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
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 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.
### About JQ

<table>
<thead>
<tr>
<th>Established</th>
<th>July 27, 1995</th>
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<tbody>
<tr>
<td>Chair</td>
<td>Hirobumi Kawakita</td>
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<tr>
<td>Projects</td>
<td>Hospital accreditation rtc.</td>
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<tr>
<td></td>
<td>• Japan Medical Association (JMA)</td>
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<td>• Ministry of Health, Labor and Welfare (MHLW)</td>
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<tr>
<td>Major Shareholders</td>
<td>• Japan Hospital Association</td>
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<td>• Japan Dentist Association</td>
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<td>• Japan Nursing Association</td>
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<td></td>
<td>• Japan Pharmacist Association</td>
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<td></td>
<td>• Japanese Federation of Health Insurance, etc.</td>
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## JQ’s Projects on Quality and Safety Improvement

<table>
<thead>
<tr>
<th>Project</th>
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<tbody>
<tr>
<td>Hospital Accreditation</td>
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<tr>
<td>Patient Safety Promotion Group of Among Accredited Hospitals</td>
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<tr>
<td>Education and Training on Patient Safety</td>
</tr>
<tr>
<td>EBM Medical Information Distribution Project (Minds)</td>
</tr>
<tr>
<td>Nationwide Adverse Events Reporting System of Medical Institutions</td>
</tr>
<tr>
<td>Nationwide Near-miss Event Reporting System of Community Pharmacy</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>
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</table>

**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

The number of publicity declined in recent years.

Citation; “NIKKEI” Telecom21
Schematic image of the “Holistic Policy on PS” (Released in 2002 from MHLW* Expert Panel)

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

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

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

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

* MHLW; Ministry of Health, Labour and Welfare
IOM (Institute of Medicine*, US) Report

Table of Contents (Excerpt)

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
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 least 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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* Current “National Academy of Medicine”, US
5. Error Reporting Systems

Recommendation 5.1

**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

Recommendation 5.1

- 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

Recommendation 5.1

(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 “Recommendation 5.1”

• 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 does 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

Recommendation 6.1

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

- Launch of Patient Safety Promotion Office in MoH
- Launch of PS Promotion Committee & National Policy Development
- Research funding
- Specific projects i.g. R/L System
- Incentives i.g. healthcare fee
- Joining in Global Action
- Others
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.
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)

**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**
### Structure of reporting items for standardized reporting

#### 1. Date of event occurrence and event summary

<table>
<thead>
<tr>
<th>Month of occurrence</th>
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<tbody>
<tr>
<td>January</td>
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<table>
<thead>
<tr>
<th>Day of occurrence</th>
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<table>
<thead>
<tr>
<th>Weekday holiday category</th>
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<tr>
<td>Holiday</td>
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<table>
<thead>
<tr>
<th>Time of occurrence</th>
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<tbody>
<tr>
<td>00:00-05:59</td>
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#### 2. Information concerning patient involved

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>Age (specify between 0 years 0 months to 129 years 11 months)</th>
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<tbody>
<tr>
<td>1</td>
<td>1-5 years 1-11 months</td>
</tr>
<tr>
<td>2</td>
<td>6-9 years 6 months 1-9 months</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Sex</th>
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<tbody>
<tr>
<td>Male</td>
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#### 3. Information concerning medical professional involved

<table>
<thead>
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<th>Person who identified event</th>
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</thead>
<tbody>
<tr>
<td>Person involved</td>
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</table>

<table>
<thead>
<tr>
<th>Job title of person involved</th>
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<tbody>
<tr>
<td>Doctor</td>
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<table>
<thead>
<tr>
<th>Specialist, certified physician/surgeon, other professional/technical certification</th>
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<tbody>
<tr>
<td>Cardiologist</td>
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<table>
<thead>
<tr>
<th>Years of experience (specify between 0 years 0 months to 99 years 11 months)</th>
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<tbody>
<tr>
<td>0-4 years 0 months</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Years of working at current department (specify between 0 years 0 months to 99 years 11 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-4 years 0 months</td>
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<table>
<thead>
<tr>
<th>Number of shifts worked in the week immediately before event occurrence</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<thead>
<tr>
<th>Shift work system</th>
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<tr>
<td>8</td>
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</table>

#### 4. Information concerning situation, place, and event details

<table>
<thead>
<tr>
<th>Situation</th>
</tr>
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<tbody>
<tr>
<td>Emergency</td>
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<table>
<thead>
<tr>
<th>Details of event</th>
</tr>
</thead>
<tbody>
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<td>Unknown</td>
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<table>
<thead>
<tr>
<th>Drug</th>
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<table>
<thead>
<tr>
<th>Situation</th>
</tr>
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<tbody>
<tr>
<td>Unknown</td>
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</table>
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
Trajectory of the AE reporting to JQ

Adverse event

Upward pressure have been successfully yielded.

4,802 AEs and 25,699 near-miss (Descriptive report)
833,074 near-miss (Frequency report) / 2020

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<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>
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<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>
</tr>
</tbody>
</table>
Average monthly reporting/year


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)

- **Internal** reporting system mandated by Health care act
- Reporting of AEs, Near-miss (a part of institutions)

**External** reporting system participated by mandatory* and voluntary hospitals

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

Central, Local governments

Regular inspection*

* Inspection under “Health Care Act”; Hospital-annually, Clinic-every 2-3 years
Trajectory of the Number of Accredited Hospital by JQ

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

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.
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

1. Introduction

2. Reporting and learning systems: current status

3. Work of WHO on patient safety incident reporting and learning

4. Developing and operating a reporting and learning system

5. Guidance

6. Self-assessment based upon the guidance

References
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
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
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.