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
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

<table>
<thead>
<tr>
<th>Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Accreditation</td>
</tr>
<tr>
<td>Patient Safety Promotion Group of Among Accredited Hospitals</td>
</tr>
<tr>
<td>Education and Training on Patient Safety</td>
</tr>
<tr>
<td>EBM Medical Information Distribution Project (Minds)</td>
</tr>
<tr>
<td><strong>Nationwide Adverse Events Reporting System of Medical Institutions</strong></td>
</tr>
<tr>
<td><strong>Nationwide Near-miss Event Reporting System of Community Pharmacy</strong></td>
</tr>
<tr>
<td>The Japan Obstetric Compensation/Investigation and Prevention System for Cerebral Palsy</td>
</tr>
<tr>
<td>National Quality Indicator (QI) Measurement Project</td>
</tr>
</tbody>
</table>

**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

  - Regular inspection*
  - Central, Local governments

  - On-site survey
  - Accreditation

  - Reporting of AEs, Near-miss

**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
Average monthly reporting/year


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)

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

Ad-hoc meetings

- Investigation committee
- M&M conference

Interview analysis

Monthly alert

KYUSHU UNIVERSITY | 7
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 metrics.

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

**Director**

- Advisor to the director (Safety on pediatric care)*
- Advisor to the director (Safety on devices)*

**Deputy director (Chief PS officer) *

**Divisional director**, **Deputy director**, **Safety managers** (Nurses**, Dentist*, Pharmacist**) , Division of PS

**Risk managers** *

* Concurrent appointment, ** Full-time appointment
Nationwide reporting/investigation/learning system with public or quasi public nature

- **2004 -**
  - AE reporting/learning system (medical institution)

- **2008 -**
  - AE reporting/learning system (Pharmacy)

- **2009 -**
  - Cerebral palsy compensation investigation/prevention/system

- **2015 -**
  - Investigation system of accidental death

- **2022**
AE reporting/learning system (medical institution)

Death
Severe harm
Mild harm
No Harm

Clinical specialties

Adverse Events
Near-Misses

Degree of harm

Internal medicine
Surgery
Cardiovascular Medicine
Obstetrics & Gynecology
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**
1. Coding
2. Text
   - Aim
   - Outline
   - Background
   - Preventive measure

**On-site visit**
(Voluntary survey)

**Annual/Quarterly report**

**Monthly alert**

**Database**

**Training program (RCA)**

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

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

**Expert Panel**

**Secretariat**

**General public**

**Health care professionals/facilities**

**Government**
### Number of institutions by registration type

<table>
<thead>
<tr>
<th>Registration type; (A), (B) or both</th>
<th>(A) Adverse event reporting system</th>
<th>(B) Near-miss reporting system</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Registered</td>
<td>Total</td>
</tr>
<tr>
<td></td>
<td>Occurrence count and Case Report</td>
<td>Occurrence count Report ONLY</td>
</tr>
<tr>
<td>Mandatory</td>
<td>122</td>
<td>85</td>
</tr>
<tr>
<td>Registered</td>
<td>513</td>
<td>335</td>
</tr>
<tr>
<td>Voluntary</td>
<td>391</td>
<td>250</td>
</tr>
<tr>
<td>Not-registered</td>
<td>163</td>
<td>283</td>
</tr>
<tr>
<td>Total</td>
<td>676</td>
<td>618</td>
</tr>
<tr>
<td></td>
<td>274</td>
<td>279</td>
</tr>
<tr>
<td></td>
<td>853</td>
<td>1,127</td>
</tr>
<tr>
<td></td>
<td>446</td>
<td>1,573</td>
</tr>
</tbody>
</table>

Statistics as of Sep 30, 2021
## Registered medical institutions with/without reporting obligation (Mandatory / Voluntary) of AE reporting

<table>
<thead>
<tr>
<th>Type</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory</td>
<td>274</td>
</tr>
<tr>
<td>Voluntary</td>
<td>853</td>
</tr>
<tr>
<td>Total</td>
<td>1,127</td>
</tr>
</tbody>
</table>

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
### Yearly Trajectory of AE Reporting to JQ

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory</td>
<td>1,114</td>
<td>1,296</td>
<td>1,266</td>
<td>1,440</td>
<td>1,895</td>
<td>2,182</td>
<td>2,483</td>
<td>2,535</td>
<td>2,708</td>
<td>2,911</td>
<td>3,374</td>
<td>3,428</td>
<td>3,598</td>
<td>4,030</td>
<td>4,049</td>
<td>4,321</td>
<td>4,674</td>
</tr>
<tr>
<td>Voluntary</td>
<td>151</td>
<td>155</td>
<td>179</td>
<td>123</td>
<td>169</td>
<td>521</td>
<td>316</td>
<td>347</td>
<td>341</td>
<td>283</td>
<td>280</td>
<td>454</td>
<td>497</td>
<td>535</td>
<td>483</td>
<td>481</td>
<td>569</td>
</tr>
</tbody>
</table>

**Adverse event Reporting / Learning System Since 2004**

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

**Upward pressure have been successfully yielded.**
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.e. 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

- Medication: 8%
- Blood transfusion: 0%
- Procedures: 28%
- Medical devices: 2%
- Tubes: 8%
- Examinations & Lab tests: 6%
- Nursing care: 35%
- Others: 13%

2019 Annual Report of JQ’s AE/Near-miss reporting system
## Frequent AEs (10 cases or more / yr)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overdose administration</td>
<td>54</td>
</tr>
<tr>
<td>Wrong drug</td>
<td>22</td>
</tr>
<tr>
<td>Overdose prescription</td>
<td>20</td>
</tr>
<tr>
<td>Wrong patient</td>
<td>19</td>
</tr>
<tr>
<td>Wrong drug dispensing</td>
<td>17</td>
</tr>
<tr>
<td>Faster setting of injection rate</td>
<td>17</td>
</tr>
<tr>
<td>Wrong method of administration (Wrong injection route, etc.)</td>
<td>12</td>
</tr>
<tr>
<td>Failure to prescribe</td>
<td>11</td>
</tr>
<tr>
<td>Administration of Contraindicated drug</td>
<td>11</td>
</tr>
<tr>
<td>Underdose administration</td>
<td>11</td>
</tr>
<tr>
<td>Failure to administer</td>
<td>11</td>
</tr>
</tbody>
</table>

(Annual report 2019)
## Themes of analysis in past quarterly reports

<table>
<thead>
<tr>
<th>Report</th>
<th>Themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>67th report</td>
<td>Medication error related to chemotherapy for outpatient (series 2)</td>
</tr>
<tr>
<td>(2021-4)</td>
<td>Medication error related to chemotherapy for outpatient (series 1)</td>
</tr>
<tr>
<td>66th report</td>
<td>Discontinued injection of cathecolamine due to delayed exchange of</td>
</tr>
<tr>
<td>(2021-3)</td>
<td>prefilled syringe</td>
</tr>
<tr>
<td></td>
<td>Error that residents are involved</td>
</tr>
<tr>
<td>65th report</td>
<td>Adverse event involving resident (series 2)</td>
</tr>
<tr>
<td>(2021-2)</td>
<td>Wrong injection through mix-up of &quot;SILECE®&quot; and &quot;SERENACE®&quot;</td>
</tr>
<tr>
<td></td>
<td>Wrong injection through mix-up of &quot;MEYLON®7%&quot; and &quot;MEYLON®8.4%&quot;</td>
</tr>
<tr>
<td></td>
<td>Wrong procedure to use tracheal tube with speaking valve</td>
</tr>
<tr>
<td>64th report</td>
<td>Adverse event involving resident (series 1)</td>
</tr>
<tr>
<td>(2021-1)</td>
<td>Adverse event involving Covid-19</td>
</tr>
</tbody>
</table>
Reporting and learning system of community pharmacy (2008~)

Aim: Prevention

Principles: No-blame, Anonymous

Web-based reporting

i) Coding

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

ii) Text

Summary
Underlying factors
Preventive measures

Annual/Half-yearly report
Sentinel case report

Steering committee (Experts, Patient representative)

Technical panel (Drug, Device, Human error)

Secretariat

Database

Iconic table
Iconic case

Japan Council for Quality Health Care
Division of AE Prevention

Community pharmacy
Voluntary-based

Near-miss

“Cases which takes place or is identified in pharmacy”

Nation
✓ Community Pharmacy
✓ Relevant Scientific Society/Organization
✓ Government etc.
Working flow of medication therapy: from prescription to administration

Hospital/Clinic

Patient

Prescription

Community pharmacy

Patient

Prescription

Dispensing
Working flow of medication therapy: from prescription to administration
Two types of errors frequently identified in community pharmacy

**Hospital/Clinic**
- Prescription error

**Community pharmacy**
- Dispensing error
Clarification of questionable prescription by pharmacist

Hospital/Clinic

Community pharmacy

Prescription

Error

Error

Error

CLARIFICATION
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

Hospital/Clinic

- Prescription
- Error

Community pharmacy

- Prescription
- Error
- Dispensing
- Error

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**

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

**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

**Enhancement of expertise including communication skills**

**Patient-centered jobs**

- Inspection of prescription i.e.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**

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

- Integrated Care Center
- Care manager

- Delivery of Home Health Care
- Outpatient, Hospital Admission
- “Day” care
- Residential care service
- Visiting nursing care, In-home care etc.

- Daily aid/care
- Prevention of frailty

NPO, Elderly Groups, Volunteers etc.
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)
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.
Cerebral palsy compensation/investigation/prevention system

Clinical specialties

Internal medicine  Surgery  Cardiovascular Medicine  ...  Obstetrics & Gynecology  ...

Death
Severe harm
Mild harm
No Harm

Degree of harm

Adverse Events

Near-Misses

Profound Cerebral Palsy
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)
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.
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

Prevention, early settlement of conflicts and Improvement of quality

20-30 pages
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

<table>
<thead>
<tr>
<th></th>
<th>No. childbirth facilities</th>
<th>No. participating facilities</th>
<th>% Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>1,173</td>
<td>1,173</td>
<td>100.0</td>
</tr>
<tr>
<td>Clinic</td>
<td>1,557</td>
<td>1,555</td>
<td>99.9</td>
</tr>
<tr>
<td>Birth center</td>
<td>445</td>
<td>445</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>3,175</strong></td>
<td><strong>3,173</strong></td>
<td><strong>99.9</strong></td>
</tr>
</tbody>
</table>

* 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

B) Deliberation of eligibility

C) Payment of monetary compensation

D) Investigation to issue report

E) Prevention by distributing knowledge for improving quality & safety

Application

Review 1

Review 2

Compensation

Investigation

Prevention
Patient participation in operating the JOCS-CP

- Steering Committee
  - Experts
  - Patient representative

- Investigation Committee
  - Experts
  - Patient representative

- Review Committee
  - Appeal Committee
  - Experts

- Prevention Committee
  - Experts
  - Patient representative
Sum of Compensation Payment (30 million 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)

  - 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)
Cerebral palsy

**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.)
## Statistics of review on eligibility

As of Jun 4th

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

* 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

Investigative Committee
- 7 Sub-committees
  - A
  - B
  - C
  - D
  - E
  - F
  - G
- Draft Report
- Final Report

Committee

◆ 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

<table>
<thead>
<tr>
<th>Year</th>
<th>Reports</th>
<th>%</th>
<th>Year</th>
<th>Reports</th>
<th>%</th>
<th>Year</th>
<th>Reports</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>72</td>
<td>49.0%</td>
<td>2009</td>
<td>29</td>
<td>70.7%</td>
<td>2009</td>
<td>63</td>
<td>49.6%</td>
</tr>
<tr>
<td>2014</td>
<td>45</td>
<td>25.7%</td>
<td>2014</td>
<td>16</td>
<td>45.7%</td>
<td>2014</td>
<td>119</td>
<td>82.6%</td>
</tr>
<tr>
<td>2009</td>
<td>72</td>
<td>60.0%</td>
<td>2009</td>
<td>29</td>
<td>80.0%</td>
<td>2009</td>
<td>63</td>
<td>90.0%</td>
</tr>
<tr>
<td>2014</td>
<td>45</td>
<td>40.0%</td>
<td>2014</td>
<td>16</td>
<td>60.0%</td>
<td>2014</td>
<td>119</td>
<td>70.0%</td>
</tr>
<tr>
<td>2009</td>
<td>72</td>
<td>50.0%</td>
<td>2009</td>
<td>29</td>
<td>50.0%</td>
<td>2009</td>
<td>63</td>
<td>50.0%</td>
</tr>
<tr>
<td>2014</td>
<td>45</td>
<td>30.0%</td>
<td>2014</td>
<td>16</td>
<td>30.0%</td>
<td>2014</td>
<td>119</td>
<td>30.0%</td>
</tr>
<tr>
<td>2009</td>
<td>72</td>
<td>40.0%</td>
<td>2009</td>
<td>29</td>
<td>40.0%</td>
<td>2009</td>
<td>63</td>
<td>40.0%</td>
</tr>
<tr>
<td>2014</td>
<td>45</td>
<td>20.0%</td>
<td>2014</td>
<td>16</td>
<td>20.0%</td>
<td>2014</td>
<td>119</td>
<td>20.0%</td>
</tr>
<tr>
<td>2009</td>
<td>72</td>
<td>30.0%</td>
<td>2009</td>
<td>29</td>
<td>30.0%</td>
<td>2009</td>
<td>63</td>
<td>30.0%</td>
</tr>
<tr>
<td>2014</td>
<td>45</td>
<td>10.0%</td>
<td>2014</td>
<td>16</td>
<td>10.0%</td>
<td>2014</td>
<td>119</td>
<td>10.0%</td>
</tr>
</tbody>
</table>
“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

JQ / Investigative committee

Issue Instruction letter

Recommendation of on-site technical advice by JAOG

Consent to disclose institutional and CP data to JAOG

Transfer of the data

JAOG

On-site visit for technical advice

JAOG : Japan Association of Obstetricians and Gynecologists

Transfer of the data

JQ / Investigative committee

Issue Instruction letter

Recommendation of on-site technical advice by JAOG

Consent to disclose institutional and CP data to JAOG

Transfer of the data

JAOG

On-site visit for technical advice

JAOG : Japan Association of Obstetricians and Gynecologists
Possible impact on lawsuit case

Lawsuit of entire medical specialties (Bar)

Launch of the system

OB-GY (Line)

* 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

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

\textit{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 \textit{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.