WHO Global Patient Safety Webinar Series

Patient Safety Incident Reporting and Learning Systems

25th July 2025
13:00-15:00 CEST

Patient Safety

WHO Integrated Health Services Hub

World Health Organization

Time	Topic	Presenter/ Moderator
13:00-13:05	Welcome and instructions Objectives and agenda	Dr Blerta Maliqi, WHO HQ
13:05-13:10	Slido Question: What kind of safety incidents do you report at your workplace?	Dr Blerta Maliqi
13:10-13:20	Setting the scene: Why Patient Safety Incident Reporting and Learning Systems (PSIRLS) are essential for delivering safe and high-quality care	Sir Liam Donaldson, WHO Special Envoy for Patient Safety
13:20-13:40	Panel 1: Turning Incidents into Insights: Establishing Strong Patient Safety Learning Systems	Moderator: Sir Liam Donaldson Dr Gaurav Loria, India Dr Clara Pareja Rossell, Spain Ms Ronel Steinhöbel, South Africa
13:40-13:55	Panel 1: Discussion, questions and answers	
13:55-14:20	Panel 2: From Vision to Action: Operationalizing Patient Safety Incident Reporting	Moderator: Sir Liam Donaldson Mr Andrew Murphy-Pittock, UK Ms Ann-Marie O'Boyle, Ireland Dr Francesco Venneri, Italy Professor Kok Hian Tan, Singapore
14:20-14:35	Panel 2: Discussion, questions and answers	
14:35-14:55	WHO Guidance on Patient Safety Incident Reporting and Learning Systems Status of PSIRLS implementation and challenges	Dr Irina Papieva, WHO HQ Dr Nikhil Gupta, WHO HQ
14:55-15:00	Discussion, questions and answers	Moderator: Dr Blerta Maliqi
15:00	Concluding remarks	Dr Blerta Maliqi

TURNING INCIDENTS INTO INSIGHTS – ESTABLISHING STRONG PATIENT SAFETY LEARNING SYSTEMS

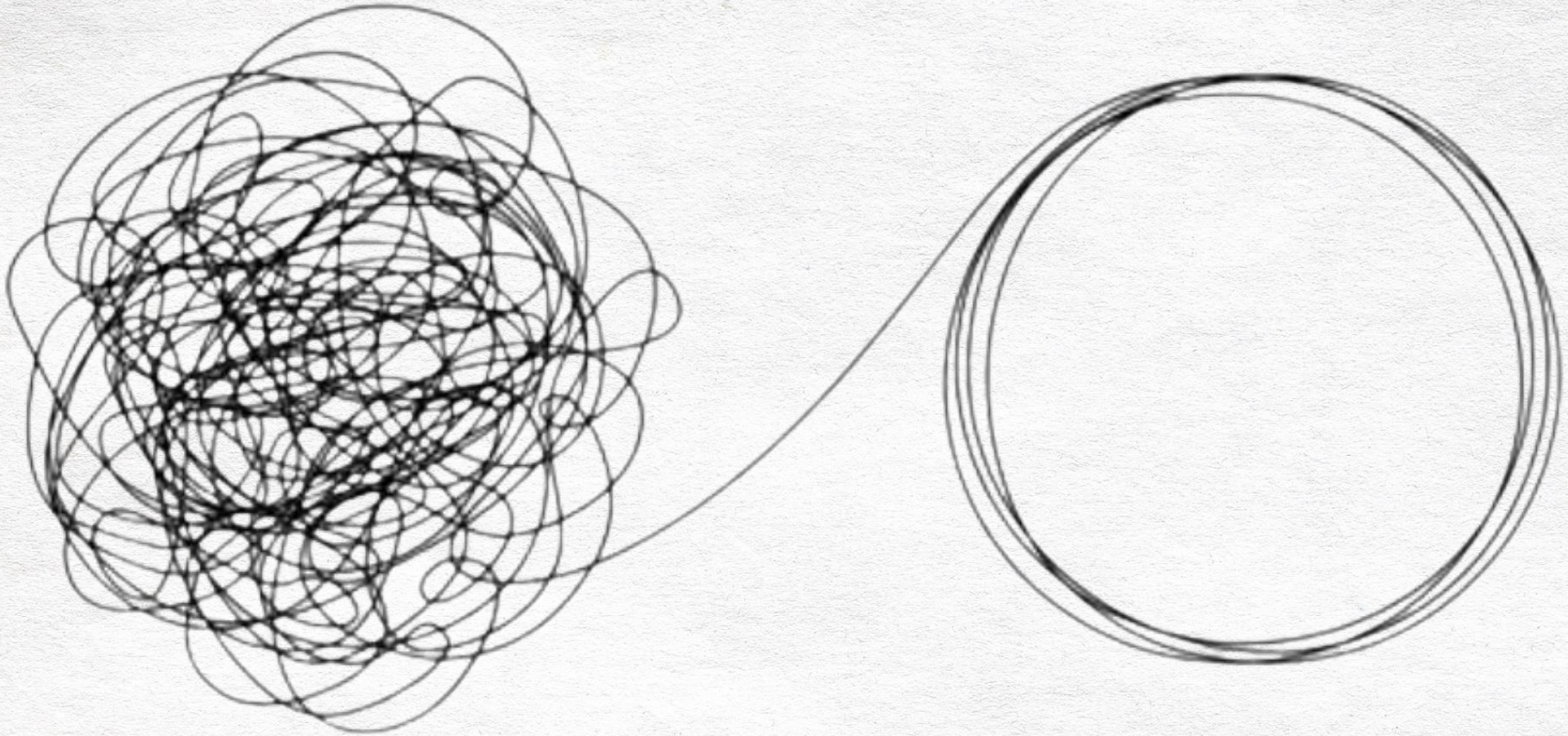
GAURAV LORIA

Senior Vice President

Group Chief- Operations, Experience & Safety

Apollo Hospitals Enterprise Ltd

India



Chaos to Clarity - How Hospitals Learn from Harm?

A Case of Missed Allergies

A 48-year-old man

Admitted for elective hernia repair.

Went into anaphylactic shock within minutes of receiving a routine antibiotic.

Chaos erupted. Code Blue was called.

The patient was stabilized – but barely.

A Case of Missed Allergies

The Revelation

- Rush of admissions and pre-op prep
- Handwritten initial assessment (penicillin allergy was missed) not clear
- Transcripted EMR did not flag it
- The consent didn’t capture it
- The nurse administering the drug never knew

RCA -blind spots

- Improper / incomplete documentation
- Incomplete pre-anesthesia checks
- Allergy was not captured properly
- No system for allergy alerts

A Case of Missed Allergies

What Changed?

- A "Red Band Protocol" - visible wrist tags for known allergies
- Allergy alerts auto-populated across EMR touchpoints
- Allergy check part of the WHO Surgical Safety Checklist
- Anonymous error reporting up by 3x
- Repeated Near misses investigated like actual harm

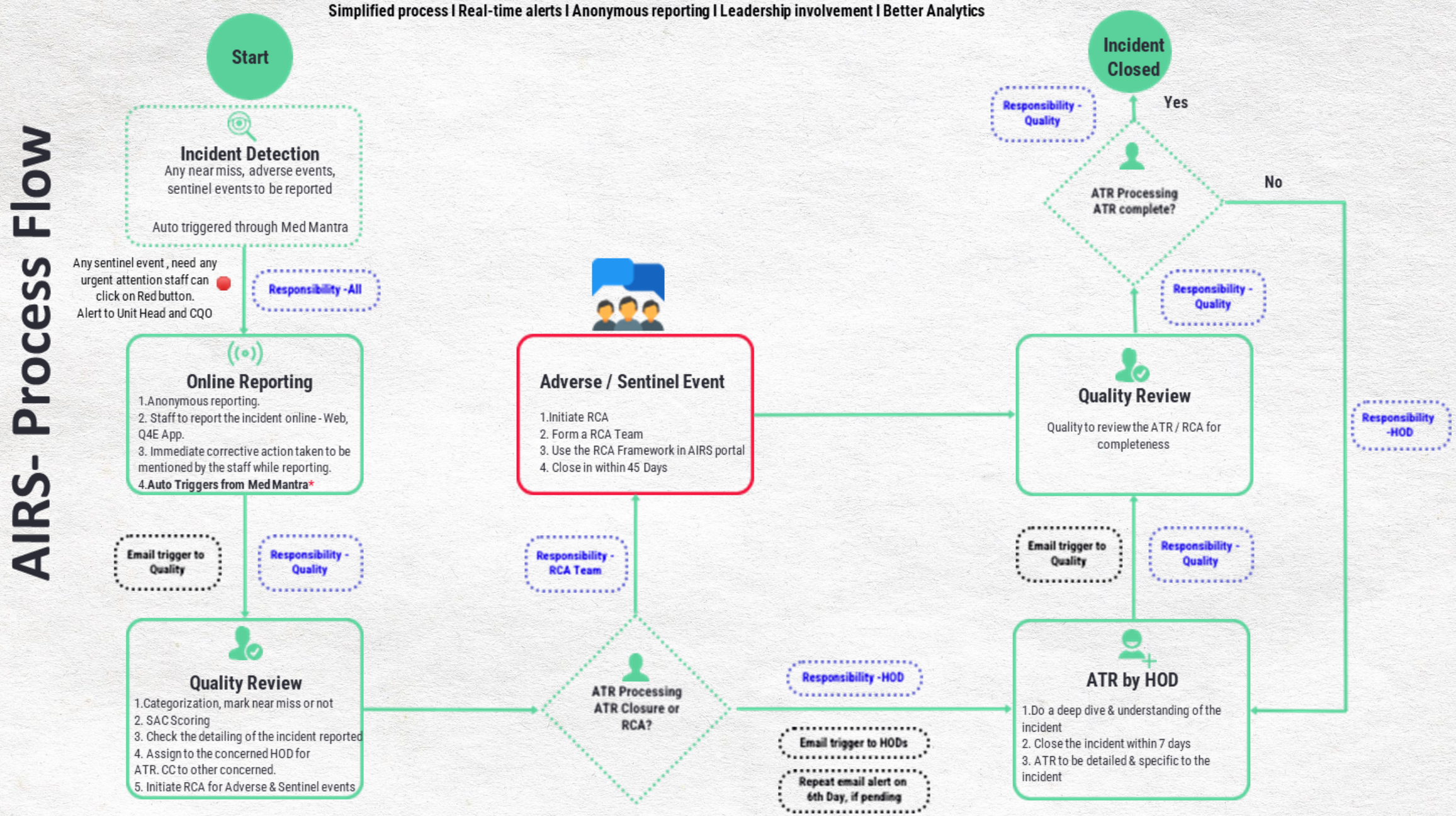
The Black Box of Healthcare

- What happened?
- Who knew what?
- Where time was lost?
- Which protocols failed silently?
- What was reported & what wasn't?

- To truly become learning organizations, hospitals must open the Black Box after every harm or near miss
- Do a detailed RCA
- Share the insights across departments, units
- Build systems that remember, so the same harm never happens twice

AIRS- Process Flow

Simplified process I Real-time alerts I Anonymous reporting I Leadership involvement I Better Analytics



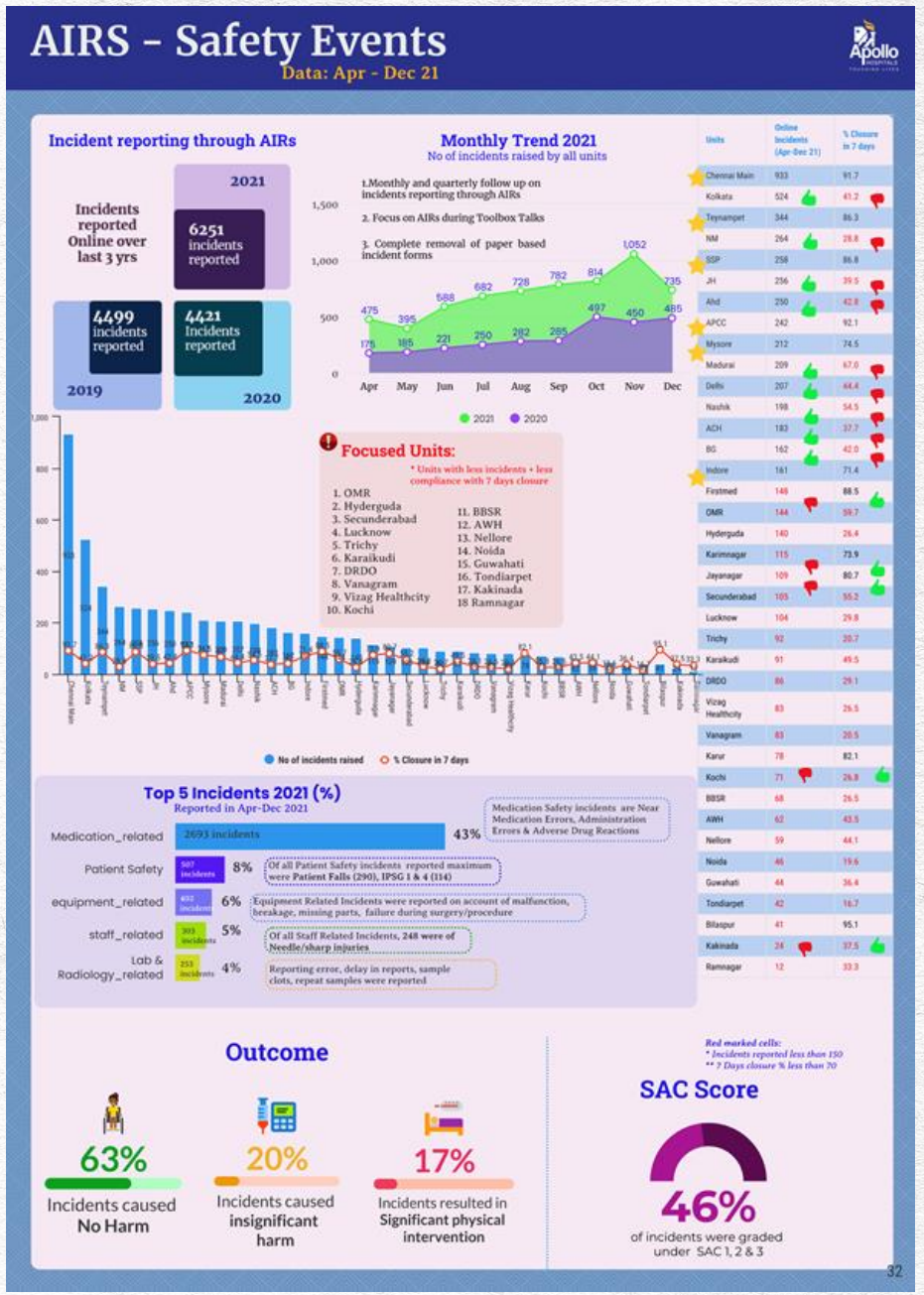
Safety Kaleidoscope

Each incident offers a different lens

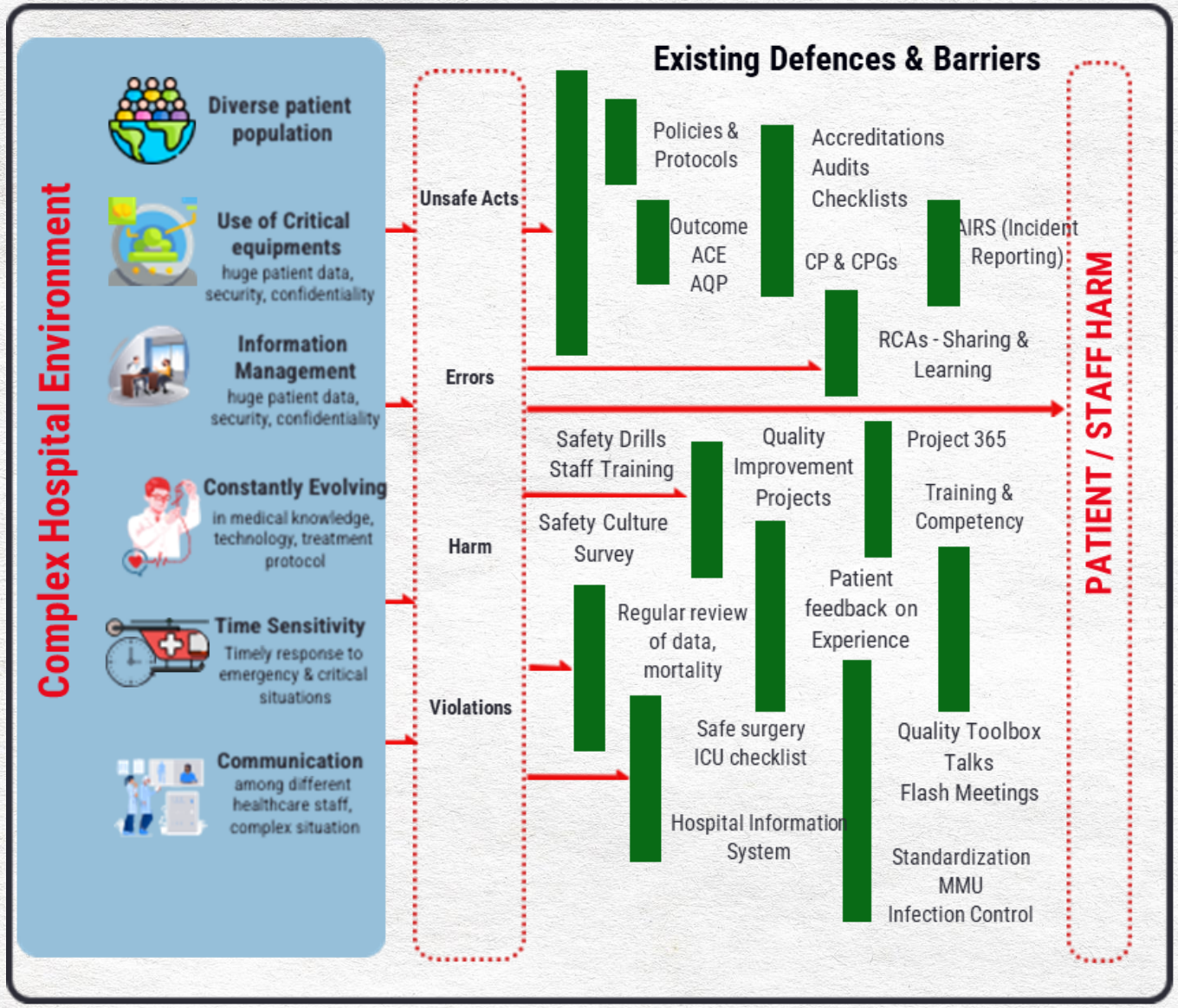
AIRS - Safety Events

- Through improved, standardized reporting, we develop insights into the underlying causes of patient safety events and ultimately develop strategies to decrease adverse events in the future.

- The reporting of near-misses specifically provides the great opportunity to work on solutions without the impact of the event or harm reaching the patient.



From Harm to Healing… to High Reliability



Globally as per WHO

- 1 in every 10 patients is harmed
- Medication Errors for 1 of 30 patients, with more than a quarter as severe or life threatening
- Above 50% of harm (1 in every 20 patients) is preventable
- 0.14% healthcare associated infections (increasing by 0.06% each year)
- 3 to 5 Patient Falls per 1000 bed-days, and > 1/3rd of these incidents result in injury
- 10% of preventable patient harm in health care was reported in surgical settings

Source: WHO; September 2023

So far @ Apollo

- 20,904 incidents including nearmisses were self reported in last 10 months (Jan - Dec 23)
- 2 incidents were captured per hour
- Out of 7154 (700/month) medication errors in last 10 months only 18% reached to patient with no significant harm
- 0.001% adverse / sentinel events of 5,95,658 discharges in last 10 months
- Out of 500 falls reported only 0.03% (17) instances where it has harmed the patient adversely

Where are we placed in a HRO Maturity Model?

Aim

We are here

Generative
Safety is how we do business around here. Constantly vigilant & transparent

Proactive
Anticipating and preventing problems before they occur; comfort speaking up

Systematic
We have systems in place to manage all hazards

Reactive
Safety is important. We do a lot every time we have an accident

Unmindful
Who cares as long as we're not caught chronically complacent

We may not be the most exceptional, but we excel in numerous areas.

SURVEY

- Assess your hospital's current safety culture performance.
- Safety culture is generally measured by surveys of providers at all levels.
  Available validated surveys include *AHRQ's Surveys on Patient Safety Culture™ (SOPS®)*
- Analyse data to make targeted improvements.

ENCOURAGE, RECOGNISE & REWARD INCIDENT REPORTING

Make error reporting transparent, and use adverse events as opportunities for improvement instead of punishment.
Simulate possible adverse events as part of training.
Initiate a rewarding system for incident reporting.

QUALITY TOOLBOX TALK

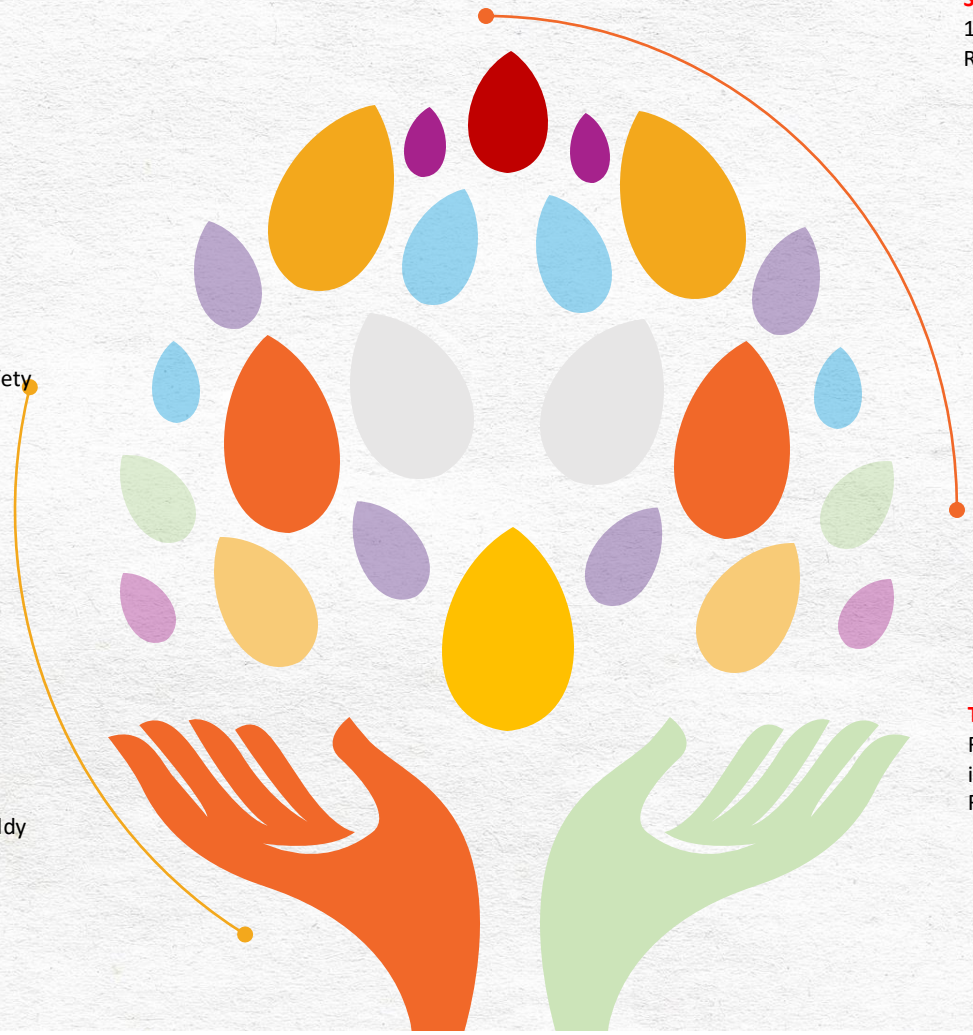
Campaign across all units on reporting of safety incidents and safety culture.
Share lessons Learnt

AUTO TRIGGERS

AI enabled auto triggers from EMR for maximum possible parameters to be identified and implemented every Quarter

SUPPORTING SECOND VICTIMS

Educational campaign to introduce the second victim concept.
Provide guidance on how staff can support each other during an adverse event (immediate peer-to-peer emotional support or buddy programs).



LEADERSHIP WALK ROUNDS

By the senior management team
Operations head to ensure minutes are documented
Unit based Walk Rounds.
Discuss Quality and Safety topics.

SAFETY AWARENESS AND LEARNING POINTS (SALP)

10 points awarded for each reported near miss incident.
R&R for the highest reporting staff on World Quality Day!

10% WEIGHTAGE IN TOTAL QUALITY SCORES

Group A - 5 Score points if unit reported >100 near miss in a month through AIRs & within 7 days closure
Group B - 5 Score points if unit reported >80 near miss in a month within 7 days closure
Group C - 5 score points if unit reported >60 near miss in a month within 7 days closure!

MONTHLY GREAT CATCH BADGE TO STAFF

Each quarter, one individual or team recognized will receive special recognition for outstanding achievement based on following criteria:
likelihood that a patient safety issue would have resulted if the Good Catch did not happen
potential impact to patients if the Good Catch did not happen.

THANK YOU CARDS/ REWARDS

Recognize staff who report safety issues or have good ideas for improvement.
Recognize staff who report incidents

Every error ignored is a lesson lost!

Localizing patient safety. Adapting incident reporting and learning systems for regional success: Catalan PSRLS

WHO: Global Webinar on Patient Safety Reporting and Learning Systems

Friday, 25 July 2025

Clara Pareja Rossell

General Directorate for Health Regulation and Organization,
Department of Health, Government of Catalonia

SNiSP Cat

Sistema de Notificació d'Incidents de Seguretat dels Pacients de Catalunya

Generalitat de Catalunya

Catalan Patient Safety Reporting and Learning System: PSRLS Cat - SNiSP Cat

Catalan Patient Safety Reporting and Learning System: PSRLS Cat - SNiSP Cat

Reporting

- Reporting forms **adapted** to all **healthcare areas** (primary care, hospitals, intermediate care and in the future mental health).
- Reporting **traceability** + **feed back** to the professional.
- **Anonymized**.

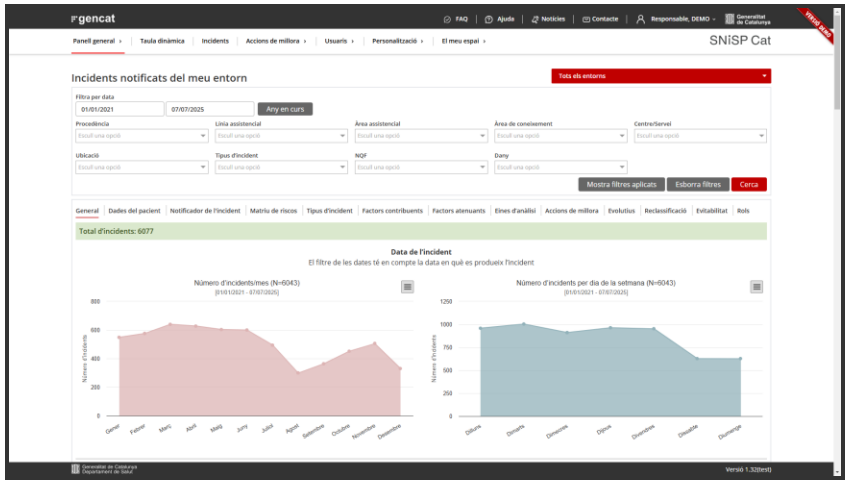
Tool

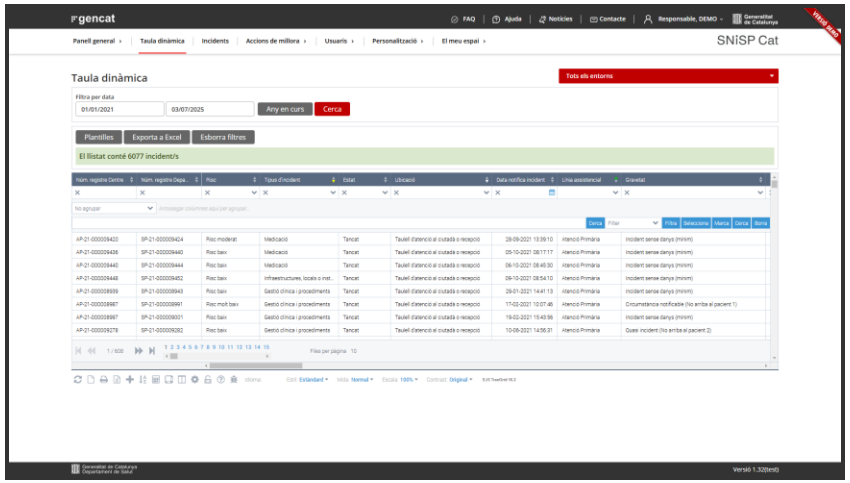
- Reporting forms, analysis tools and monitoring of improvement actions **integrated** in the same **tool**.
- Integrated **dashboard**.
- Adapted to the **legal framework**.

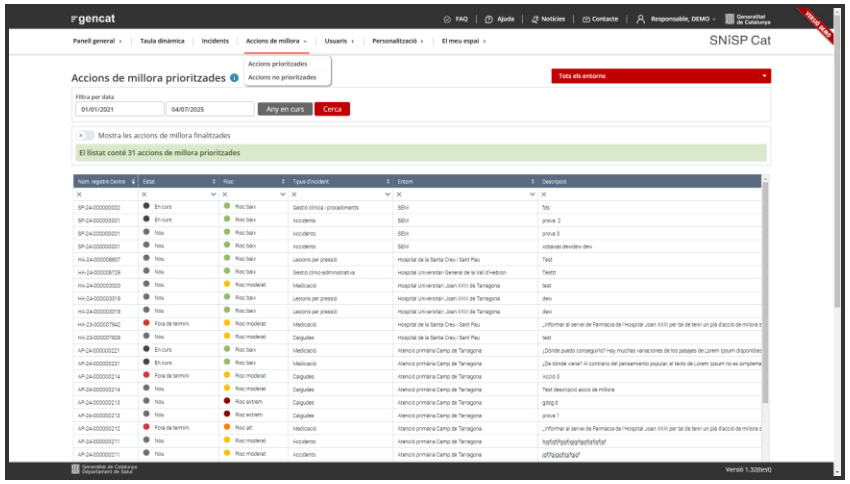
Training

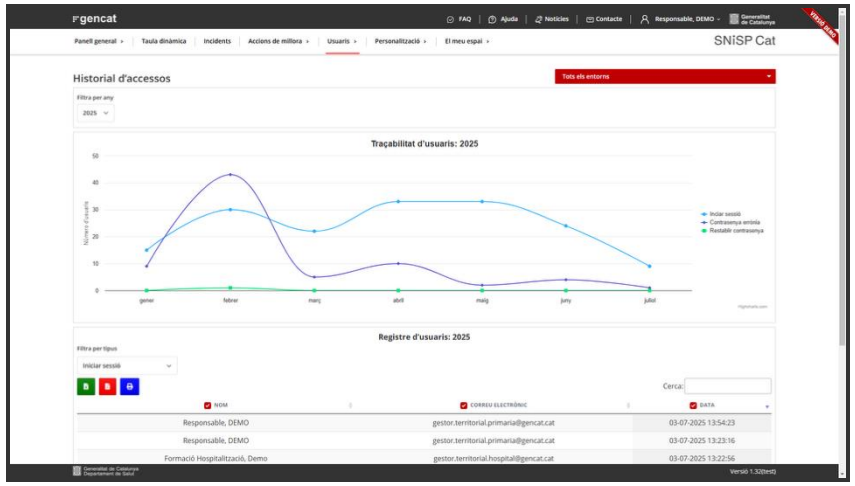
- For reporting **professionals**.
- For **tool managers**.

Catalan Patient Safety Reporting and Learning System: PSRLS Cat - SNiSP Cat









PSRLS Cat: Implementation and main results

PSRLS Cat: Implementation and main results - July 2025 (1)

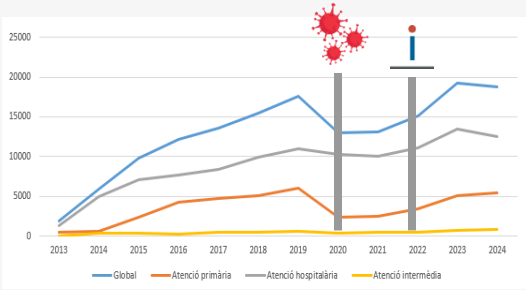
Implementation data

- Registered reporters: **5.373**
- Managers: **90**
- Territorial managers: **441**
- Center managers: **2.941**
- User administrators: **232**
- Viewers: **951**

Implementation: healthcare areas

- Primary care (PC): **379** **(100%)**
- Acute Hospitals (AH): **63 (100%)**
- Intermediate Care Centers (ICC): **20**
- Medical Emergency System (EMS) (100%)

PSRI: 183.774



Reporting Forms

- PC
- AH
- ICC
- MES

In process:

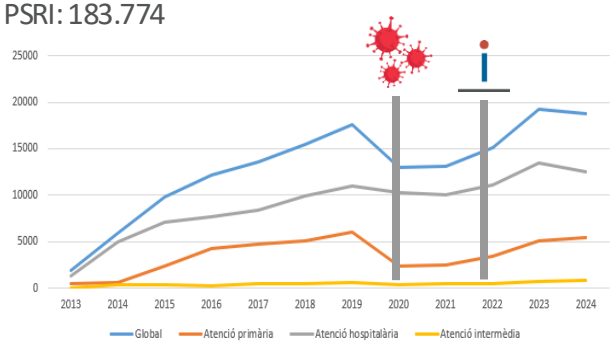
- OCATT
- Sentinel Pharmacies
- Mortality Committee
- Pharmacovigilance
- Citizens

	2023	2024	2025
Number of versions	7 (1.14-1.20)	8 (1.21-1.28)	4 (1.29-1.32)
Tasks completed	136	146	62
Optimizations	64	86	24
Functionalities	53	44	17

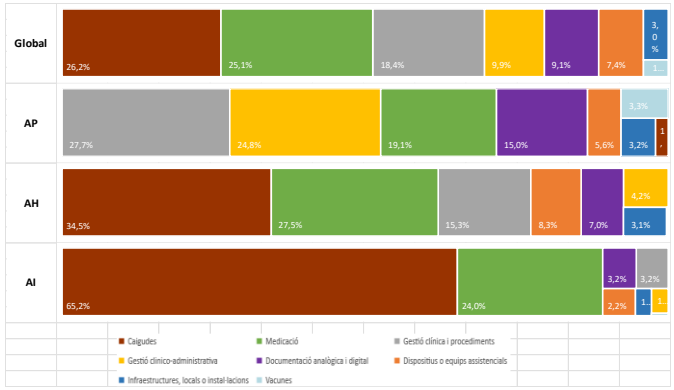
PSRLS Cat: Implementation and main results (2)

Nº PS reported incidents (2013-2025)

PSRI: 183.774

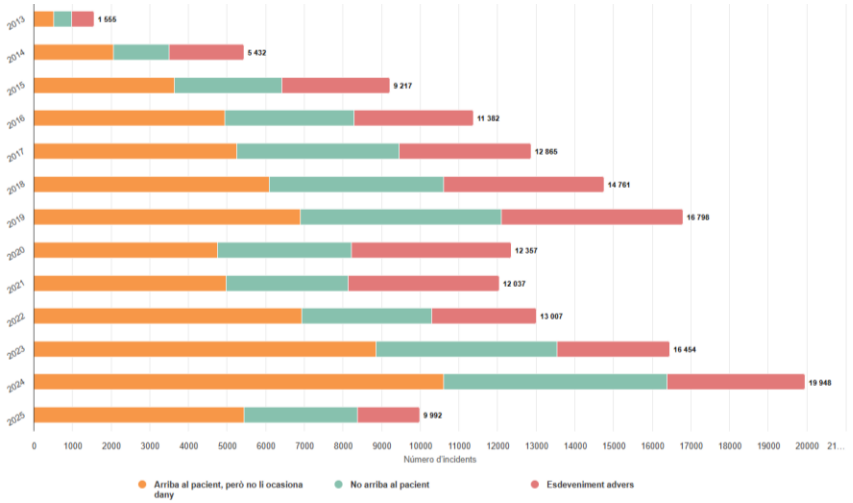


PSRI: Healthcare area & type (2013-2025)



PSRI: WHO taxonomy

PSRI: Degree of harm (2013-2025)



PSRLS Cat: Conclusions and future challenges

PSRLS Cat: Conclusions and future challenges

Extend the PSRLS to other **healthcare devices** such as community pharmacies.

System tool integrated into the **technological platform** that is part of the **risk management strategy**.

PSRLS Cat: **tailored** to healthcare organizations.

Integrated tool to support reporting, analysis, management and monitoring of improvements measures.

Advance in **learning** about patient safety incidents.

Data at all levels of care for **decision-making**.

Integrate improvement actions into **healthcare practice**.

Article

Pareja-Rosell, C., Rabanal-Tornero, M., Oliva-Oliva, G., Gens-Barberà, M., Hospital-Guardiola, I., Hernandez-Vidal, N., Capella-Gonzalez, J., Ayala-Villuendas, D., Vidal-Melgosa, E., Mansergas-Collado, N., López-Sanz, E., & Astier-Peña, M.P. (2024). Patient safety reporting and learning system of Catalonia (SNiSP Cat): A health policy initiative to enhance culture, leadership and professional engagement. *BMJ Open Quality, 7*(3), e002610. https://doi.org/10.1136/bmjoq-2023-002610

BMJ Open Quality

Patient safety reporting and learning system of Catalonia (SNiSP Cat): a health policy initiative to enhance culture, leadership and professional engagement

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ABSTRACT

Patient safety reporting and learning systems (PSRLS) are tools to promote patient safety culture in healthcare organisations (HCO). Many PRSLS are locally developed. WHO Global Action Plan on Patient Safety 2021–2030 urges governments to deploy policies for healthcare risk management including PSRLS. The Ministry of Health of Catalonia (MHC) faced challenges in addressing quality and patient safety (Q&PS) issues due to disparate information systems. To address these challenges, the MHC developed a territorial PSRLS and embedded it in the Quality and Patient Safety Strategic Plan of Catalonia 2023–2027 (QPSS Plan Cat).

Methods Four-step process: (1) creation of a governance model, a web platform and reporting forms for a PSRLS in Catalonia (SNiSP Cat); (2) SNiSP Cat roll out; (3) embed SNiSP Cat information in the accreditation model for HCO and the PS scorecard; (4) Development of SNiSP Cat within the QPSS Plan Cat 2023–2027.

Results The SNiSP Cat is in use by 63/64 acute care hospital (ACH), 376/376 primary healthcare teams (PCT) and 17/98 long-term care facilities (LTCF). 1335/109 273 professionals were trained. Until 2022, 127 051 incidents have been migrated and reported (2013–2022). The system has generated three comprehensive risk maps for HCO: one for ACH, including patients' falls, medication, clinical process and procedures; second for PCT, including clinical process and procedures, clinical administration and medication; and a third for LTCF, included patients' falls, medication, digital/analogical documentation. SNiSP Cat provided information to support 53 standards out of 1312 of the ACH accreditation model and 14 standards out of 379 of PCT one. Regarding the MHC patient safety scorecard, 14 indicators out of 147 of ACH and 4 out of 41 of PCT are supported by SNiSP Cat data.

Conclusions The availability of a territorial PSRLS (SNiSP Cat) allows MHC leads the Q&PS policy with direct information, risk maps and data support to the standards for the Catalan accreditation models and PS scorecard linked to incentivisation, turning the SNiSP Cat into a driven tool to implement the Quality and Patient Safety Strategic Plan of Catalonia 2023–2027.

WHAT IS IT ALREADY KNOWN ON THIS TOPIC?

⇒ Patient safety reporting and learning systems (PRSLS) serve as valuable instruments for fostering risk management within healthcare systems. However, its effectiveness has been a subject of debate, primarily due to the insufficient engagement of healthcare leaders and policy-makers. The omission of the inclusion of PRSLS as a crucial element of quality and patient safety plans has contributed to this uncertainty.

WHAT THIS STUDY ADDS?

⇒ Our study underscores the importance of engaging policy-makers, such as the Health Department of Catalonia, to prioritise patient safety policies and ensure compliance with regulatory quality and safety standards. Through the development of a territorial PSRLS integrated into the Quality and Patient Safety Strategic Plan 2023–2027 for the Catalan healthcare system, policy-makers gain awareness of healthcare challenges in real time. This commitment to implementing territorial PSRLS empowers stakeholders to gain timely insights into healthcare risks, enabling informed policy decisions aimed at resolving them.

BACKGROUND

The Institute of Medicine's report 'To err is human' addressed the burden and cost of low healthcare quality and, moreover, quantify the harm caused to patients and their families.[1] It placed patient safety as the basic dimension of healthcare quality in health services. Today, many healthcare systems report quality and safety indicators providing an impetus for quality improvement in health systems worldwide.[2]

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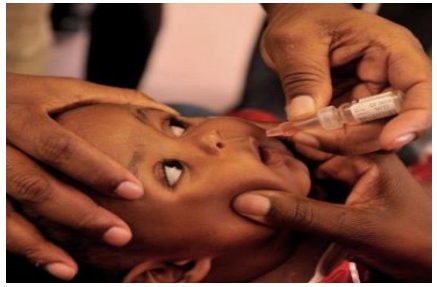
Establishment of a Patient Safety Reporting and Learning Systems (PSRLS) in South Africa



WHO Global Patient Safety Webinar

Ronel Steinhobel
Deputy Director: Quality Assurance and Improvement
National Department of Health
South Africa

25 July 2025

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Setting up a patient safety reporting and learning systems (PSRLS) in South Africa

Why develop a PSRLS?

- No National uniform system to report patient safety incidents (PSIs)
- WHO call to countries
- South Africa hosted a Medico legal summit 2015 – setup a national PSRLS

First steps?

- Rapid assessment 2015 of current situation in country
- Nine provinces each had their own guideline/ policy to manage PSIs, very few similarities

How?

- Drafted first National Guideline for PSI Reporting and Learning
- Shared draft with 9 provinces & WHO for input
- Hosted National consultative workshop to finalise

Results

- Approved by National Health Council
- National Guideline for PSI Reporting and Learning effective on 1 April 2018
- Web-based information sytem launched simultaneously

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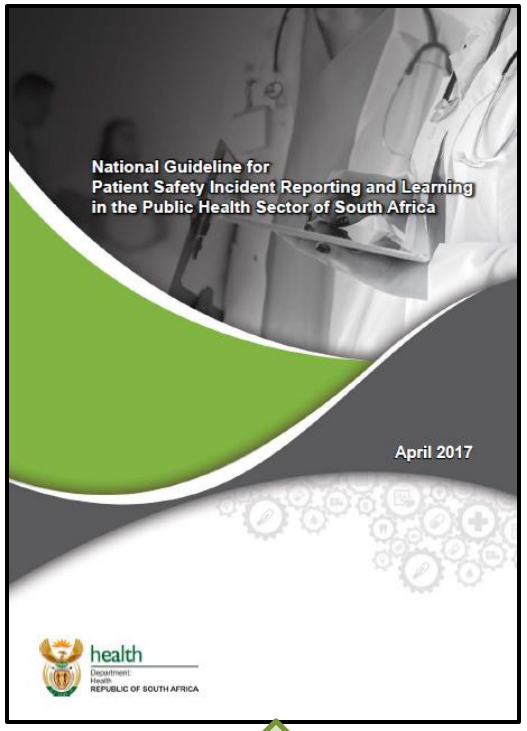
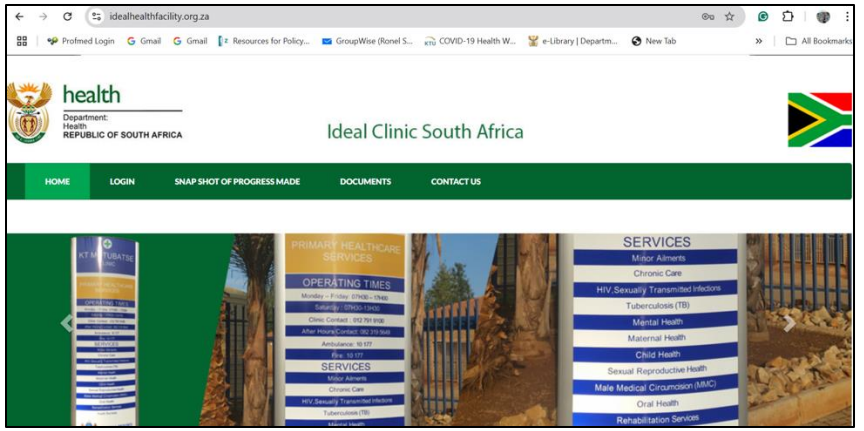
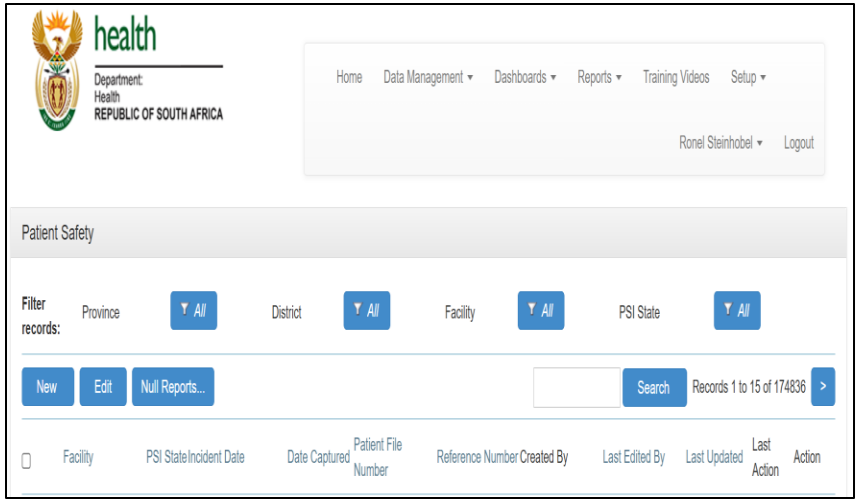
Setting up a patient safety reporting and learning systems (PSRLS) in South Africa



1 April 2018





WHO Minimum Information Model (MIM)
Severity Assessment Code (SAC)
3 Indicators in National Data Set

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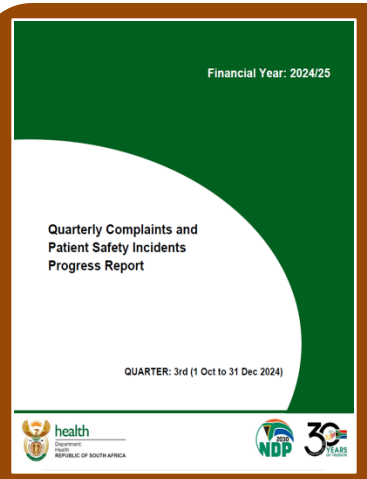
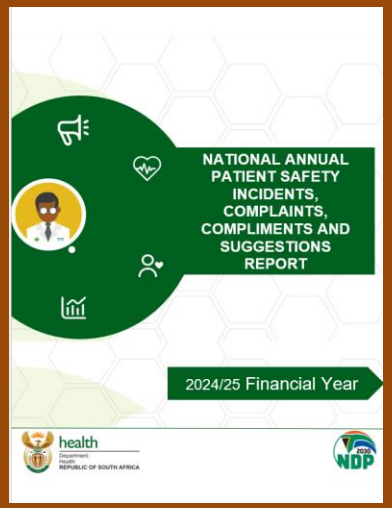
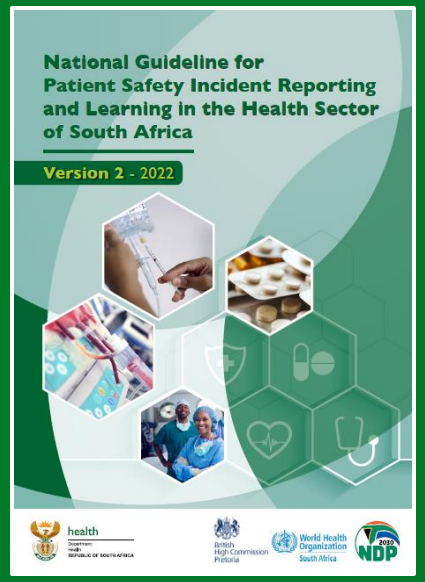
Progress made since implementation in 2018





Quarterly & Annual reports

- Quarterly reports shared with Provincial Quality Assurance managers
- Annual report shared with Provincial Heads of Health



Revision of Guideline 2022

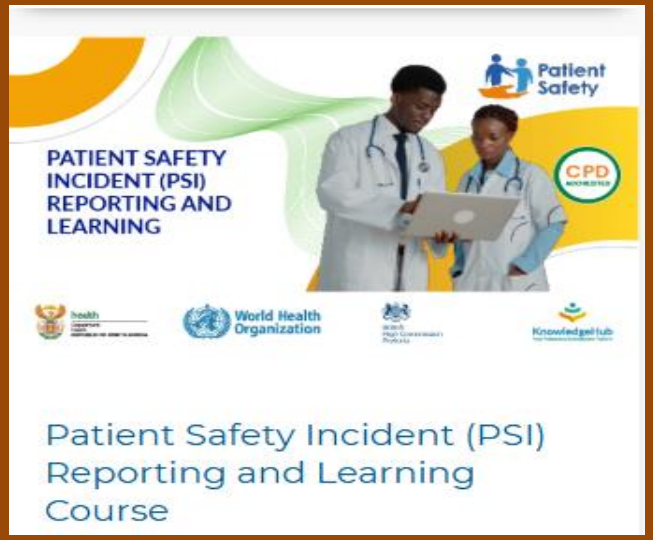
Prompted by:

- Annual Report of 2021/22
- WHO Global Patient Safety Action Plan 2021 to 2023

Progress made since implementation in 2018

Added Automated Notification

- Setup by Provincial Departments of Health
- Notification sent via e-mail and/or SMS



Online Training modules

- Available at https://knowledgehub.health.gov.za/
- Continuous Professional Development (CPD) - 3 CPD points (3 Hours)

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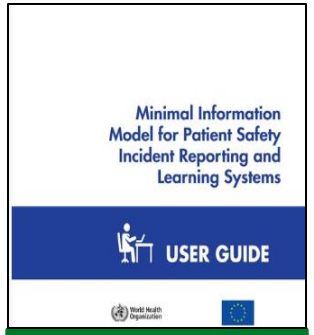
Challenges

- Not all stakeholders initially particiated
- Poor Data Quality (Description and classification)
- Just Culture: Under reporting, fear of disciplinary action
- Data not used to drive improvement = Complaince exercise?
- Training Courses not optimally utilised

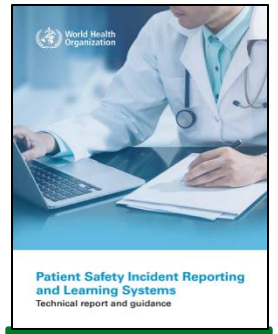
Leasons Learned



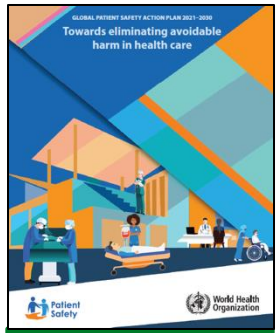
World Health Organization

British High Commission Pretoria

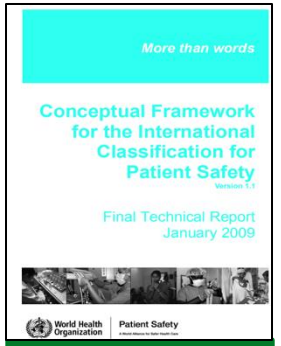
Partnerships & Resources If you don't know how



Pilot in a subset of facilities to identify gaps



Guideline/ policy to standardise before developing monitoring system



Leadership com-mitment at all levels & Involve everyone

Continious monitoring and feedback to all stakehol-ders

Change takes time.... Don't give up.

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END

Thank you!

https://www.health.gov.za

https://knowledgehub.health.gov.za

https://www.idealhealthfacility.org.za

Health Services Safety Investigations Body

An introduction to PSIRF and HSSIB

Andrew Murphy-Pittock, Education Director

PSIRF

A new approach to responding to patient safety incidents.

Replaces SIF

Tested in 2020 – 2021. Updated 2022. Transition started in 2023, now 100% complete

4 pillars:

- Compassionate engagement with those affected
- Systems-based approaches
- Proportionate response
- Supportive oversight

World Health Organization

LFPSE

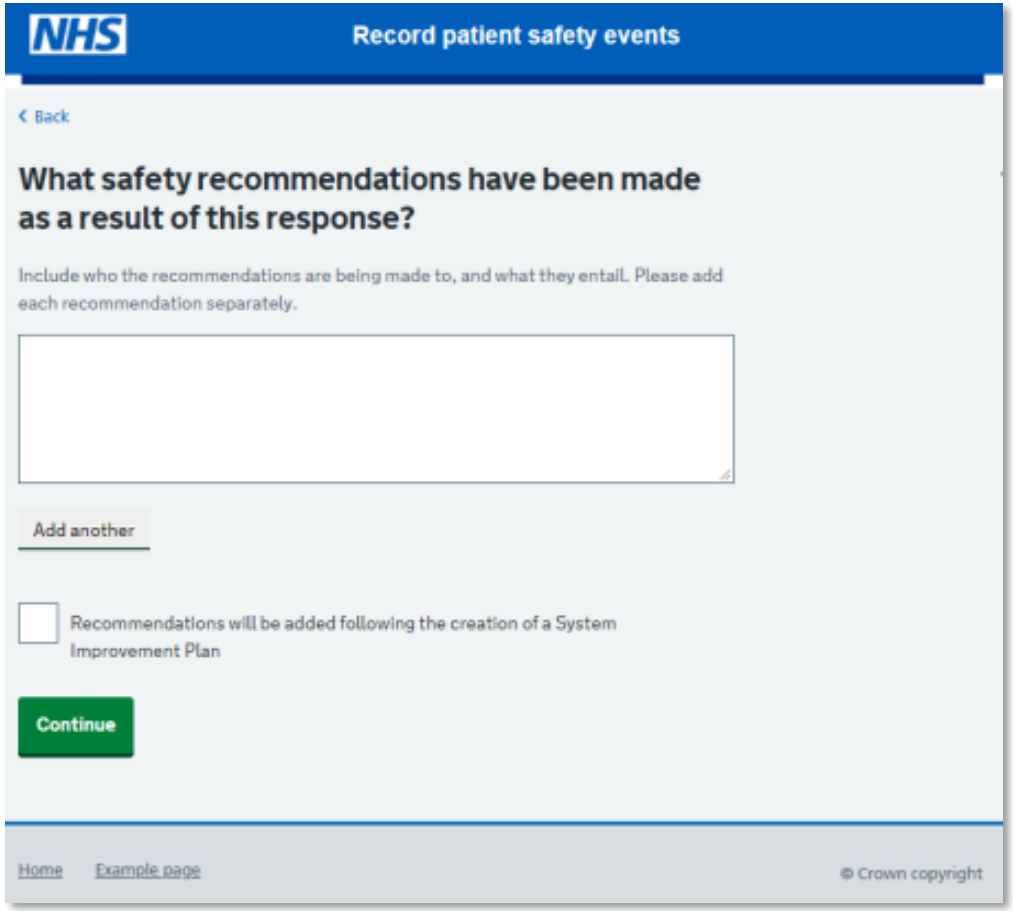
National, centralised platform for recording and analysing patient-safety events

Alignment with national frameworks (e.g., PSIRF, just culture) to standardise investigation, reporting and learning processes

Self-service dashboards and visualisation tools for providers, commissioners and ICBs to explore trends and guide improvement work

Tiered access model (standard, organisational, admin) enabling appropriate data governance, oversight and compliance reporting

Flexible event capture—including incidents, risks, outcomes of concern and “good care” examples—to support comprehensive learning



HSSIB

- We came into operation on 1 October 2023, established by the Health and Care Act 2022, as a fully independent arm's length body of the Department of Health and Social Care.
- Our core role is to carry out independent patient safety investigations, that do not find blame or liability with individuals or organisation across the NHS and in independent settings.
- We want to understand why patients may have been harmed or could be at risk of harm. We take a system perspective and aim to reduce the likelihood of patient safety incidents occurring. We share learning and support patient safety improvements across the whole healthcare system in Engl

World Health Organization

Investigations and insights

10 key principles for investigation

1. We do not attribute blame or liability in our investigations.
2. We underpin investigations with the most appropriate and robust safety science methodologies.
3. Our investigations take a system perspective and aim to reduce the likelihood of incidents happening.
4. We involve patients, families, and healthcare staff in our investigations.
5. We consider how to improve care for those subjected to health inequalities in all our investigations.
6. We have a multidisciplinary team approach to investigations using skilled investigators.
7. We involve appropriate subject matter advisors in our investigations.
8. Safety recommendations will be impactful and we will work with the system to ensure there is maximum effect.
9. We are open and transparent about how we work while protecting the disclosure of specific evidence that we gather during investigations.
10. We undertake investigations in a timely manner, and in the most cost-effective way.

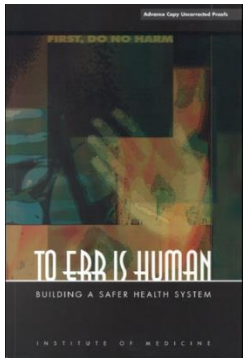
How we identify new areas for investigation*

*this is not an exhaustive list of sources

Learning from safety events	Remember, human error is not a cause
	Consider interactions and feedback mechanisms
	Fix processes and systems, not people
	Build in ‘controls’ to common hazards
	Involve users in testing changes
	Think differently about safety, consider variability and adaptability
	Think about all those affected and their support
	Remember ‘just culture’ is a restorative mindset, not a process

Education Programmes

World Health Organization



PATIENT SAFETY FIRST

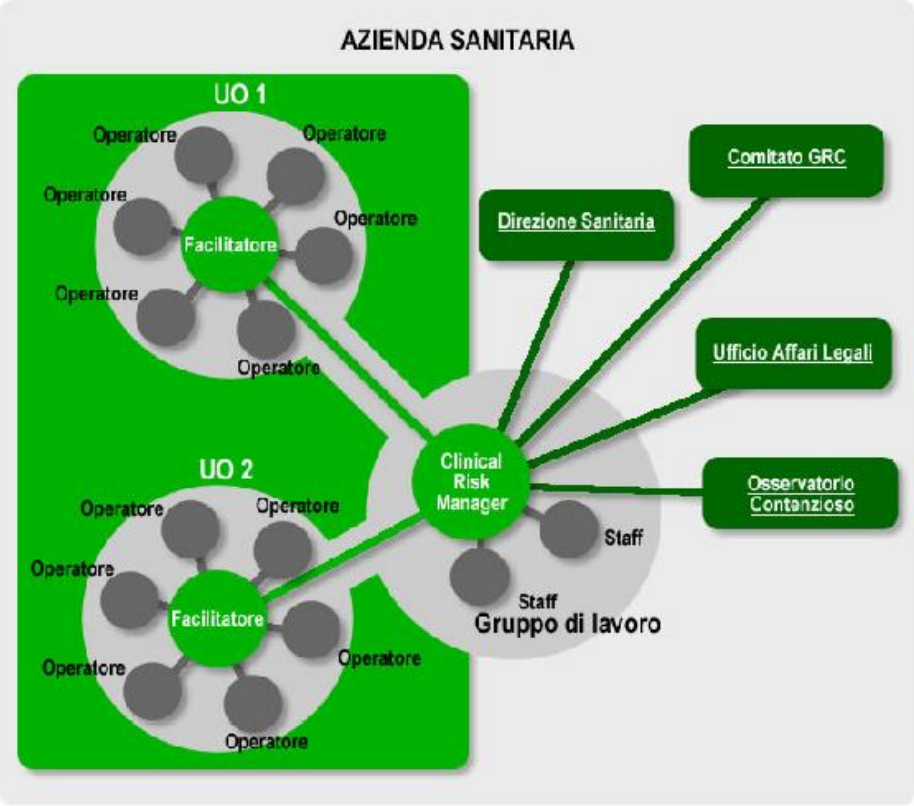
Global Patient Safety Webinar Series 2025

Patient Safety Incident Reporting and Learning Systems

July 25, 2025

Francesco Venneri, M.D.,Ph.D.,F.A.C.S.
Clinical Risk Manager
Center for Patient Safety
Tuscany - Italy

Organisation Outline in Healthcare Services



Every Hospital has:

- **An Organisationl Staff for CRM**
- **Training programme**
- **A Hospital Patient Safety Plan**
- **An ICT for Incident Reporting and Learning**

Accreditation requisites since 2008

Patient Safety Indicators

New Indicators

C6	**CRM indicators**
C6.1	Claims index
C6.1.1	*Malpractice index- in hospital events*
C6.1.2	*Malpractice index- out-of-hospital events*
C6.1.3	*Lawsuite average management*
C6.2	**IRLS indicators**
C6.2.1	N. Of Clinical Audits
C6.2.2	N. Of M&Ms
C6.4	***Patient Safety Indicators***
C6.4.1	*Post Operative Sepsis*
C6.4.2	*Unexpected mortality rates*
C6.4.3	*Pulmonary embolism and post operative DVT*
C6.5	N. Of Best Practies
C6.6	The capacity of managing and restricting patient falls

Clinical Risk Management Approach

National and Regional Basis

1. Clinical Audits: SEA, RCA
2. M&M: aggregated data study
3. Feedback to all professionals

Ministry of Health: Sentinel Event reporting

PROs & CONs of Incident Analysis

Individual review / Aggregated study/ Full Investigation

- Gathering as much information as possible
- Evidence of common causes to share among settings
- Implementing the just culture
- Training on the job
- Sharing experiences among professionals and other stakeholders
- Involve top management levels
- If possible, patient and/or family involvement

- Time consuming
- Unavailability of some stakeholders
- Fear to report for medical-legal issues

Mission impossible ?

THANK YOU FOR YOUR ATTENTION

NPSO Presentation to

WHO Global Webinar on Patient Safety Reporting and Learning Systems

Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Ann-Marie O'Boyle

Patient Safety Legislation & Advocacy Unit, National Patient Safety Office, Department of Health

Background - NPSO Formation

- Nov 2015 - Government approved a major programme of patient safety reforms
- 2016 - National Patient Safety Office (NPSO) established to provide the required leadership with regard to patient safety policy, legislation and oversight.

Open Disclosure in Ireland

Legislation

Policy

Patient Safety (*Notifiable Incidents and Open Disclosure*) Act 2023

The Open Disclosure Framework

Patient Safety Act 2023

Number 10 *of* 2023

Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

World Health Organization

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

An Roinn Sláinte
Department of Health

Background to the Development of the Patient Safety Act 2023

- **Patient Safety *(Notifiable Incidents and Open Disclosure)* Act 2023:**

- Provides a legislative framework for a number of important patient safety issues, including the **mandatory open disclosure of a list of specified serious patient safety incidents** that must be disclosed to the patient and/or their family and the notification of the same to the Health Information and Quality Authority, Chief Inspector of Social Services and the Mental Health Commission.

The Patient Safety Act 2023 – Key Features

- **Mandatory Open Disclosure and Notification of Serious Patient Safety Incidents:**

- Patients and their families must have **access to comprehensive and timely information**, including **an apology where appropriate**, in relation to serious patient safety incidents.

- Embedding a **culture** whereby clinicians, and the health service as a whole, engage **openly, transparently, and compassionately** with patients and their families when things go wrong.

- Mandatory **open disclosure to relevant person(s)** of specified serious patient safety incidents and also provides for the **mandatory external notification** of those same events to the appropriate body.

The Patient Safety Act 2023 – Key Features

Open Disclosure Process – Key Points:

- Appointment of Designated person by Healthcare Provider
- Formal Meeting
- Provide Information to the patient/family in writing
- Option for patient to decline/re-engage at a later date
- Apology if appropriate

Benefits for Practitioners:

- Cultural Change – Move **from blame culture to a 'Just Culture'**. Creating Space for Openness & Transparency
- Protections – Apology in line with the provisions of the Act does not invalidate insurance, constitute an admission of liability or fault, and is not admissible in legal proceedings

Implementation

- These preparatory steps were required:

1. A **new module to the existing National Incident Management System (NIMS)** had to be designed, tested and implemented to facilitate the notification of certain serious patient safety incidents.

2. The **HSE** had to roll out their new open disclosure **training policy and communications plan** to all staff

3. Open Disclosure for patient requested reviews of cancer screening and the implementation of a communications programme regarding such reviews. **The HSE and Screening Services** had to currently finalise these processes.

Enactment & Implementation

- The Bill was passed by Dáil Éireann on 15 February 2023 and following passage through the Seanad, the Bill was enacted on **2 May 2023**.

- The Act was commenced on **26 September 2024** (other than Section 68)

- A regulation was passed on **2 October 2024**: S.I. No. 501/2024 - Patient Safety (Notifiable Incidents and Open Disclosure) Regulations 2024 – to provide required technical detail for 2 Notifiable Incidents

The Patient Safety Act 2023 – Notification System

Notifiable Incidents (Sept 2024 – April 2025)

Reference & Support

- **Patient Safety Act 2023**

Full text of the Patient Safety Act 2023 can be found at:

- https://data.oireachtas.ie/ie/oireachtas/act/2023/10/eng/enacted/a1023.pdf

DOH guidance on the Act can be found at:

- https://assets.hse.ie/media/documents/Department_of_Health_Patient_Safety_Act_2023_guidance.pdf

Thank You

WHO Global Patient Safety Webinar Series
Patient Safety Incident Reporting and Learning Systems (PSIRLS)
Friday 25th July 2025, 13.00pm – 15.00pm CEST I 7.00pm -9.00pm SG Time

SingHealth DukeNUS ACADEMIC MEDICAL CENTRE
Institute for Patient Safety & Quality

Incident Reporting & Learning Systems Singapore & Singapore Healthcare Services (SingHealth)

Prof Tan Kok Hian
Group Director and Senior Associate Dean
SingHealth Duke-NUS Institute for Patient Safety & Quality (IPSQ)

Incident Reporting & Learning Systems in Singapore

1. Regulated by MOH via the Healthcare Services Act (HCSA) 2020

Predecessor of HCSA is the Private Hospitals and Medical Centre (PHMC) Act (1980)

Under Section 51 (3) of the HCSA, an individual who is or was a member of a quality assurance committee appointed by licensee is not competent or compellable:

a) to produce before any court, tribunal, board or person any document in his possession or under his control that was created by, at the request of or solely for the purpose of the quality assurance committee; or

b) to disclose to any court, tribunal, board or person any information that has come to his knowledge as a member of the quality assurance committee.

2. Primary aim & exceptions

- Primary aim – learning and improvement
- Findings of review committee are not admissible in court
- Exceptions:
  - A criminal act or deliberate harm,
  - use of alcohol or illicit drugs,
  - a deliberate unsafe act, and
  - professionally unethical practice resulting in death or a clinical incident

3. Types, QAC, review & corrective actions, reporting to MOH

- Types of incidents to report (31 types)
- Each “Licensees”/Institution forms Quality Assurance Committees
- Monitor, review, evaluate serious reportable events
- Take corrective actions
- Report to MOH Clinical Quality, Performance and Value (CQPV) Division
- Provide updates to MOH CQPV on implementation of actions

Serious Reportable Events (SRE) 2023 Singapore

ADVERSE EVENTS	
I.	**Surgical or Other Invasive Procedure Adverse Events**
1.	Surgical or other invasive procedure performed on the wrong body site
2.	Surgical or other invasive procedure performed on the wrong patient
3.	Wrong surgical or other invasive procedure performed on a patient
4.	Wrong implant/prosthesis/invasive device inserted into a patient
5.	Unintended retention of a foreign object in a patient after surgical or other invasive procedure
6.	Intraoperative or immediately post-operative/post-procedure death in an American Society of Anesthesiologists (ASA) Class I patient, according to the American Society of Anesthesiologists Physical Status Classification System
II.	**Product or Medical Device Adverse Events**
7.	Patient death or serious injury associated with the use of contaminated drugs, medical devices or biologics provided by the prescribed licensee
8.	Patient death or serious injury associated with the use or function of a medical device in patient care
9.	Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a licensed premise
III.	**Patient Protection Adverse Events**
10.	Unauthorised discharge or release of an infant, a child or any person who lacks capacity, as referred to in section 4(1) of the Mental Capacity Act 2008
11.	Patient death or serious injury associated with patient abscondment
12.	Patient suicide, attempted suicide or self-harm that results in patient death or serious injury, while being cared for in a licensed premise
IV.	**Environmental Adverse Events**
13.	Any incident in which systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas or are contaminated by toxic substances
14.	Patient death or serious injury associated with a burn incurred while being cared for in a licensed premise
15.	Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a licensed premise
V.	**Care Management Adverse Events**
16.	Patient harm, death or serious injury associated with a medication error falling within Categories E to I of Appendix 2
17.	Patient death or serious injury or risk thereof associated with the unsafe administration of blood or blood products
18.	Transmission of communicable diseases following blood transfusion or organ/tissue transplant
19.	Maternal death or serious injury associated with pregnancy or delivery
20.	Infant death or serious injury associated with labour or delivery in a low-risk pregnancy
21.	Patient death or serious injury resulting from the irretrievable loss of a biological specimen
22.	Patient death or serious injury resulting from failure to follow up or communicate clinical test results
23.	Unexpected death[4] or serious injury as a result of lack of treatment or delay in treatment which could have been preventable otherwise
24.	Unexpected death[6] or serious injury as a result of medical intervention which could have been preventable otherwise
25.	Any assisted human reproductive procedure which has or, may have, resulted in insemination of wrong gamete or transfer of wrong embryo
VI.	**Radiological Adverse Events**
26.	Ionising radiological procedure performed on a wrong patient or site, or a wrong ionising radiological procedure performed on a patient
27.	Ionising radiological procedure performed on a pregnant patient
28.	Radiopharmaceutical and contrast media administered (i) to a wrong patient; (ii) through a wrong route; or (iii) with a wrong type or dose
29.	Radiation therapy delivered (i) to a wrong body site; (ii) to a wrong patient; or (iii) with a wrong dose
30.	Death or serious injury of a patient associated with the introduction of a metallic object into the magnetic resonance imaging (MRI) area
31.	PATIENT SAFETY INCIDENTS : unintended harm or risk of unintended harm to a patient while being cared for in a licensed premise

National directives for review of Serious Reportable Events (SREs)

Upon its identification of an SRE, the healthcare facility must:

- Immediately carry out a preliminary assessment to determine if the harm arising from the SRE has the potential to spread and affect a large number of people

- Notify the Clinical Quality, Performance and Value Division of MOH ("CQPV") **within two (2) working days** of the date of its identification of the SRE:
  - via the online reporting system, National Quality Assurance System ("NQAS"), or
  - in the event of network connection or technical issues, via electronic mail to the ministry

Persons appointed or assigned as members of the healthcare facility's SRE QAC shall include:

a) a doctor registered with the Singapore Medical Council ("SMC") who has experience in the relevant discipline;
b) a medical, nursing or allied health professional;
c) a non-clinical staff (e.g. an administrator, Quality Coordinator, Quality Manager
or equivalent); and
d) such other person(s) as the Director of Medical Services may appoint.

Peer review process.
Foster open sharing & trust

✓ Since 1999, under Section 11 of the Private Hospitals and Medical Clinics Act, hospitals are required to set up **Quality Assurance Committees** to facilitate the conduct of effective quality assurance programmes by **reviewing "the quality and appropriateness of services provided, and the practices and procedures carried out"** at the institution.

✓ In return, **members of the Quality Assurance Committees are granted protection from personal liability**, and their findings cannot be used as evidence that the service or practice was inadequate or inappropriate. Neither can they be compelled to disclose their findings before a court or tribunal.

✓ Such protection was **important** as the quality assurance programmes were based on a **peer review process**, which require doctors to evaluate and pass judgment on each other's professional performance, and removal of the possible legal consequences of participation has helped to facilitate the current high levels of **open sharing and trust** among healthcare professionals and institutions, both in the public and private sectors.

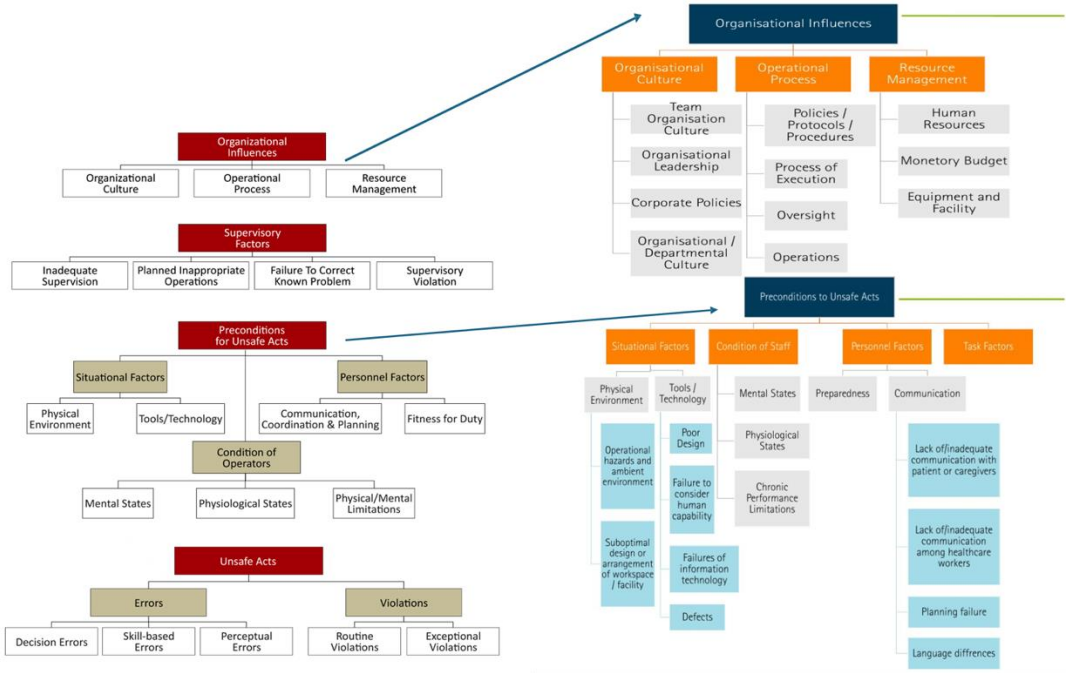
MOH Clinical Quality, Performance & Value (CQPV) Division

1. Provides guidance and training for incident investigation
2. MOH Serious Reportable Events (SRE) review guide
3. Collates and shares incidents occurring nationally with all Quality Officers
4. Conduct forums for sharing and discussion of clinical events
5. Direct conduct of RCAs for events that do not fit criteria but could have learning value

SRE Review Guide

- Reporting an incident
- Preparing for RCA
- Value of conducting RCA
- Conduct RCA
- Follow up of RCA findings and recommendations
- Leadership involvement

Included Human Factors Analysis & Classification System



Ministry of Health (MOH), and hospital leadership roles in patient safety & RCA oversight

Oversight of RCA Recommendations

Ensure that all recommendations arising from Root Cause Analyses (RCAs) are thoroughly implemented and completed in a timely manner.

Evaluation of RCA Quality

Review the quality of RCA reports and the relevance and strength of the recommendations made, providing guidance and advice to improve systemic learning and effectiveness.

Dissemination of Learning

Key learnings from RCA investigations are regularly disseminated across institutions with appropriate de-identification, using platforms such as internal emails, safety bulletins, or professional conferences to promote shared learning and prevention of recurrence.

Collaborative Learning Platform

A recent initiative includes **Joint MOH–Cluster Board Shared Responsibility Events (SREs)**, where significant cases and systemic issues are presented and discussed jointly by MOH, healthcare clusters, and board members to drive leadership accountability and system-level improvements.

SingHealth's approach

A **three-pronged approach** in its ERM implementation. Led by Office of Risk Services (ORS)

1 Data & Analytics

Through Cluster Incident Reporting System (Online since 2023) – includes M&M and SREs:

"Data Analytics" track comprises the gathering of risk related data for collation, analysis and trending to facilitate the following:

- Identification of common key risk areas that cut across the Cluster for addressing
- Initiation of projects/programmes to raise risk management performance

2 Education & Training

- Pre, conducing and post RCA

3 Sharing & Learning

Learnings from RCA and Recommendation shared at:

- Senior leadership platform
- Centres of excellences
- Cluster webinars
- Cluster bulletins
- Patient safety & quality archives on implemented improvements, results and lessons learned

Patient Safety Webinar

Foster cross sharing and learning for the Cluster

18 webinars included 2 at the World Health Organisation (WHO) platform

~5,000 attendees*

- ✓ The True Test of Resilience is now. What can we do to support our healthcare workers in a COVID-19
- ✓ ARTpreciate
- ✓ Patient Safety & COVID-19
- ✓ Medication Delivery Service and Tele-consultation – A new norm of providing pharmacy service?
- ✓ Together, We Can Achieve Safe Social Distancing
- ✓ Self-Care during a Pandemic
- ✓ Envisioning Healthcare after COVID-19
- ✓ Telepresence Robots & many other topics.....

* bi-weekly webinar from May 2020 with an average of 300 attendees per session.

Annual Patient Safety Week Kickoff Event

Recognize and Pledge for Patient Safety

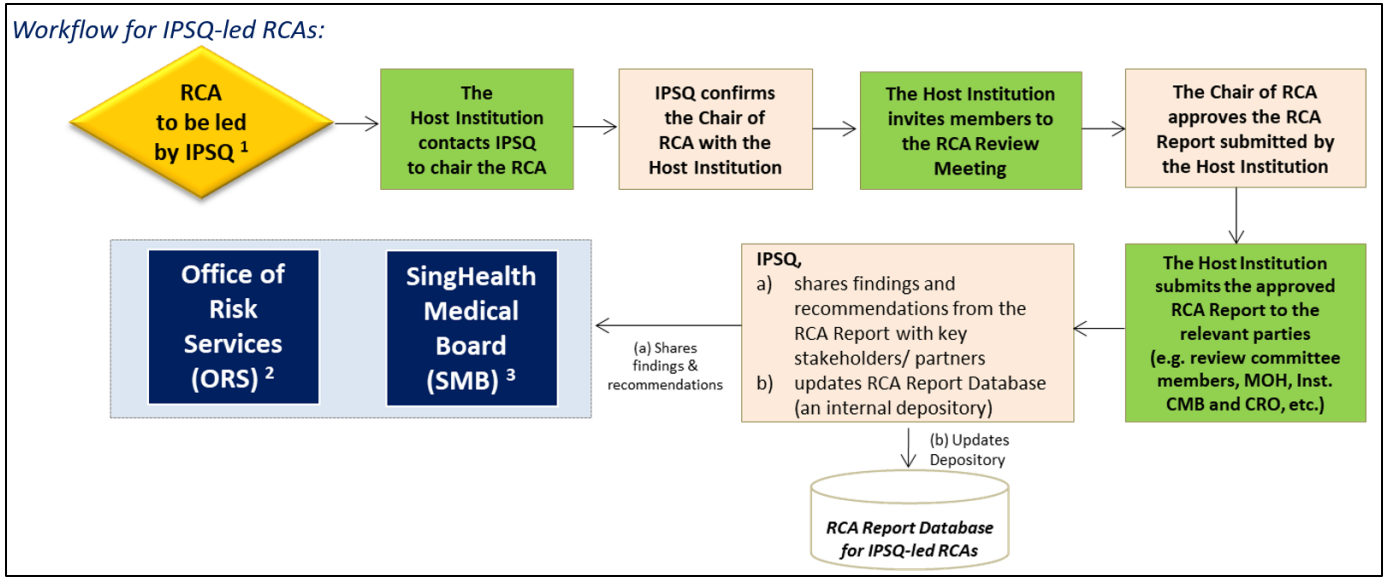
- Patient Safety Sharing via Webinar
- Virtual Target Zero Harm Award Ceremony
- Videoconferencing recital of SingHealth Patient Safety Pledge

RCAs shared through Institution as well as IPSQ bulletins for Organizational Learning

PSQI BULLETINS

1. Independent reviews led by IPSQ & learnings shared at various platforms

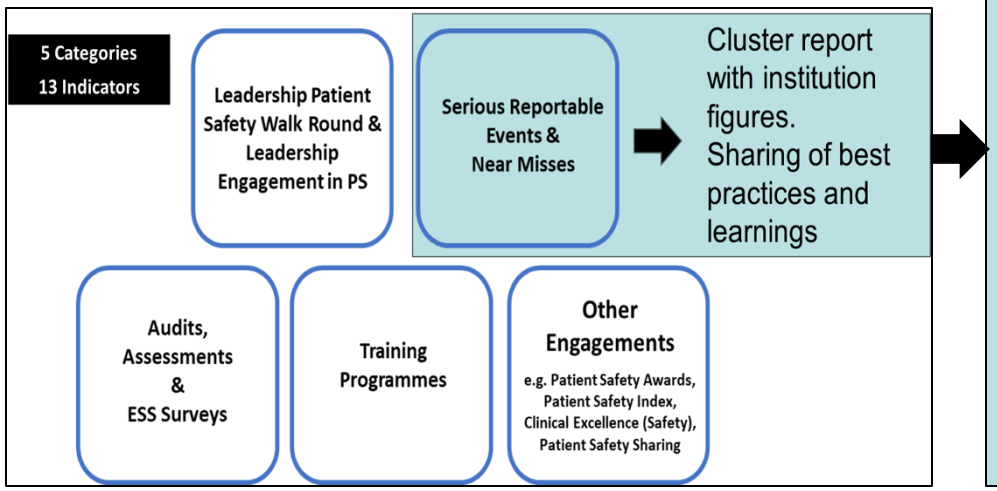
Workflow for IPSQ-led RCAs:

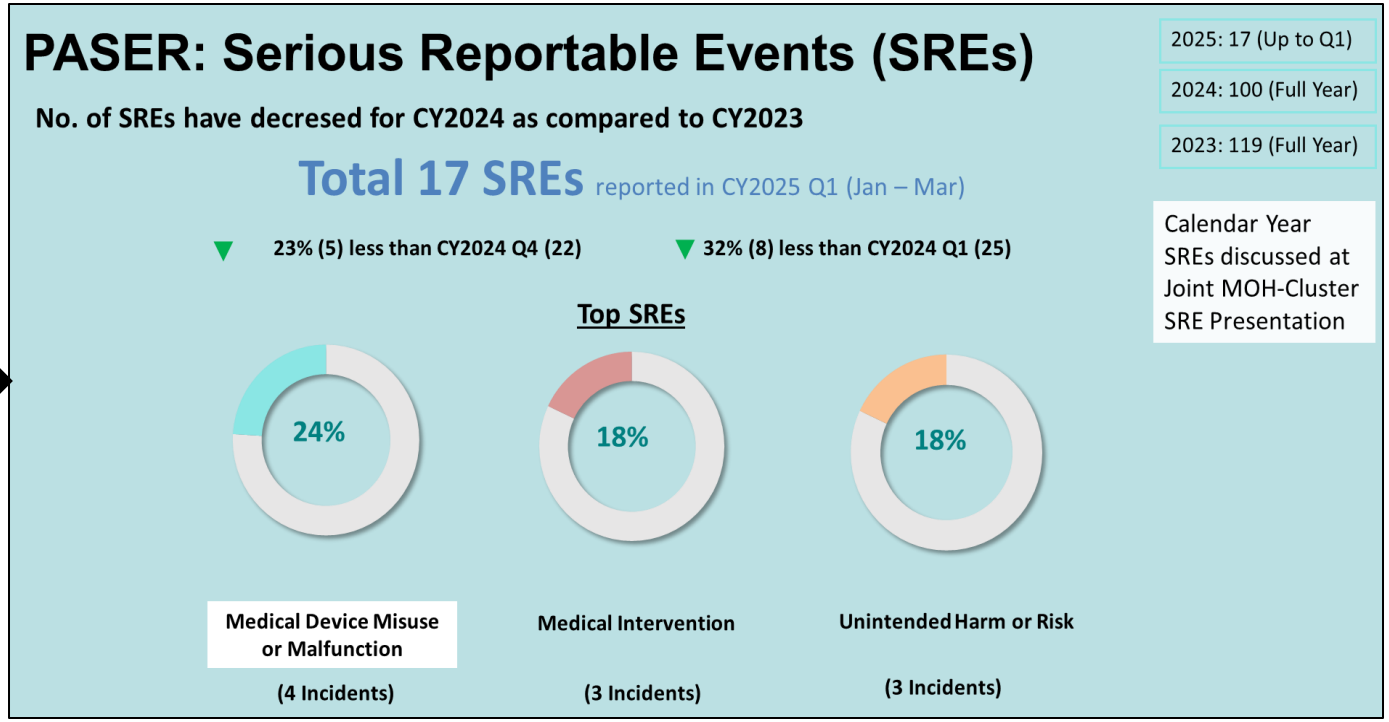


2. Patient Safety Engagement Report (PASER)

IPSQ prepares quarterly reports to cluster & institutions' c-suites

Aim: strengthen commitment & accountability for patient safety, patient safety culture, improvement efforts, & identify opportunities for cluster-wide sharing & learning



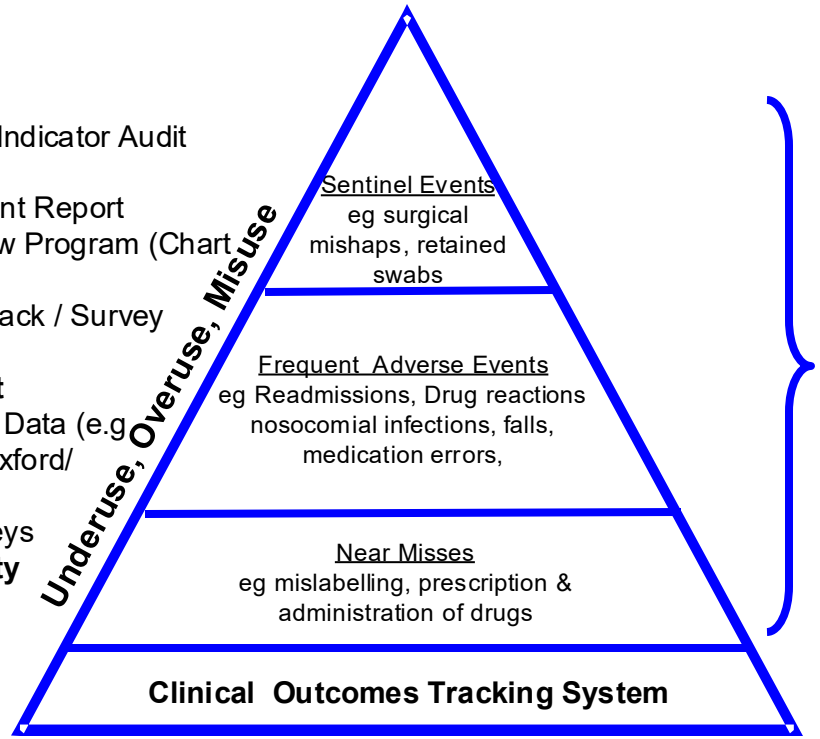


Patient Safety Learning System Framework

DETECTION **ANALYSIS** **IMPROVEMENT**

PSYCHOLOGICAL SAFETY WITH JUST CULTURE & ACADEMIC CULTURE

- SRE/ Clinical Indicator Audit Form
- Hospital Incident Report
- Clinical Review Program (Chart reviews)
- Patient Feedback / Survey
- Casemix Data
- **Clinical Audit**
- Benchmarking Data (e.g QIP/Vermont Oxford/ NSQIP)
- -JCI/ESS Surveys
- **High Reliability Assessments**



Sentinel Event Review /
Root Cause Analysis
Systems Thinking
Risk Assessment
FMEA

Review by QA / Peer Review Committees
(eg Divisional Medical Review, Medication Safety Committee, Infection Control Committee)
Clinical Audit and Review
Survey Gaps & Findings Analysis

Quality Improvement

- Clinical Practice Improvement Programme (CPIP)
- Process Improvement Projects (PIP)
- Clinical Pathways (CP)
- Div/Dept Process Improvements (e.g. Work Redesign, Protocols, Risk Management Activities)
- QA Programmes (eg QIP & Cluster & MOH Indicators
- Communities of Practice
- Collaborative Projects (e.g. MOH Collaboratives)
- Innovation

REPORT & SPREAD

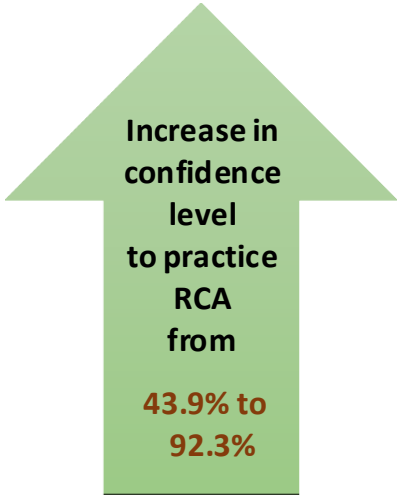
EFFECTIVE CHANGE MANAGEMENT & PLATFORM TO TEACH, LEARN, SCALE & SPREAD

Education & Training

Root Cause Analysis (RCA)

Programme in identifying and analyzing root causes in healthcare

- Appreciate the role of systems factors in problems and the importance of identifying fundamental systems issues in problem solving
- Understand the importance of Human Factors in system performance, problem analysis and problem solving
- Understand the Root Cause Analysis process and how to organize and carry out an effective Root Cause Analysis
- Understand the Root Cause Analysis process and how to organize and carry out an effective Root Cause Analysis
- Understand the use of relevant tools in Root Cause Analysis
- Be able to identify fundamental system issues (Root Causes) underlying a problem
- Understand the approach to development
- of effective solutions for a problem



"The activities were well thought out & relevant. Workshop was very application-based, helped to consolidate our learning. ″

"The real-life examples given by the speakers were eye-opening. ″

"Enjoyed it - interesting , practical and good pace ″

TeamCHOICE™

Programme in Making Safe Choices and Promoting Just Culture

Initiated a cluster programme to promote accountability and just culture

Level 1: E-learning *(Meant for all staff)*	Level 2: Workshop *(Meant for staff with supervisory role)*
Learning Objectives By the end of the course, participants will have an understanding of: 1. The Benefits of TeamCHOICE 2. The Different Behavioral Choices & Its Impact on Making Safe Choices 3. The Five Components of TeamCHOICE	**Learning Objectives** By the end of the course, participants will have an understanding of: 1. Importance of Just Culture in SingHealth 2. Human Choice & Fallibility 3. Event Investigation Basics for a Just Culture 4. Managing Human Choices & Behaviours 5. Using the Just Culture Algorithm

Formal Graduate Programs in Patient Safety & Healthcare Quality (PSHQ)

www.singhealthdukenus.com.sg/ipsq/acad

1. 1st Cohort Started in 2023 and 28 (14 Masters) graduated in May 2025
2. 3rd Cohort commencing in August 2025

Graduate Certificate

Conferred by
Duke-NUS Medical School (Duke-NUS)
- 4 courses
- 12 months part-time

Graduate Diploma

Conferred by
National University of Singapore (NUS)
- 5 courses (includes 1 Elective) + 1 Capstone Project
- 18 months part-time

Master's Degree

Conferred by
National University of Singapore (NUS)
- 8 courses (includes 2 Elective Courses) + 1 Thesis
- 24 months part-time

Winner of Interprofessional Education (IPE) Programme Excellence 2025
recognised for applying best practices in education philosophies and following a scholarly approach.

C1: Quality & Improvement Science
C2: Patient Experience & Engagement
C3: Clinical Governance & Risk Management
C4: Quality Patient Safety Science & Leadership for High Reliability in Healthcare

E1: Psychological & Workplace Safety
E2: Design Thinking & Human Factors in Healthcare
CM1: Patient Organizational Effectiveness & Global Health Leadership for Patient Safety
CM2: Education Approaches & Simulations in Patient Safety

Includes:
- **Root Cause Analysis to Facilitate Effective Problem Solving**
- **Applying a Systems Lens to Healthcare and Learning from Clinical Safety Incidents and Adverse Events**

SingHealth DukeNUS
ACADEMIC MEDICAL CENTRE

Institute for Patient Safety & Quality

Academic Medicine
improving patients' lives

TARGET ZERO HARM

SingHealth

WHO Guidance on Patient Safety Incident Reporting and Learning Systems

Dr Irina Papieva

Technical Officer

Patient Safety and Quality of Care Unit

WHO Headquarters

World Health Organization

Patient Safety

Global framework

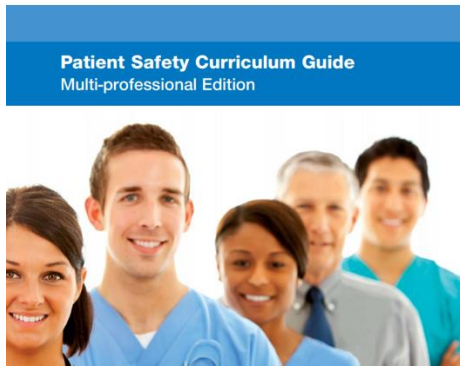
- **Global Patient Safety Action Plan 2021-2030**
- **Strategic Objective 6**: Ensure a constant flow of information and knowledge to drive the mitigation of risk, a reduction in levels of avoidable harm, and improvements in the safety of care
- **Strategy 6.1**: Establish or strengthen patient safety incident reporting and learning systems
- **Actions**: governments, health care facilities, stakeholders and WHO

World Health Organization

9789240032705-eng.pdf

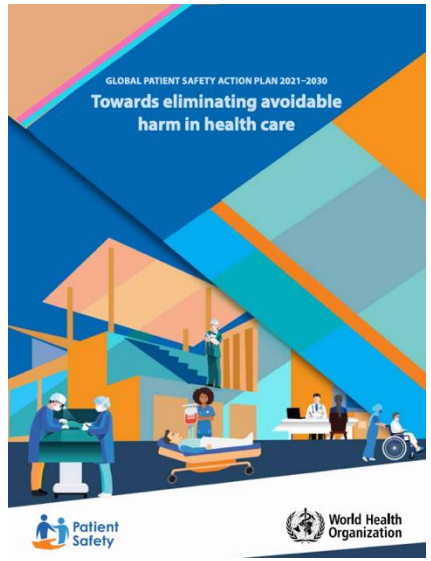
WHO’s guidance on PSIRLS

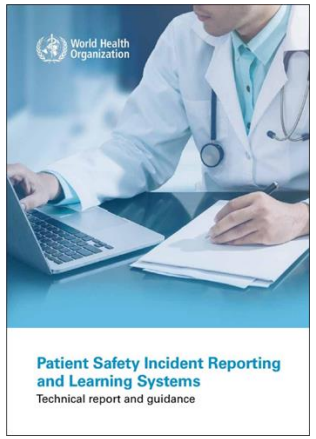
World Health Organization | Patient Safety

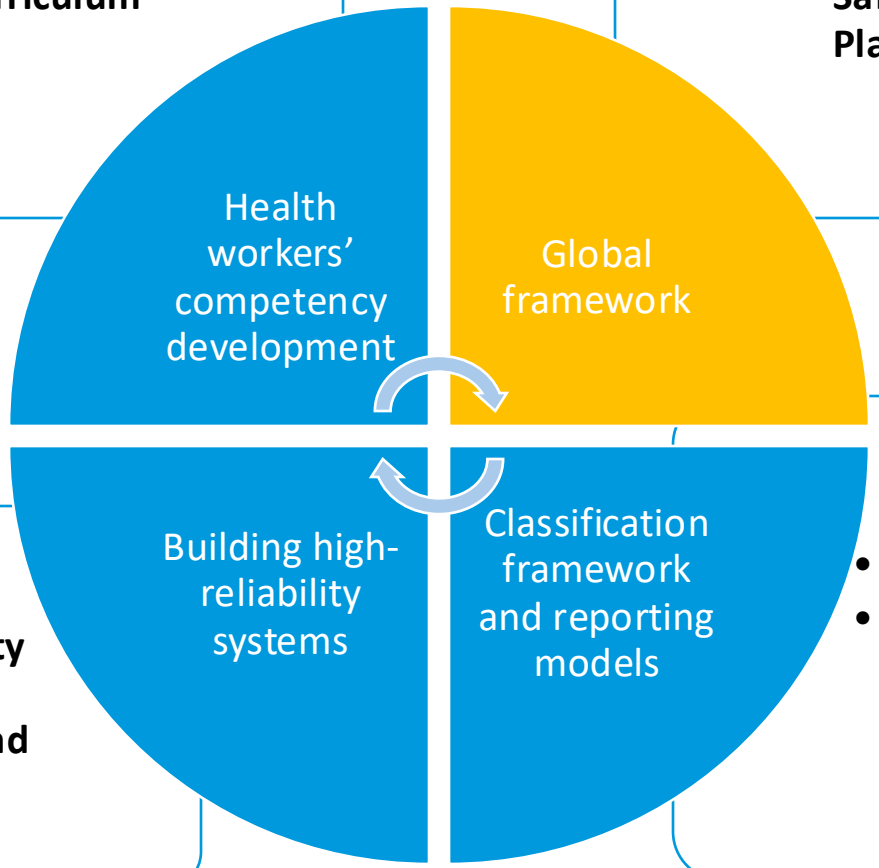


- **WHO Patient Safety Curriculum Guide**

- **Global Patient Safety Action Plan 2021-2030**

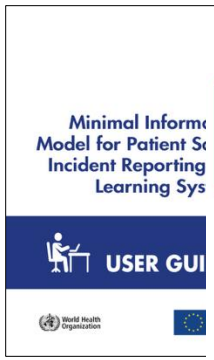






- **Patient Safety Incident Reporting and Learning Systems**

- **MIM PS**
- **Conceptual framework for International classification for Patient Safety**



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Key principles

- Reporting must lead to learning
- Non-punitive and just culture
- Voluntary and mandatory elements
- Confidentiality and data protection
- System-based analysis
- Timely feedback and communication
- Integration and alignment

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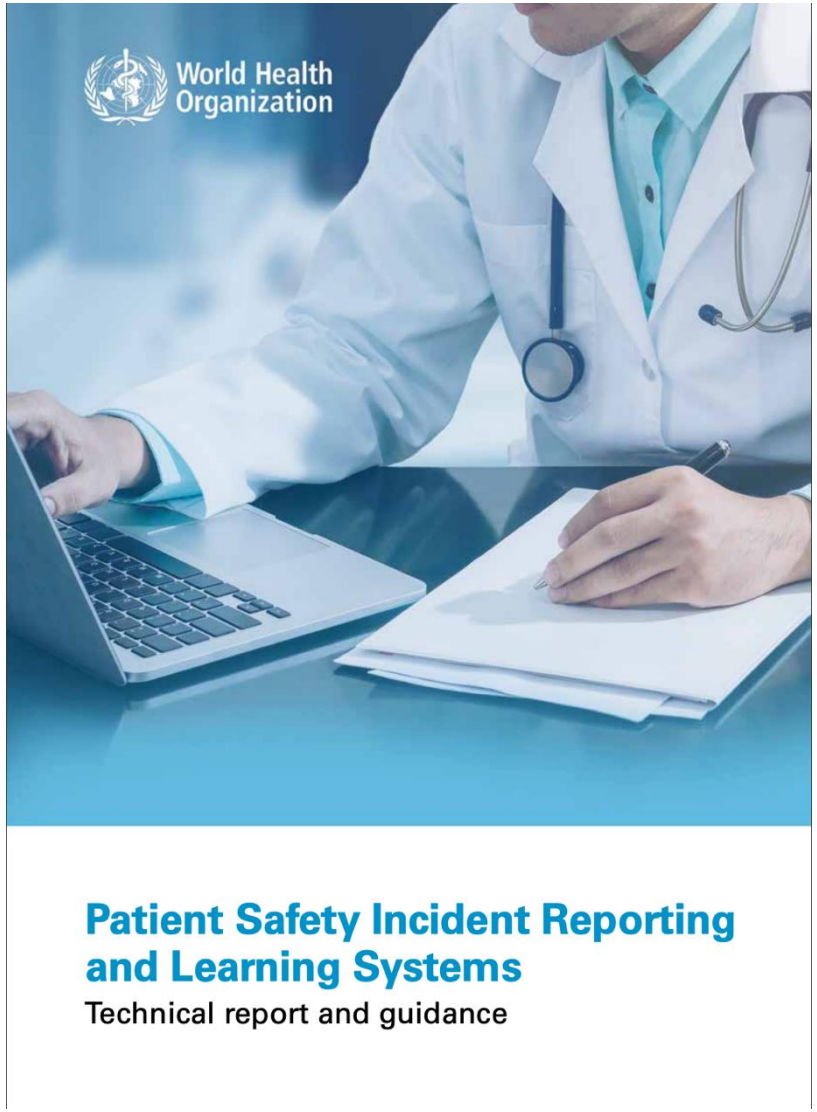

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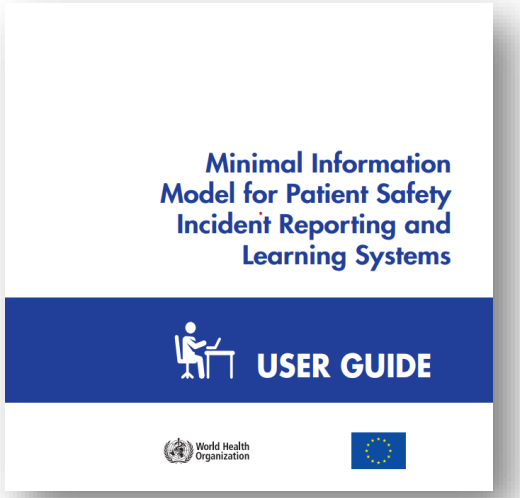
Minimum Information Model for PSIRLS



Purpose: provide a list of information categories that should be collected as a minimum when reporting an adverse event

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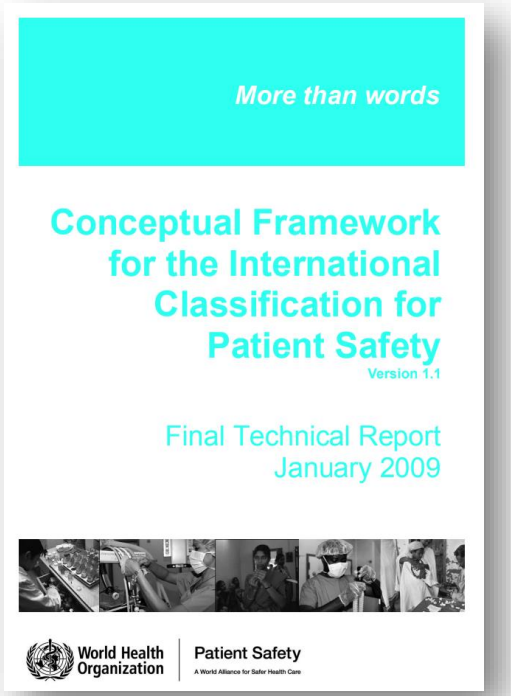
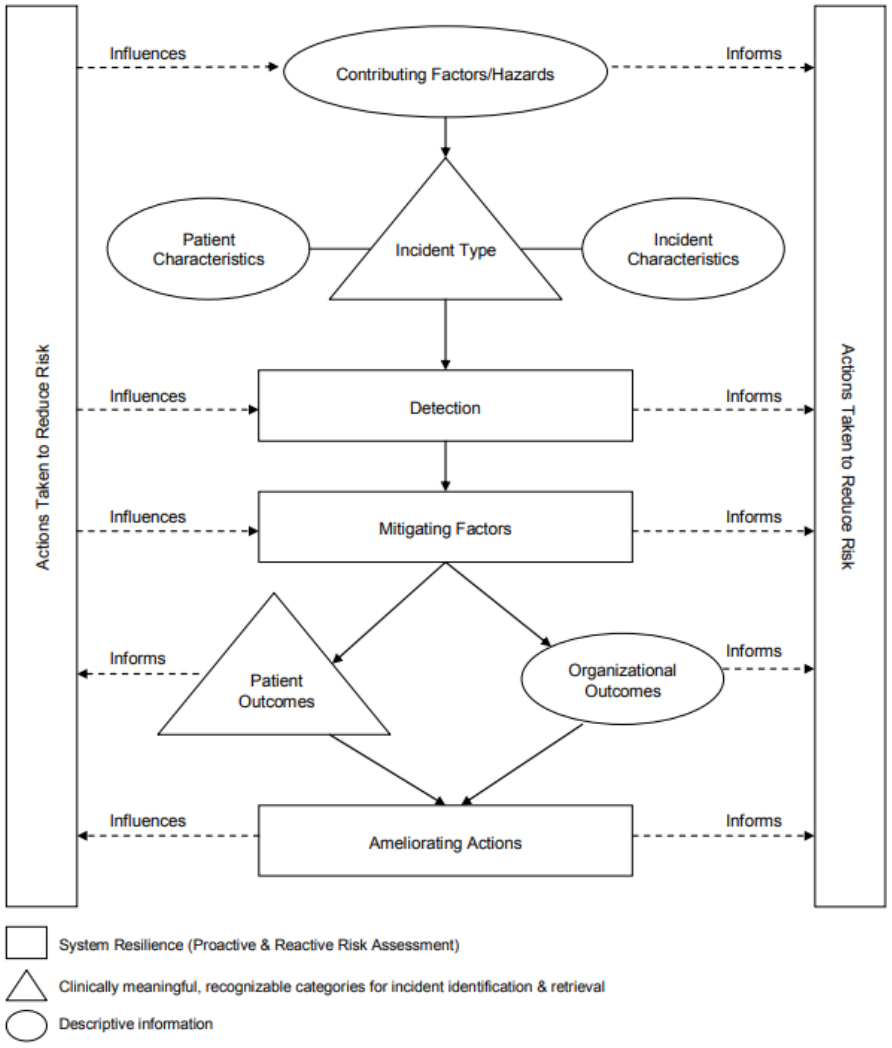
BASIC MIM PS	ADVANCED MIM PS
a) **Structured part**	a) **Structured part**
PATIENT INFORMATION	PATIENT INFORMATION
Age	Age
Sex	Sex
INCIDENT TIME	INCIDENT TIME
INCIDENT LOCATION	INCIDENT LOCATION
AGENT(S) INVOLVED	**CAUSES**
(Suspected) cause?	**CONTRIBUTING FACTORS**
Contributing factor?	**MITIGATING FACTORS**
Mitigating factor?	
INCIDENT TYPE	INCIDENT TYPE
INCIDENT OUTCOME	INCIDENT OUTCOME
RESULTING ACTION	RESULTING ACTIONS
REPORTER'S ROLE	REPORTER'S ROLE
b) **Free text part**	b) **Free text part**

The Conceptual Framework for the International Classification for Patient Safety





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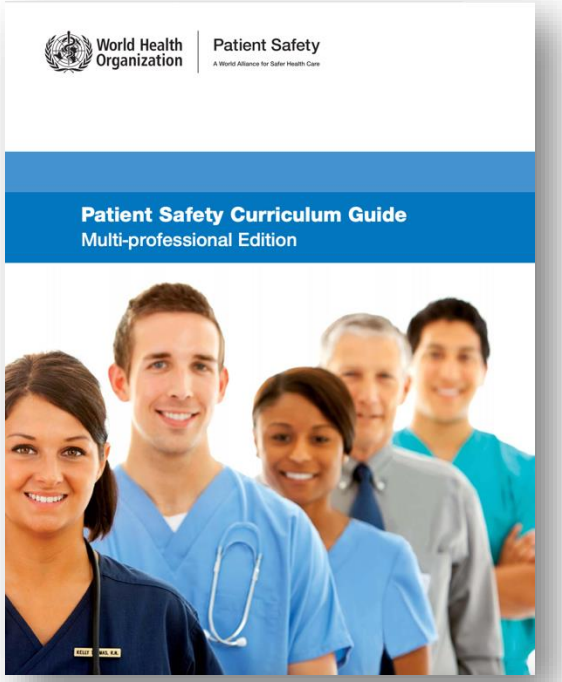
https://iris.who.int/bitstream/handle/10665/70882/WHO_IER_PSP_2010.2_eng.pdf

Capacity development



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[Who1-17 FirstPages]

Part B: Curriculum Guide Topics

Definitions of key concepts

Key to icons

Introduction to the Curriculum Guide topics

Topic 1: What is patient safety?

Topic 2: Why applying human factors is important for patient safety

Topic 3: Understanding systems and the effect of complexity on patient care

Topic 4: Being an effective team player

Topic 5: Learning from errors to prevent harm

Topic 6: Understanding and managing clinical risk

Topic 7: Using quality-improvement methods to improve care

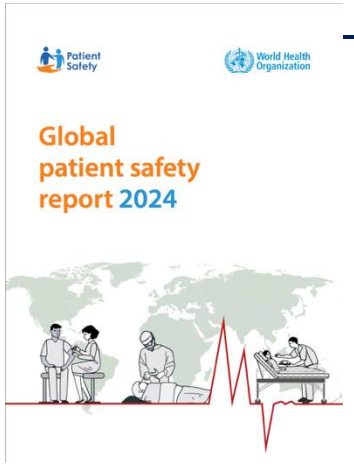
Topic 8: Engaging with patients and carers

Introduction to Topics 9-11

Topic 9: Infection prevention and control

Topic 10: Patient safety and invasive procedures

Topic 11: Improving medication safety



STRATEGIC OBJECTIVE

6

GPSAP Targets

Indicator

Number of countries that have 60% or more health care facilities participating in a patient safety incident reporting and learning system

Global targets

Percentage of countries with 60% or more health care facilities participating in a patient safety incident reporting and learning system

2022	Baseline established
2023	20% of countries
2025	40% of countries
2027	60% of countries
2030	80% of countries

Indicator

Number of countries that publish an annual report on patient safety

Global targets

Percentage of countries that publish an annual report on patient safety

2021	Baseline established
2023	20% of countries
2025	40% of countries
2027	60% of countries
2030	70% of countries

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Status of Patient Safety Incident Reporting and Learning Systems implementation and challenges

Dr Nikhil Gupta

Technical Officer

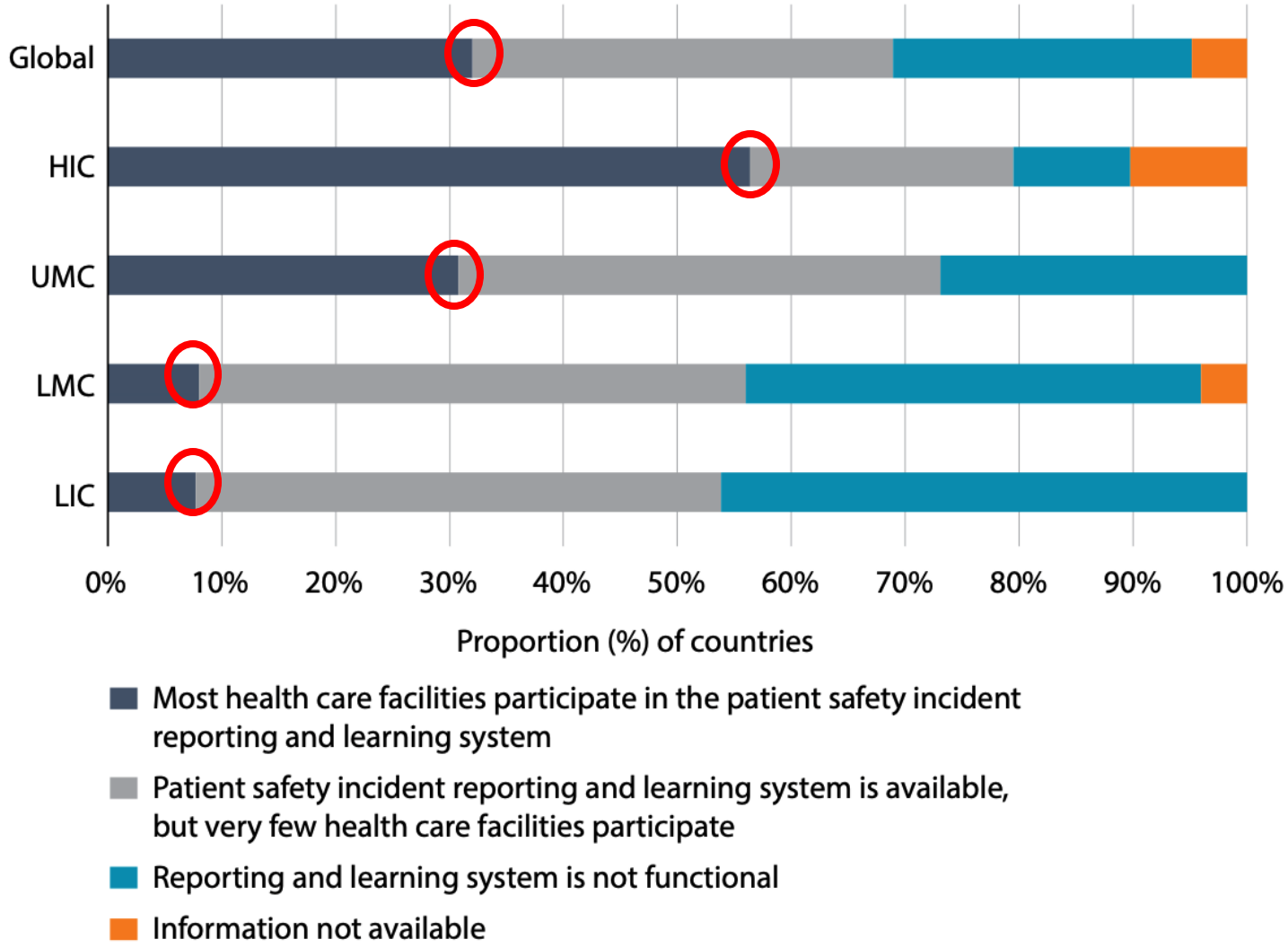
Patient Safety and Quality of Care Unit

WHO Headquarters

World Health Organization

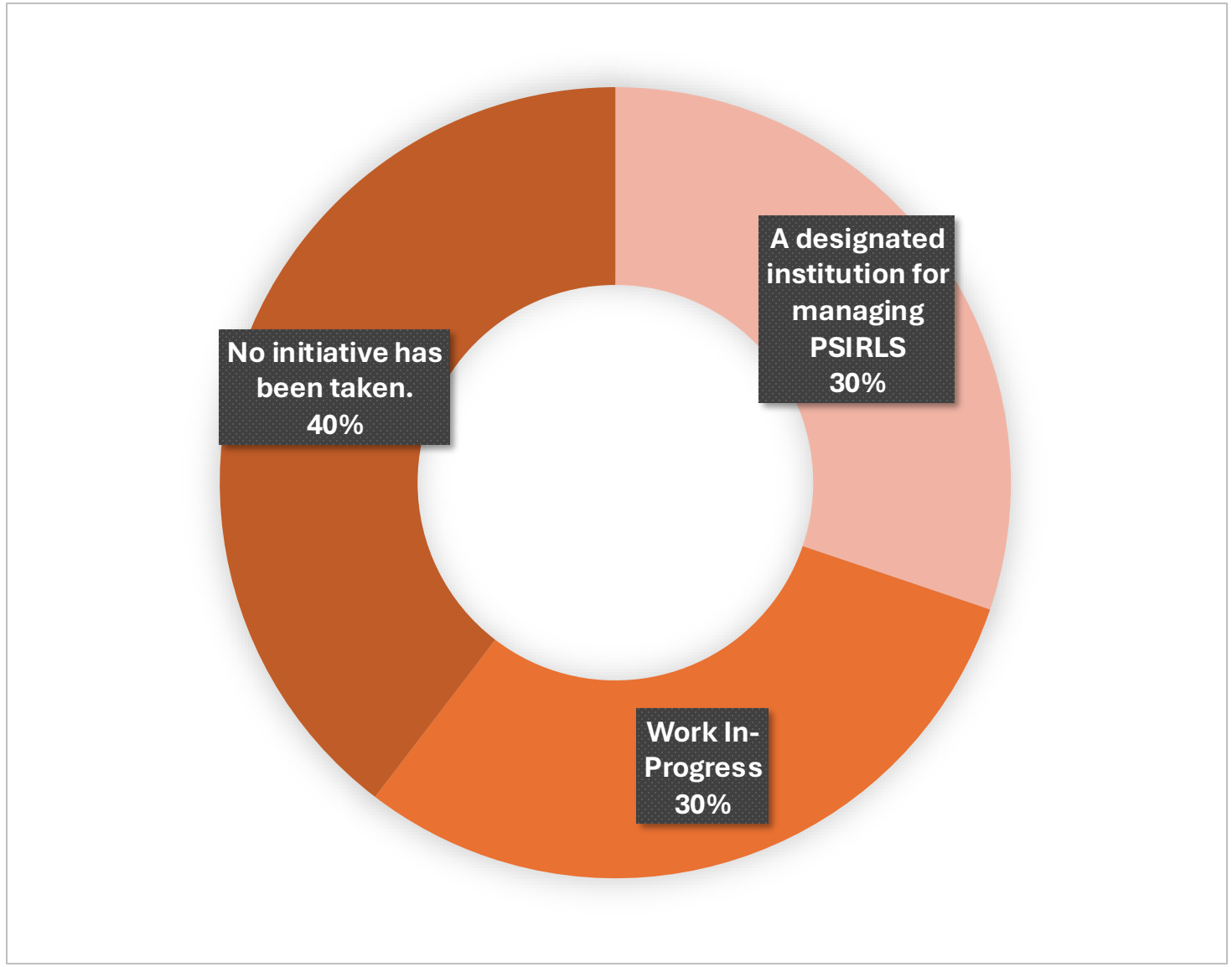
Patient Safety

Functionality of patient safety incident reporting and leaning systems



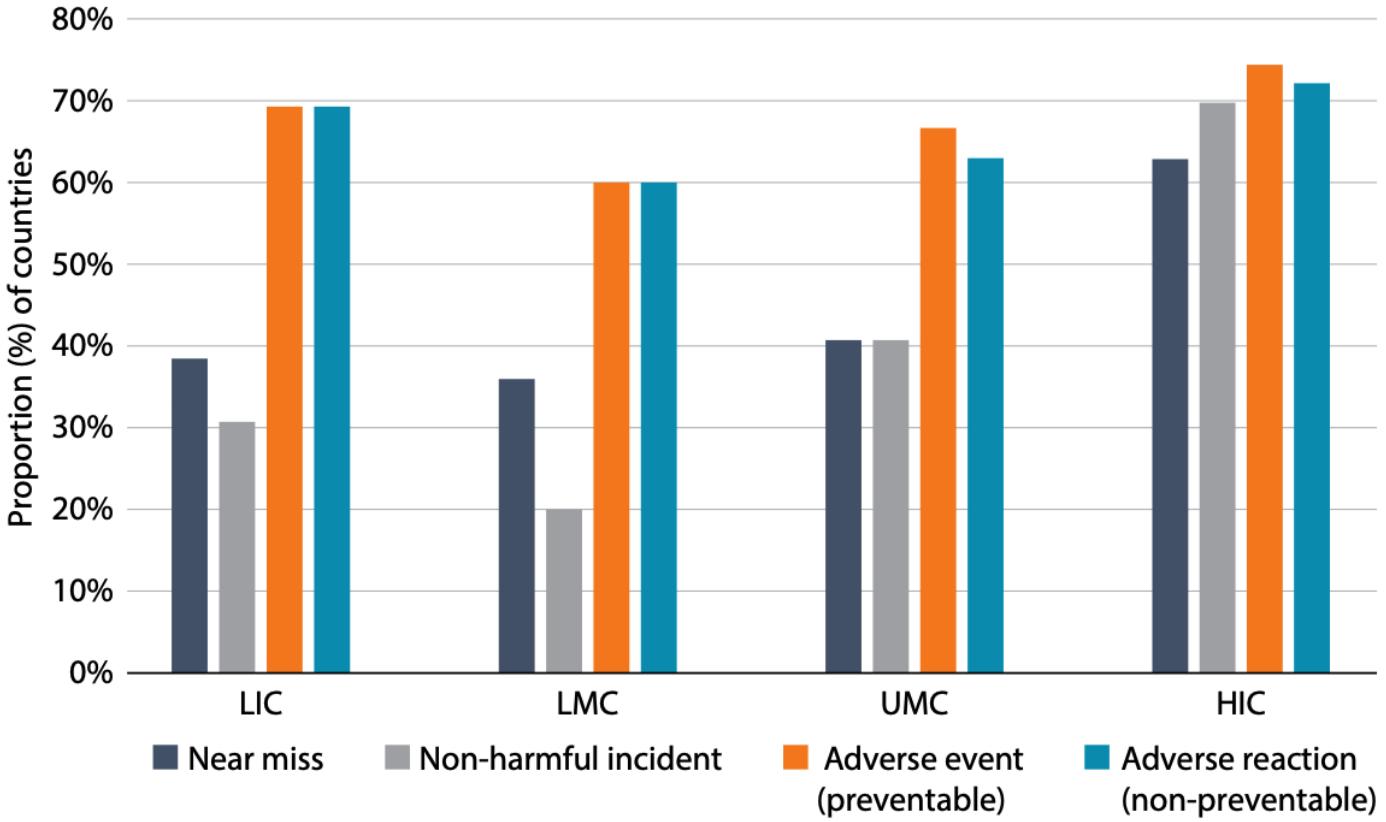
Systems are available, though their functionality and coverage are limited

Availability of a designated institution for managing PSIRLS



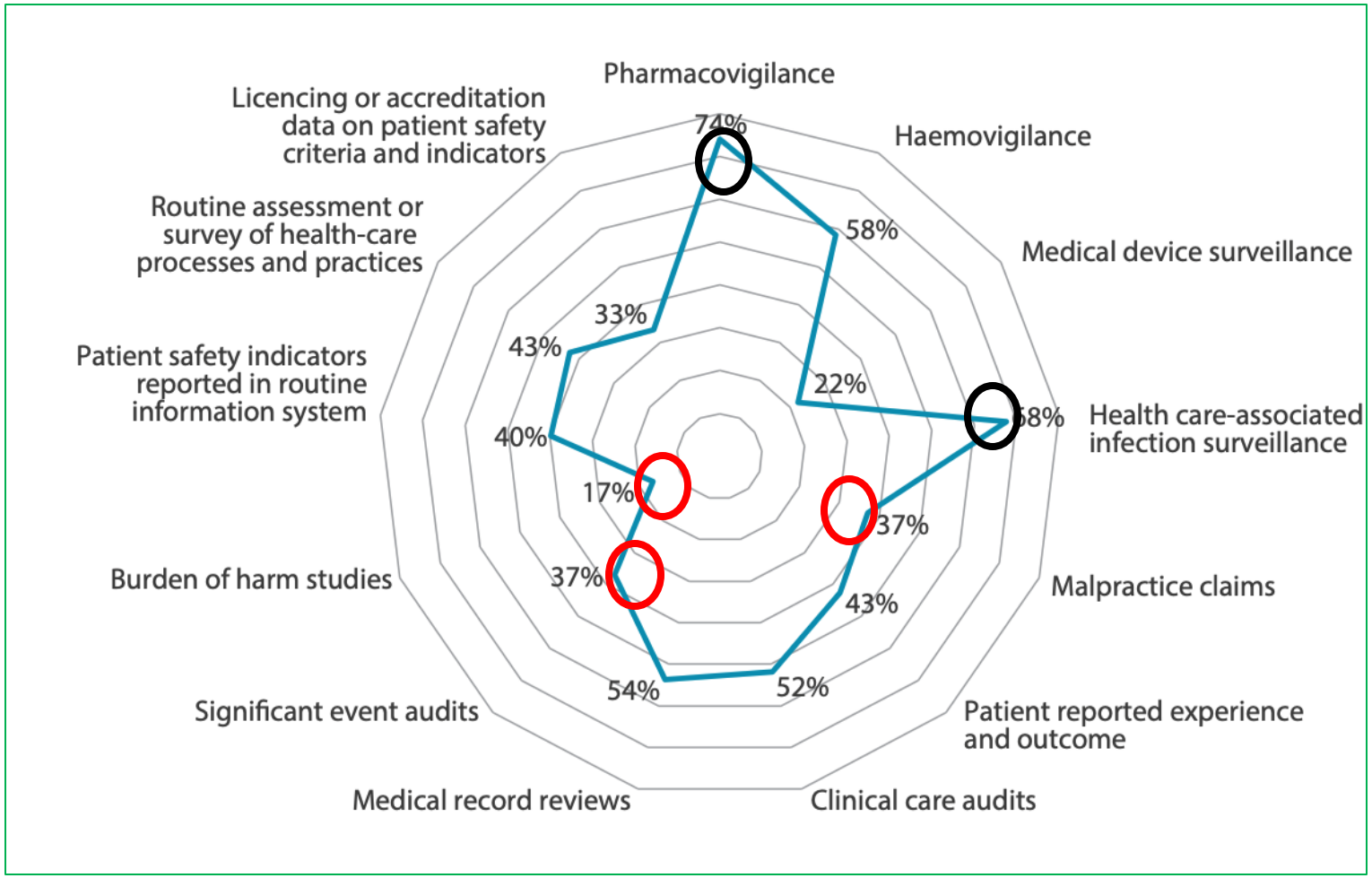
Many countries lack a designated body to oversee PSIRLS

Types of patient safety incidents reported



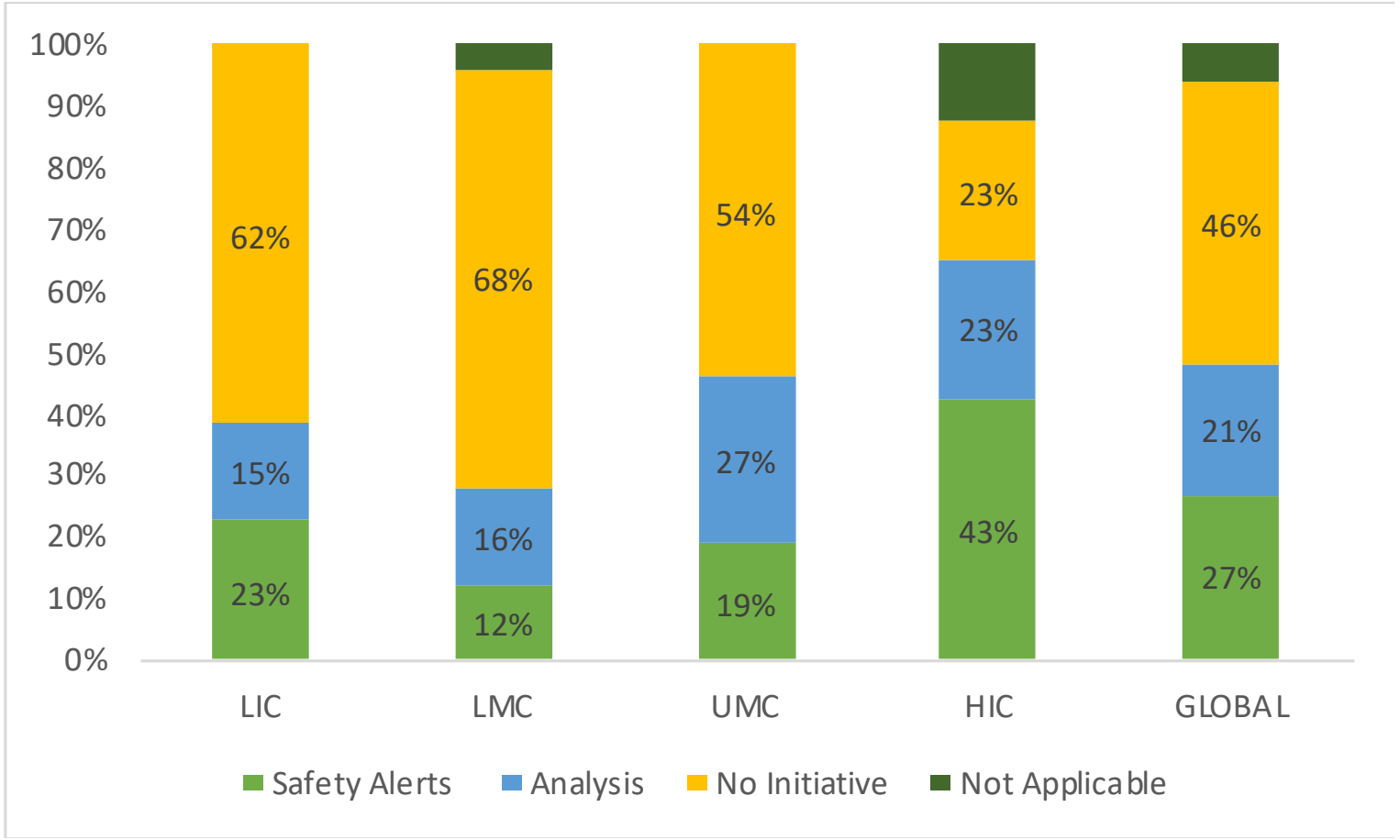
The spectrum of reported safety incidents differs across income groups

Global distribution of data sources utilized for surveillance of patient safety



There is untapped potential in understanding safety through various data sources

Analysis and Safety alerts



Capacity to analyze safety data and generate safety alerts remains severely limited

Challenges in implementing Patient Safety Reporting and Leaning systems

Lack of a centralized coordinating institution
Narrow focus on specific incident types
Underuse of data for improvement
Blame culture and fear of repercussions
Inadequate legal and policy frameworks
Resource and capacity constraints
Systems that are complex discourage reporting
Poor leadership support reduces system adoption
Little or delayed feedback lowers engagement
Too much data can overwhelm teams and hide real issues

Optimizing PSIRLS

Level	Strengths	Challenges
National level PSIRLS	• Comprehensive trend surveillance • Standardised taxonomy enabling macro-level risk signals • National alerts/toolkits scale quickly • Benchmarking across the system	• High reporting delay; data latency • Signal dilution from volume overload • Resource-intensive central analytics • Perceived remoteness reduces frontline feedback
Regional Level PSIRLS *(Provinces/states/Districts)*	• Balances data mass with manageability • Better compliance and protect reporting • Peer-to-peer learning within local context • Faster thematic reviews	• Fragmentation—varied taxonomies hinder cross-state comparisons • Uneven funding streams threaten sustainability • -Political shifts can disrupt priorities
Organizational level PSIRLS *(Individual hospitals, clinics, or healthcare organizations)*	• Immediate feedback shorter cycle times • High staff ownership interventions • Enables rapid microsystem improvements	• Limited ability to detect rare but catastrophic hazards Variable quality, under-reporting if blame culture persists • Lacks view of larger, multi-organization trends or systemic issues • Potential legal exposure without statutory protections

Thank You

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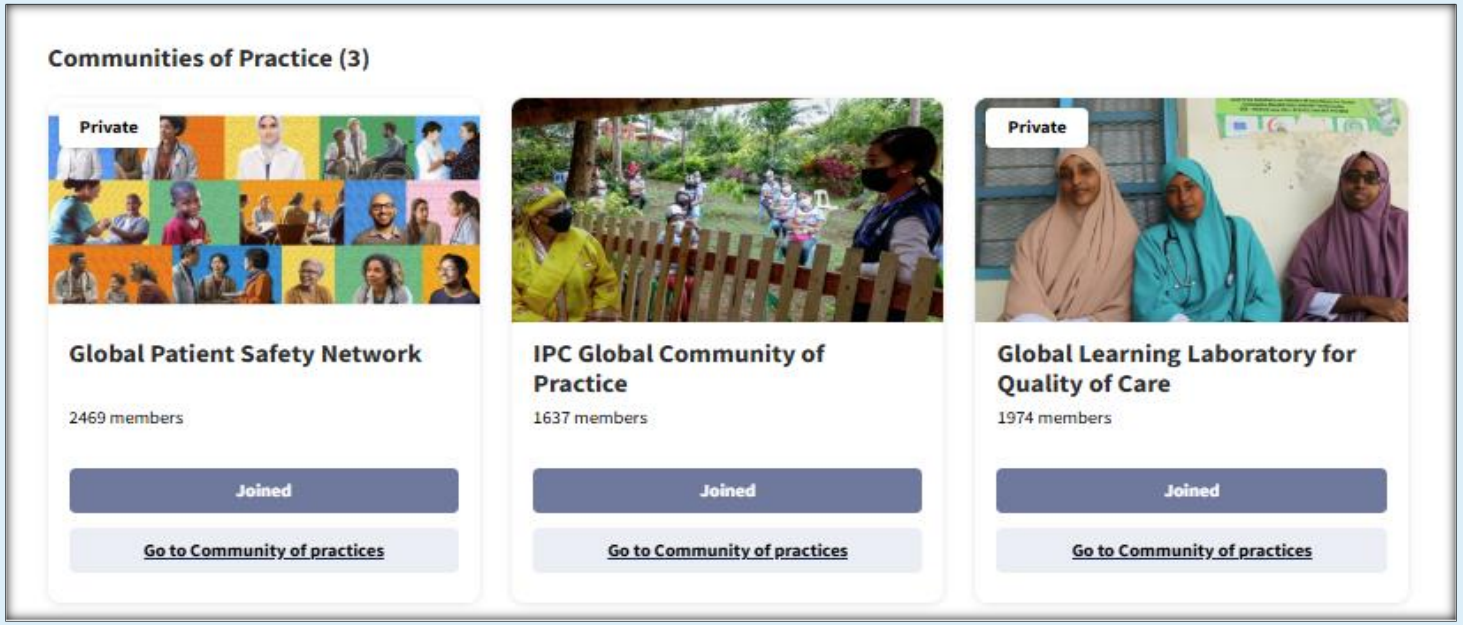

SCAN ME!

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Thank you

For more information, please contact:
patientsafety@who.int

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