1.3 Knowledge on the creation of a safe environment for health workers to report patient safety incidents

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

Aims

- To learn about;
  - how reporting and learning system (RLS) is installed at institutional and national levels.
  - how development of national policy works effectively to launch RLS.
  - how “To Err Is Human” (IOM report) mentioned to RLS.
  - how legislation and relevant regulation worked effectively to initiate RLS.
  - How RLS is ingrained in my country.
  - WHO’s report on RLS and highlighting of it in GPSAP 2021-2030.

Kyushu University Hospital (KUH)

- Kyushu University Hospital is a national university hospital, located in Fukuoka City, a gateway to Asia, and a hospital having more than 100 years of history.
- Our hospital is one of the leading affiliated medical and dental school hospitals in Japan with nearly 3,200 staff.
- We accept 3,100 outpatients per day on average and have a hospital bed capacity that exceeds 1,400.
- The branch hospital, Kyushu University Beppu Hospital, is located in Beppu City, Oita Prefecture known for its hot spring therapeutics.

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

About JQ

Established	July 27, 1995
Chair	Hirobumi Kawakita
Projects	Hospital accreditation rtc.
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.

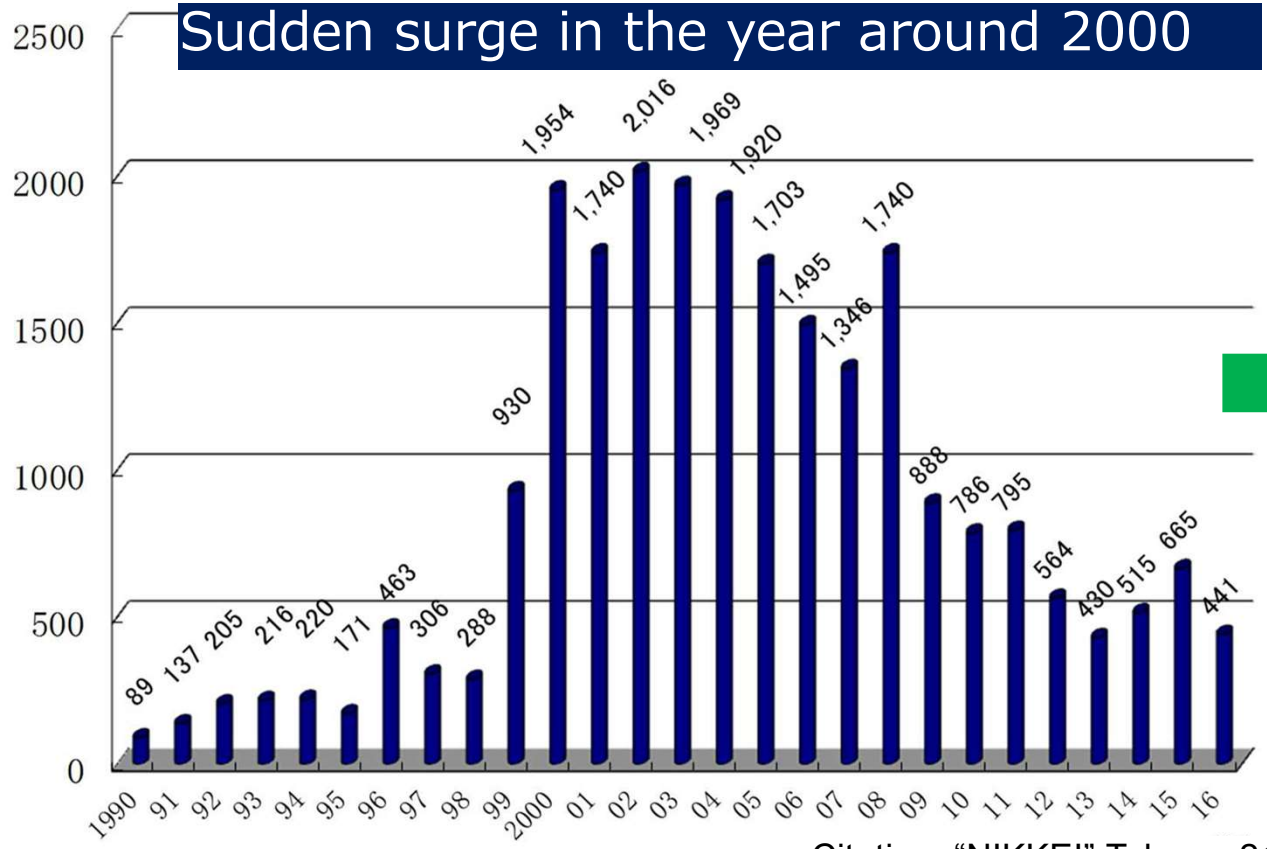
Devastating medical malpractice cases that triggered public concern

- **Jan 1999: Yokohama City University Hospital**
  Two patients were mixed-up in the operation theater and the wrong organs (Heart and Lung) were operated.
- **Feb 1999: Tokyo Metropolitan Hiroo Hospital**
  A patient after surgery was mistakenly injected disinfectant instead of Heparin, an anticoagulant. The patient was dead.
- **Feb 2000: Kyoto University Hospital**
  The hospital staff mistakenly poured ethanol into a humidifying unit of a ventilator instead of distilled water. The patient was dead.
- **Apr 2000: Tokai University Hospital**
  An oral drug was mistakenly given through intravenous route. The pediatric patient was dead.

Media coverage of “Medical accident”

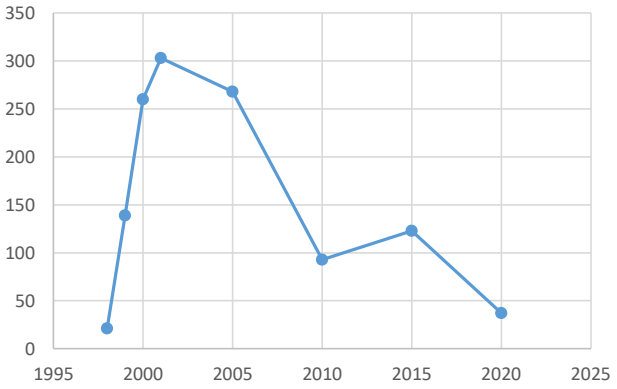
Frequency of “Medical accident” in five major newspapers in Japan

Sudden surge in the year around 2000



Citation; “NIKKEI” Telecom21

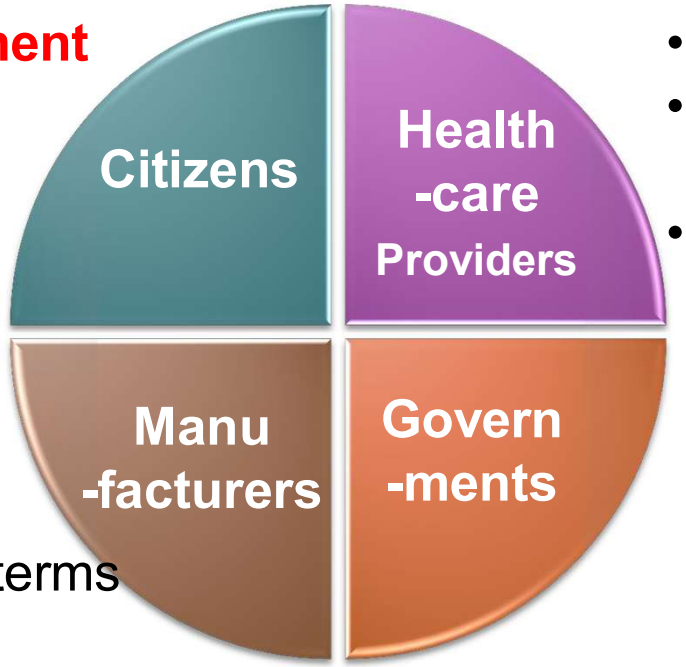
The number of publicity declined in recent years.



読売新聞データベース「ヨミダス歴史館」で検索

Schematic image of the “Holistic Policy on PS”(Released in 2002 from MHLW* Expert Panel)

- **Patient participation/empowerment**
- Spread and enhanced informed consent
- Engaged in healthcare improvement process



- **In-hospital reporting system**
- Safety management structure
- Guidelines for safety improvement
- Education & Training

- **Fail safe design**
- Improvement of drugs in terms of labelling and package, design of medical devices for user-friendly purpose, etc.

- **National incident reporting and learning system**
- Educational workshops
- Instructions/Directives to medical institutions / manufacturers
- Research funding, etc.

* MHLW; Ministry of Health, Labour and Welfare

IOM (Institute of Medicine*, US) Report

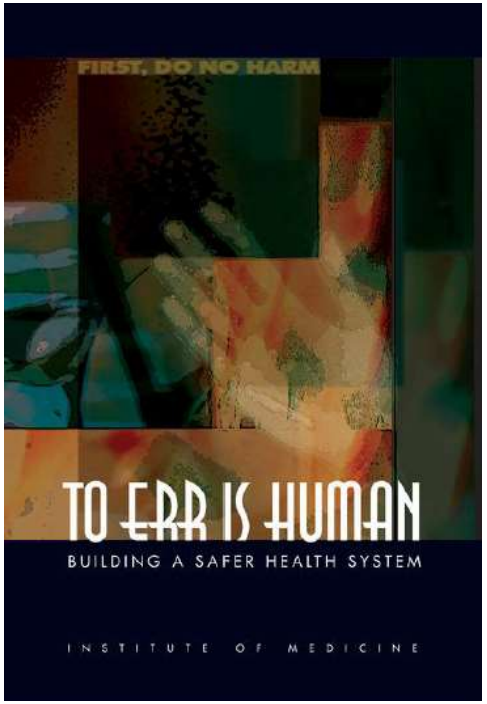


Table of Contents (Excerpt)

* Current “National Academy of Medicine”, US

2. Errors in Health Care: A Leading Cause of Death and Injury

How Frequently Do Errors Occur?

- Extrapolation of the results of the Colorado and Utah study to the over 33.6 million admissions to hospitals in the United States in 1997, implies that at lease **44,000** Americans die in hospitals each year as a result of preventable errors.
- Based on the results of the New York study, the number of deaths due to medical error may be as high as **98,000**.
- By way of comparison, the lower estimate is greater than the number of deaths attributable to the **8th-leading cause of death**.

2. Errors in Health Care: A Leading Cause of Death and Injury

Key messages

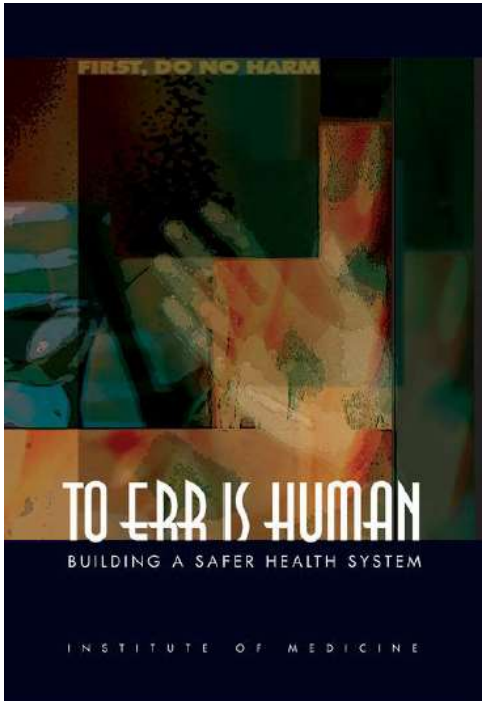
- 44,000-98,000 Americans die due to preventable error annually.
- Medical adverse events is the 8th-leading cause of death in the US.

Number of deaths for leading causes of death, US

1. Heart disease: 696,962
2. Cancer: 602,350
3. COVID-19: 350,831
4. Accidents (unintentional injuries): 200,955
5. Stroke (cerebrovascular diseases): 160,264
6. Chronic lower respiratory diseases: 152,657
7. Alzheimer's disease: 134,242
8. Diabetes: 102,188
9. Influenza and pneumonia: 53,544
10. Nephritis, nephrotic syndrome, and nephrosis: 52,547

Source: Mortality in the United States, 2020, data table for figure 4

IOM (Institute of Medicine*, US) Report



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1. A Comprehensive Approach to Improving Patient Safety
2. Errors in Health Care: A Leading Cause of Death and Injury
3. Why Do Errors Happen?
4. Building Leadership and Knowledge for Patient Safety
5. **Error Reporting Systems**
6. Protecting Voluntary Reporting Systems from Legal Discovery
7. Setting Performance Standards and Expectations for Patient Safety
8. Creating Safety Systems in Health Care Organizations

* Current “National Academy of Medicine”, US

5. Error Reporting Systems

Recommendation5.1

A nationwide mandatory reporting system should be established that provides for the collection of **standardized information** by state governments about adverse events that result in death or serious harm. **Reporting should initially be required of hospitals** and eventually be required of other institutional and ambulatory care delivery settings.

Congress should

-designate the National Forum for Health Care Quality Measurement and Reporting as the **entity responsible for promulgating and maintaining a core set of reporting standards** to be used by states, including a nomenclature and taxonomy for reporting;

5. Error Reporting Systems

Recommendation5.1

-require all healthcare organizations to report **standardized information** on a defined list of adverse events;

-provide **funds and technical expertise** for state governments to establish or adapt their current error reporting systems to collect the **standardized information**, analyze it and conduct follow-up action as needed with health care organizations. Should a state choose not to implement the mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity; and designate the Center for Patient Safety to:

5. Error Reporting Systems

Recommendation5.1

(1) convene states to **share information and expertise**, and to evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of state programs; and

(2) receive and **analyze aggregate reports** from states to **identify persistent safety issues** that require more intensive analysis and/or a broader-based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers or others).

5. Error Reporting Systems

Key messages of "Recommendation5.1"

- Mandatory reporting system should be established.
- Standardized information should be collected.
- Entity responsible for RLS should be assigned.
- Fund and expertise should be provided.
- Analysis and feedback are necessary in identifying persistent safety issues.

5. Error Reporting Systems

Recommendation 5.2

The development of **voluntary reporting efforts should be encouraged**. The Center for Patient Safety should

-describe and disseminate information on **existing voluntary reporting programs** to **encourage greater participation** in them and track the development of new reporting systems as they form;

-convene **sponsors and users** of external reporting systems to evaluate what works and what dues not work well in the programs, and ways to make them more effective;

5. Error Reporting Systems

-**periodically assess** whether additional efforts are needed to **address gaps in information** to improve patient safety and to **encourage healthcare organizations to participate in voluntary reporting programs**; and

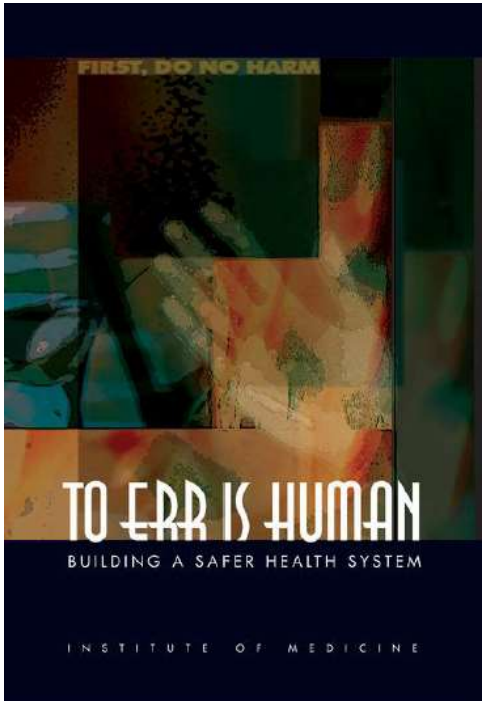
-**find and evaluate pilot projects** for reporting systems, both within individual health care organizations and collaborative efforts among health care organizations.

5. Error Reporting Systems

Key messages of "Recommendation 5.2"

- Voluntary reporting system and participation should be encouraged.
- Voices of stakeholders for improving RLS should be collected to exchange views on the system.
- RLS should be periodically assessed to fill in the gap in information.
- Pilot projects of RLS should be identified and evaluated.

IOM (Institute of Medicine*, USA) Reports



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* Current “National Academy of Medicine”, US

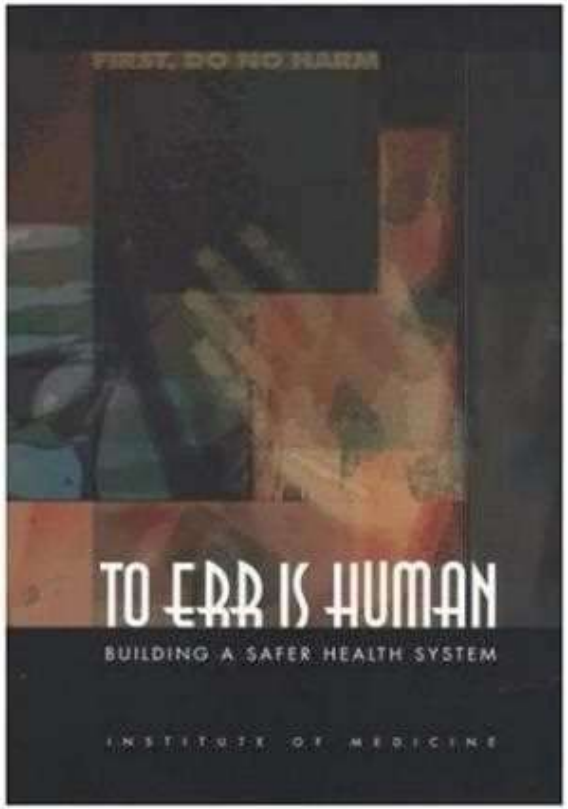
5. Protecting Voluntary Reporting Systems from Legal Discovery

Recommendation6.1

Congress should pass legislation to extend **peer review protections to data related to patient safety and quality improvement** that are collected and analyzed by health care organizations for internal use and shared with others solely for purposes of improving safety and quality.

Key phrase: Data of reporting for patient safety and quality improvement should be dealt with in non-punitive way.

IOM (Institute of Medicine*, USA) Report



Key question in other chapters;

- How can we prevent devastating accident from happening even if incident takes place on daily basis with precondition of “To Err is Human”?

Key idea in other chapters;

- Do not blame an individual for incident happening, instead, review and redesign healthcare delivery system with aim of preventing similar event happening again.

Shift of perception: How do we see accident and prevention?

Until 1990's

"Accident should never happen."

Preventable through efforts by individual staff members

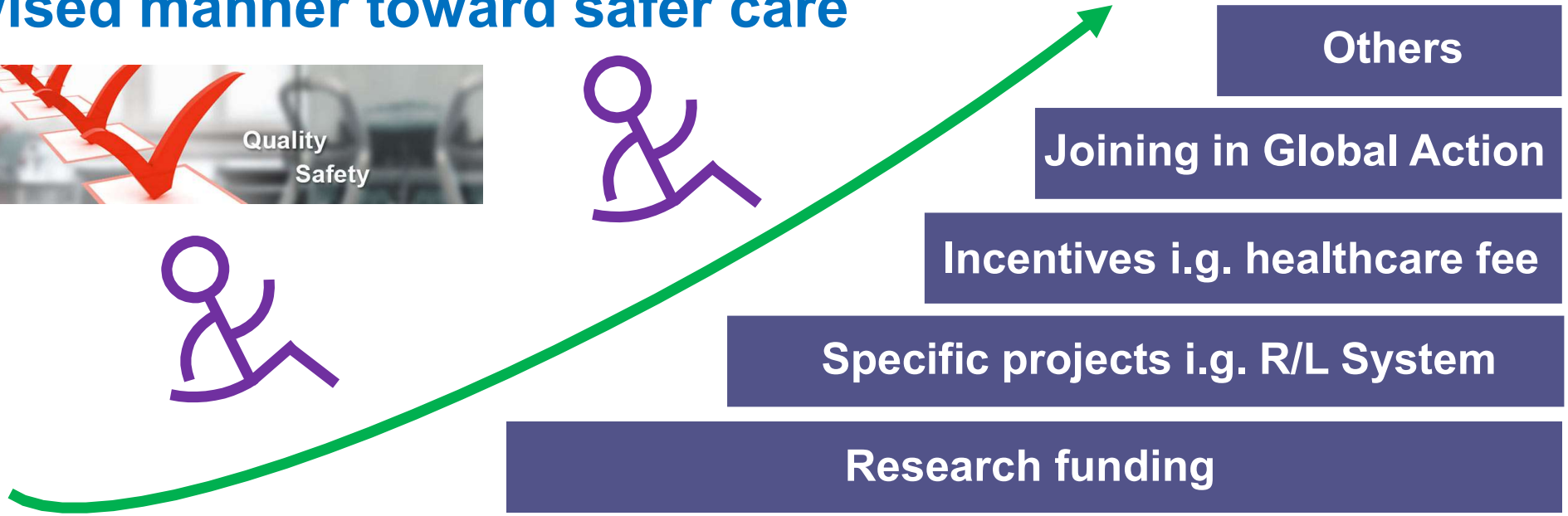
2000 or later

"Error happens."

Not preventable unless team, organization and healthcare delivery system are redesigned for improvement.

"SYSTEM APPROACH"

Japan has promoted patient safety in step-wised manner toward safer care



Others

Joining in Global Action

Incentives i.g. healthcare fee

Specific projects i.g. R/L System

Research funding

Launch of PS Promotion Committee & National Policy Development

Launch of Patient Safety Promotion Office in MoH

Health Care Act (Article 6.12) – amended for promoting Patient Safety in 2006

Administrators of hospital, clinic and birthing center shall undertake such measures as,

i. the establishment of policy to ensure safety in health care

ii. the provision of education and training for employees

iii. **Implementation of other measures to ensure safety in health care**

Ministerial ordinance for enforcement of the Revised Health Care Act (Article 1.11), 2007

Administrators of the hospitals, etc. shall install such policies and systems on patient safety according to Health Care Act Article 6.12

i. Crafting guidelines for patient safety control.
ii. Installing committee on patient safety.
iii. Providing education and training on patient safety to staffers.
iv. Introducing improvement measures aimed at ensuring patient safety, such as, reporting of medical incidents that occur in medical institutions.

Ministerial ordinance for enforcement of Health Care Act

9.22.1.14

Administrator of Minister's approved hospital designated for advance treatment* should produce report on the event pursuant to following i-iii.

i. **Apparent error** in treatment or management that resulted in patient's death or mental or physical disability or entailed unexpected treatment, treatment to an unexpected extent, or other medical procedure.

* Minister's approved hospital designated for advance treatment: Most of them are university hospitals certified by the Minister of Health by fulfilling requirements such as i) advanced care, ii) education and training of medical professionals, iii) research and development of new technology and iv) advanced patient safety measures in operation

Ministerial ordinance for enforcement of Health Care Act

ii. **Unapparent error** in treatment or management that resulted in patient's death or mental or physical disability or entailed unexpected treatment, treatment to an unexpected extent, or other medical procedure (including events possibly associated with treatment or management provided; limited to unforeseeable events).

iii. Other than those described in i) and ii), **information conducive to prevention** of medical adverse events and their recurrence at medical institutions.

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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, Non-punitive）

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

Expert Panel

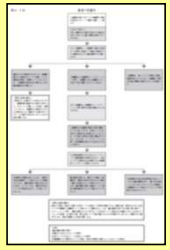
Secretariat

Annual/Quarterly report

Monthly alert

Database

Training program (RCA)



General public

Health care professionals/ facilities

Government

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

Structure of reporting items for standardized reporting

1. Date of event occurrence and event summary

1 Month of occurrence
☐ January ☐ February ☐ March ☐ April ☐ May ☐ June
☐ July ☐ August ☐ September ☐ October ☐ November ☐ December

2 Day of occurrence
☐ Mon. ☐ Tue. ☐ Wed. ☐ Thu. ☐ Fri. ☐ Sat. ☐ Sun.

Weekday/holiday category
☐ Weekday ☐ Holiday

3 Time of occurrence
☐ 0:00 - before 2:00 ☐ 2:00 – before 4:00 ☐ 4:00 – before 6:00 ☐ 6:00 – before 8:00 ☐ 8:00 – before 10:00 ☐ 10:00 – before 12:00
☐ 12:00 – before 14:00 ☐ 14:00 – before 16:00 ☐ 16:00 – before 18:00 ☐ 18:00 – before 20:00 ☐ 20:00 – before 22:00 ☐ 22:00 – before 24:00
☐ Unknown

4 Severity of event
☐ Death ☐ Potential residual disability (likely) ☐ Potential residual disability (unlikely) ☐ Unknown

5 Place of occurrence (multiple answers acceptable)
☐ Outpatient examination room ☐ Outpatient treatment room ☐ Outpatient lobby ☐ Emergency room ☐ Critical care center ☐ Patient room
☐ Ward treatment room ☐ Operation room ☐ ICU ☐ CCU ☐ NICU ☐ Examination room
☐ Catheterization laboratory ☐ Radiotherapy room ☐ Radiography room ☐ Radioactive scanning room ☐ Dialysis room ☐ Delivery room
☐ Rehabilitation room ☐ Restroom ☐ Hallway ☐ Bathroom ☐ Stairway ☐ Unknown
☐ Others ( )

6 Event summary
☐ Ordering ☐ Drug ☐ Blood transfusion ☐ Treatment/procedure ☐ Medical equipment
☐ Drainage tube ☐ Dental equipment ☐ Examination ☐ Nursing care ☐ Others ( )

7 Clinical department (multiple answers acceptable)
☐ Internal medicine ☐ Anesthesiology ☐ Cardiovascular medicine ☐ Neurology ☐ Respiratory tract medicine ☐ Gastrointestinal medicine
☐ Hematology ☐ Circulatory surgery ☐ Allergy ☐ Rheumatism ☐ Pediatrics ☐ General surgery
☐ Orthopedics ☐ Plastic surgery ☐ Cosmetic surgery ☐ Neurosurgery ☐ Respiratory surgery ☐ Cardiovascular surgery
☐ Pediatric surgery ☐ Pain clinic ☐ Dermatology ☐ Urology ☐ Venereology ☐ Proctology
☐ Gynecology/Obstetrics ☐ Obstetrics ☐ Gynecology ☐ Ophthalmology ☐ Otolaryngology ☐ Psychosomatic medicine
☐ Psychiatry ☐ Rehabilitation ☐ Unknown ☐ Radiology ☐ Dentistry ☐ Orthodontics
☐ Pediatric dentistry ☐ Dental/oral surgery ☐ Others( )

2. Information concerning patient involved

8 Number of patient(s)
☐ 1 ☐ Multiple

Age (specify between 0 years 0 months to 120 years 11 months)
( ) years ( ) months

Sex
☐ Male ☐ Female

9 Patient category 1
☐ Inpatient ☐ Outpatient (initial visit) ☐ Outpatient (follow-up visit)

Patient category 2
☐ Inpatient (0 to 31 days) ☐ Inpatient (32 days or longer) ☐ General outpatient ☐ Emergency outpatient ☐ Others ( )

10 Disorder
Disorder directly associated with event ( )
Related disorder 1 ( )
Related disorder 2 ( )
Related disorder 3 ( )

11 Patient condition immediately before event occurrence (multiple answers acceptable)
☐ Disturbance of consciousness ☐ Visual impairment ☐ Hearing impairment ☐ Dysarthria ☐ Mental disorder ☐ Dementia/amnesia
☐ Upper extremity disability ☐ Lower extremity disability ☐ Gait disorder ☐ Bed rest ☐ Sleeping ☐ Delirious
☐ Under drug influence ☐ Anesthetized/pre- or post-anesthesia ☐ Others ( )

3. Information concerning medical professional involved

12 Person who identified event
☐ Person involved himself/herself ☐ Coworker with same job title ☐ Coworker with different job title ☐ Patient himself/herself ☐ Family/care giver ☐ Other patient ☐ Others ( )

13 Job title of person involved
☐ Doctor ☐ Dentist ☐ Nurse ☐ Assistant nurse ☐ Pharmacist ☐ Clinical engineering technologist
☐ Midwife ☐ Nursing assistant ☐ Radiological technologist ☐ Clinical technologist ☐ Physical therapist (PT) ☐ National registered dietitian
☐ Dietitian ☐ Cook/cooking staff ☐ Speech therapist (ST) ☐ Occupational therapist (OT) ☐ Medical technologist ☐ Dental hygienist
☐ Dental technician ☐ Others ( )

Specialist, certified physician/surgeon, other professional/technical certification

Years of experience (specify between 0 years 0 months to 50 years 11 months)
( ) years ( ) months

Years of working at current department (specify between 0 years 0 months to 50 years 11 months)
( ) years ( ) months

Number of night shift works in the week immediately before event occurrence
( ) times

Shift work system
☐ 1-shift system ☐ 2-shift system ☐ 3-shift system ☐ 4-shift system ☐ Others ( )

Working hours in the week immediately before event occurrence (specify between 1 to 150 hours; enter "unknown" if information is unavailable)
( ) hours

13-2 Person involved 2
Same as 13

13-3 Person involved 3
Same as 13

13-4 Person involved 4
Same as 13

13-5 Person involved 5
Same as 13

13-6 Person involved 6
Same as 13

13-7 Person involved 7
Same as 13

13-8 Person involved 8
Same as 13

13-9 Person involved 9
Same as 13

13-10 Person involved 10
Same as 13

14 Job title other than that of person involved (multiple answers acceptable)
☐ Doctor ☐ Dentist ☐ Nurse ☐ Assistant nurse ☐ Pharmacist ☐ Clinical engineering technologist
☐ Midwife ☐ Nursing assistant ☐ Radiological technologist ☐ Clinical technologist ☐ Physical therapist (PT) ☐ National registered dietitian
☐ Dietitian ☐ Cook/cooking staff ☐ Speech therapist (ST) ☐ Occupational therapist (OT) ☐ Medical technologist ☐ Dental hygienist
☐ Dental technician ☐ Others ( )

4. Information concerning situation, place, and event details

Ordering and communication process

15 Situation
☐ Preparation of order ☐ Order in writing ☐ Order based on ordering system
☐ Oral order (with written memo) ☐ Oral order (without written memo) ☐ Frequent change in order
☐ Ordering/communication process, others ( )

16 Details of event
☐ Forgot to order ☐ Delayed order ☐ Inadequate ordering ☐ Giving wrong order
☐ Receiving order, misconception ☐ Receiving order, forgot to communicate ☐ Receiving order, delayed communication ☐ Receiving order, inadequate communication
☐ Receiving order, miscommunication ☐ Others ( )

Drug

15 Situation
Drug preparation
☐ Drug preparation ☐ Other ( )
Drug prescription/administration
☐ Subcutaneous /intramuscular ☐ Intravenous injection ☐ Arterial injection ☐ Peripheral intravenous drip ☐ Central venous injection ☐ Oral administration
☐ Topical application ☐ Suppository ☐ Inhalation ☐ Nose drop/eye drop/ear drop
☐ Other ( )
Drug dispensing/management
☐ Oral drug dispensing / management ☐ Injection dispensing management ☐ Blood product management
☐ Other ( )

Type of drug/product
☐ Blood product ☐ Narcotic ☐ Anti-tumor drug ☐ Cardiovascular drug ☐ Antidiabetic ☐ Antidiabetic ☐ Hypnotic
☐ Other ( )

Structured items for standardized and digitized reporting

Advantages

- Easy to have a grasp of incident
- Easy to tabulate to produce tables
- Easy to retrieve specific type of incident
- Useful for a person with research interest

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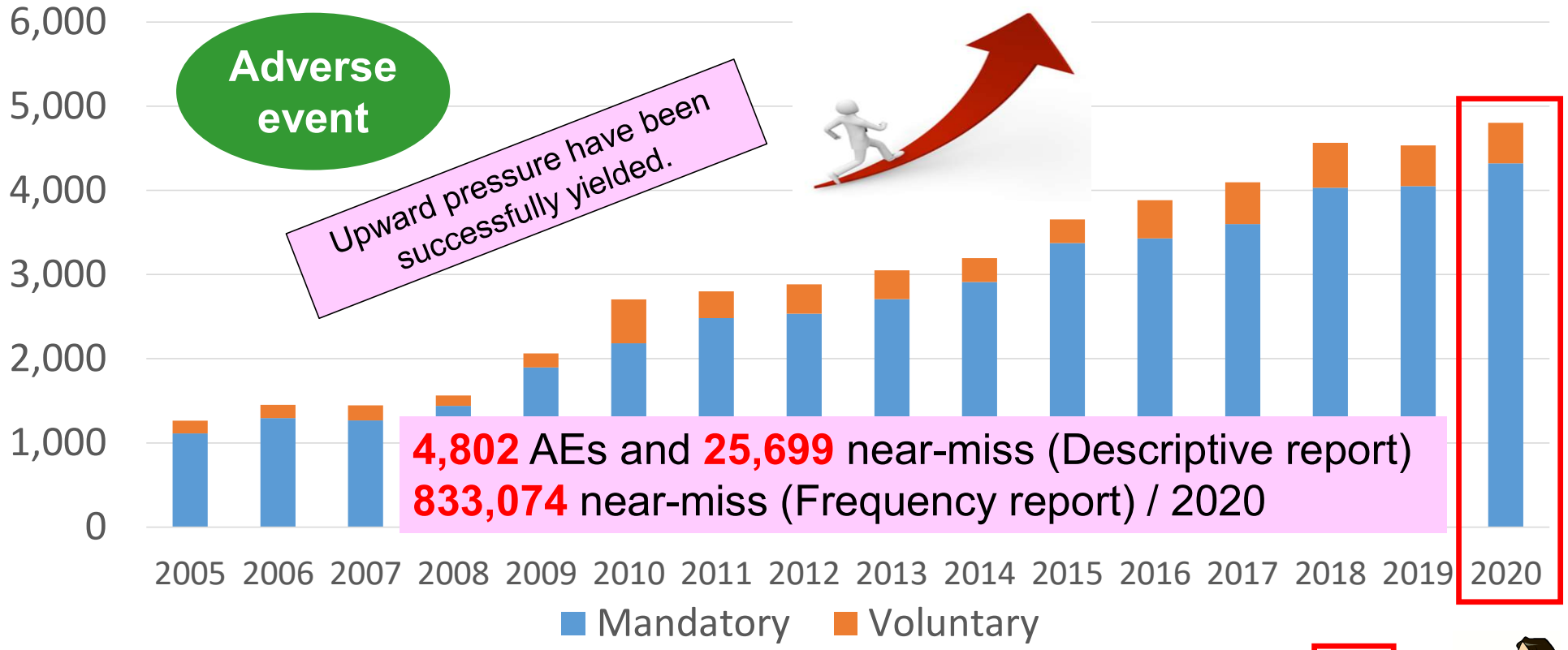
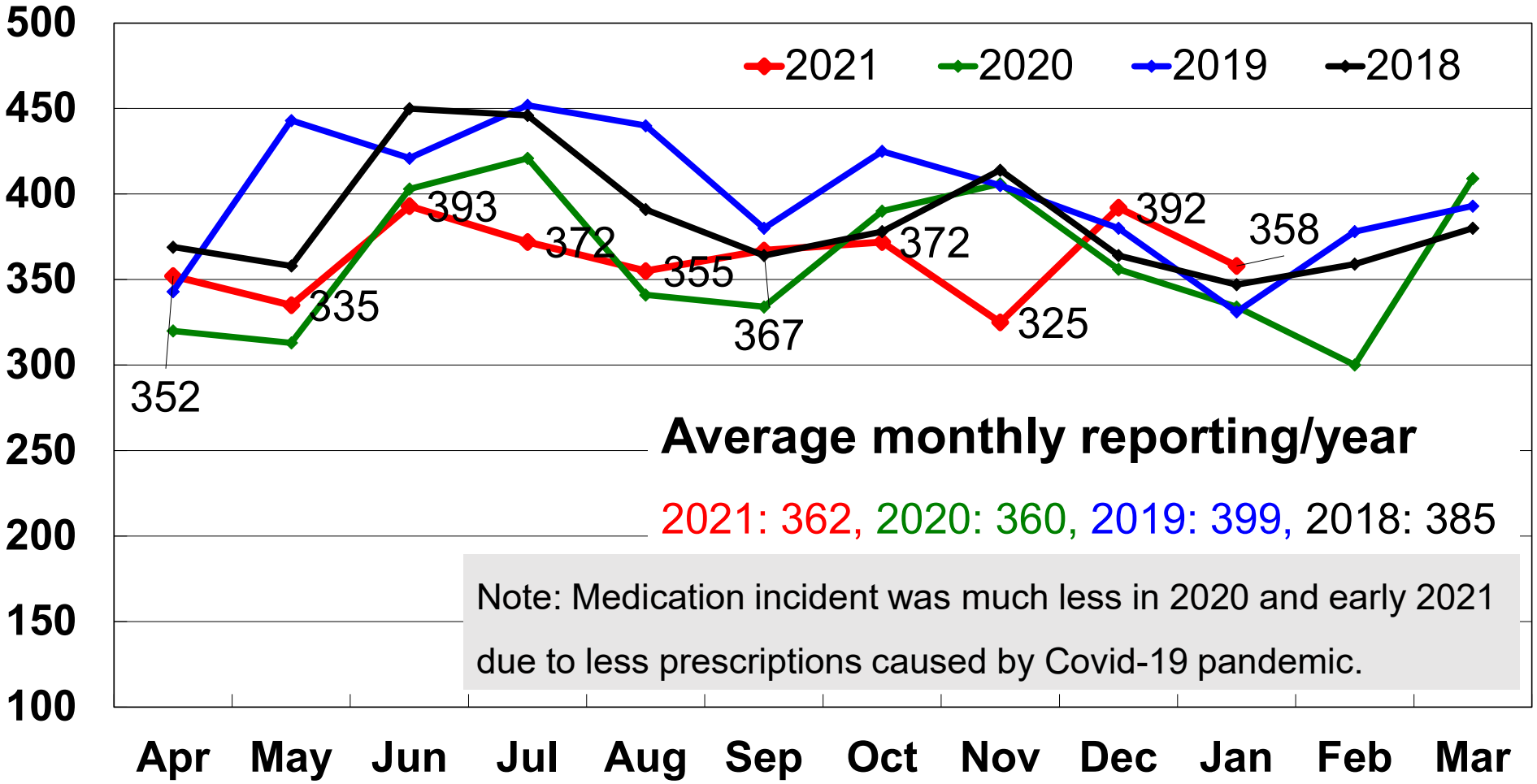
Adverse event Reporting / Learning System Since 2004
Japan Council for Quality Health Care

Trajectory of the AE reporting to JQ



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

Monthly reporting statistics (Kyushu University Hospital)

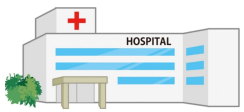


Average monthly reporting/year

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.

Reporting & Learning System institutionalized in healthcare system in Japan



Medical institution
(Hospital, Clinic)

Reporting of AEs, Near-miss (a part of institutions)

Internal reporting system mandated by Health care act

External reporting system participated by mandatory* and voluntary hospitals

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

On-site survey Accreditation

Regular inspection*

Central, Local governments

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

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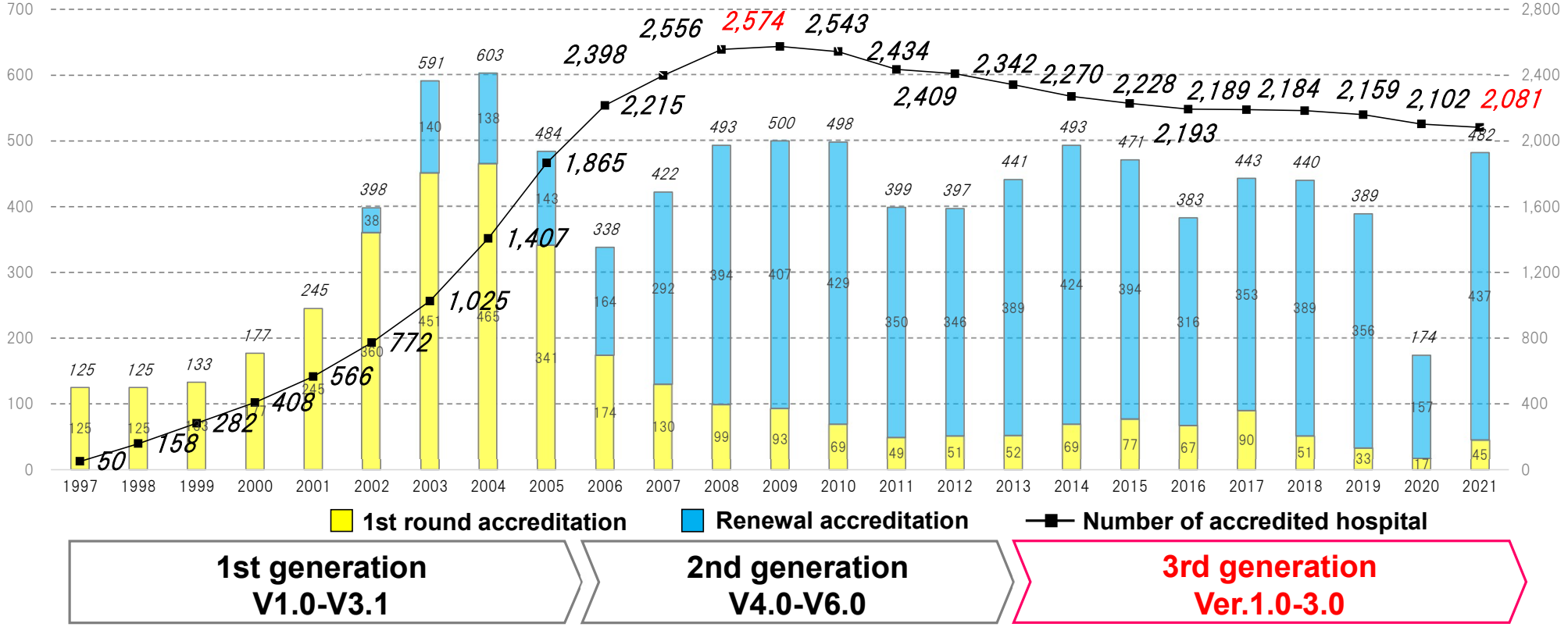
Adverse event Reporting / Learning System Since 2004
Japan Council for Quality Health Care

Trajectory of the Number of Accredited Hospital by JQ

As of Sep 3, 2021

2,081 Hospitals（Total 8,236 hospitals, Accreditation rate: 25.3% ）



1st generation V1.0-V3.1	2nd generation V4.0-V6.0	3rd generation Ver.1.0-3.0

Assessment of incident reporting in survey for accreditation

Accreditation standard, 3rd generation ver.2.0

1 Delivery of patient-centered care
1.3 Ensuring patient safety
1.3.2 Data collection on ensuring patient safety

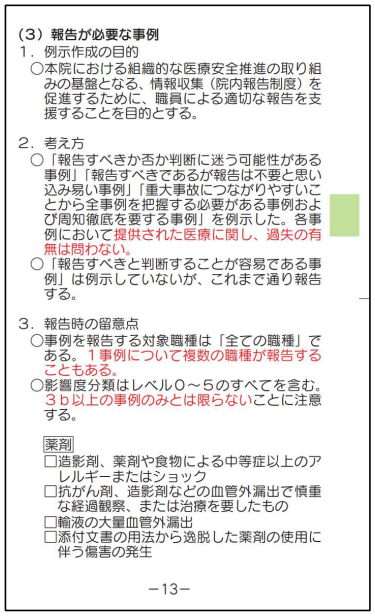
Surveyor's viewpoints

- Hospital **collects information on patient safety** such as data, **incidents** etc. to implement action for preventing accident in continued fashion.
- Hospital **collects external information on patient safety incident** and preventive measures to ensure patient safety at the institution.

Elements for evaluation

- **In-house patient safety incident reporting and learning system**
- Collection of external information on patient safety
- Analysis of reports collected in in-house system in an attempt to formulate preventive measure(s)
- Follow-up of implementation of the preventive measure(s) and revise the measure(s) if necessary

Exemplified events subject to reporting in “Patient Safety Manual”



(3) 報告が必要な事例

1. 例示作成の目的
○本院における組織的な医療安全推進の取り組みの基盤となる、情報収集（院内報告制度）を促進するために、職員による適切な報告を支援することを目的とする。

2. 考え方
○「報告すべきか否か判断に迷う可能性がある事例」「報告すべきであるが報告は不要と思い込み易い事例」「重大事故につながりやすいことから全事例を把握する必要がある事例および周知徹底を要する事例」を例示した。各事例において提供された医療に関し、過失の有無は問わない。
○「報告すべきと判断することが容易である事例」は例示していないが、これまで通り報告する。

3. 報告時の留意点
○事例を報告する対象職種は「全ての職種」である。１事例について複数の職種が報告することもある。
○影響度分類はレベル０～５のすべてを含む。３ｂ以上の事例のみとは限らないことに注意する。

薬剤
□造影剤、薬剤や食物による中等症以上のアレルギーまたはショック
□抗がん剤、造影剤などの血管外漏出で慎重な経過観察、または治療を要したもの
□輸液の大量血管外漏出
□添付文書の用法から逸脱した薬剤の使用に伴う傷害の発生

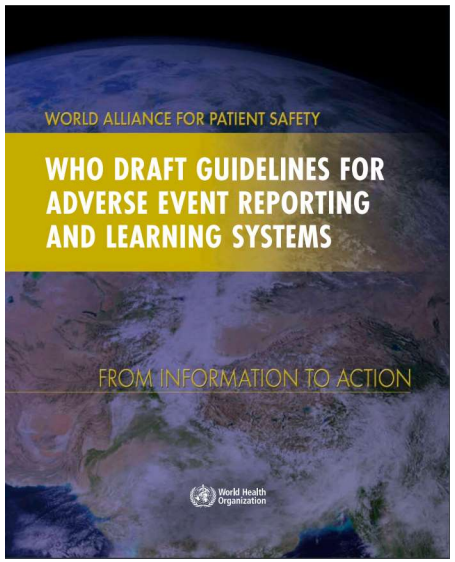
−13−

Patient safety manual (In-pocket manual)

i. **Medication:** Allergic reaction or shock to moderate extent or beyond
ii. **Examination, procedure:** Unforeseeable massive bleeding, Severe pancreatitis after endoscopy
iii. **Diagnosis:** Failure to diagnose with serious finding(s) which is obviously visible on X-ray, CT or MRI images
iv. **Surgery:** Deferred operation due to failed management of anticoagulant prescription
v. **Blood transfusion:** Order of blood products with mismatched type
vi. **Complication:** Unprecedented complication in no relation to procedure(s)

etc.

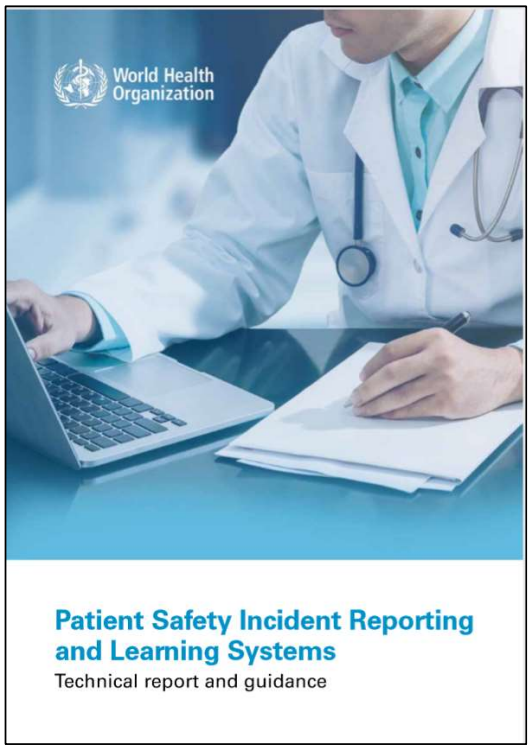
2005 WHO Draft Guideline for Adverse Event Reporting and Learning Systems



Japan

- Type of reporting system: In Japan, **hospitals are mandated** by the Ministry of Health, Labour and Welfare to have internal reporting systems.
- The **Japan Council for Quality Health Care** collects voluntary incident reports and implemented a national reporting system in **2004**.
- Reporting to the new system is **mandatory for teaching hospitals**, voluntary for others reporting systems exist on three levels; hospital or health facility; voluntary system in several different forms such as accreditation body for hospitals and a research group, and at national level which is mandatory.

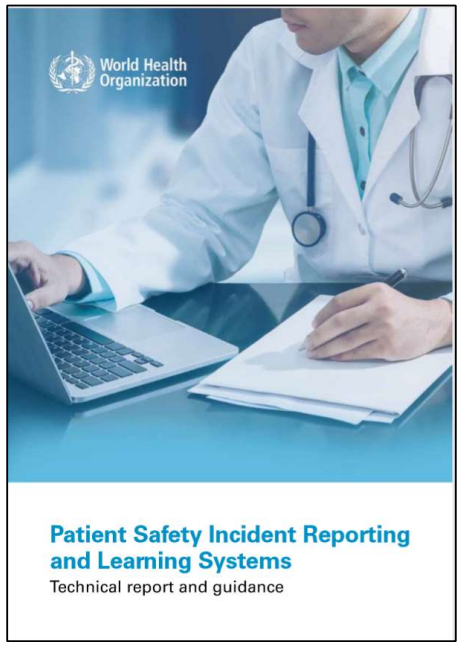
2020 WHO Patient Safety Incident Reporting and Learning Systems



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).

2020 WHO Patient Safety Incident Reporting and Learning Systems



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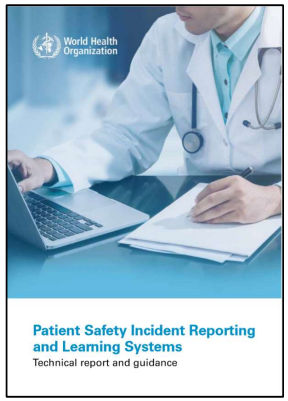
Foreword – Sir Liam Donaldson, WHO Patient Safety Envoy



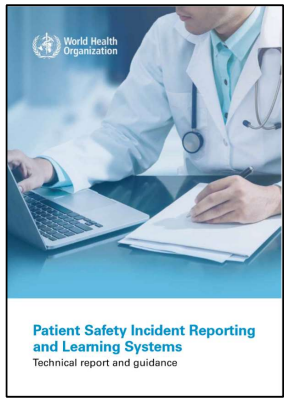
3 challenges:

i. Establishing a safety culture that is based on **blame-free reporting** is difficult. Too often, individuals had to be held accountable despite of poorly designed systems and processes of care.

ii. **Detailed multidisciplinary investigation** is less commonly undertaken, even though it would lead to much deeper insights into systemic issues. This is primarily for logistic reasons, insufficient resources, and lack of coordination to bring the right people together.

iii. The process of achieving sustainable reductions in risk and improvements in patient safety seldom works well. Measures such as **issuing new guidelines, one-off training initiatives etc. have been shown to be relatively weak change strategies**.

5. Guidance (Recap)



5.2 Creating a positive environment for reporting

5.2.2 The organization should make a formal commitment to eliminate the blame culture and encourage blame free reporting; this is by far the most widely cited factor influencing the success and failure of incident reporting systems across all sectors.

5.2.3 Create the environment for health care professionals to make a report. Where feasible, electronic methods of reporting are preferable to filing of paper forms.

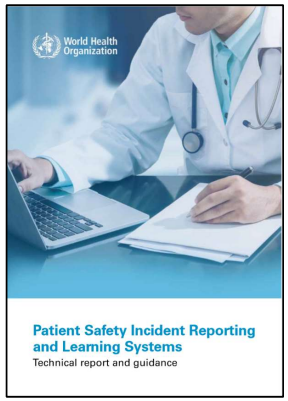
5.3 Identification and recording of incidents

5.3.2 Publish and communicate clear guidance and definitions for staff on what should be reported.

5.4 Choosing the information to be captured

5.4.3 All incident reports should contain structured information gathering and a free text narrative account.

5. Guidance (Recap)



5.6 Review and investigation of individual incidents

5.6.5 When the volume of incident reports precludes looking at all of them, there should be a clear policy on which categories should be reviewed and investigated.

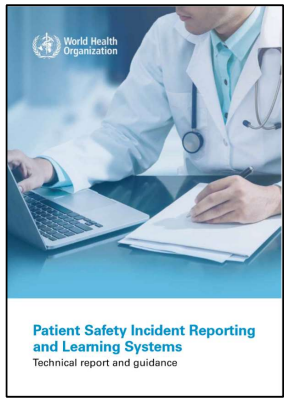
5.7 Systemic insights from aggregated incident data

5.7.6 Carry out regular thematic reviews using incident reports and other sources of data. Such an approach (in areas such as anticoagulant therapy, insulin dosage errors and radiation overdose) can allow sources of risk to be explored and preventive measures to be instituted.

5.8 Learning, formulating action and managing change

5.8.3 Patient safety alerts, warnings, and advisory notices should be appropriately designed and piloted, and their communication targeted well.

5. Guidance (Recap)

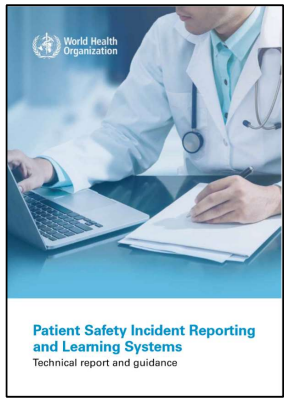


5.9 Openness and independence of data analysis

5.9.1 The organization responsible for gathering, aggregating and analyzing patient safety incidents should identify all individuals and organizations with an interest in the data, giving priority to those with a role in improving safety. Data should be provided in the format that best meets their needs.

5.9.2 This agency or organization should ideally be an independent entity separate from government and the health system. It should operate in the patient and public interest without fear or favour and with no perception that it has any conflict of interest.

5. Guidance (Recap) to call for patient/family engagement



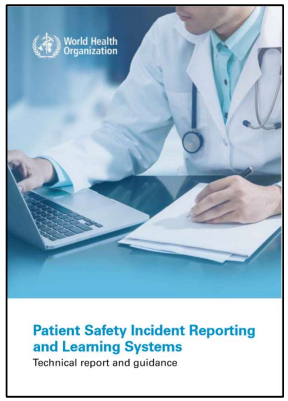
5.3 Identification and recording of incidents

5.3.3 A special strand of reporting should be established for patients and family members to make patient safety incident reports. It is essential that patients and family members are encouraged to report.

5.11 Engaging patients and families

5.11.1 All health organizations should have a “duty of candour” towards any victim of harm. All patients whose care has involved a patient safety incident should receive (a) a full disclosure of what went wrong; (b) an explanation of why it happened; (c) a full apology; (d) a description of the action being taken to prevent; (e) the provision of support, including fair compensation; and (f) access to further treatment for the original condition and consequences of the harm.

5. Guidance (Recap) to call for patient/family engagement



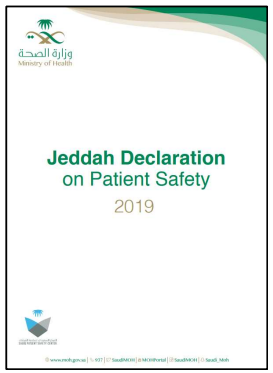
5.11 Engaging patients and families

5.11.2 The stories of patients and families who have suffered avoidable harm should be a regular part of the discussions of health organizations' governing bodies and clinical teams.

5.11.3 Patients and families who have suffered avoidable harm should be invited to share their experience and stories as a core component of the educational programmes of health care professionals.

5.11.4 Patients and families who have suffered avoidable harm should be embedded as advisers in all governance and service design structures within health organizations.

Jeddah Declaration on Patient Safety 2019



1. Promote patient safety in Low- and Middle -Income Countries (LMIC)
2. Utilize Digital Health to support Patient Safety across the globe
3. Promote Patient Empowerment & Community Engagement for Patient Safety
4. Leverage the ICD through the creation of ICAE for Patient Safety
5. **Implement and Sustain National Reporting & Learning System for Patient Safety**
6. Invest on Workforce knowledge and safety as the drivers for Patient Safety
7. Learn from other industries
8. Promote Medication Safety in Community Pharmacies
9. Consider Medical Devices and Human interface as crucial factor for Patient Safety
10. Enforce Infection Prevention Control (IPC) & Antimicrobial Resistance (ANR) strategies for Patient Safety
11. To reduce the 2nd Translational Gap by supporting implementation and sustainable scale-up of patient safety interventions of known efficacy/effectiveness at national and global level

WHO Global Patient Safety Action Plan 2021-2030

1. Policies to eliminate avoidable harm
2. High-reliability systems
3. Safety of clinical processes
4. Patient and family engagement
5. Health worker education, skills and safety
6. Information, research and risk management
7. Synergy, partnership and solidarity

World Health Organization

WHO Global Patient Safety Action Plan 2021-2030

6.1
Patient safety incident reporting and learning systems

4.4
Patient safety incident disclosure to victims

1.4
Safety standards, regulation and accreditation

1.5
World Patient Safety Day and Global Patient Safety Challenges

World Health Organization

Takeaways

- “To Err Is Human” emphasized need to install reporting and learning system on both mandatory and voluntary basis.
- The reporting and learning system for patient safety should be carried out in no-blame/non-punitive culture for promoting reporting.
- Incident subject to reporting needs to be clearly defined in protocol for promoting reporting.
- Data needs to be reported in standardized fashion for analysis to generate preventive/improvement measures.