Promoting Patient Safety Best Practices in Japan

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Japan Council for Quality Health Care (JQ)
International Society for Quality in Health Care (ISQua)
Ministry of Health, Labour and Welfare (MoHLW), Japan

Project line-up of JQ 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.

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

2023

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

2023～
AE reporting/learning system (Dental clinic)

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 culture**）

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

Expert Panel

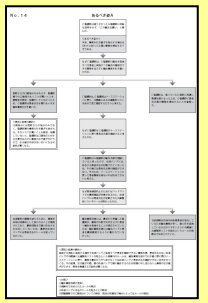
Secretariat

Annual/Quarterly report

Monthly alert

Database

Training program (RCA)

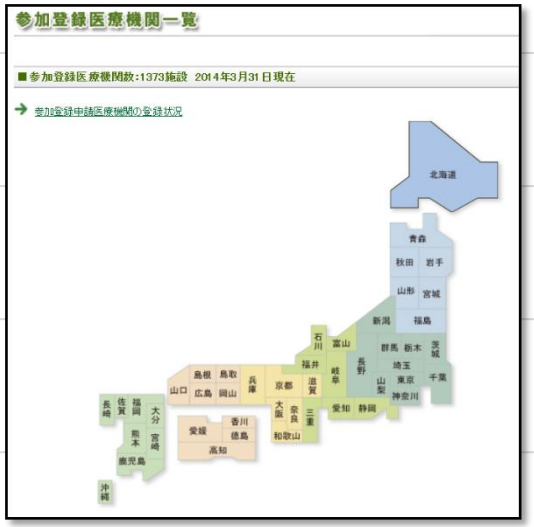


General public

Health care professionals/ facilities

Government

Trajectory of the AE reporting to JQ



6,000
5,000
4,000
3,000
2,000
1,000
0

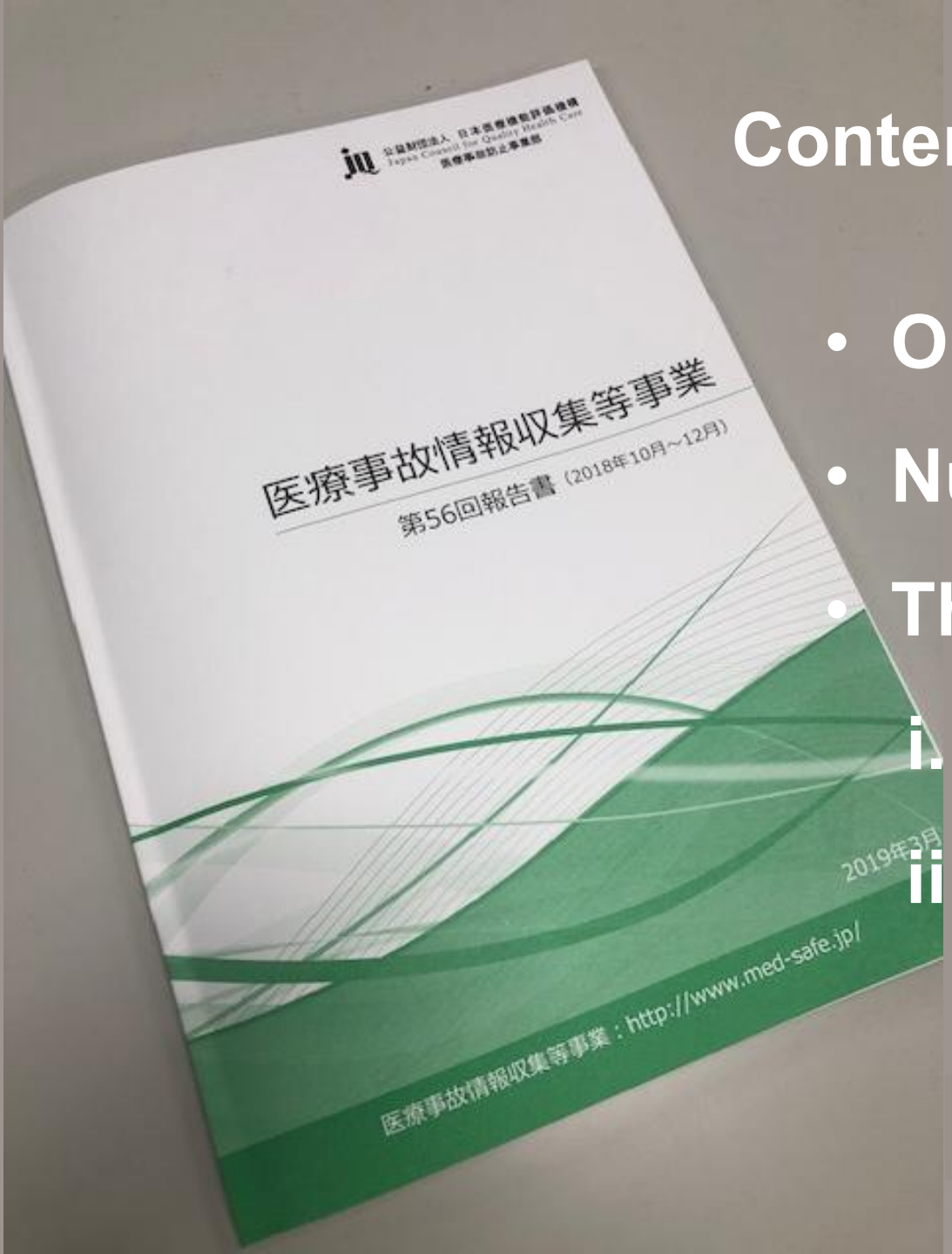
2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022

5,313 AEs / 2022 were reported.

Mandatory Voluntary

Japan National University Hospital Alliance on Patient Safety (JANUHA-PS) Annual Congress, 2022

Chair; Nagoya University Hospital, Vice chair; Tohoku University Hospital

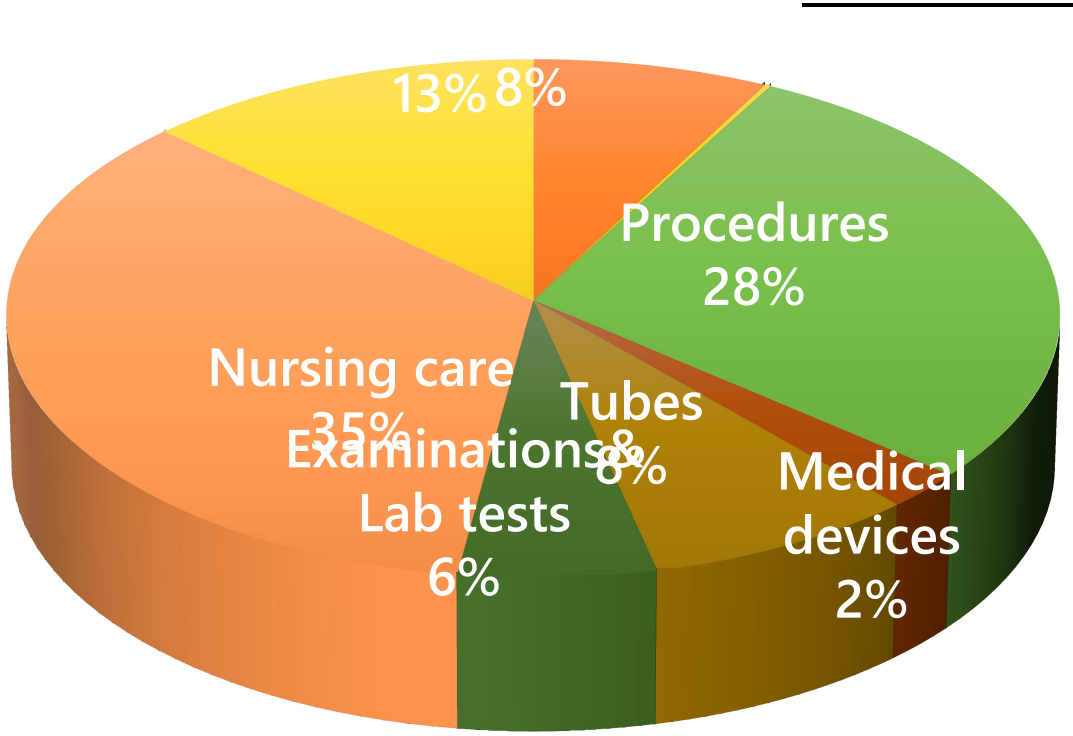


Contents of Annual/Quarterly report *

- Outline of the system
- Numerical analysis
- Thematic analysis
  - i. “New themes; 252 themes
  - ii. “Recurrent” themes; 134 themes

* 72 Quarterly reports & 17 Annual reports

Types of Adverse Event



- Medication
- Blood transfusion
- Procedures
- Medical devices
- Tubes
- Examinations& Lab tests
- Nursing care
- Others

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

Themes of analysis in past quarterly reports

72nd report (Marr, 2023)	Failed "Double-check"
	Error in setting "Unit" on infusion pump
71st report (Dec, 2022)	Wrong-patient care (series 4)
	Failed sensoring system to detect patient movement for preventing falls
70th report (Sep, 2021)	Wrong-patient care (series 3)
69th report (Sep, 2021)	Wrong-patient care (series 2)
68th report (Jun, 2021)	Wrong-patient care (series 1)
	Event related to Covid-19 infection (series 2)
67th report (Apr, 2021)	Medication error related to chemotherapy for outpatient (series 2)
	Pressure ulcer developed by medical devices

Failure to Confirm CT, MRI Imaging Report

Thematic analysis

再発・類似事例の分析　「画像診断報告書の確認不足」（医療安全情報 No. 63）

【2】「画像診断報告書の確認不足」（医療安全情報 No. 63）

（1）発生状況

画像診断報告書の内容が伝達されなかった事例について、第26回報告書（2011年9月公表）において、画像診断報告書を見なかった事例と画像診断報告書の記載内容を見落とした事例に大別して分析を行った。その後、医療安全情報 No. 63（2012年2月提供：集計期間：2008年1月～2011年12月）では「画像診断報告書の確認不足」として、画像検査を行った際、画像診断報告書が報告されているにもかかわらず内容を確認しなかったため、想定していなかった診断に気付かず、治療の遅れを生じた可能性のある事例について取り上げた。さらに、第40回報告書（2015年3月公表）の「再発・類似事例の発生状況」において、医療安全情報 No. 63「画像診断報告書の確認不足」について、新たに報告された事例を紹介し、画像検査の目的と画像診断報告書を確認していなかった背景・要因について取りまとめた。

今回、本報告書分析対象期間（2017年7月～9月）においても類似の事例が13件報告されたため、再び取り上げることとした。第40回報告書の集計期間後の2015年1月以降に報告された再発・類似事例は32件であった（図表Ⅲ - 3 - 4）。

図表Ⅲ - 3 - 4 「画像診断報告書の確認不足」の報告件数

	1～3月（件）	4～6月（件）	7～9月（件）	10～12月（件）	合計（件）
2015年	3	2	2	4	11
2016年	0	0	3	1	4
2017年	2	2	13	－	17

図表Ⅲ - 3 - 5 医療安全情報 No. 63「画像診断報告書の確認不足」

- 59 -　医療事故情報収集等事業　第51回報告書

Monthly Alert

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

Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.191, October 2022

Local Injection of High-Concentration Adrenaline Due to Container Mix-Up

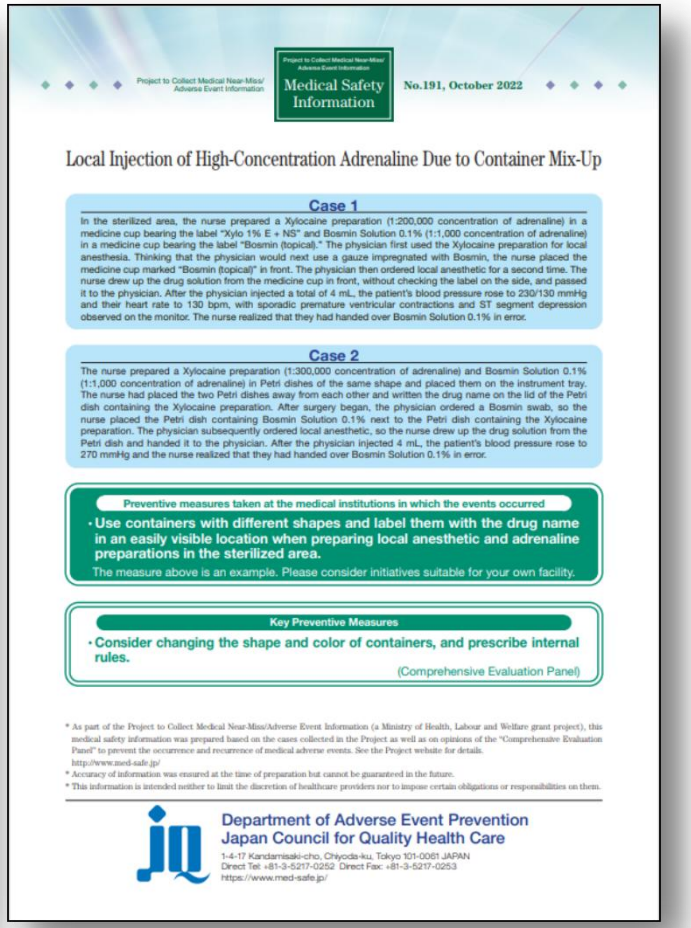
Three cases have been reported in which high-concentration adrenaline was erroneously injected when injecting local anesthetic during surgery, due to the wrong container being picked up (information collection period: from January 1, 2019 to August 31, 2022). This information was compiled on the basis of the content featured in the Details of Events section of the 69th Quarterly Report.

Cases have been reported in which the local injection of high-concentration adrenaline during surgery due to picking up the wrong container affected the patient's hemodynamics.

Concentration of Adrenaline as Local Anesthetic	Concentration of Adrenaline Injected	Main Background Factors
1:200,000 concentration	1:1,000 concentration	• Prepared in a medicine cup with the same shape • Could not see the label affixed to the side
1:300,000 concentration	1:1,000 concentration	• Prepared in a Petri dish with the same shape • The location and presence or absence of a lid were usually used to distinguish the two, but the lid was removed and the dish was placed next to the other
1:100,000 concentration	1:5,000 concentration	• Prepared in a medicine cup with the same shape • The containers were put in separate places, but the container had been moved and placed nearer during surgery

Image of case

◆ In the reported cases, the two drugs were placed in containers with the same shape and the drug name was written on one or both of the containers.



Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.191, October 2022

Local Injection of High-Concentration Adrenaline Due to Container Mix-Up

Case 1

In the sterilized area, the nurse prepared a Xylocaine preparation (1:200,000 concentration of adrenaline) in a medicine cup bearing the label "Xylo 1% E + NS" and Bosmin Solution 0.1% (1:1,000 concentration of adrenaline) in a medicine cup bearing the label "Bosmin (topical)." The physician first used the Xylocaine preparation for local anesthesia. Thinking that the physician would next use a gauze impregnated with Bosmin, the nurse placed the medicine cup marked "Bosmin (topical)" in front. The physician then ordered local anesthetic for a second time. The nurse drew up the drug solution from the medicine cup in front, without checking the label on the side, and passed it to the physician. After the physician injected a total of 4 mL, the patient's blood pressure rose to 230/130 mmHg and their heart rate to 130 bpm, with sporadic premature ventricular contractions and ST segment depression observed on the monitor. The nurse realized that they had handed over Bosmin Solution 0.1% in error.

Case 2

The nurse prepared a Xylocaine preparation (1:300,000 concentration of adrenaline) and Bosmin Solution 0.1% (1:1,000 concentration of adrenaline) in Petri dishes of the same shape and placed them on the instrument tray. The nurse had placed the two Petri dishes away from each other and written the drug name on the lid of the Petri dish containing the Xylocaine preparation. After surgery began, the physician ordered a Bosmin swab, so the nurse placed the Petri dish containing Bosmin Solution 0.1% next to the Petri dish containing the Xylocaine preparation. The physician subsequently ordered local anesthetic, so the nurse drew up the drug solution from the Petri dish and handed it to the physician. After the physician injected 4 mL, the patient's blood pressure rose to 270 mmHg and the nurse realized that they had handed over Bosmin Solution 0.1% in error.

Preventive measures taken at the medical institutions in which the events occurred

- **Use containers with different shapes and label them with the drug name in an easily visible location when preparing local anesthetic and adrenaline preparations in the sterilized area.**

The measure above is an example. Please consider initiatives suitable for your own facility.

Key Preventive Measures

- **Consider changing the shape and color of containers, and prescribe internal rules.**

(Comprehensive Evaluation Panel)

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

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Japan Council for Quality Health Care
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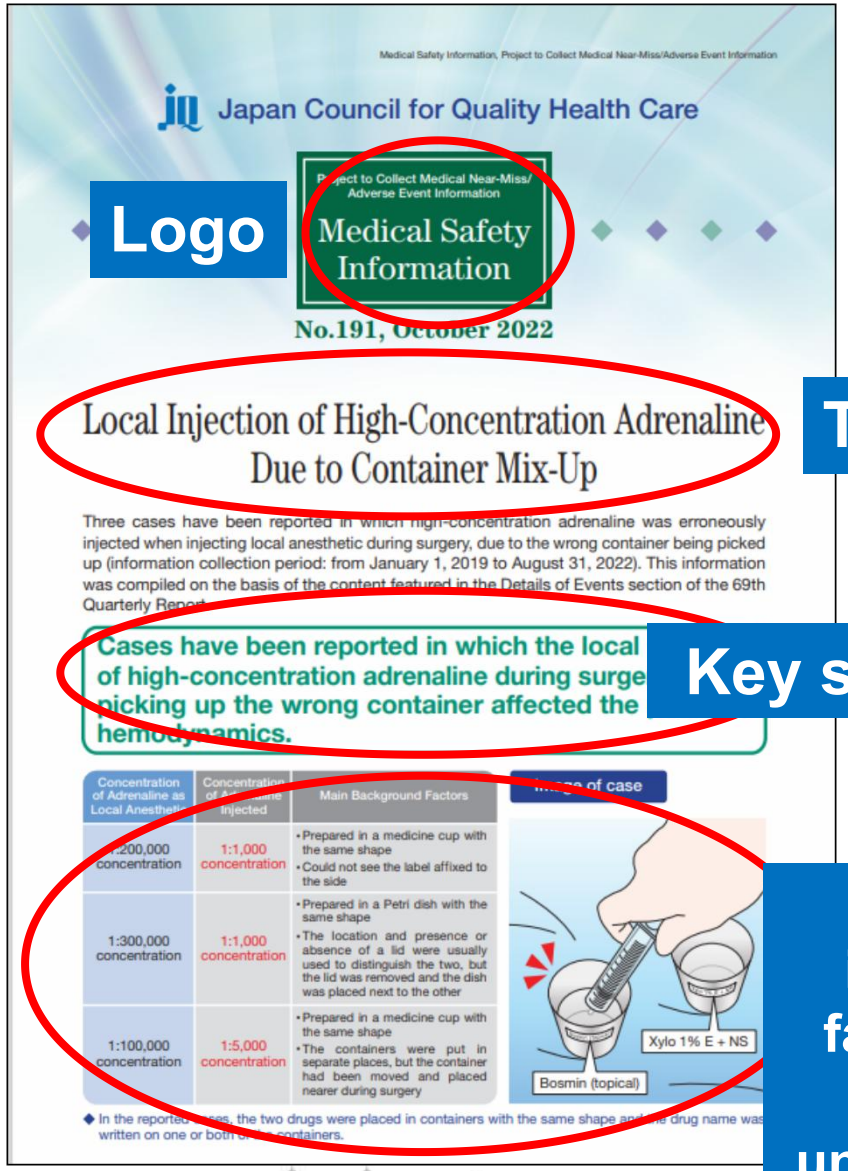
https://www.med-safe.jp/

Monthly alert produced in RLS



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

Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.191, October 2022

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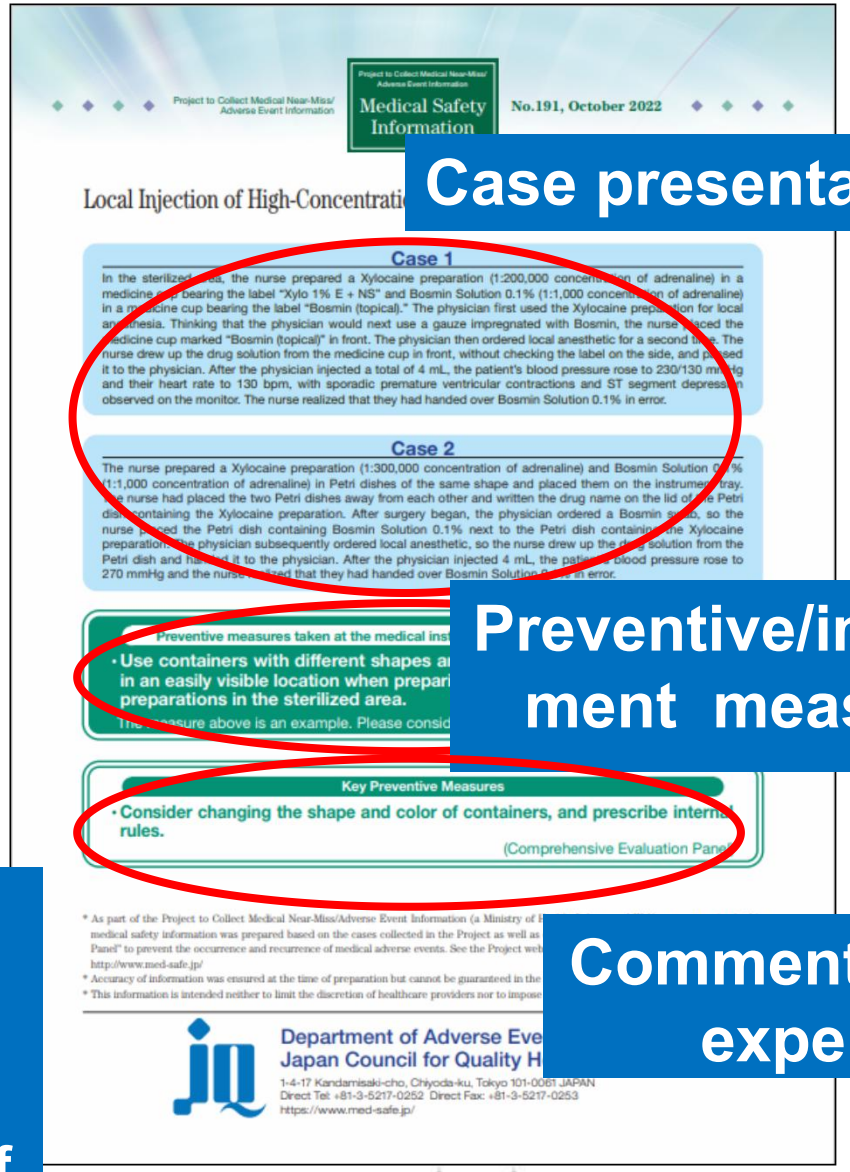

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.191, October 2022

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Department of Adverse Eve Japan Council for Quality H

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https://www.med-safe.jp/

Logo

Title

Key statement

Table and illustration to facilitate better and instant understanding of the key statement

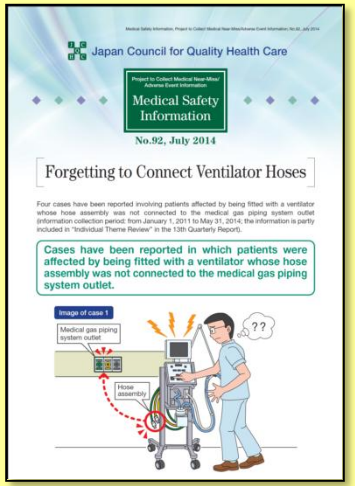
Case presentations

Preventive/improvement measures

Comments from experts

7th Edition CAHOCON 2023

Distribution of monthly alert


Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/Adverse Event Information

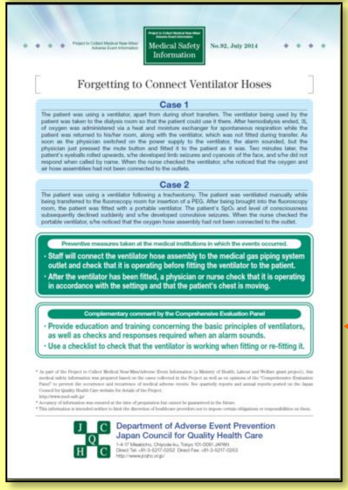
Medical Safety Information

No.92, July 2014

Forgetting to Connect Ventilator Hoses

Four cases have been reported involving patients affected by being fitted with a ventilator whose hose assembly was not connected to the medical gas piping system outlet (information collection period: from January 1, 2011 to May 31, 2014; the information is partly included in "Individual Theme Review" in the 13th Quarterly Report).

Cases have been reported in which patients were affected by being fitted with a ventilator whose hose assembly was not connected to the medical gas piping system outlet.


Medical Safety Information

No.92, July 2014

Forgetting to Connect Ventilator Hoses

Case 1

The patient was using a ventilator, apart from during short transfers. The ventilator being used by the patient was taken to the dialysis room so that the patient could use it there. After hemodialysis ended, 3L of oxygen was administered via a heat and moisture exchanger for spontaneous respiration while the patient was returned to his/her room, along with the ventilator, which was not fitted during transfer. As soon as the physician switched on the power supply to the ventilator, the alarm sounded, but the physician just pressed the mute button and fitted it to the patient as it was. Two minutes later, the patient's eyeballs rolled upwards, s/he developed limb seizures and cyanosis of the face, and s/he did not respond when called by name. When the nurse checked the ventilator, s/he noticed that the oxygen and air hose assemblies had not been connected to the outlets.

Case 2

The patient was using a ventilator following a tracheotomy. The patient was ventilated manually while being transferred to the fluoroscopy room for insertion of a PEG. After being brought into the fluoroscopy room, the patient was fitted with a portable ventilator. The patient's SpO_2 and level of consciousness subsequently declined suddenly and s/he developed convulsive seizures. When the nurse checked the portable ventilator, s/he noticed that the oxygen hose assembly had not been connected to the outlet.

Preventive measures taken at the medical institutions in which the events occurred.

- Staff will connect the ventilator hose assembly to the medical gas piping system outlet and check that it is operating before fitting the ventilator to the patient.
- After the ventilator has been fitted, a physician or nurse check that it is operating in accordance with the settings and that the patient's chest is moving.

Complementary comment by the Comprehensive Evaluation Panel

- Provide education and training concerning the basic principles of ventilators, as well as checks and responses required when an alarm sounds.
- Use a checklist to check that the ventilator is working when fitting or re-fitting it.

Department of Adverse Event Prevention
Japan Council for Quality Health Care

FAX

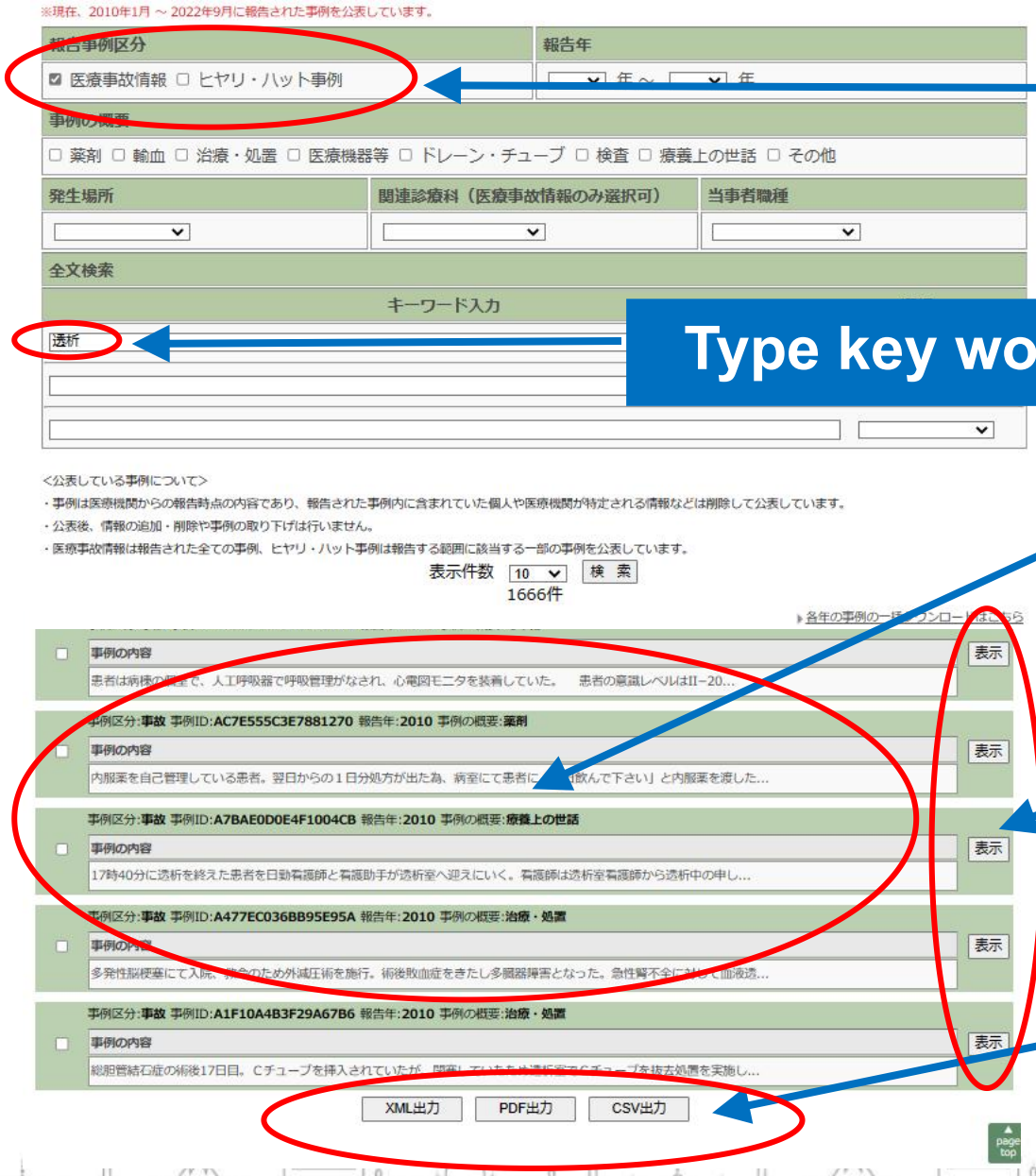
Notice by Central, Local authorities

Website

Medical institutions & professionals including **5,933*** institutions receiving it through **FAX**, i.e. approximately **70%** of Japanese hospitals

* Registration figure as of March, 2023

Database of AE / Near-miss on homepage



- Choose “Adverse event” and/or “Near-miss”
- Choose “Type of events”

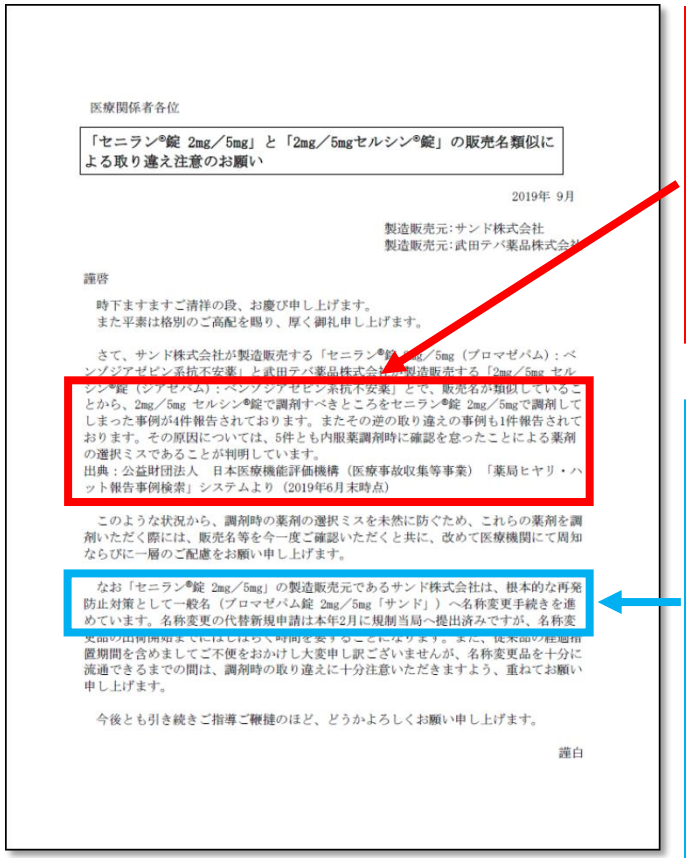
Type key word for search : “Dialysis”

1,666 AEs are matched.

“Browse”

“Download” in three different formats i.e. XML, PDF, CSV

Release of alert by manufactures on sound-alike drugs: “SENIRAN” vs “CERCINE” (2019)



医療関係者各位

「セニラン®錠 2mg／5mg」と「2mg／5mgセルシン®錠」の販売名類似による取り違え注意のお願い

2019年 9月

製造販売元:サンド株式会社
製造販売元:武田テバ薬品株式会社

謹啓

時下ますますご清祥の段、お慶び申し上げます。
また平素は格別のご高配を賜り、厚く御礼申し上げます。

さて、サンド株式会社が製造販売する「セニラン®錠 2mg／5mg（ブロマゼパム）：ベンゾジアゼピン系抗不安薬」と武田テバ薬品株式会社が製造販売する「2mg／5mg セルシン®錠（ジアゼパム）：ベンゾジアゼピン系抗不安薬」とで、販売名が類似していることから、2mg／5mg セルシン®錠で調剤すべきところをセニラン®錠 2mg／5mgで調剤してしまった事例が4件報告されております。またその逆の取り違えの事例も1件報告されております。その原因については、5件とも内服薬調剤時に確認を怠ったことによる薬剤の選択ミスであることが判明しています。
出典：公益財団法人 日本医療機能評価機構（医療事故収集等事業）「薬局ヒヤリ・ハット報告事例検索」システムより（2019年6月末時点）

このような状況から、調剤時の薬剤の選択ミスを未然に防ぐため、これらの薬剤を調剤いただく際には、販売名等を今一度ご確認いただくと共に、改めて医療機関にて周知ならびに一層のご配慮をお願い申し上げます。

なお「セニラン®錠 2mg／5mg」の製造販売元であるサンド株式会社は、根本的な再発防止対策として一般名（ブロマゼパム錠 2mg／5mg「サンド」）へ名称変更手続きを進めています。名称変更の代替新規申請は本年2月に規制当局へ提出済みですが、名称変更品の出荷開始までにはしばらく時間を要することになります。また、従来品の経過措置期間を含めましてご不便をおかけし大変申し訳ございませんが、名称変更品を十分に流通できるまでの間は、調剤時の取り違えに十分注意いただきますよう、重ねてお願い申し上げます。

今後とも引き続きご指導ご鞭撻のほど、どうかよろしくお願い申し上げます。

謹白

- Events of drug mix-up due to phonetic similarity have been reported in JQ’s national RLS.

- We have submitted a request that “SENIRAN”, a trade name, is removed from the market to be replaced with generic name “Bromazepam” for radical measure for prevention.

	“SENIRAN” Anti-anxiety agent	“CERCINE” Minor tranquilizer
製造販売元	サンド株式会社	武田テバ薬品株式会社
販売名	セニラン®錠 2mg セニラン®錠 5mg	2 mg セルシン®錠 5 mg セルシン®錠
一般名	ブロマゼパム	ジアゼパム
薬効分類名	精神神経安定剤	マイナートランキライザー
PTP シート	セニラン®錠 2 mg セニラン®錠 5 mg	2 mg セルシン®錠 5 mg セルシン®錠
お問合せ先	サンド株式会社 カスタマーケアグループ 0120-982-001 受付時間 9:00～17:00 （土・日・祝日及び当社休日を除く）	武田テバ DI センター 0120-923-093 【受付時間】9:00～17:30 （土日祝日・弊社休業日を除く）

（注）セニラン®錠は、2mg、5mg の他に 1mg、3mg の規格があります。

※製品をご使用の際は最新の添付文書をご確認ください。

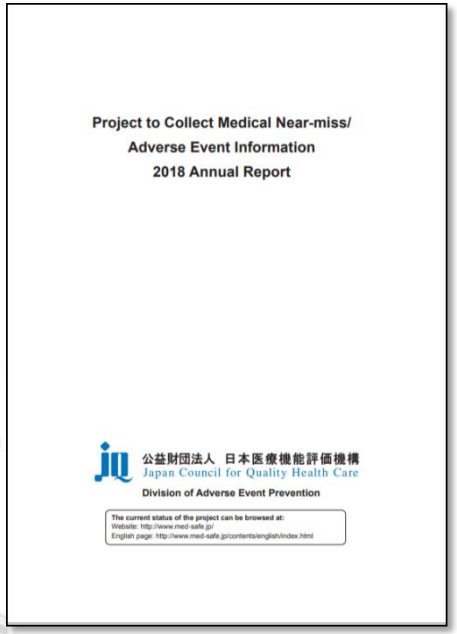
Sound-alike drugs

"***Almarl***" *vs* "***Amaryl***"

"***Almarl***"

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

Ensuring transparency through disclosure and publicity


Project to Collect Medical Near-miss/
Adverse Event Information
2018 Annual Report

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. 1-72
- **Annual** report 2005-2021
- Reports are Released at press conference

NHK News (TV News), August 29, 2016

医療事故情報収集等事業について説明する後理事＝3日、医療機能評価機構

MediFax (Daily Healthcare News), July 3, 2020

Reporting and learning system of community pharmacy (2008~)

Community pharmacy
Voluntary-based

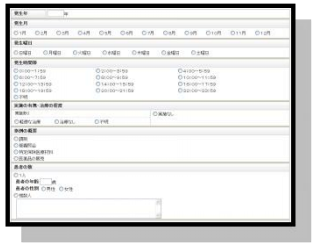
Near-miss

"Cases which tokes place or is identified in pharmacy"

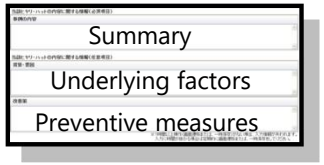
Categories
- ✓ Prescription
- ✓ Dispensing
- ✓ Designated insured materials
- ✓ OTC: Over The Counter Drug

Web-based reporting

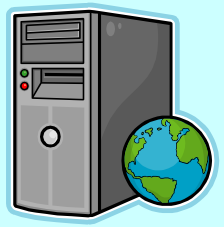
i) Coding



ii) Text



Japan Council for Quality Health Care
Division of AE Prevention



Data server

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

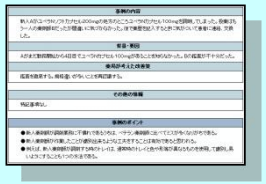
Aim : Prevention
Principles : No-blame, Anonymous

Technical panel
(Drug, Device, Human error)

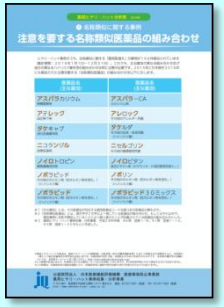
Secretariat

Annual/Half-yearly report

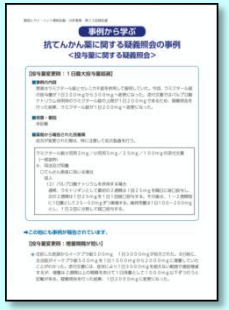
Sentinel case report



Iconic table



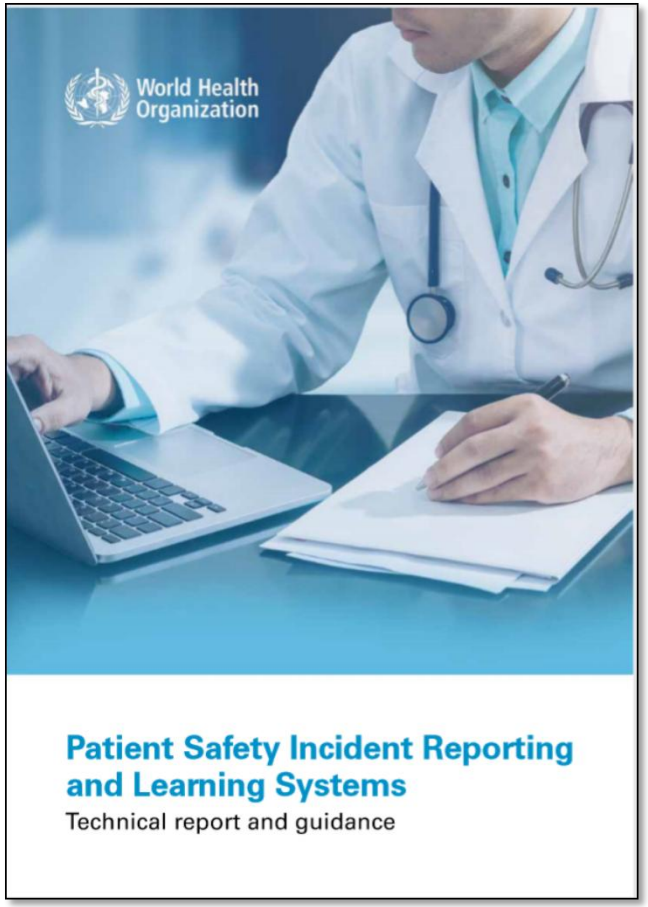
Iconic case



Database

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

2020 WHO Patient Safety Incident Reporting and Learning Systems



3.3 WHO consultation on patient safety incident reporting and learning systems

In an **expert consultation** in March **2016 in Colombo, Sri Lanka**, WHO brought together staff from ministries of health and health experts **from low- and middle-income countries** to discuss their experience of establishing and operating patient safety incident reporting and learning systems (19). The three-day meeting was attended by representatives of **18 countries** – Afghanistan, Bangladesh, Canada, Ethiopia, Ghana, India, Italy, **Japan**, Malaysia, Morocco, Nigeria, Oman, the Philippines, Poland, South Africa, Sri Lanka, Thailand and Viet Nam – and two WHO regional offices (for the South-East Asia and Eastern Mediterranean regions).

WHO Global Patient Safety Action Plan 2021-2030

1.4
Safety standards, regulation and accreditation

1.5
World Patient Safety Day and Global Patient Safety Challenges

3.4
Safety of medical devices, medicines, blood and vaccines

6.1
Patient safety incident reporting and learning systems

4.4
Patient safety incident disclosure to victims

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

Statistics of eligible case by birth year

(As of Nov 30, 2021)

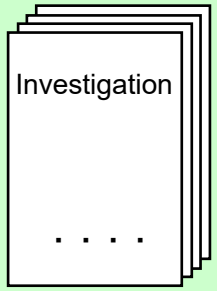
Birth year	No. case reviewed	Eligible	Not-Eligible				Petition
		Eligible	Not Eligible	Preliminary to review	Total	In process	
2009	561	419	142	0	142	0	Expired
2010	523	382	141	0	141	0	Experied
2011	502	355	147	0	147	0	Experied
2012	517	361	155	0	155	0	Experied
2013	476	351	125	0	125	0	Experied
2014	469	326	143	0	143	0	Experied
2015	475	376	99	0	99	0	Expired
2016	432	363	69	0	69	0	Expired
2017-2021	1,072	873	137	59	196	3	Valid
Total	4,456	3,374	1033	41	1,074	11	

Publication of Prevention Report based on aggregative analysis of Investigative Report

Investigation committee

Report of

“Individual case”

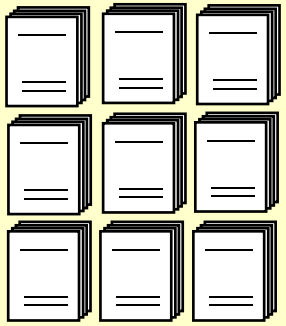


- Cause
- Appraisal
- Preventive measures

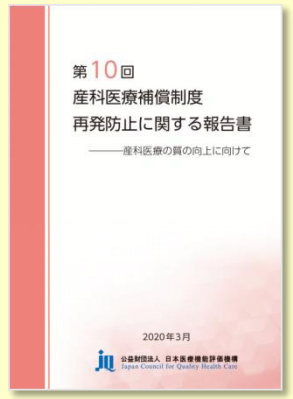
Prevention committee

Report of

“Aggregated cases”



- Collective analysis
- Thematic analysis
- Recommendation, etc.

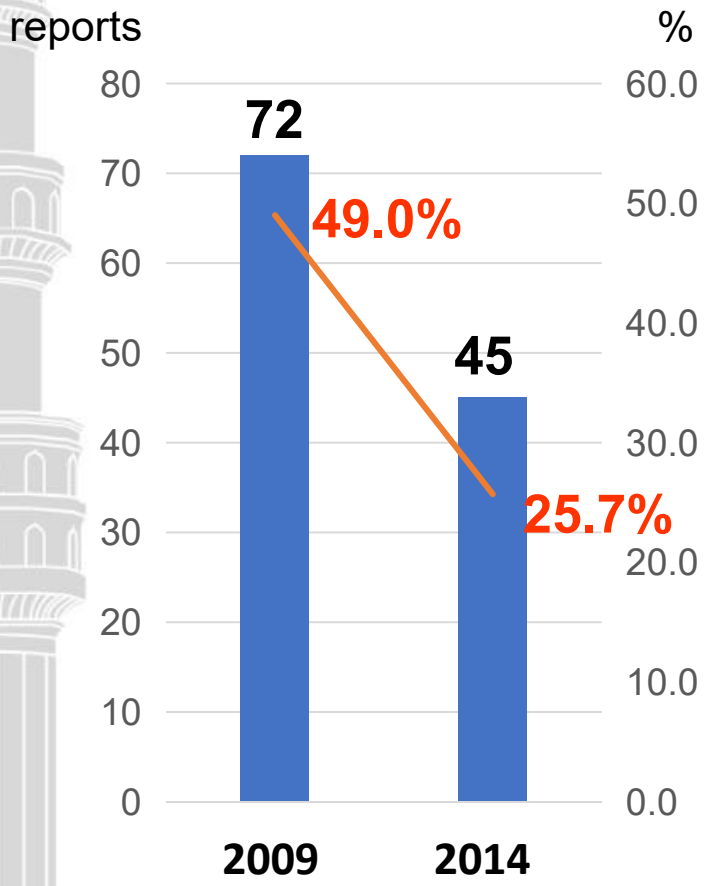


A) Report; Delivered both to **family** and **childbirth facility**
B) Synthesized report; Posted on the web
C) Report with identifiers deleted; Available only for research use through internal ethical process

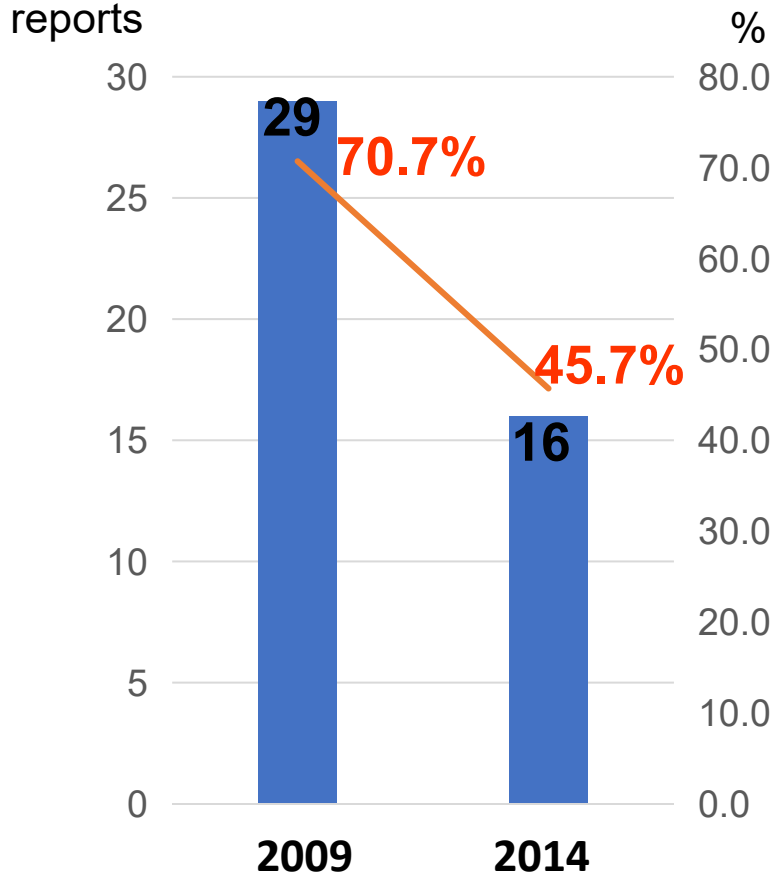
A) Delivered to **Childbirth facility, Scientific societies**, Government, etc.
B) Posted on the web open to the public

Improvement of specific practices between 2009 and 2014

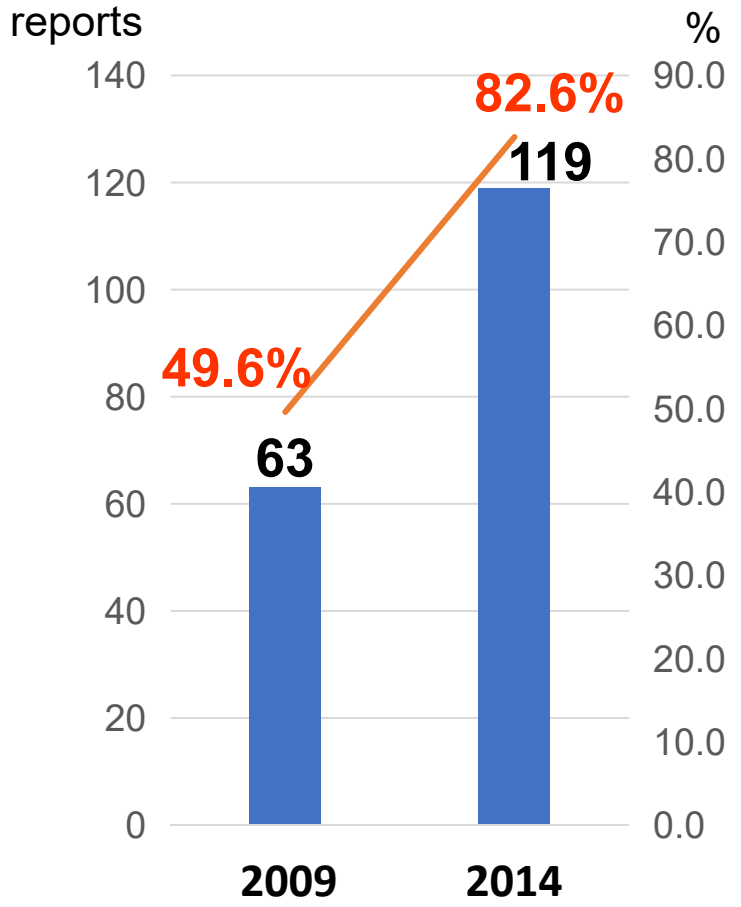
Comment on FHR monitoring for improvement



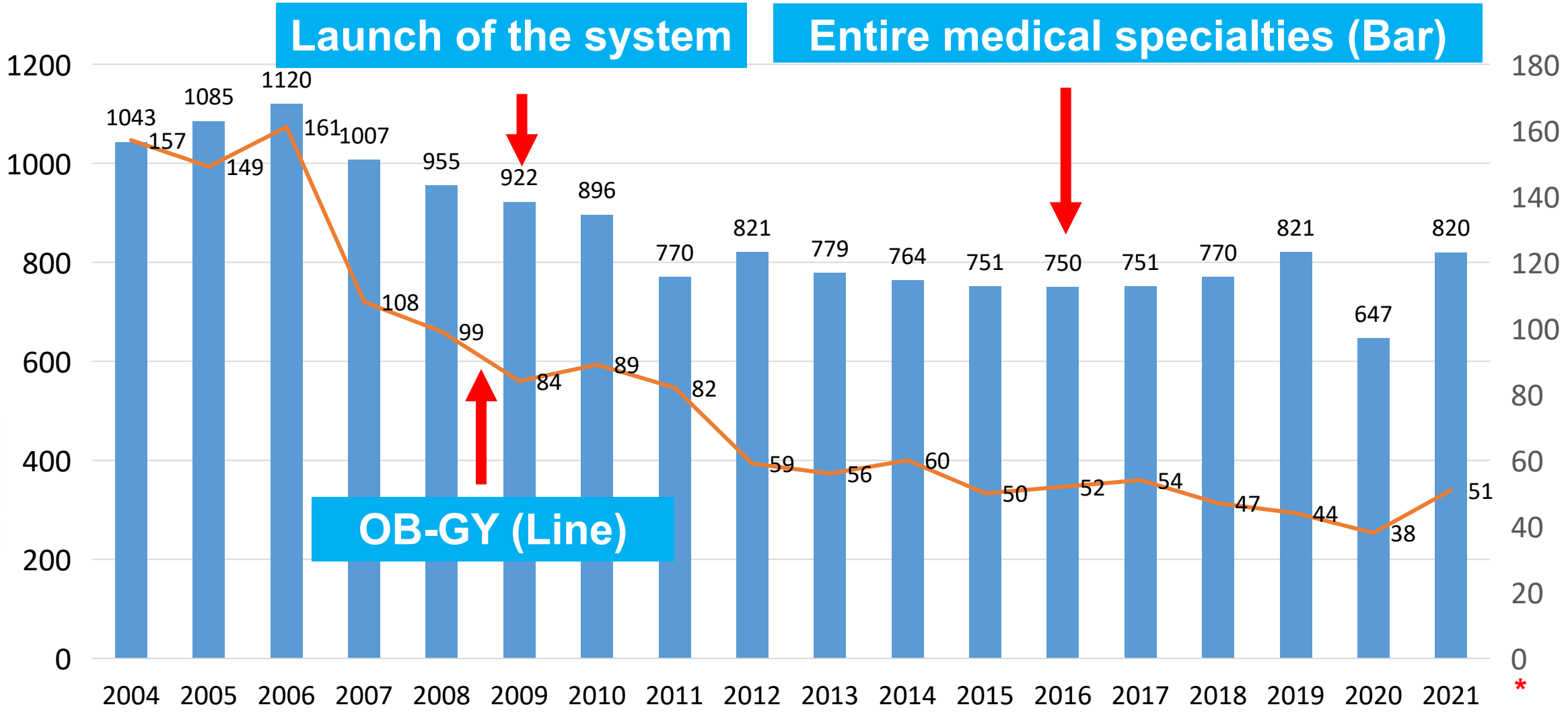
Excess administration of oxytocin



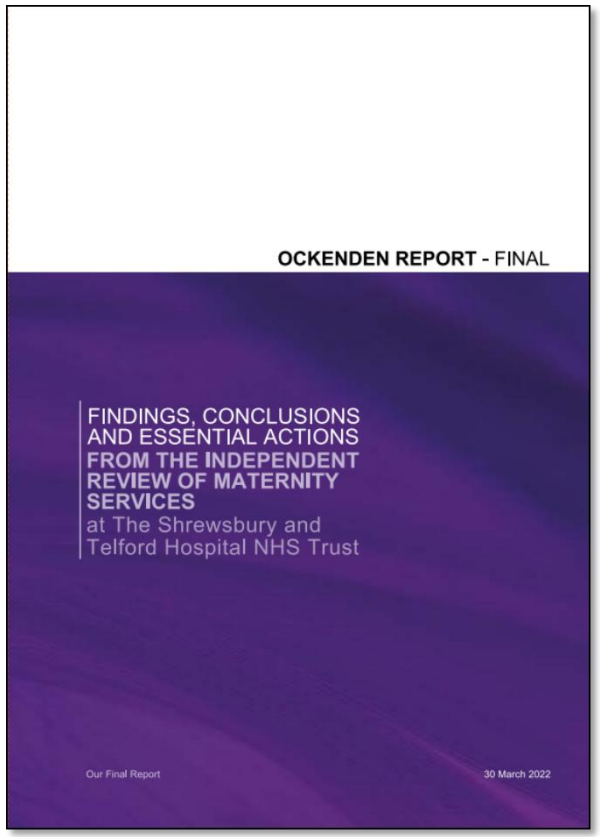
Mechanical ventilation within 1 min after birth



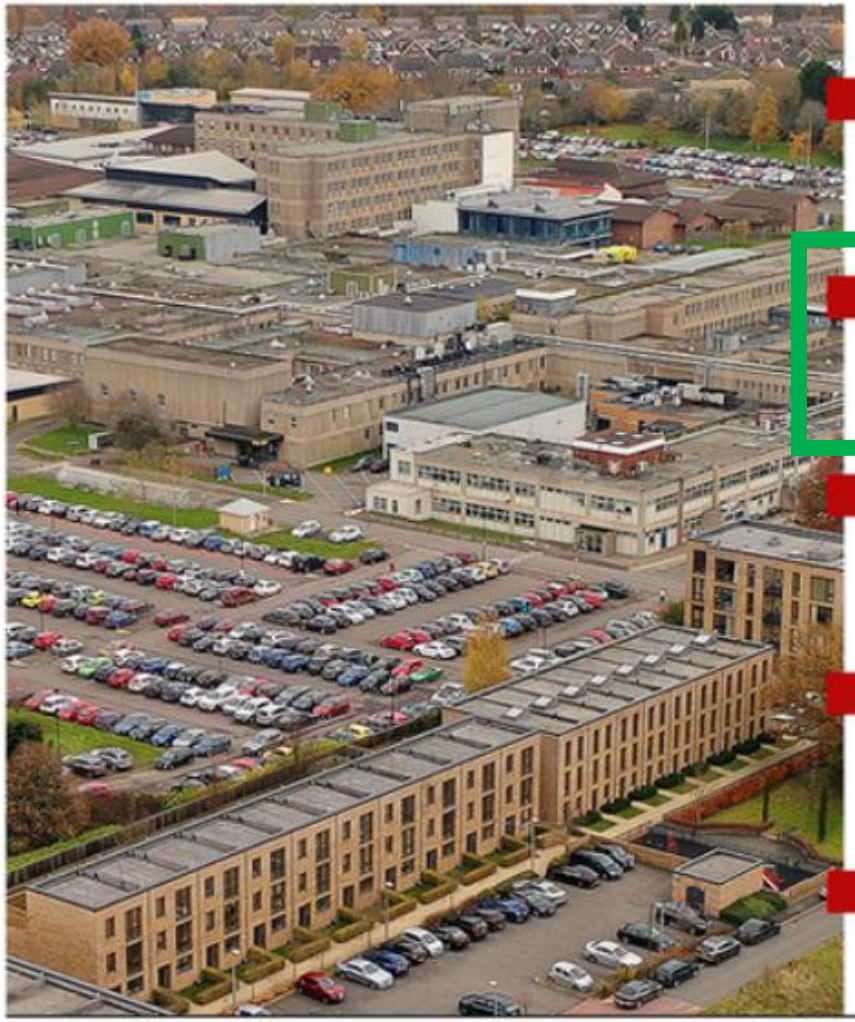
Impact on lawsuit statistics on OB-GY



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



The Ockenden report findings



- Examined almost **1,600 cases** spanning **20 years**
- **201 deaths** where concerns over care found
- **131 stillbirths** and **70 neonatal deaths** affected
- Also **29 cases** where babies suffered severe **brain injuries**
- And **65** incidents of **cerebral palsy**

Source: Ockenden Maternity Review

BBC

BBC, May 30th, 2022


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

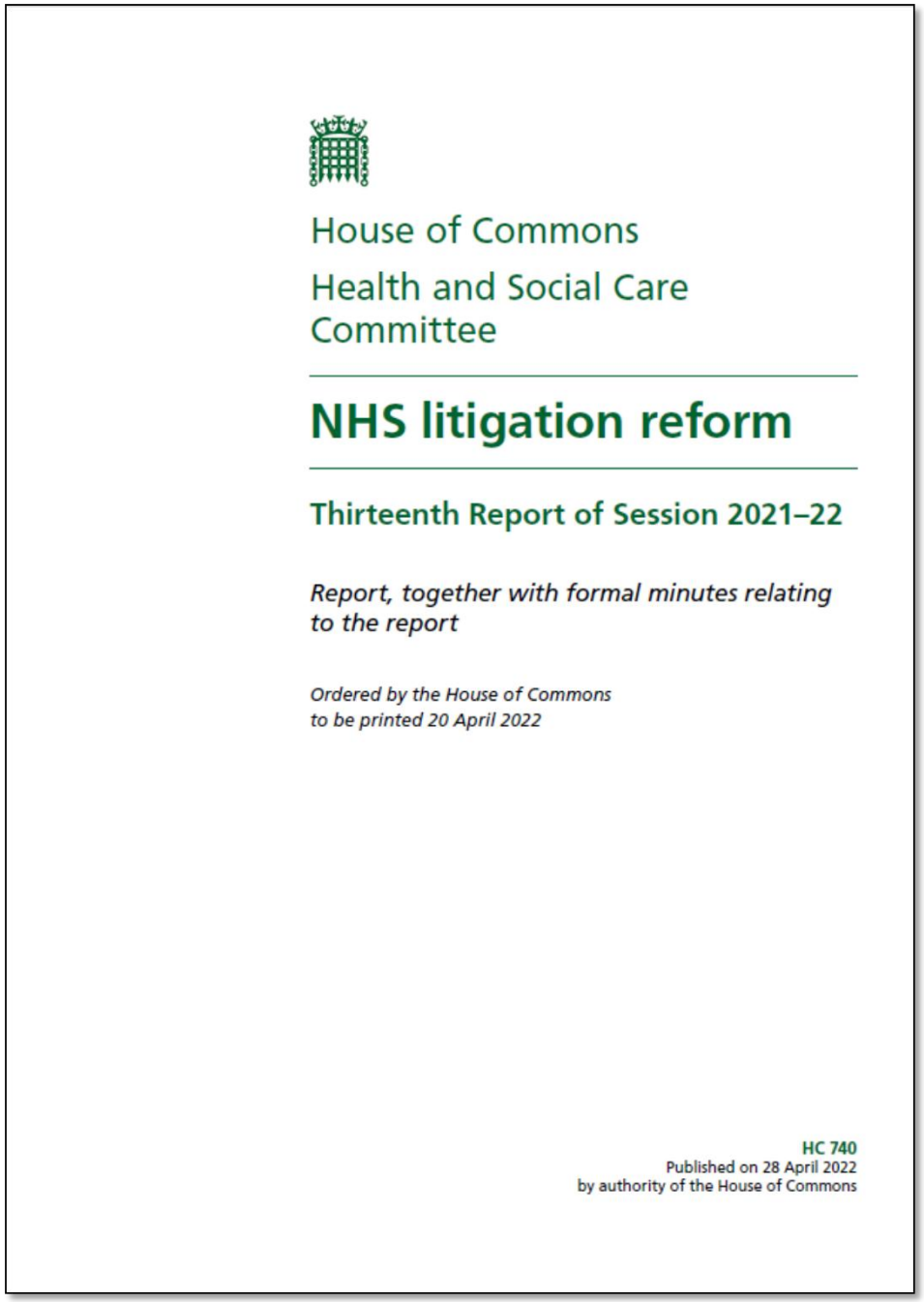

Rt. Hon. Jeremy Hunt, Chair


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



133. Professor Shin Ushiro told us that the Japanese birth injury compensation scheme had a formal process for disseminating learning and an illustration of its success was that it had recorded a reduction in the number of cases coming into the system.[203] In 2009, its first year of operation, 419 cases were entered into the Japanese Cerebral Palsy scheme, by 2014 that figure had reduced to 326 and even when the eligibility criteria were widened the following year eligible cases only increased to 376.[204] Professor Ushiro added that investigative reports into Cerebral Palsy cases increasingly find that cases have resulted from unknown genetic causes and there has been a decline in cases related to error or malpractice.[205]

(As of Jun 5, 2020)

Birth year	No. case reviewed	Eligible	Not-Eligible				Petition
		Eligible	Not Eligible	Preliminary to review	Total	In process	
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2010	523	382	141	0	141	0	Experied
2011	502	355	147	0	147	0	Experied
2012	517	361	155	0	155	0	Experied
2013	476	351	125	0	125	0	Experied
2014	469	326	143	0	143	0	Experied
2015-2018	1,000	846	101	46	147	7	Valid
Total	4,048	3,041	954	46	1,000	7	

Takeaways

i. JQ launched the national system in 2004 and has successfully run it with production of reports, alerts DB and so on. The products of the system have been widely utilized for practical and research use.

ii. Equivalent systems were built step-by-step such as systems for community pharmacy and perinatal care. No-fault compensation/investigation/prevention system for cerebral palsy is so unique that deserves distribution on global basis.

iii. Japan including JQ is keen to work in close cooperation with global community on patient safety as expected by WHO which launched Global Patient Safety Action Plan 2021-2030.

World Health Organization