
Appeal Committee
Experts

Investigation Committee
Experts
Patient representative

Prevention Committee
Experts
Patient representative

Sum of Compensation Payment (30million JPY=285,000 USD)

Lump-sum payment

To compensate for expenses on nursing case facilities

6 million JPY (57,000 USD)

+

Annual installments

To compensate for annual nursing care expenses

total **24 million JPY (228,000 USD)**

6 million JPY

+

Annual payment of 1.2 million JPY

× **20 years**

Eligibility Criteria for Compensation

i. General criteria (2009-present)

ii. “Case-by-Case Review” criteria (2009-2021)

iii. Exclusion criteria (2009-present)

Image of eligible CP i.e. “CP possibly due to delivery”

Not-eligible

Cerebral palsy

Eligible (Yellow)

CP** in accordance with **A) and B)

A) General criteria (Gestational week, Birth weight) or “Case-by-Case Review” criteria (pH of umbilical blood, Patterns of bradycardia)

B) 1st-2nd grade impairment (in accordance with the standard of public social welfare system)

Exclusion criteria (Congenital cause, Cause which obviously takes place after birth etc.)

Not-eligible

Statistics of review on eligibility

As of Jun 4th

Birth year	Review counts	Approved	Not-approved *			In progress	Window for petition
			Not-approved	Allowed to file in the future **	Total		
2009	561	**419**	142	0	142	0	Expired
2010	523	**382**	141	0	141	0	Expired
2011	502	**355**	147	0	147	0	Expired
2012	517	**361**	155	0	155	0	Expired
2013	476	**351**	125	0	125	0	Expired
2014	469	**326**	143	0	143	0	Expired
2015	475	**376**	99	0	99	0	Expired
2016～2018	933	803	81	41	122	8	Valid
Total	**4,456**	**3,374**	1,033	41	1,074	8	—

* Cases not-approved are allowed to file to appeal committee. “Not-approved” includes cases approved at appeal committee.

** Cases preliminary for review in terms of clinical manifestations of too early time points. They are allowed for future reviews.

Production of standardized investigative report

Childbirth facility

Records, Laboratory data, etc.

Data on device and human resources and location of the childbirth facility, etc.

Guardians

Question on the delivery, CP etc.

JQ

Theoretical productivity: 504 reports /year

Complete "Fact" sheet of clinical course

Investigative Committee

7 Sub-committees

A B C D E F G

Draft Report

Committee

Final Report

◆**Delivery** to childbirth facility and family

◆**Disclosure** on HP on condition of **anonymity**

Technical assistance

Secretariat (Midwife, Obstetrician, Technical staff)

Attainment of compiling investigative report

3,522 petitions were approved for compensation*.

3,048 (86.5%) investigative reports have been published*.

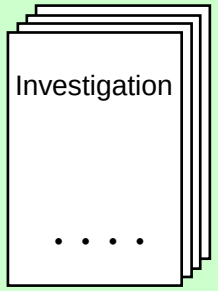
* Statistics as of November 2021

Publication of Prevention Report based on aggregative analysis of Investigative Report

Investigation committee

Report of

“Individual case”

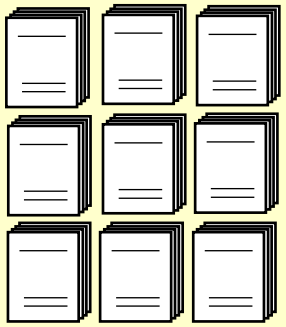


- Cause
- Appraisal
- Preventive measures

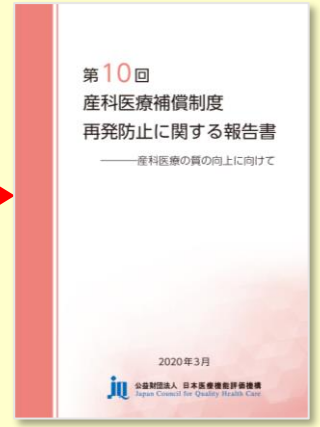
Prevention committee

Report of

“Aggregated cases”



- Aggregative analysis
- Thematic analysis
- Recommendation, etc.

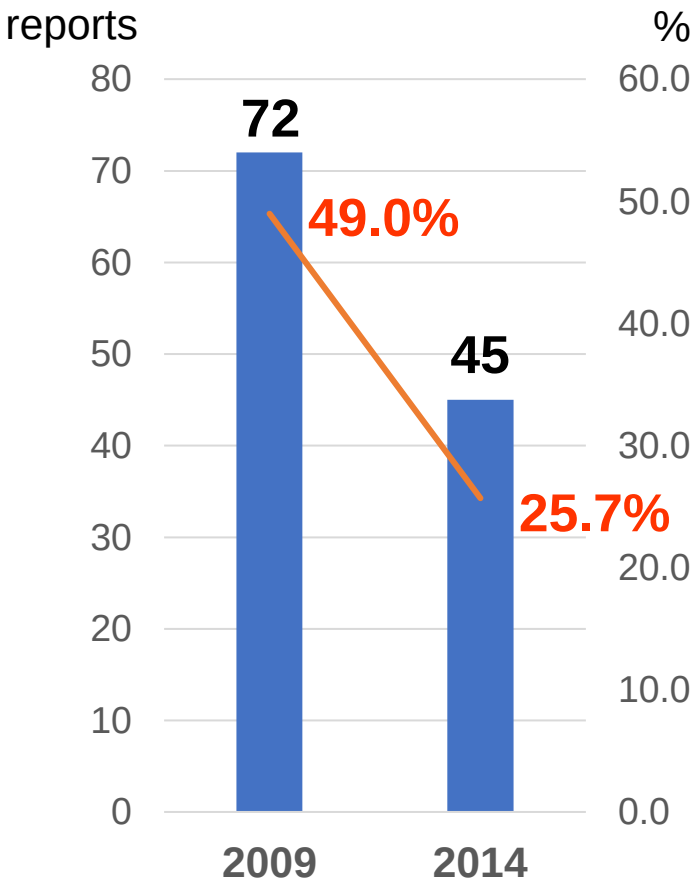


A) Report; Delivered both to **family** and **childbirth facility**
B) Summarized report; Posted on the web
C) Report with identifiers deleted; Available only for research use through internal process

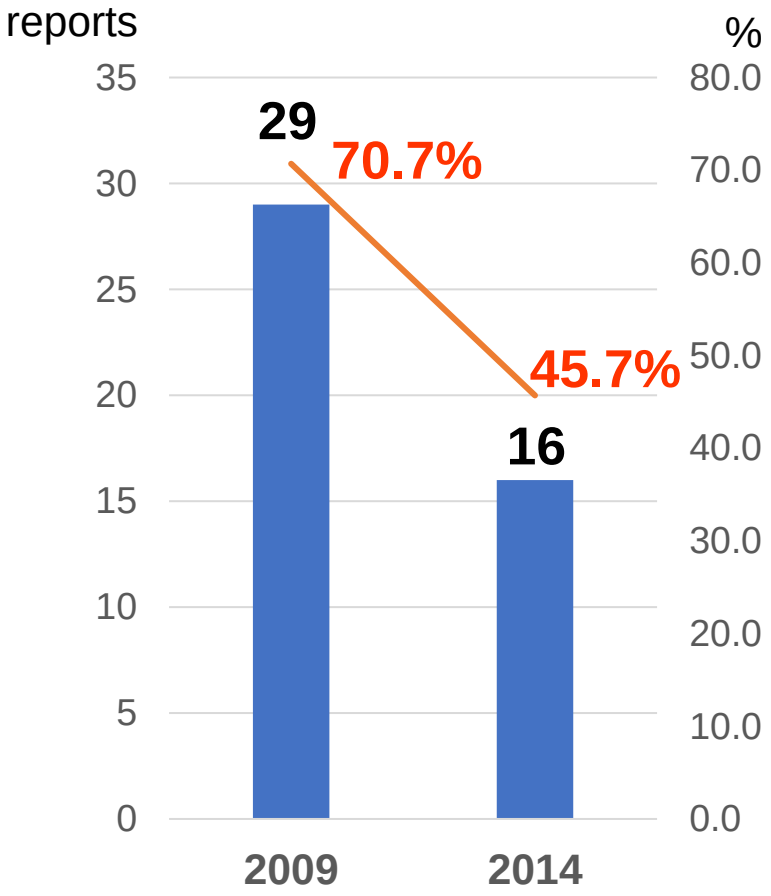
A) Delivered to **Childbirth facility, Scientific societies**, Government, etc.
B) Posted on the web open to the public

Improvement of specific practices between 2009 and 2014

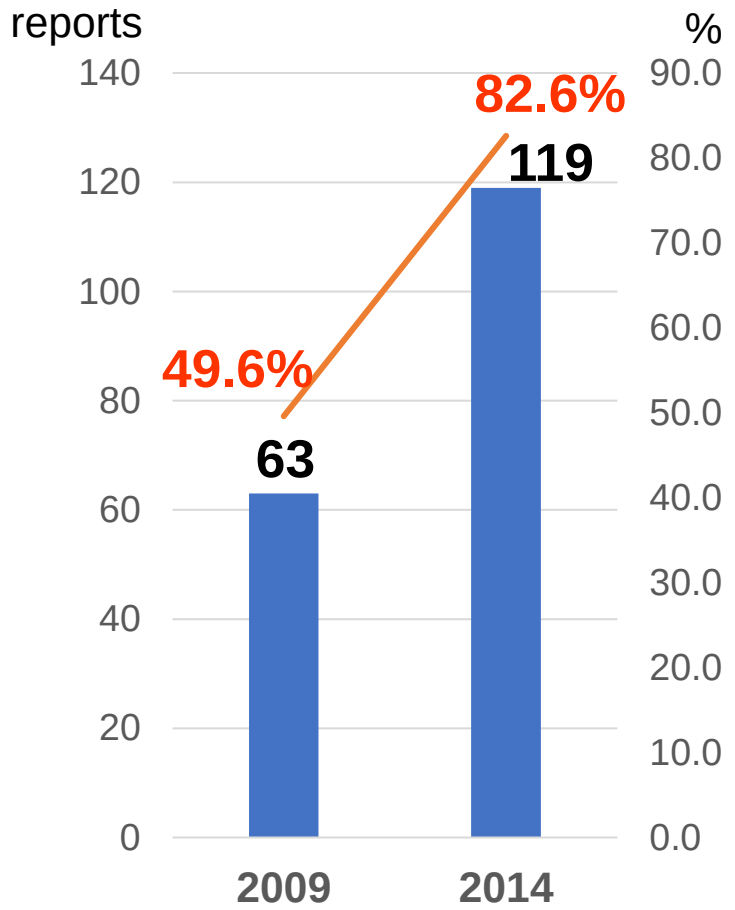
Comment on FHR monitoring for improvement



Excess administration of oxytocin



Mechanical ventilation within 1 min after birth



“Stepwise disciplinary action” to individual facility for quality improvement on condition of anonymity

Procedure which needs improvement is clearly mentioned in the Investigative report.

Report of Case A mentioned to a specific procedure for improvement.

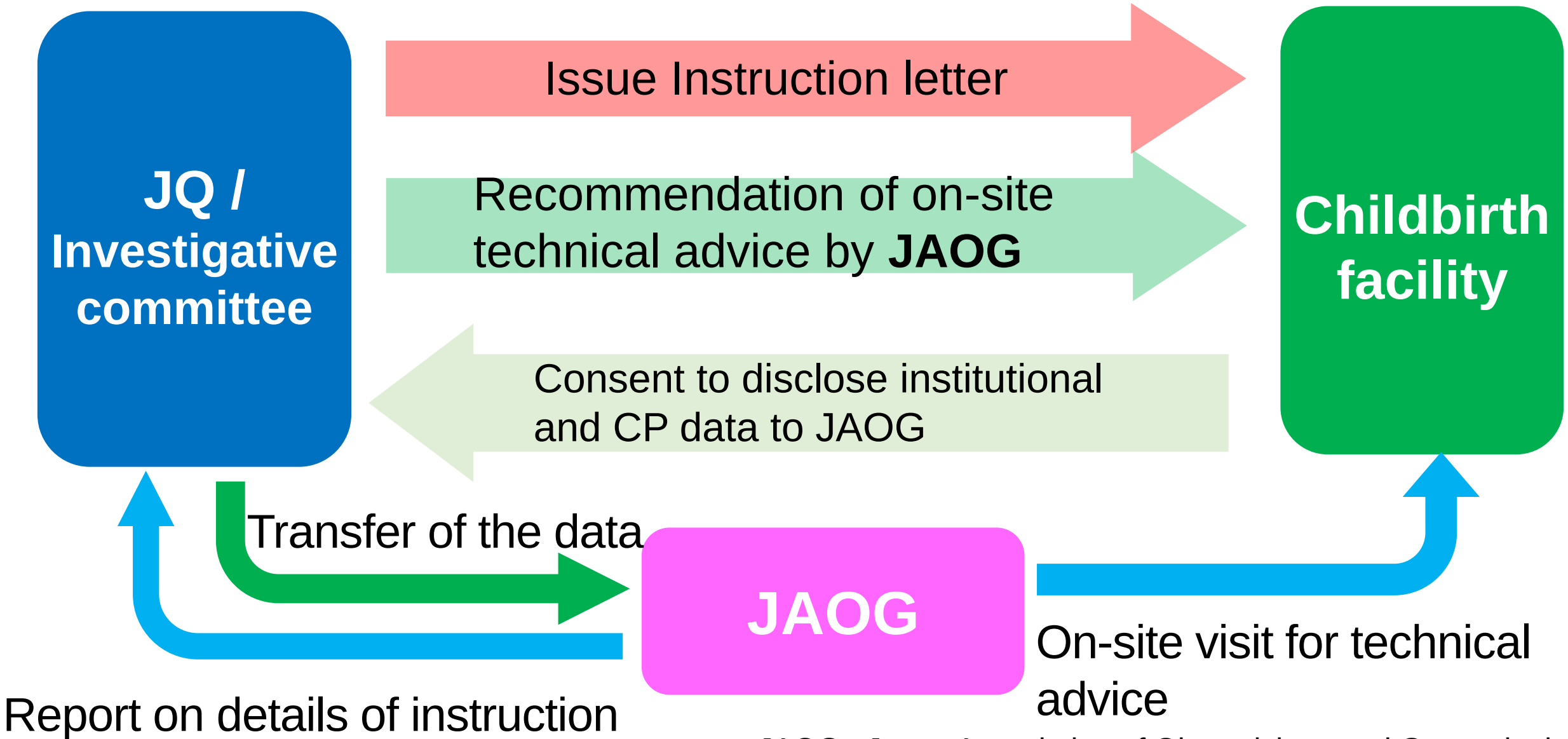
Report of Case B also mentioned to the same or similar procedure for improvement.

ii. Issue an “***Instruction letter****” to urge facility in question for improvement.

iii. Request to return “***Improvement report***” in which the facility has to describe the implementation of improvement in detail.

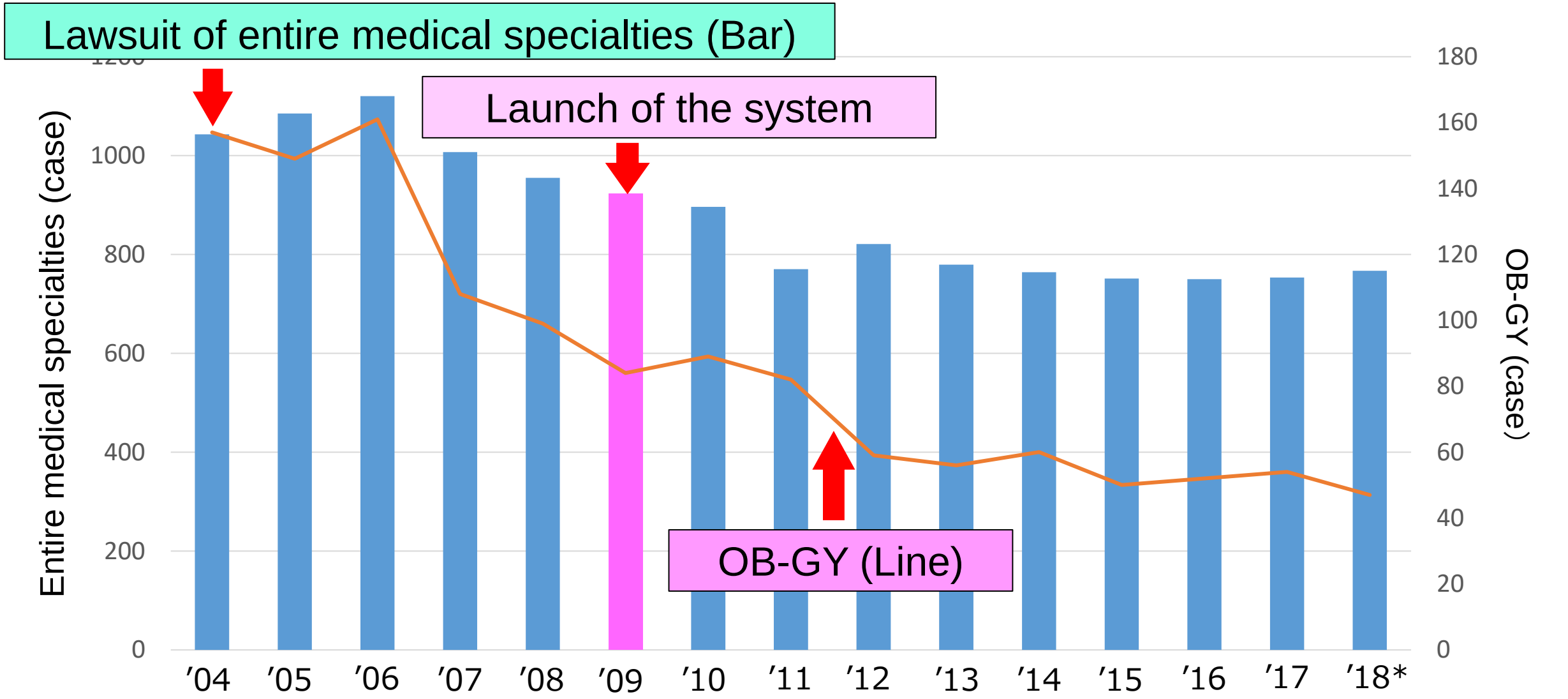
110 instruction letters were issued to childbirth facilities (Statistics during Jan, 2009 - Nov, 2021).

2020 New scheme for instructing childbirth facility



JAOG : Japan Association of Obstetricians and Gynecologists

Possible impact on lawsuit case



* Preliminary data　Statistics of lawsuit trend by medical specialties by the Supreme Court

Report on achieving early completion of litigation process - The Supreme Court of Japan

*"**It is noteworthy** that the Japan Obstetric Compensation System for Cerebral Palsy has brought **investigative system by a third party** and **system of equally imposing financial burden for monetary compensation** in Japanese society sharing the idea that perinatal care inherently holds a potential risk.*

*It is concerned whether the system expands to **cover other medical specialties**.*

*The system having approved significant number of CP cases **supposedly has affected** to a certain extent **statistics of lawsuit cases of medicine**."*

Select Committee: NHS Litigation Reform of the Health and Social Care Committee, House of Commons, UK Parliament, Jan 11, 2022

Rt. Hon. Jeremy Hunt, Chair

Professor Shin Ushiro
Kyushu University Hospital, Japan Council for Quality Health Care

Michael Mercier, Accident Compensation Corporation, NZ

Dr Pelle Gustafson, Swedish Patient Insurer, Sweden

George Deebo
Executive Officer at Virginia Birth-Related Neurological Injury Compensation Program, US

Takeaways

- Reporting and learning system is a tool and a platform for quality and safety improvement.
- There are institutional and national systems which play different role and exert synergistic impact.
- Hospital, clinic, birth center and pharmacy are subject to reporting on mandatory and voluntary basis in Japan.
- Japan Obstetric Compensation System for Cerebral Palsy is a unique reporting and learning system in a sense that it only focuses on brain injury which often ignites conflict and medical institution subject to reporting is incentivized by no-fault compensation.
- As such, reporting and learning system could be modified depending on its goals.