



MINISTRY OF HEALTH MALAYSIA

Guidelines on Implementation

INCIDENT REPORTING & LEARNING SYSTEM

2.0

for Ministry of Health
Malaysia Hospitals



**Patient Safety Unit
Medical Care Quality Section**

Medical Development Division
Ministry of Health Malaysia

2017





**Guidelines on
Implementation –
Incident Reporting and
Learning System 2.0**
for Ministry of Health
Hospitals

Patient Safety Unit
Medical Care Quality Section
Medical Development Division
Ministry of Health Malaysia
2017

Copyright © Ministry of Health Malaysia

All rights reserved. This book may not be reproduced, in whole or in part, in any form or means, electronic or mechanical, including photocopying, recording, or by any information storage and retrieval system now known or here after invented, without written permission from the publisher.

Guidelines on Implementation - Incident Reporting and Learning System 2.0 for Ministry of Health Hospitals

First Edition 2017

Produced & Distributed by :

Patient Safety Unit,
Medical Care Quality Section,
Medical Development Division,
Level 4, Block E01, Complex E,
Federal Government Administrative Centre,
62590 Putrajaya.

ISBN :

| Content

PAGE

Acknowledgement	4
Advisor, Author & Co-Authors	5
Foreword by Director General Of Health Malaysia	6
Message From The Author	7
What Do Our Leaders Think of Patient Safety Incident Reporting & Learning System	8
Chapter 1 - Concept, Principle & Process of Incident Reporting & Learning System	12
Chapter 2 - Definitions of Key Concepts	18
Chapter 3 - About This Guideline	24
Chapter 4 - Use of Incident Reporting 2.0 Form	32
Chapter 5 - Definition of Incidents	44
Chapter 6 - Use of Incident Reporting & Learning System 'Prescription Slip'	50
Chapter 7 - Ministry of Health Malaysia Online Incident Reporting System : e-IR	54
Chapter 8 - Overview of Patient Safety Incident Investigation	62
Chapter 9 - Root Cause Analysis (RCA) & RCA ²	72
Chapter 10 - Multi Incident Root Cause Analysis (MIRCA)	82
Chapter 11 - Risk Reduction Strategies & Action Plan	88
Chapter 12 - Staff Responsibilities	96
Appendices	102
References	116

Acknowledgement :

The authors would like to gratefully acknowledge the following individuals and organisations, whose works have been referred to, in the preparation of this manual:

- The authors of the “1999 Quality Manual - Incident Reporting” and authors of the “2013 Incident Reporting & Learning System: from Information to Action Manual”.
- Hospitals involved in testing the new Incident Reporting Form IR 2.0 :
 1. Hospital Kuala Lumpur
 2. Hospital Tuanku Ja'afar Seremban
 3. Hospital Putrajaya
 4. Hospital Sungai Buloh
 5. Hospital Banting
- Team members of the Patient Safety Unit, Medical Care Quality Section, Medical Development Division, Ministry of Health Malaysia: Dr. Mohd Suffian Mohd Dzakwan, Mrs. Nurhaslina Nahar, Sister Sharmila Mat Zain and Mrs. Shazleen Zakariya.

All individuals and organizations that have contributed directly or indirectly to the production of this guideline. Immense gratitude is also extended in advance to everyone who will be involved in implementing this guideline.

Advisors :

YBhg. Datuk Dr. Noor Hisham bin Abdullah

Director-General of Health Malaysia
Ministry of Health Malaysia

YBhg. Datuk Dr. Jeyaindran Tan Sri Sinnadurai

Deputy Director-General of Health (Medical)
Ministry of Health Malaysia

YBhg. Dato' Dr Hj. Azman Abu Bakar

Director of Medical Development Division
Ministry of Health Malaysia

Dr. PAA Mohamed Nazir Abdul Rahman

Deputy Director of Medical Care Quality Section, Medical Development Division
Ministry of Health Malaysia

Author :

Dr. Nor'Aishah Abu Bakar

Senior Public Health Physician & Senior Principal Assistant Director
Head of Patient Safety Unit, Medical Care Quality Section, Medical Development
Division, Ministry of Health Malaysia
@ Chairperson of MPSG No.13 - Incident Reporting and Learning System

Co-Authors :

Dr Khairulina Haireen Khalid

Senior Principal Assistant Director
Medical Care Quality Section, Medical Development Division
Ministry of Health Malaysia

Dr Ahmad Muzammil Abu Bakar

Principal Assistant Director
Medical Care Quality Section, Medical Development Division
Ministry of Health Malaysia

Foreword By Director General of Health Malaysia



‘The practice of incident reporting and learning from the analysis of incident reports are amongst some of the most widespread patient safety improvement strategies used in healthcare, both within individual organisations and across the entire healthcare systems. The main aim is to use the incident to reflect upon on what is revealed about gaps and weaknesses in our healthcare system. In Ministry of Health, the Incident Reporting and Learning System has been in existence since 1999. Over the past 18 years, the number of patient safety incidents that have been reported to Ministry is quite small, amounting to 2,769 cases in 2016. There are three elements in the Incident Reporting and Learning System and they are - “Reporting, Responding and Sharing”. Reporting an incident alone without responding by investigating and taking action is certainly a waste. Taking action without considering the “effectiveness of action” will not solve the issues identified. Keeping the lessons learnt without sharing with others is certainly ill-advised and selfish. Hence it is about time that we transform the way things are being done and implement all three elements to make improvement that are of significance and impactful to our healthcare system.

The National Patient Safety Foundation has introduced RCA² which means Root Cause Analysis and Action. Its main objective is to emphasize the key element which are “responding” by taking “effective action” following an incident. To epitomise good clinical governance, leaders of healthcare organisations need to show tangible involvement in the implementation of the Incident Reporting and Learning System. Providing support and resources are necessary in implementing effective action. Hospital Directors, Head of Departments as well as senior staff need to be proactive and accountable in ensuring the smooth implementation of Incident Reporting and Learning System. Team work and excellent communication between the Hospital Directors, Risk Managers/Quality Managers, Departmental leaders/staff as well as the State Health Department and Ministry are essential. I hope with this new approach of reporting system which is “more comprehensive” and “more user friendly” as well as the production of this new guidelines which is informative, practical and easy to understand, will encourage hospitals to report and take effective action in preventing future harm to our patients. This is crucial in transforming our healthcare organisations towards becoming High Reliability Organisations. I would like to thank and congratulate each and everyone involved in the production of the new Incident Reporting Form 2.0 and the new Implementation Guidelines spearheaded by the Patient Safety Unit, Medical Care Quality Section of the Medical Development Division, MoH. May our passion, commitment and effort in striving to improve patient safety in this country grow from strength to strength. As Hellen Keller once said, “Alone we can do so little together, we can do so much”.



Datuk Dr. Noor Hisham Abdullah
Director General of Health Malaysia and
Chairman of Patient Safety Council Malaysia

Message From the Author

Dear readers,

I thought I should make some transformation in the way this book is written by making it simpler, practical and adding some element of "art" in it. I believe policy document should not be boring. Instead, it should be "exciting" and "informative" for everyone to read.

Hopefully the "passion" in PATIENT SAFETY can be felt and the "positive aura" of this book can be transmitted to you
... and together, we will form a "BIG TEAM TO CHAMPION PATIENT SAFETY".

All the best...

Nov' Michael Alan Baker
23 September 2017
L.



**WHAT DO OUR
LEADERS THINK
OF PATIENT SAFETY
INCIDENT REPORTING
& LEARNING
SYSTEM?**

**“Reporting itself does not improve safety.
It is the response to report that leads to change.”**

*Dr. PAA Mohamed Nazir b Abdul Rahman , Deputy Director
Medical Care Quality Section, Medical Development Division, Ministry of Health Malaysia*

“Incident Reporting...Report and Respond!”

*Dr. Nor'Aishah Abu Bakar,
Senior Public Health Physician, Head of Patient Safety Unit, MoH*

**“The IR is a double edged sword. We need to wield it carefully so that
we can cut away the incompetency and showcase our
healthcare system as a safe, patient centred and service focused.”**

*Dr. J Ravichandran R Jeganathan,
Head of Obstetric & Gynecology Service, Ministry of Health Malaysia*

**“An effective incident reporting system and good analysis are
crucial in achieving patient safety. This is what I can say about
incident reporting. Unfortunately, we are weak in analysis.”**

*Dato' Dr. Mohammad Anwar Hau Abdullah , Senior Consultant Orthopaedic Surgeon
Raja Perempuan Zainab II Hospital, Kota Bharu Kelantan*

“Managing incident reporting efficiently is a gift towards becoming a high reliability organization”

*Dr. Siti Zaleha Mohd Salleh,
Director of Selayang Hospital*

“No new learning process if no incident reporting... like a lock without the key.”

*Dato’ Dr. Khalid Bin Ibrahim ,
Director of Sungai Buloh Hospital*

“Incident reporting is the “pulse” of the hospital. It is very important to report. However, what is more important is getting to the “Root” of the issue!”

*Dr. Ding Lay Ming,
Director of Tengku Ampuan Rahimah Hospital, Klang*

“Making I.R System easier will improve Patient Safety.”

Dr. Asmayani binti Khalib, Director of National Cancer Institute, MOH

“Staff poor reporting is due to fear of blame and the complexity of reporting interfaces, rigid & difficult to administer”

*Dr Kuldip Kaur Prem Singh , Deputy Director (Medical),
Kuala Lumpur Hospital*

“Incident reporting contained in a learning system allows scrutiny of negative events leading to their better understanding and improvement opportunities; these when acted on can result in a perpetual positive healthcare impact.”

*Dr. Ahmad Tajuddin Mohamad Nor , Head of Department & Consultant
Emergency & Traumatology, Tengku Ampuan Rahimah Hospital, Klang*

“Let’s report..a gateway to life saving.”

*Dr. Azizul Awaluddin, Head of Department &
Consultant Psychiatrist, Putrajaya, Hospital*

“Incident reporting: Learning towards a safer care.”

*Dr. Saari bin Mohamad Yatim, Head of Rehabilitation Department,
Serdang Hospital*

“Incident Report is a key habit that creates safety culture.”

*Dr. Maizun binti Mohd Zain,
Head of Quality Unit, Kelantan State Health*

“Incident reporting is one of the important learning tools: we learn by reflecting on our experience from the incidents so that they won’t recur”

*Dr. Mithali Abdullah @ Jacqueline Sapen,
Director of Yan Hospital*

“The Malaysian IR System is very helpful in providing systematic records of incidents in hospital which can be analysed to identify risk and planning preventive measures”

*Dato’ Dr. Norsidah Bt. Ismail,
Director of Pulau Pinang Hospital*

“Biggest weakness is the dissemination of the learning which is limited to those involved or doing the investigation. A mechanism such as monthly tabling of the incidences, and learning points should be done. People don’t take it as learning but as a chore or duty to do so and get it over with”

*Dr. Andre Dass,
Head of Surgical Department, Kajang Hospital*

□ **Chapter 1**

Concept, Principle &
Process of Incident
Reporting & Learning
System

“REPORT, RESPOND & SHARE!”

“PRIMUM NON NOCERE.... ABOVE ALL DO NO HARM”

- This is the fundamental ethics of healthcare practitioners which highlight the importance of “**do no harm to patient**”.
- It is therefore pertinent for us to continually strive to reduce the occurrence of avoidable harm in healthcare through various **Patient Safety initiatives**.
- Incident Reporting is one of the **Patient Safety Tool** which can be **powerful** to prevent subsequent harm by learning from previous failures, if it used effectively.

WHAT IS INCIDENT REPORTING & LEARNING SYSTEM?

- It is a system of **reporting** patient safety incidents that happen in healthcare, **investigate or review** why the incident happen, learn from the incident, take appropriate **action** to prevent similar incident from happening and **share** with others.
- It involves “**holistic improvement of the system**” and not about “**finding an individual to be blamed**”.

WHAT ARE THE 3 MAIN ELEMENTS OF INCIDENT REPORTING?

“Report + Respond + Share = Incident Reporting & Learning System”

Report - when patient safety incident occur. Incident which result in “severe” patient outcome or “death” should not be left unreported.

Respond - this includes the following:

- Investigating the incident to find the weakness of the system
- Taking suitable action or control measures to improve the system. This may prevent similar incident from happening and also future incidents which have not happened

Share - with others about the lessons learnt from the incident to prevent similar incident from happening

WHY DO WE NEED INCIDENT REPORTING?

- It provides **valuable information** into why and how patients can be harmed in healthcare organization.
- The information can then be used to **improve** the healthcare system in a **holistic** manner.
- The lessons learnt can also be **shared** with others. Hence similar incidents can be **prevented**.

SOME OF THE NEGATIVE PERCEPTIONS ON INCIDENT REPORTING

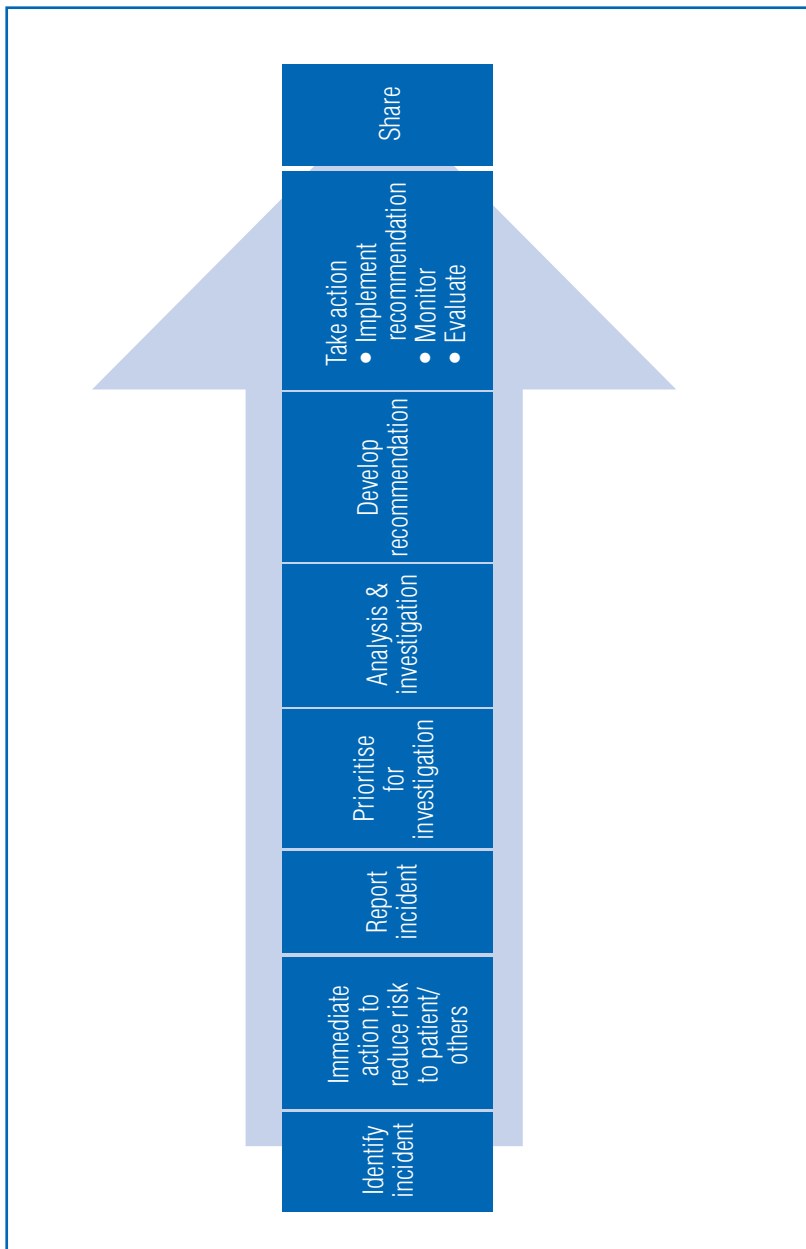
- Incident reporting is mainly about “filling up forms” and “paper work”.
- Patient Safety is all about incident reporting
- Incident reporting is about trying to find “the person to blame” or “trying to find fault”
- Incident reporting is a “waste of time”. Nothing is done following the reporting.
- If a person report an incident, he or she will be punished
- If number of reporting increases, the organisation will have “bad reputation”



10 WAYS ON HOW TO MAKE OUR INCIDENT REPORTING & LEARNING SYSTEM A SUCCESS?

- 1. Leadership** on patient safety is **clearly seen** by the staff and patient safety is an important agenda of all leaders.
- Each and every healthcare leaders and staff **understand “patient safety”** and the **principle** behind Incident Reporting.
- Reporting is “safe”** (i.e “non-punitive”) for the individuals who report (i.e the “reporter”)
- No “filter system”** to prevent incident report from being escalated up to relevant leaders at facility, state or national level.
- Expertise and resources** are available to allow/support meaningful analysis at various level of healthcare system – facility, state and national level
- Reporting leads to **“immediate action”** and **“visible improvement”** which is **impactful**.
- Incident reporting involves more **“active process”** with **“two-way engagement”** and **“participative improvement”** between the person who reports and the organisation.
- Actions should be:
 - Targeted on **“managing the risk”**, **“eliminating”** the “root cause” or “significant contributing factors” to the incident
 - “Doable, practical, effective”** which focus on the **“improvement of systems”** rather than being targeted at individual staff.
 - Creative, thinking **“out of the box”**, business process engineering, effective. Focus on “low lying fruits” which involve minimal resources.
 - Actions are being **“followed up”**, **“followed through”** for effectiveness.
- Resources and support** are available for implementation of action plan.
- The incidents and lessons learnt are **shared** with others.

Key Steps In Managing Patient Safety Incident





□ **Chapter 2**

Definitions of Key
Concepts



“KNOWLEDGE
IS POWER...”

Definitions

- **Adverse event:** An injury that was caused by medical management or complication instead of the underlying disease and that resulted in prolonged hospitalization or disability at the time of discharge from medical care or both.
- **Adverse reaction:** Unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred.
- **Agent:** a substance, object or system which acts to produce change.
- **Complication:** Include the following :
 - o A detrimental patient condition that arises during the process of providing health care, regardless of the setting in which the care is provided.
 - o A diagnosis occurring during hospitalization that is thought to extend the hospital stay at least one day for roughly 75% or more of the patients.
 - o A disease or injury that arises subsequent to another disease and/ or health-care intervention.

- **Contributing factor:** A circumstance, action or influence (such as poor rostering or task allocation) that is thought to have played a part in the origin or development, or to increase the risk, of an incident. Contributing factors may be external (i.e., not under the control of a facility or organization), organizational (e.g., unavailability of accepted protocols), related to a staff factor (e.g., an individual cognitive or behavioral defect, poor team work or inadequate communication) or patient-related (e.g., nonadherence). A contributing factor may be a necessary precursor of an incident and may or may not be sufficient to cause the incident.
- **Disability:** Any type of impairment of body structure or function, activity limitation and/ or restriction of participation in society, associated with past or present harm.
- **Error:** Failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase. It is unintentional.
- **Event:** Something that happens to or involves a patient.
- **Failure Mode :** The manner in which a process has failed or could fail or the manner in which a failure is observed.
- **Failure Mode and Effect Analysis (FMEA) :** A risk assessment method based on the simultaneous analysis of failure modes, their consequences and their associated risk factors.
- **Harmful incident (adverse event):** An incident which resulted in harm to a patient
- **Harm:** Implies impairment of structure or function of the body and/ or any deleterious effect arising there from harm, of impairment of body structure or function, activity limitation and/ or restriction of participation in society, associated with past or present harm.
- **Hazard:** A circumstance, agent or action with the potential to cause harm.
- **Health:** A state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity.
- **Healthcare:** Services received by individuals or communities to promote, maintain, monitor or restore health.
- **Healthcare-associated harm:** Harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury.
- **Human factor:** Study of the interrelationships between humans, the tools, equipment and methods they use, and the environments in which they live and work.

- **Incident** : Refer to definition of ‘patient safety incident’
- **Near miss**: An incident which did not reach the patient.
- **No harm incident**: One in which an event reached a patient but no discernable harm resulted
- **Patient**: A person who is a recipient of healthcare.
- **Patient outcome**: The impact upon a patient which is wholly or partially the severity and duration of any harm, and any treatment implications, that result from an incident.
 - o **None** – patient outcome is not symptomatic or no symptoms detected and no treatment is required.
 - o ***Mild** – patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g., extra observation, investigation, review or minor treatment) is required, increase length of stay (up to 72 hours)
 - o ***Moderate** – patient outcome is symptomatic, requiring intervention (e.g., additional operative procedure; additional therapeutic treatment), an increased length of stay (more than 72 hours to 7 days) .
 - o ***Severe** – patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, an increased length of stay (more than 7 days), shortening life expectancy or causing major permanent or long term harm or loss of function.
 - o **Death** – on balance of probabilities, death was caused or brought forward in the short term by the incident.

*Some amendment is made from the original WHO definition in order to prevent confusion. Additional information is used using definition from Government of Western Australia, Department of Health- Clinical Incident Management Toolkit, 2016

- **Patient Safety**: The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum; Absence of preventable harm to a patient during process of health care.
- **Patient safety incident**: an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient. An incident can be a reportable circumstance, near miss, no harm incident or harmful incident (adverse event).
- **Reportable circumstance**: a situation in which there was significant potential for harm, but no incident occurred.
- **Risk**: The probability that an incident will occur.

- **Risk assessment:** An assessment that examines a process in detail, including sequencing of events; assesses actual and potential risk, failure, or points of vulnerability; and, through a logical process, prioritizes areas for improvement based on the actual or potential patient care impact (criticality).
- **Root cause:** The original cause for the failure or inefficiency of a process; The most fundamental reason an event has occurred.
- **Root cause analysis:** A systematic iterative process whereby the factors that contribute to an incident are identified by reconstructing the sequence of events and repeatedly asking “why” until the underlying root causes (contributing factors or hazards) have been elucidated.
- ****RCA²** : Traditionally, the process employed to accomplish this learning has been called root cause analysis (RCA), but it has had inconsistent success. To improve the effectiveness and utility of these efforts, concentration need to the given to on the ultimate objective: preventing future harm. Prevention requires actions to be taken, and so NPSF have renamed the process Root Cause Analysis and Action, RCA² (RCA “squared”) to emphasize this point.
- **Risk management:** The process of identification, assessment, analysis and management of all risks and incidents for every level of the organization, and aggregating the results at a corporate level, which facilitates priority-setting and improved decision-making to reach optimal balance of risk, benefit and cost.
- **Safety:** The reduction of risk of unnecessary harm to an acceptable minimum.
- **Sentinel Event:** Patient safety event that reaches a patient and results in any of the following- death , permanent harm or severe temporary harm and intervention is required to sustain life .Such events are called “sentinel” because they signal the need for immediate investigation and response.
- **Violation:** deliberate deviation from an operating procedure, standard or rule.

REFERENCES

- World Health Organization 2009, Conceptual Framework for the International Classification for Patient Safety Version 1.1
- *Government of Western Australia, Department of Health- Clinical Incident Management Toolkit, 2016
- **National Patient Safety Foundation. RCA² Improving Root Cause Analyses and Actions to Prevent Harm Version 2, 2016

□ **Chapter 3**

About This Guideline



The Evolution...

- “Incident Reporting” started as part of Quality Assurance tool in MOH Hospitals. First document on Incident Reporting was produced as part of Quality Manual in 1999.
- A specific policy and guideline on Incident Reporting & Learning System 1.0 was produced in 2013 as part of Patient Safety initiative, to learn from error and improve healthcare system.
- In 2013, the scope of IR implementation was extended to all healthcare facilities in Malaysia when Incident Reporting and Learning System was included as one of the Malaysian Patient Safety Goals.
- In Ministry of Health hospitals, IR system is further strengthen with the development of National online reporting, e-IR.
- This new Incident Reporting & Learning System 2.0 is produced based on the feedback of the implementers and Ministry’s aspiration in improving Patient Safety further and to be High Reliability Organisation.

- This is the reason why incidents should not be ignored and should be seen as an opportunity for improvement. Although priority should be given to incident with “severe” patient outcome or death, ‘near miss’ that could have resulted in serious harm or death should also be taken seriously, reviewed and managed before actual harm occurs.
- Modification has also been made in the format of the IR form 2.0 and the process involved, to make it user friendly, more efficient and fair.

Objectives of The Guidelines

1. To disseminate important knowledge on patient safety and incident reporting which is crucial in ensuring successful implementation of Incident Reporting and Learning System
2. To disseminate relevant information on the implementation of the new Incident Reporting and Learning System 2.0 - The technical “know how” and “process involved”
3. To highlight responsibilities of each healthcare staff in the organisation in making this system a success.
4. To inspire and motivate each and every healthcare staff in the organisation to improve patient safety by using Incident Reporting and Learning System.

New Approach To The IR 2.0 Form

This form was formulated based on the feedback received from hospital staff since the implementation of IR 1.0 Form in 2013 and various engagement sessions with hospital staff of various categories. Pilot study to test the new IR 2.0 Form was also conducted in 2017 involving 5 hospitals. Further improvement was made based on the findings of the study. The new approach of the form include:

1. **“Simpler, more user friendly”** - IR 2.0 Form mainly involves “fill in the blanks” and “ticking boxes”. Narrative text is minimal.

2. “Shorter process”

- a. Reporting involves 2 persons which are (i) “reporter of incident” (person who reports the incident) or “witness” and (ii) “Risk Manager/Quality Manager”.
- b. This will speed up the process of reporting from Departmental level to Hospital level
- c. Prevent reporting of incidents from being “blocked” at Departmental level and not escalated to Hospital level

3. “Open concept of reporting”

- a. Previous concept of “mandatory incidents that need to be reported” has been changed to “open concept of reporting”.
- b. This means **ALL “patient safety incidents” that happen, “near miss”** need to be reported.
- c. Nevertheless, examples of incidents that need to be reported are included to remind staff and not to be missed.
- d. Despite the “open concept of reporting”, Risk Manager/ Quality Manager should be able to identify and prioritize:
 - i. Incidents which lead to “severe” patient outcome or death
 - ii. ‘Near miss’ that could have resulted in serious harm or death

4. “Incident Reporting & Learning System Prescription Slip”

- a. The main use of this “Prescription Slip” is to facilitate communication and as a “simple feedback message” from the Risk Manager/ Quality Manager to the relevant leaders of Department/ Ward/ Clinics where the incident or near miss has happened.
- b. This can be given to the Head of Departments, Head of Unit, Nursing Matrons/ Sisters, Supervisors etc, staff involved in the incident, staff witness the incident

MOH Malaysia Incident Reporting Form 2.0

SULIT



MINISTRY OF HEALTH MALAYSIA
PATIENT SAFETY INCIDENT REPORTING FORM



IR 2.0/2017

*Borang boleh diisi dalam Bahasa Malaysia

DATE OF REPORTING: ___ / ___ / ___

SECTION A: TO BE COMPLETED BY THE REPORTER OF THE INCIDENT																											
INCIDENT DESCRIPTION (Please fill in the blanks)																											
1.	NAME OF FACILITY/ INSTITUTION	PATIENT'S NAME																									
2.	<input type="text"/> / <input type="text"/> / <input type="text"/>	DATE OF INCIDENT	IF UNCERTAIN APPROXIMATE DATE: ___ / ___ / ___																								
3.	<input type="text"/> : <input type="text"/> AM/PM	TIME OF INCIDENT	IF UNCERTAIN APPROXIMATE TIME: ___ : ___ AM/PM																								
4.	PATIENT'S RN/ OTHER IDENTIFICATION NUMBER : _____ AGE: _____ ETHNIC: _____ GENDER : MALE / FEMALE / UNKNOWN STATUS : ALIVE / DECEASED LANGUAGE BARRIER: YES / NO (please circle) DIAGNOSIS : _____																										
5.	TYPE OF PATIENT (please tick one) <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="text-align: center;"><input type="checkbox"/> INPATIENT</td> <td style="text-align: center;"><input type="checkbox"/> DAY CARE</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/> OUTPATIENT</td> <td style="text-align: center;"><input type="checkbox"/> OTHERS: SPECIFY _____</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/> A&E</td> <td style="text-align: center;"><input type="checkbox"/> _____</td> </tr> </table> LOCATION / WARD / CLINIC : _____	<input type="checkbox"/> INPATIENT	<input type="checkbox"/> DAY CARE	<input type="checkbox"/> OUTPATIENT	<input type="checkbox"/> OTHERS: SPECIFY _____	<input type="checkbox"/> A&E	<input type="checkbox"/> _____	DEPARTMENT(S) INVOLVED (please tick) <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="text-align: center;"><input type="checkbox"/> MEDICAL</td> <td style="text-align: center;"><input type="checkbox"/> O&G</td> <td style="text-align: center;"><input type="checkbox"/> ONCOLOGY</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/> SURGICAL</td> <td style="text-align: center;"><input type="checkbox"/> PHARMACY</td> <td style="text-align: center;"><input type="checkbox"/> GERIATRIC</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/> ORTHOPAEDIC</td> <td style="text-align: center;"><input type="checkbox"/> RADIOLOGY & IMAGING</td> <td style="text-align: center;"><input type="checkbox"/> REHABILITATION</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/> PAEDIATRIC</td> <td style="text-align: center;"><input type="checkbox"/> A&E</td> <td style="text-align: center;"><input type="checkbox"/> ICU/CCU</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/> LABORATORY</td> <td style="text-align: center;"><input type="checkbox"/> PSYCHIATRY</td> <td style="text-align: center;"><input type="checkbox"/> _____</td> </tr> <tr> <td colspan="3" style="text-align: center;"><input type="checkbox"/> OTHERS: SPECIFY _____</td> </tr> </table>		<input type="checkbox"/> MEDICAL	<input type="checkbox"/> O&G	<input type="checkbox"/> ONCOLOGY	<input type="checkbox"/> SURGICAL	<input type="checkbox"/> PHARMACY	<input type="checkbox"/> GERIATRIC	<input type="checkbox"/> ORTHOPAEDIC	<input type="checkbox"/> RADIOLOGY & IMAGING	<input type="checkbox"/> REHABILITATION	<input type="checkbox"/> PAEDIATRIC	<input type="checkbox"/> A&E	<input type="checkbox"/> ICU/CCU	<input type="checkbox"/> LABORATORY	<input type="checkbox"/> PSYCHIATRY	<input type="checkbox"/> _____	<input type="checkbox"/> OTHERS: SPECIFY _____		
<input type="checkbox"/> INPATIENT	<input type="checkbox"/> DAY CARE																										
<input type="checkbox"/> OUTPATIENT	<input type="checkbox"/> OTHERS: SPECIFY _____																										
<input type="checkbox"/> A&E	<input type="checkbox"/> _____																										
<input type="checkbox"/> MEDICAL	<input type="checkbox"/> O&G	<input type="checkbox"/> ONCOLOGY																									
<input type="checkbox"/> SURGICAL	<input type="checkbox"/> PHARMACY	<input type="checkbox"/> GERIATRIC																									
<input type="checkbox"/> ORTHOPAEDIC	<input type="checkbox"/> RADIOLOGY & IMAGING	<input type="checkbox"/> REHABILITATION																									
<input type="checkbox"/> PAEDIATRIC	<input type="checkbox"/> A&E	<input type="checkbox"/> ICU/CCU																									
<input type="checkbox"/> LABORATORY	<input type="checkbox"/> PSYCHIATRY	<input type="checkbox"/> _____																									
<input type="checkbox"/> OTHERS: SPECIFY _____																											
6.	TYPE OF INCIDENT <input type="checkbox"/> Actual <input type="checkbox"/> Near Miss (please tick one)																										
Examples of incidents that need to be reported: (Note that this list is not exhaustive)																											
	i.	Wrong surgery/procedure --wrong site, side or patient																									
	ii.	Unintended retained foreign body in patient after an operation/procedure																									
	iii.	Error in transfusion of blood/blood products																									
	vi.	Medication error (please fill in MERS form as well)																									
	v.	Patient fall in the facility																									
	vi.	Obstetric related incidents																									
	vii.	Adverse outcome of clinical procedure																									
	viii.	Pre-hospital care and ambulance service related incident																									
	ix.	Radiotherapy related incident																									
	x.	Patient suicide / attempted suicide																									
	xi.	Patient discharged to wrong family members / next-of-kin																									
	xii.	Assault/ battery of patient																									
	xiii.	Unanticipated Fire – Fire, flame, or unanticipated smoke, heat, or flashes occurring in the facility																									
	xiv.	Others type of incident : _____																									
7.	BRIEF DESCRIPTION OF WHAT HAPPENED (Please fill in the blanks) The description should explain what happen prior and during the incident and how it occurred. Do include any additional information which you think may lead to the incident.																										

SULIT

IR 2.0/2017

PATIENT OUTCOME (please tick one) & IMMEDIATE ACTION – ONLY FOR ACTUAL INCIDENT							
8. OUTCOME OF INCIDENT	<input type="checkbox"/> NONE						
	<input type="checkbox"/> MILD						
	<input type="checkbox"/> MODERATE						
	<input type="checkbox"/> SEVERE						
	<input type="checkbox"/> DEATH						
	<input type="checkbox"/> CURRENTLY CANNOT BE DETERMINED						
9. IMMEDIATE ACTION FOLLOWING INCIDENT							
REPORTED BY							
10. DESIGNATION: (please tick one)	SIGNATURE OF REPORTER:						
<table border="1"> <tr> <td><input type="checkbox"/> NURSE</td> <td><input type="checkbox"/> SPECIALIST</td> </tr> <tr> <td><input type="checkbox"/> HOUSE OFFICER</td> <td><input type="checkbox"/> PHARMACIST</td> </tr> <tr> <td><input type="checkbox"/> MEDICAL OFFICER</td> <td><input type="checkbox"/> OTHERS:</td> </tr> </table>	<input type="checkbox"/> NURSE	<input type="checkbox"/> SPECIALIST	<input type="checkbox"/> HOUSE OFFICER	<input type="checkbox"/> PHARMACIST	<input type="checkbox"/> MEDICAL OFFICER	<input type="checkbox"/> OTHERS:	NAME: DATE:
<input type="checkbox"/> NURSE	<input type="checkbox"/> SPECIALIST						
<input type="checkbox"/> HOUSE OFFICER	<input type="checkbox"/> PHARMACIST						
<input type="checkbox"/> MEDICAL OFFICER	<input type="checkbox"/> OTHERS:						
Note: As part of good leadership and clinical governance, please inform the incident to your Head of Department(s) immediately.							

SECTION B : TO BE COMPLETED BY THE RISK MANAGER/ QUALITY MANAGER OF HOSPITAL									
1. ACTION TAKEN: <i>Mandatory Root Cause Analysis: 1) Incident with Severe or Death outcome 2) Other incident/near miss based on the Risk Manager/ Quality Manager assessment 3) Directive from State Health Department / Ministry.</i>	(Please tick) <table border="1"> <tr> <td><input type="checkbox"/></td> <td>"PRESCRIPTION SLIP"</td> </tr> <tr> <td><input type="checkbox"/></td> <td>MONITOR THE TREND FIRST</td> </tr> <tr> <td><input type="checkbox"/></td> <td>RCA</td> </tr> <tr> <td><input type="checkbox"/></td> <td>MIRCA (Multi-incident Root Cause Analysis)</td> </tr> </table> Additional comments :	<input type="checkbox"/>	"PRESCRIPTION SLIP"	<input type="checkbox"/>	MONITOR THE TREND FIRST	<input type="checkbox"/>	RCA	<input type="checkbox"/>	MIRCA (Multi-incident Root Cause Analysis)
<input type="checkbox"/>	"PRESCRIPTION SLIP"								
<input type="checkbox"/>	MONITOR THE TREND FIRST								
<input type="checkbox"/>	RCA								
<input type="checkbox"/>	MIRCA (Multi-incident Root Cause Analysis)								
2. e-IR SUBMITTED? Please submit to e-IR within 5 days from the date of the incident.	Date of Submission: ____-____-____								
3. RISK MANAGER/ QUALITY MANAGER OF HOSPITAL	(please fill in the blanks) NAME: SIGNATURE: DESIGNATION: DATE:								

Incident Reporting & Learning System “ Prescription Slip”



Ministry of Health Malaysia
Incident Reporting & Learning System “Prescription Slip”

Serial No.

To: Department / Ward:

Issue(s)/Comment(s):

- Please Take Note
 Please Take Necessary Action

Others :

From
Name & Stamp:
Date:



Ministry of Health Malaysia
Incident Reporting & Learning System “Prescription Slip”

Serial No.

To: Department / Ward:

Issue(s)/Comment(s):

- Please Take Note
 Please Take Necessary Action

Others :

From
Name & Stamp:
Date:

□ **Chapter 4**

Use of Incident
Reporting 2.0 Form



What Is Incident Reporting 2.0 Form?

This IR 2.0 Form is a 2–pages form which is used to report:

- i) Any **‘patient safety incidents’ that happened** or
- ii) **‘Near miss’ patient safety incidents**

What Is The Scope of IR 2.0 Form?

- The use of this form is specifically to capture patient safety related incidents, near miss or patient safety related issues.
- Other incidents such as accident or chemical poisoning involving staff, staff being harmed by patients etc. should not used this form. Instead, it should use other relevant mechanism of reporting system such as Notification of Accident, Dangerous Occurrence, Occupational Poisoning and Occupational Disease or well known as WEHU Form.
- For violence among staff, a specific form- Notification of Workplace Violence Form need to be used for notification.
- Reporting of administrative issues such as detection of faulty equipment during regular monitoring activities should not used this form.

Who Can Report An Incident (I.e The “Reporter”)?

These are examples of staff that can make a report using the IR 2.0 Form.

- Staff involved in the incident
- Staff who witness the incident
- Staff who detect an “error” or “near miss”

All categories of staff can make a report using this form.

How To Complete The IR 2.0 Form?

The I.R 2.0 Form consists of **two (2)** sections – Section A and Section B that need to be completed.

Section A:


- Section A is divided into 3 parts and consists of 9 items
 - (i) Incident description
 - (ii) Patient Outcome and Immediate Action Following the Incident
 - (iii) Details of Reporter
- It should be filled up by the “reporter of the incidents”.
- He/ she should be the hospital staff.
- **All categories** of staff can make a report.
- Section A must be completed and forwarded to Risk Manager/ Quality Manager **within 48 hours** from the time of the incident.


Section B:

- Section B consists of 3 items
 - Action taken by risk manager/ Quality Manager e-IR
 - e-IR Submission
 - Details of Risk Manager/ Quality Manager
- It should be filled up by the “Risk Manager/ Quality Manager” of the hospital
- The form must be filled up as soon as the Risk Manager/ Quality Manager received the form from the reporter of the incident.
- In a situation where the hospital is very big and has a specific Risk Manager/ Quality Manager at Departmental level, Section B can be filled by Risk Manager/ Quality Manager at Departmental level. However, the form still need to be sent to the Quality Department of Hospital. This will enable total supervision of all departments at hospital level.

Section A: Completed By The “Reporter of The Incident”

SULIT


 MINISTRY OF HEALTH MALAYSIA
 PATIENT SAFETY INCIDENT REPORTING FORM

 IR 2.0/2017

DATE OF REPORTING: ___ / ___ / ___

**Barang boleh diisi dalam Bahasa Malaysia*

SECTION A: TO BE COMPLETED BY THE REPORTER OF THE INCIDENT																											
INCIDENT DESCRIPTION (Please fill in the blanks)																											
1.	NAME OF FACILITY/ INSTITUTION	PATIENT'S NAME																									
2.	DATE OF INCIDENT	<input type="text"/> / <input type="text"/> / <input type="text"/>	IF UNCERTAIN APPROXIMATE DATE: ___ / ___ / ___																								
3.	TIME OF INCIDENT	<input type="text"/> : <input type="text"/> AM/ PM	IF UNCERTAIN APPROXIMATE TIME: ___ : ___ AM / PM																								
4.	PATIENT'S RN/ OTHER IDENTIFICATION NUMBER : GENDER : MALE / FEMALE / UNKNOWN (please circle)	STATUS : ALIVE / DECEASED DIAGNOSIS :	AGE: _____ ETHNIC: _____ LANGUAGE BARRIER: YES / NO																								
5.	TYPE OF PATIENT (please tick one) <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td><input type="checkbox"/> INPATIENT</td> <td><input type="checkbox"/> DAY CARE</td> </tr> <tr> <td><input type="checkbox"/> OUTPATIENT</td> <td><input type="checkbox"/> OTHERS: SPECIFY _____</td> </tr> <tr> <td><input type="checkbox"/> A&E</td> <td></td> </tr> </table>	<input type="checkbox"/> INPATIENT	<input type="checkbox"/> DAY CARE	<input type="checkbox"/> OUTPATIENT	<input type="checkbox"/> OTHERS: SPECIFY _____	<input type="checkbox"/> A&E		DEPARTMENT(S) INVOLVED (please tick) <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td><input type="checkbox"/> MEDICAL</td> <td><input type="checkbox"/> O&G</td> <td><input type="checkbox"/> ONCOLOGY</td> </tr> <tr> <td><input type="checkbox"/> SURGICAL</td> <td><input type="checkbox"/> PHARMACY</td> <td><input type="checkbox"/> GERIATRIC</td> </tr> <tr> <td><input type="checkbox"/> ORTHOPAEDIC</td> <td><input type="checkbox"/> RADIOLOGY & IMAGING</td> <td><input type="checkbox"/> REHABILITATION</td> </tr> <tr> <td><input type="checkbox"/> PAEDIATRIC</td> <td><input type="checkbox"/> A&E</td> <td><input type="checkbox"/> ICU/ CCU</td> </tr> <tr> <td><input type="checkbox"/> LABORATORY</td> <td><input type="checkbox"/> PSYCHIATRY</td> <td></td> </tr> <tr> <td colspan="3">OTHERS: SPECIFY _____</td> </tr> </table>		<input type="checkbox"/> MEDICAL	<input type="checkbox"/> O&G	<input type="checkbox"/> ONCOLOGY	<input type="checkbox"/> SURGICAL	<input type="checkbox"/> PHARMACY	<input type="checkbox"/> GERIATRIC	<input type="checkbox"/> ORTHOPAEDIC	<input type="checkbox"/> RADIOLOGY & IMAGING	<input type="checkbox"/> REHABILITATION	<input type="checkbox"/> PAEDIATRIC	<input type="checkbox"/> A&E	<input type="checkbox"/> ICU/ CCU	<input type="checkbox"/> LABORATORY	<input type="checkbox"/> PSYCHIATRY		OTHERS: SPECIFY _____		
		<input type="checkbox"/> INPATIENT	<input type="checkbox"/> DAY CARE																								
<input type="checkbox"/> OUTPATIENT	<input type="checkbox"/> OTHERS: SPECIFY _____																										
<input type="checkbox"/> A&E																											
<input type="checkbox"/> MEDICAL	<input type="checkbox"/> O&G	<input type="checkbox"/> ONCOLOGY																									
<input type="checkbox"/> SURGICAL	<input type="checkbox"/> PHARMACY	<input type="checkbox"/> GERIATRIC																									
<input type="checkbox"/> ORTHOPAEDIC	<input type="checkbox"/> RADIOLOGY & IMAGING	<input type="checkbox"/> REHABILITATION																									
<input type="checkbox"/> PAEDIATRIC	<input type="checkbox"/> A&E	<input type="checkbox"/> ICU/ CCU																									
<input type="checkbox"/> LABORATORY	<input type="checkbox"/> PSYCHIATRY																										
OTHERS: SPECIFY _____																											
LOCATION/ WARD / CLINIC : _____																											

(I) Incident Description

1. Name of Facility

- Please fill in the name of the facility where the incident had happened.
 - Hospital XXY
 - Patient's Name
- Please fill in the full name of patient involved in the actual incident or near miss incident

2. Date of Incident

- Please fill in the date of the incident in dd/mm/yyyy (Date, month, year) format.
- If unsure about the date of the incident, write down the approximate date of incident in dd/mm/yyyy (Date, month, year) format.

3. Time of Incident

- Please fill in the time of the incident in hh:mm (Hour, minute) format.
- If unsure about the time of the incident, write down the approximate time of incident in hh:mm (Hour, minute) format.

4. Patient's Particular

- Please fill in these details:

- Patient's Hospital Registration Number (RN) or any other reliable identification number (such as NRIC).
- Patient's age
- Patient's ethnic group.

- Please circle:

- Patient's gender
- Patient's status (either alive or deceased when the incident happened). This is relevant because some incidents involved deceased body.
- Whether there is a problem in communicating with patient due to language barrier.
- Diagnosis of patient.

5. Type of Patient

- Please tick the “type of patient” based on category of service received (e.g.: inpatient–patient in the ward, outpatient – patient at Specialist Clinic), as listed in the table.
- If the location is different from the one listed, please specify at the space given.
- A&E means Accident & Emergency Department which include Red, Yellow and Green zone

Location/ Ward/ Clinic

- Please write down “specific location” of the incident at the space provided.
- e.g Ward 7E, Ward Melati, Red Zone, Labour Room

Department(s) Involved

- Please tick at the relevant department or departments involved in the incident. It can be more than one departments. If the department is different from the one listed, please specify at the space given.

6. TYPE OF INCIDENT		<input type="checkbox"/> Actual	<input type="checkbox"/> Near Miss
(please tick one)			
Examples of incidents that need to be reported: (Note that this list is not exhaustive)			
i.	Wrong surgery/procedure –wrong site, side or patient		
ii.	Unintended retained foreign body in patient after an operation/procedure		
iii.	Error in transfusion of blood/blood products		
vi.	Medication error (please fill in MERS form as well)		
v.	Patient fall in the facility		
vi.	Obstetric related incidents		
vii.	Adverse outcome of clinical procedure		
viii.	Pre-hospital care and ambulance service related incident		
ix.	Radiotherapy related incident		
x.	Patient suicide / attempted suicide		
xi.	Patient discharged to wrong family members / next-of-kin		
xii.	Assault/ battery of patient		
xiii.	Unanticipated Fire – Fire, flame, or unanticipated smoke, heat, or flashes occurring in the facility		
xiv.	Others type of Incident :		
7. BRIEF DESCRIPTION OF WHAT HAPPENED (Please fill in the blanks)			
The description should explain what happen prior and during the incident and how it occurred. Do include any additional information which you think may lead to the incident.			

6. Type of incident

- Please tick at the appropriate box- “Actual Patient Safety Incident” or “Near Miss”.
- Definition:
 - o Actual Patient Safety Incident: The incident happen and reach the patient
 - o Near miss – The incident did not reach the patient
 - o The incidents listed are examples of incident that need to be reported.
 - o If the type of the incident is not listed, please select ‘Other type of incident’ and write down the type of incident at the space given.
 - o Please refer to the section on ‘Incident Definition’ for specific definition of each incident.
 - o In the new approach of Incident Reporting & Learning System 2.0, all patient safety incidents that happen including “near miss” need to be reported. This is called ‘Open System’ in which patient safety incidents or near miss need to be taken seriously. Hence, reporting is essential as it provides opportunity to analyse the weakness of the system and improve patient safety.

7. Brief description on what happen prior to the incident, during the incident and how it happen. Do include any additional information which you think may lead to the incident.

- It is important that only facts are stated, and not opinion.
- Example - Patient XYZ was diagnosed as having Left Subdural Haemorrhage. Left side craniotomy was planned. In the OT, the surgeon (Mr M) positioned the patient and marked the Right side of the skull instead of the Left. He did not use Safe Surgery Check List and no “time out” session was done prior to incision. Mr M made the surgical marking without being confirmed by other staff. The mistake was only discovered when he opened the dura and no blood clot was found. He looked at the CT scan again and realized that the patient was reversely placed and hence, he marked on the wrong side. He closed the dura and continued with Left Craniotomy. The patient condition was stable post surgery. Head of Neurosurgery Department and Hospital Director were informed by Mr M.

ii) Outcome of Incident & Immediate Action Following Incident

SULIT		IR 2.0/2017
PATIENT OUTCOME (please tick one) & IMMEDIATE ACTION – ONLY FOR ACTUAL INCIDENT		
8. OUTCOME OF INCIDENT	<input type="checkbox"/>	NONE
	<input type="checkbox"/>	MILD
	<input type="checkbox"/>	MODERATE
	<input type="checkbox"/>	SEVERE
	<input type="checkbox"/>	DEATH
	<input type="checkbox"/>	CURRENTLY CANNOT BE DETERMINED
9. IMMEDIATE ACTION FOLLOWING INCIDENT		

8. Outcome of Incident

- This is only applicable if the report is on “Actual” incident.
- Please select the type of ‘Patient Outcome’ due to the incident (i.e. what happened to the patient following the incident). The definition of each ‘Patient Outcome’ category is as follows:

Patient Outcome	Definition
None	Patient outcome is not symptomatic or no symptoms detected and no treatment is required. e.g. Wrong dose of medication given to a patient but the patient did not suffer any harm
*Mild	Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g., extra observation, investigation, review or minor treatment) is required, increase length of stay (up to 72 hours)

Patient Outcome	Definition
*Moderate	Patient outcome is symptomatic, requiring intervention (e.g., additional operative procedure; additional therapeutic treatment), an increased length of stay (more than 72 hours to 7 days)
*Severe	Patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, an increased length of stay (more than 7 days), shortening life expectancy or causing major permanent or long term harm or loss of function
Death	On balance of probabilities, death was caused or brought forward in the short term by the incident.
Unsure	The definite outcome is yet to be determined, cannot be certain during the time of reporting.

*Some amendment is made from the original WHO definition in order to prevent confusion. Additional information is used using definition from Government of Western Australia, Department of Health- Clinical Incident Management Toolkit, 2016

9. Immediate Action Following The Incident

- Describe the immediate action taken by the staff following the incident.
- Examples:
 - o Transfusion was stopped immediately when Staff Nurse X realised wrong blood was transfused.
 - o Dr C was called immediately to assess the patient condition after the patient fell. XRay revealed fracture neck of femur. Signage of slippery floor was put up to warn others on the slippery floor.

(III) Details of The Reporter (Person Who Reports The Incident)

REPORTED BY			
10. DESIGNATION: (please tick one)		SIGNATURE OF REPORTER:	
<input type="checkbox"/> NURSE	<input type="checkbox"/> SPECIALIST	NAME:	
<input type="checkbox"/> HOUSE OFFICER	<input type="checkbox"/> PHARMACIST	DATE:	
<input type="checkbox"/> MEDICAL OFFICER	<input type="checkbox"/> OTHERS:		
<p>Note: As part of good leadership and clinical governance, please inform the incident to your Head of Department(s) immediately.</p>			

- The reporter of the incident must be staff of the healthcare facility.
- These are examples of staff that can make a report :
 - o Staff involved in the incident
 - o Staff who witness the incident
 - o Staff who detect an “error” or “near miss”
- The reporter needs to tick the appropriate box, write down his/ her name and date of reporting at the space provided. If ‘others’ is selected, please specify it at the space provided. Official stamping is also acceptable.
- The reporter needs to sign the form before sending the form to Risk Manager/ Quality Manager.

Section B: Completed By Risk Manager/ Quality Manager

SECTION B : TO BE COMPLETED BY THE RISK MANAGER/ QUALITY MANAGER OF HOSPITAL									
<p>1. ACTION TAKEN:</p> <p><i>Mandatory Root Cause Analysis:</i> 1) Incident with Severe or Death outcome 2) Other incident /near miss based on the Risk Manager/ Quality Manager assessment 3) Directive from State Health Department / Ministry.</p>	<p>(Please tick)</p> <table border="1"> <tr> <td><input type="checkbox"/></td> <td>"PRESCRIPTION SLIP"</td> </tr> <tr> <td><input type="checkbox"/></td> <td>MONITOR THE TREND FIRST</td> </tr> <tr> <td><input type="checkbox"/></td> <td>RCA</td> </tr> <tr> <td><input type="checkbox"/></td> <td>MIRCA (Multi-incident Root Cause Analysis)</td> </tr> </table> <p>Additional comments :</p>	<input type="checkbox"/>	"PRESCRIPTION SLIP"	<input type="checkbox"/>	MONITOR THE TREND FIRST	<input type="checkbox"/>	RCA	<input type="checkbox"/>	MIRCA (Multi-incident Root Cause Analysis)
<input type="checkbox"/>	"PRESCRIPTION SLIP"								
<input type="checkbox"/>	MONITOR THE TREND FIRST								
<input type="checkbox"/>	RCA								
<input type="checkbox"/>	MIRCA (Multi-incident Root Cause Analysis)								
<p>2. e-IR SUBMITTED?</p> <p>Please submit to e-IR within 5 days from the date of the incident.</p>	<p>Date of Submission: ____-____-____</p>								
<p>3. RISK MANAGER/ QUALITY MANAGER OF HOSPITAL</p>	<p>(please fill in the blanks)</p> <p>NAME: SIGNATURE: DESIGNATION: DATE:</p>								

1. Action Taken

- The Risk Manager/ Quality Manager need to assess the case and determine further action that need to be instituted and tick the appropriate action.
- More than one(1) tick is possible. For instance: Prescription Slip +RCA
- The action can be one of these:
 - o Send “Prescription Slip” to the appropriate person in charge of the relevant Ward/ Department/ Clinic/ OT etc.
 - o Monitoring the trend of the incident or near miss first before taking any action
 - o Start to form suitable Root Cause Analysis(RCA) team and conduct investigation
 - o Start to form a team to conduct ‘Multiple Root Cause Analysis’ (MIRCA)

- Additional comments related to the action taken can be written in the space provided such as:
 - o Prescription slip was sent to – Dr Y, Head of Surgery and Matron B on the 7/7/2017 to inform them about the 4th case of patient fell in Ward 11A/ Surgical in the past one month. 2 cases with minor outcome and 2 cases with moderate outcome.
- Mandatory Root Cause Analysis is required in any of these situation:
 - i) Incident with “Severe” or ‘Death” patient outcome or
 - ii) Other incidents/ near miss based on the Risk Manager/ Quality Manager assessment
 - iii) Directive from State Health Department or Ministry

2. e-IR Submitted? (Please refer to Chapter 7 on e-IR)

- The Risk Manager/ Quality Manager need to submit the essential information of the incident online as per the requirement of e-IR System. e-IR is an online reporting of incident which facilitates reporting directly to the Patient Safety Unit, Ministry of Health Malaysia.
- Reporting need to be done **within 5 working days** from the date of incident.
- Date of e-IR reporting need to be written at the form.
- Please refer to **‘Chapter 7 on e-IR ’** for further details.

3. Risk Manager/ Quality Manager of Hospital Reviewing Incident Case

- The Risk Manager/ Quality Officer who reviewed the report need to write down his/ her name, designation, the date of completing the form and sign the form together with official stamping of the Quality Unit or Department.



□ **Chapter 5**

Definition of Incidents

“CLARITY....”

Examples of incidents that need to be reported: (Note that this list is not exhaustive)

i.	Wrong surgery/procedure –wrong site, side or patient
ii.	Unintended retained foreign body in patient after an operation/procedure
iii.	Error in transfusion of blood/blood products
vi.	Medication error (please fill in MERS form as well)
v.	Patient fall in the facility
vi.	Obstetric related incidents
vii.	Adverse outcome of clinical procedure
viii.	Pre-hospital care and ambulance service related incident
ix.	Radiotherapy related incident
x.	Patient suicide / attempted suicide
xi.	Patient discharged to wrong family members / next-of -kin
xii.	Assault/ battery of patient
xiii.	Unanticipated Fire – Fire, flame, or unanticipated smoke, heat, or flashes occurring in the facility
xiv.	Others type of incident : _____

Incident

Definition

Wrong surgery or wrong procedure

Patient received unintended surgery or procedure
 Examples: Surgery performed on wrong patient, wrong site or wrong side; Left craniotomy instead of right craniotomy (with tumor) ; Radiotherapy given to wrong patient or wrong site

Incident	Definition
Unintended retained foreign body in patient after invasive procedure/surgery	<p>Unintended retention of a foreign object in patient after an invasive procedure including surgery .This includes retention of surgical instruments (eg: needle, clamp, retractor) or other materials such as surgical sponge, gauze and tampons.</p> <p>(Exclude objects intentionally implanted as part of planned intervention and objects present prior to surgery that are intentionally retained. e.g Retained abdominal packs after a laparotomy, retained tampon in vagina after delivery, retained guide wire during triple lumen insertion, retained drill bit during orthopaedic surgery)</p>
Error in transfusion of blood or blood products	<p>Incident in which a patient was transfused with a blood/blood component:</p> <ol style="list-style-type: none"> which was intended for another patient OR in which the primary error occurred in the laboratory during the selection, testing or issuing of blood or other procedural error which resulted in a patient being transfused with an incorrect unit OR phlebotomy errors resulting in “Wrong Blood In the Tube”- e.g Due to wrong labelling of tube
Medication Error	<p>Any preventable incident that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional. This include:</p> <ul style="list-style-type: none"> • Prescribing error • Omission error • Wrong time error • Dose error • Route of administration error • Monitoring error • Drug preparation error

Incident	Definition
	<p>*Notification should also be made to the MERS (Medication Error Reporting System) using MERS form and sent to the Pharmacy Department for further action.</p>
Patient fall	Unplanned descent to the floor with or without injury to the patient
Obstetrics related incidents	This incident may involve mother, baby or both. Examples are uterine rupture of mother, unplanned admission of mother to ICU/CCU/HDW post-delivery, failed instrumental delivery, unplanned post-delivery procedure on mother, shoulder dystocia, birth trauma to the baby, undiagnosed fetal anomaly etc.
Adverse Outcome of Clinical Procedure	Outcome of any clinical procedures that are not intended or desired to occur as a result of performing a particular procedure. Examples Pneumothorax following central venous access, GIT perforation following endoscopy, perforation of bowel following peritoneal dialysis etc.
Pre-Hospital Care & Ambulance Service Related Incident	Any patient safety incident affecting patient or person either directly or indirectly related to the care or services in a pre-hospital and ambulance environment. Examples : Death in ambulance, fall from ambulance stretcher, ambulance or equipment malfunction during transfer, unnecessarily delay and wrong triage.
Radiotherapy related incident	Incident related to radiotherapy treatment which may jeopardise patient condition. Examples- Inaccuracy of radiotherapy delivery, delay in receiving radiotherapy
Patient suicide or attempted suicide	Patient receiving care in hospital. Committed suicide/ attempted suicide

Incident	Definition
Patient discharged to wrong family members/ next-of-kin.	Patient (alive or deceased) being discharged to wrong family members or next of kin.
Assault or battery of patient	Assault or battery of a patient by staff, another patient or by any other person while the patient is under the care of hospital.
Unanticipated fire	Fire, flame, or unanticipated smoke, heat, or flashes occurring in hospital

□ **Chapter 6**

Use of Incident Reporting
& Learning System
'Prescription Slip'

“COMMUNICATE,
COMMUNICATE,
COMMUNICATE ...”

The image shows a screenshot of a web-based form titled "Ministry of Health Malaysia Incident Reporting & Learning System 'Prescription Slip'". The form includes a header with the Ministry of Health Malaysia logo and name. A "Serial No." field is located in the top right. Below the header, there are fields for "To:" and "Department / Ward:". A large text area for "Issue(s)/Comment(s):" is provided. At the bottom left, there are two checkboxes: "Please Take Note" and "Please Take Necessary Action". An "Others:" field is also present. On the bottom right, there is a box labeled "From" containing fields for "Name & Stamp:" and "Date:".

What Is It For?

- The main use of this “Prescription Slip” is mainly **to facilitate communication**. It can be used as a **“simple feedback message”** from the Risk Manager/ Quality Manager to specific personnel in the healthcare facility.

- “Prescription Slip” can be given to:
 - o Any personnel in charge of the Department or staff. Examples are the Head of Departments, Head of Unit, Nursing Matrons/ Sisters, Assistant Medical Officer Supervisor, Head of Physiotherapist etc
 - o Staff involved in the incident
 - o Staff witnessed the incident
- The sender of the ‘Prescription Slip’ should use it wisely with positive approach and the receiver should receive it ‘positively’ and take necessary action.
- It is aimed that the “Prescription Slip” can improve and facilitate the ‘communication’ process between Department/Clinic/Ward staff and Risk/Quality Manager by using a “simple” approach without wasting too much time on writing lengthy letter.

Scope of Use

- The scope may include the followings:
 - o To give information on incidents, related issues, current status
 - o To give directive or suggestion on necessary action
 - o To get feedback on actions that have been taken to prevent further incident
- Examples of use:
 - o Informing about specific incident or near miss that happened recently etc.
 - o Informing the relevant personnel in charge about RCA which will be conducted following major incident
 - o Informing staff involved in the incident or witnessing the incident regarding the need for him/ her to have discussion with Risk Manager/ Quality Manager or Special Investigation Committee.
 - o Informing the relevant Head of Department or officer in charge to monitor the trend of similar incident, review record of a case and discussion, conduct risk assessment, audit etc at departmental level.

How To Complete The ‘Prescription Slip’?

- Fill in the name of the recipient, the department/ ward, name, date and official stamp of the Department/Unit.
- Fill in “Serial No”. This need to be created in systematic order. Hence it is easy for the Risk Manager/ Quality Manager to do further follow up.
- State the issue(s)/ comment(s) that the Risk Manager/ Quality Manager would like to highlight. (Refer to section “Examples of Use”)
- Tick the appropriate box either
 - o “Please Take Note” - i.e the sender would like the recipient to “know” about certain issues
 - o “Please Take Necessary Action”- i.e the sender would like the recipient to take action regarding certain issues. If possible try to be very specific and include time duration for the action to be completed.
 - o If there is any other comment”, please write in the space provided.
- Write down the “name of Risk Manager/Quality Manager” writing/ sending the “IR Prescription Slip”, the stamp of the Quality Department/Unit and date of issue.

Follow Up Process

- All incidents received by Risk Manager/Quality Manager and “IR Prescription Slip” issued by Risk Manager/Quality Manager” need to be followed up or monitored after certain interval to ensure necessary actions has been done by the relevant individual(s).
- Good team work and good communication between the Risk Manager/ Quality Manager and relevant individual(s) are essential in this process.

Record Keeping

- Systematic record keeping is important for both “IR Notification Form” and “IR Prescription Slip”.
- Confidentiality and security of these documents, together with any form of investigation findings need to be ensured.

□ **Chapter 7**

Ministry of Health Malaysia
Online Incident Reporting
System: e-IR



What Is e-IR?

- e-IR is an **online reporting system of patient safety incident** directly from each hospital/ institution to Patient Safety Unit, Ministry of Health Malaysia.
- Only **essential information** from the Reporting Form need to be sent.
- **Risk Manager/ Quality Manager** of hospitals is responsible to submit the information for each incident report received from staff
- Submission should be done within **five(5) working days**.
- The e-IR system can be reached via official Patient Safety Council Malaysia/ Patient Safety Unit MOH website www.patientsafety.moh.gov.my.
- **e-IR Reports** are also available through this website.

What Is The Origin of e-IR?

- e-IR is one of the innovation from Patient Safety Unit, Ministry of Health Malaysia to enable important information on incidents being captured in one national database which is “almost real-time” data.

- This was developed using “free online system” using specific code for each hospital/ institution to ensure confidentiality.
- This 2-tier reporting system was established to replace 3-tier reporting system using “matrix system” (i.e from hospital to State Health Department to Ministry)
- It was launched on the 30th March 2015 by Director General of Health Malaysia, YBhg. Datuk Dr. Noor Hisham Abdullah.

What Are The Benefits of e-IR System?

- **Shorter & quicker process of data submission**
Essential information of incident is directly reported to Ministry from hospital/institution. Data received is almost real time.
- **More user friendly system**
Since it is using online system, it can be accessed through any computer or smart phone with internet connection. The system is very easy to understand and notification can be completed in few minutes.
- **More efficient data analysis and generation of report**
Data received is automatically downloadable at Ministry or State level and can be immediately analysed. This improves effectiveness and efficiency of data analysis and generation of report
- **Better data accuracy**
Data received are more accurate as the process of “manual data entry” by the staff at state level has been eliminated.
- **More meaningful information**
In the past, Ministry only received total number of incidents for each type of incidents that happened. With the use of e-IR, other important information related to the incident is also available such as time of incident and severity of Incident.

What Are The Products of e-IR After 2 Years of Implementation?

- Since its establishment in 2015, e-IR has received a total of 3,556 notification of incidents (787 cases in 2015 (half a year) and 2,769 cases in 2016). This is the first time Ministry of Health Malaysia managed to gather such a big number of national statistics on incidents since the establishment of Incident Reporting in 1999.
- More meaningful information of incidents that occurred throughout the country is now available and can be used for national improvement of services or for further research
- National report is produced regularly by Patient Safety Unit, Ministry of Health which is useful for State Health Department and hospitals. Reports are available at Patient Safety Council Malaysia/ Patient Safety Unit Website.
- Comparison of notification received is used to motivate staff, hospitals and states to improve their reporting system.

Scope of e-IR?

Incidents occurred in **MoH Hospitals and Institutions** only

Who Should Do The e-IR Data Entry?

To prevent duplication of data entry, notification via e-IR need to be done by **Hospital/ Institution Risk Manager/ Quality Manager or representative.**

Notification Period Via e-IR

- The data must be submitted via e-IR **within 5 working days** from the date of incident.
- Monitoring of the timeliness of reporting is done at the State Health Department and Ministry level.

How to Get Access to e-IR?

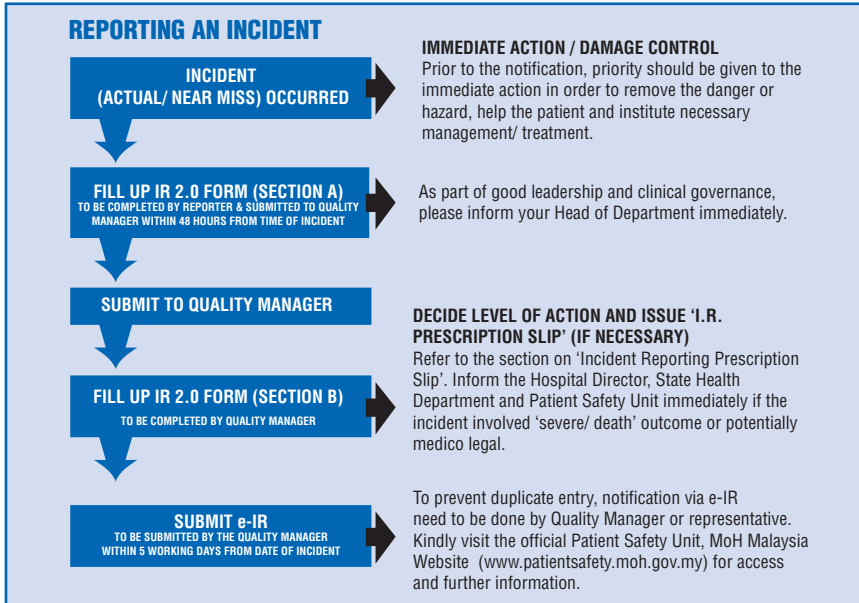
- 1) Visit www.patient.safety.moh.gov.my
- 2) Scroll down the page and click on e-Incident Reporting
- 3) Select the relevant state and your facility
- 4) Fill in the “information required” in e-IR

*To avoid unnecessary problems, please make sure the IR Form is fully completed before accessing the e-IR system.

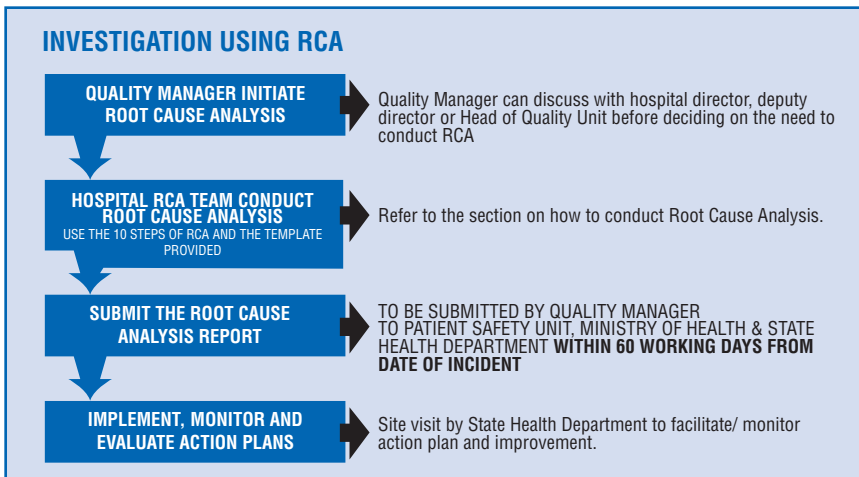
Where Can I Get An Update On e-IR System?

- e-IR system is very dynamic and will be updated from time to time.
- Therefore hospitals/ institutions need to get the most recent update via official Patient Safety Council Malaysia/Patient Safety Unit MOH website **www.patientsafety.moh.gov.my**.

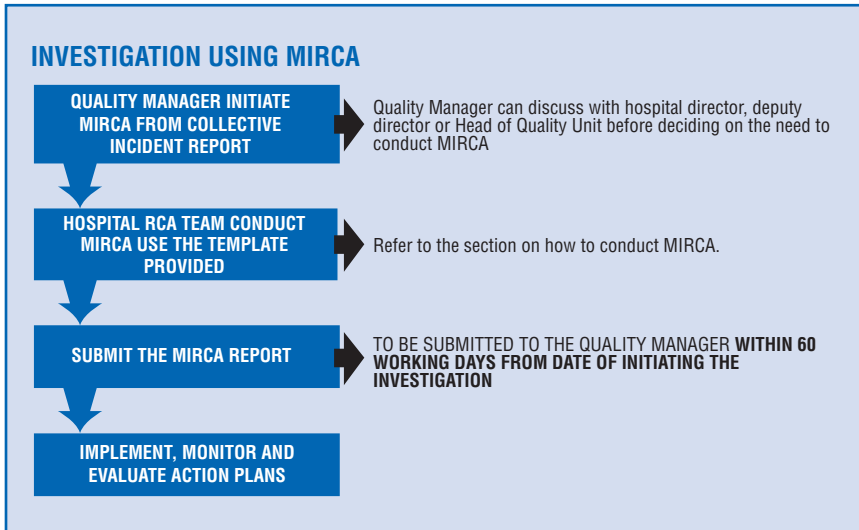
FLOW CHART FOR REPORTING INVESTIGATING AND IMPLEMENTING ACTION FOLLOWING AN INCIDENT



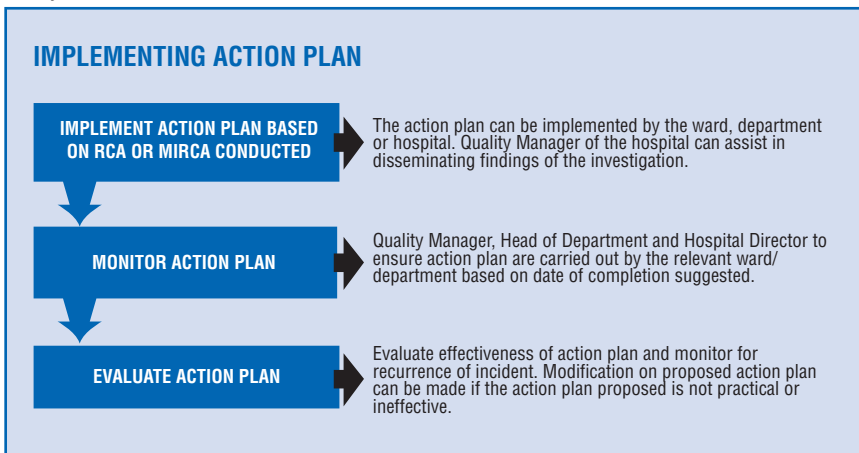
Investigation using Root Cause Analysis:



Investigation using MIRCA (Multi-Incident Root Cause Analysis):



Actions following Root Cause Analysis or MIRCA (Multi-Incident Root Cause Analysis):



□ **Chapter 8**

Overview of Patient Safety
Incident Investigation



What Are The Main Aim Of Investigation?

- To find weakness of the system that can be improved and reduce patient harm
- To find effective actions or solutions to prevent similar incident from happening.

Are All Incidents Being Reported Need To Be Reviewed & Investigated?

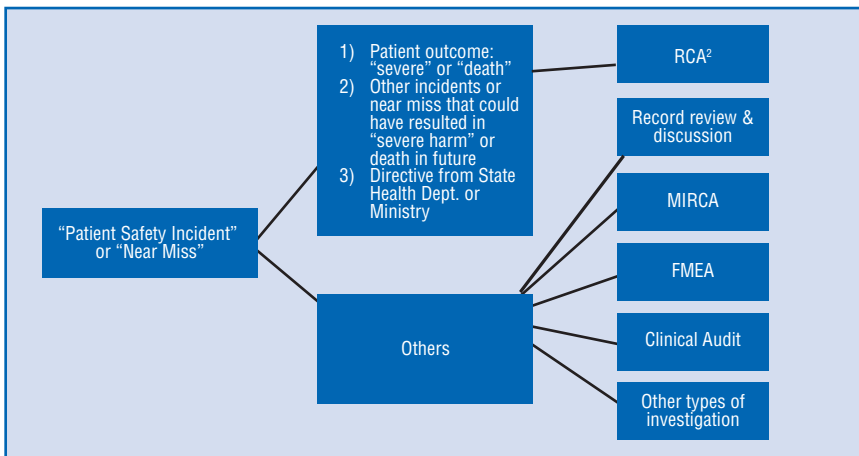
- Yes, all incidents reported need to be reviewed and investigated and should not be left “unattended on the desk” of the Risk Manager/ Quality Manager.
- Actions may include one of the followings:
 - o The relevant Head of Department, supervisor etc will be informed about the need to take specific action to manage the situation.
 - o The incident will be investigated by a specific investigation team of the hospital.
 - o The incident will be monitored by the Risk/Quality Manager since specific action is already in progress (e.g Hospital is in the process of conducting MIRCA, Clinical Audit, FMEA etc on similar incident).
 - o Others deem necessary.

- Risk Manager/ Quality Manager need to review all IR forms received, \prioritize and determine the depth/type of investigation required.
- Discuss with Head of Quality Unit/Hospital Director or Deputy Director if there is uncertainty about the type and depth of investigation required.

What Is The Difference Between “Patient Safety Incident Investigation” And Other Investigation?

- Patient Safety Incident investigation looks into “system issues” which is multi-factorial
- It does not focus on “clinical management” only.
- The main aim is to improve the weakness in the system.
- Hence, it is essential for the Investigation Team members to have some knowledge on Patient Safety.

What Is The Basic Rule To Determine Type/ Depth of Investigation?



Rule 1- Root Cause Analysis is a **MUST** when :

1. Incident results in “death” or “severe” patient outcome
2. Other incident or near miss that could have resulted in “severe harm” or death in future if not managed – this is based on the assessment of Risk/ Quality Manager
3. Directive from the State Health Department or Ministry.

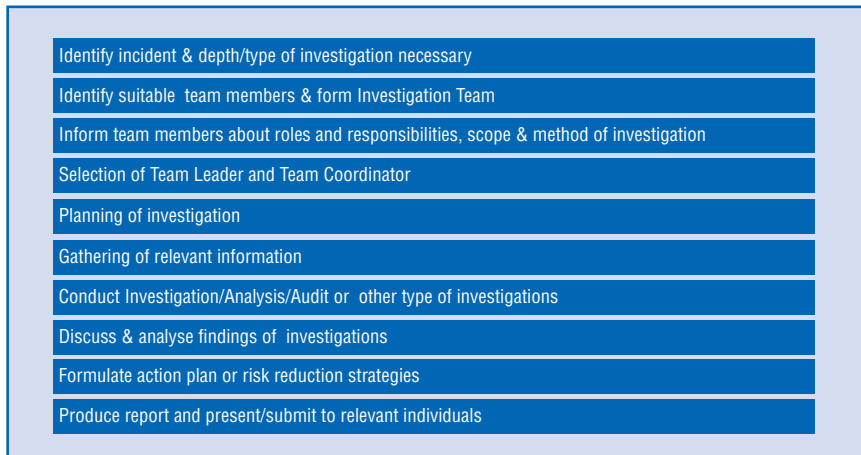
Rule 2 – Other type of incidents or “near miss” require one of these investigations based on the assessment of Risk Manager. It can be:

1. Record review and discussion with relevant people
2. MIRCA (multiple incident RCA)
3. FMEA (Failure Mode Effect Analysis)
4. Clinical audit
5. Other types of investigation

**When confusion arise whether RCA should be done, the best practice is to be safe and conduct RCA.*

Key Steps In Conducting Investigation

In general, investigation process involve these steps



Who Should Initiate An Investigation?

- Risk Manager or Quality Manager of the hospital need to start initiating the process of investigation which may include the following:
 1. Forming suitable Investigation Team
 2. Notification of the relevant Head of Department(s) and staff involved

Who Are The Investigation Team – Composition & Requirement?

- Team members must be trained in conducting Patient Safety Investigation and understands the specific type of investigation that need to be conducted- either RCA, MIRCA, Clinical Audit, Record Review and Discussion, Failure Mode Effect Analysis and other methods.
- Members of the investigation team should at least consists of the following:
 1. Risk Manager/ Quality Manager
 2. Clinician trained in the relevant discipline; has been trained in patient safety and incident investigation. (To avoid conflict of interest, the specialist should not be in the same team that manage the patient)
 3. Other staff - clinicians from other disciplines, allied health officers or paramedics.
- Number of team members are depending on the severity and complexity of incident being investigated.
- Members should be credible, knowledgeable, objective and non-bias in conducting the investigation.
- Team members must have sufficient knowledge on:
 1. Clinical management or care process of incident under investigation
 2. Patient safety which looks into system improvement in a more comprehensive manner.
 3. The method/ mode of investigation used and analysis.

This knowledge is crucial to identify weakness of the system objectively and recommend effective action or solutions.

How To Ensure Smooth Process of Investigation?

- Appoint among the team member:
 1. Investigation team leader – Credible, knowledgeable officer who is objective, non-bias and able to control the team.
 2. Investigation team coordinator – Can be Risk Manager/ Quality Manager of hospital or any of the team members who is efficient in coordinating. This is flexible and depends on the situation and human resource capacity of the hospital.

- Team members are properly trained and fulfil requirement mentioned earlier
- Team members are committed to patient safety and serious in improving weakness of the system
- Good communication in the team. Allowing expression of ideas and concern. Ability to listen to opinion, suggestions or concern of other team members. One member should not dominate the whole team.

What Are The Responsibilities of The Investigation Team?

- Investigation team is the team responsible to get detail information on **“what happen, who are involved, where it happen, why it happen, when it happen and how it happen” (5 Ws + 1 H)**
- Analysis is then conducted after relevant information has been gathered.
- Analysis should be able to :
 1. Identify weakness of the system
 2. What can be done to prevent it from happening again?
 3. Provide useful recommendations which is doable and impactful.

How To Plan, Gather Information & Conduct The Investigation?

I) PLANNING

Depending on the type/ depth of investigation, planning may include the following:

- Plan duration of investigation, time line of each activity
- Plan what information/evidence need to be gathered
- Plan people that need to be interviewed or discussed – can be staff, patient, relative, Head of Department involved, supervisors, equipment supplier etc.
- Plan locations that need to be visited
- Plan other necessary resource/expert which is needed apart from the team member. For instance Hospital Support Service officers etc.

II) GATHERING OF INFORMATION

Depending on the type/ depth of investigation, gathering of information may include the following:

- All documents, materials, evidence pertaining to the incident should be collected as soon as possible.
- Essential information include:
 - o Incident Reporting Form received by the Risk Manager/ Quality Manager containing basic information of the incident
 - o Patient's case notes, monitoring charts, check list used (example: Safe Surgery Check List) from the departments involved
 - o Relevant guidelines, policies and procedures
 - o Relevant physical evidence or photographs- e.g faulty equipment, power source involved in fire, condition of the environment involved
 - o Staffing information such as staff roster

Identify appropriate expertise to understand the incident being investigated. This may require discussion with internal and/or external parties such as hospital support service companies, manufacturers, vendors, professional organizations, regulatory bodies.

III) CONDUCTING INVESTIGATION

Depending on the type/depth of investigation, investigation may include the following:

- Graphically describe the event using a chronological Flow Diagram or timeline and identify gaps in knowledge about the incident.
- Visit incident scene
- Discussion with staff/ patient involve/ other patients/relatives,
 - o Obtain information and comments about details of incident, patient care, staff responsibility, team dynamic, work issues, safety culture, leadership
- Discussion on work process
- Discussion with expertise
- The team may need to conduct specific interview with the staff to obtain these information.
- Depending on the type/depth of investigation, investigation team can divide the group to perform specific task concurrently. This will able to save time.

How To Discuss & Analyse Findings Of Investigation?

- Team members need to meet after completing the task and present findings of investigation.
- Based on the findings of the investigation, team members discuss and analyse what are the issues, or problems detected, contributing factors and root cause(s) that lead to the incident.
- Analysis should be able to :
 - ç Identify weakness of the system
 - o What can be done to prevent it from happening again?
 - o Provide useful recommendations which is doable and impactful.
- It is useful to systematically categorize the contributing factors of the incident into 7 categories. This is because the action plan for each category may be similar or related. It is also easier to prioritize the action based on the risk, resources and capacity available.
- Based on London Protocol (Please refer to Appendix 1), the categories can be divided into seven (7)
 1. Organizational factors
 2. Team factors
 3. Staff or individual factors
 4. Task and technology factors
 5. Environmental factors
 6. Patient factors
 7. External factors
- If possible try to find root cause(s) that lead to an incident. Nevertheless, in many cases, this may not be possible as the incident is not due to a singular or linear cause.

How To Formulate Action Plan And Risk Reduction Strategies?

- In order to address the identified contributing factors, effective risk reduction strategies/ action plan need to be formulated.
- Taking effective action is the most important step in Incident Reporting and Learning system.
- Lots of effort is wasted if the action plan is not effective and will not able to reduce harm in the healthcare.

- Investigation team should strive to identify actions that prevent the event from recurring or, if that is not possible, reduce the severity or consequences if it should recur.
- Refer to Chapter 11 – Risk Reduction Strategies and Action Plan.

How To Produce Report of The Investigation?

- Report should be produced based on the findings of investigation
- It should be factual, based on evidence.
- At minimum, Patient Safety Incident Investigation Report should include the following:
 1. Background of the incident, officers conducting the investigation
 2. Analysis/ investigation Findings
 3. Recommendations & Action Plan
 4. Lessons Learnt

What To Do With The Report?

- Investigation Report should not be left in the files after all the hard work.
- The report should be presented or disseminated to relevant individuals for further action
- Confidentiality and security of the report must be ensured at all times
- All investigation report must be managed by Risk Manager/ Quality Manager of the Hospitals.
- Systematic and safe archiving of report need to be established and ensured



□ **Chapter 9**

Root Cause Analysis
(RCA) & RCA²



What Is Root Cause ?

Root cause is the original cause for the failure or inefficiency of a process or the most fundamental reason why an event has occurred.

What Is Root Cause Analysis (RCA)?

- Root Cause Analysis (RCA) is a structured investigation that aims to identify the “root cause” of the problem and actions necessary to eliminate it. It is a risk management tool to understand WHY the problem occurs.
- Nevertheless, in many cases, it is not that easy to find the “root cause(s)” of the problem as the incident may not be due to a singular or linear cause.
- Hence, it is important to find the “significant contributing factors” leading to the incident and formulate risk reduction strategies that can control the risk effectively.

What Is RCA²?

- Concept of RCA² was introduced by National Patient Safety Foundation, USA in 2015.
- The rationale is because the traditional RCA process has had inconsistent success.

- Hence, in order to improve the effectiveness and utility of RCA, emphasis on the “Action” part with the ultimate objective to prevent future harm from the lessons learnt need to be emphasized.

(Source: National Patient Safety Foundation. Improving Root Cause Analyses and Actions to Prevent Harm. Version 2, 2016)

What Is The Main Goal of RCA²?

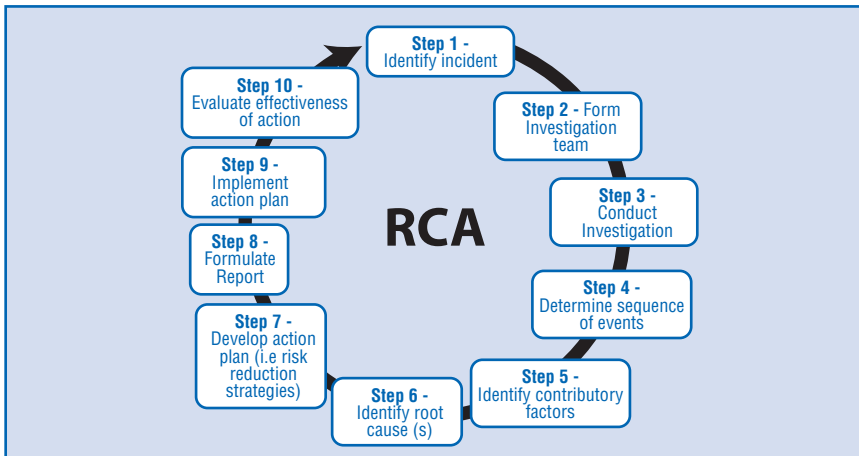
- To find the contributing factors, root cause(s)
- To find effective actions or solutions. Emphasize should be given to formulating effective risk reduction strategies and ensuring its implementation,

What Are The Characteristics of An Effective Analysis?

1. Analysis that focuses on systems and processes, not individual performance or blame
2. Analysis that focuses on both clinical and organisational processes.
3. Analysis that repeatedly digs deeper by asking ‘why?’, then when answered continues to keep asking ‘why?’ (i.e Using “Five Whys”).
4. Analysis that identifies changes to be made in systems and processes (redesign or development of new systems/processes) that effectively reduce the recurrence of clinical incidents.
5. An investigation team that is multidisciplinary in nature with involvement of those closest to the process. Team members should be familiar with the area in which the clinical incident occurred but not involved in the clinical incident.
6. An investigation that is thorough and credible.

(Source: Government of Western Australia, Department of Health- Clinical Incident Management Toolkit, 2016)

What Are The Key Steps In RCA?



STEP 1 – Identify incident & investigation level

- Identify incident which require RCA (Please refer to Chapter 8- Overview of Patient Safety Incident Investigation).

STEP 2- Select investigation team

- Select team members which fulfil the requirement (Please refer to Chapter 8- Overview of Patient Safety Incident Investigation).
- It is suggested that the investigation team is limited in size to 4 to 6 members. This is because larger team will use more person-hours to complete the review as well as increase the difficulty of scheduling team meetings.

STEP 3- Plan and conduct investigation (Please refer to Chapter 8- Overview of Patient Safety Incident Investigation).

STEP 4-Determine sequence of events (using flow chart or tabulation of events)

- Tabulate sequence of events which describe the incident using a Flow Diagram or timeline.
- Emphasis on what actually happened PRIOR to the incident.

- Based on Ministry experience, many RCA reports received gave emphasis and describe in length on the process after the incident instead of prior to the incident.

STEP 5-Identify contributing factors

- Based on the investigation, find the contributing factors that lead to the incident.
- It is useful to systematically categorize the contributing factors of the incident. This is because the action plan for each category may be similar or related. It is also easier to prioritize the action based on the risk, resources and capacity available.
- Based on the London Protocol, the contributing factors can be divided into seven(7) categories:
 - Management and organizational factors
 - Team factors
 - Staff or individual factors
 - Task and technology factors
 - Work and care environment factors
 - Patient factors
 - External factors

Categories of Contributing Factors Using London Protocol

CONTRIBUTORY FACTORS USING THE LONDON PROTOCOL			External Factor <ul style="list-style-type: none"> Political Economic Laws
Patient Factor <ul style="list-style-type: none"> Co-morbidity Difficulty in diagnosis Physical factor Personality 	Individual/ Staff Factor <ul style="list-style-type: none"> Competency Fatigue, stress, lapse in concentration Domestic Issues Staff-patient relationship 	Work and Care Environment <ul style="list-style-type: none"> Building, design layout Physical environment Structural, surrounding safety 	
Team Factor <ul style="list-style-type: none"> Communication Supervision Leadership in the team Clarity of responsibilities Support by staff, by superior: Work dynamic 	Task/ Technology Factor <ul style="list-style-type: none"> Availability of guideline, policy, protocols, SOP etc Availability of equipment LASA medication 	Management & Organization <ul style="list-style-type: none"> Leadership, governance of hospital Hospital policy & standard Resource, constrain Safety culture Work schedule 	

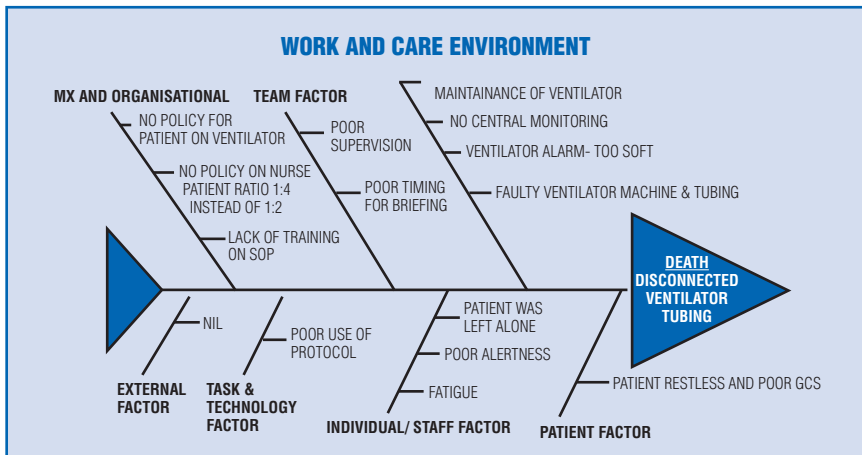
STEP 6-Determine root cause

- Root cause is defined as the original cause for the failure or inefficiency of a process; The most fundamental reason an event has occurred.
- Root cause may be one of the contributing factors that have been identified.
- In many instances, it is not easy to find the root cause(s) that lead to an incident as the incident may not due to a singular or linear cause. Most of the time, the incident is due to many contributing factors which are very significant to be controlled in order to reduce the risk in future.
- In order to determine the Root Cause, few methods can be used:

1. “Fish Bone Diagram” or “Ishikawa Diagram”

- This can be used as an effective step in problem solving by generating comprehensive list of possible contributing factors of the clinical incidents. From this, significant contributing factors or root cause(s) can be identified.

Example of Ishikawa Diagram (Fish Bone Diagram)

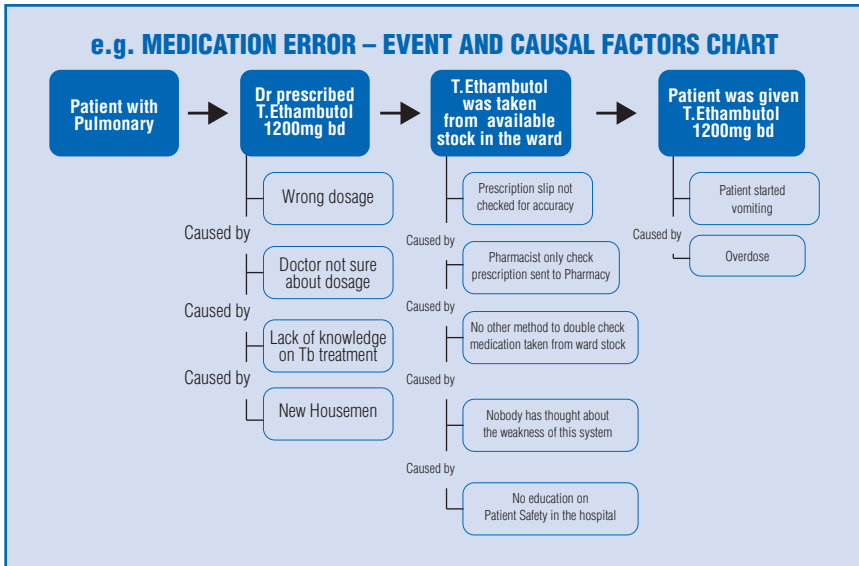


2. “Five Whys” Approach

- Repeatedly asking the question “why” which allows penetrating various layers of an issue which may lead to the root cause of the problem. This may assist the team to drill down and explore potential issues or real causes contributed to the incident which may lead to identifying the root cause.
- This is an example of “5 Whys” approach in a case of Medication Error :
 - o Why did the nurse give wrong medication to the wrong patient? Because she thought he was the right patient.
 - o Why did she think he was the right patient? She did not use “two identifiers” identify the correct patient.
 - o Why didn’t she use two identifier to identify correct patient? She did not know this policy.
 - o Why was she not trained in this policy? Because she is a senior staff and has been working for 10 years
 - o Why senior staff were not included in the training? We assume senior staff know what to do

3. Event and Causal Factors Charting

- Event and causal factor charting is a written or graphical description for the time sequence of contributing events associated with an accident.
- Although event charting is an effective tool for understanding the sequence of contributing events that lead to an accident, it may not necessarily yield root causes unless the causal factor is the root cause.



STEP 7- Develop risk reduction strategies/ action plan

- In order to address the root cause(s) or significant contributing factors, effective risk reduction strategies/ action plans need to be formulated.
- This is the most important step in the RCA² process.
- Investigation team should strive to identify actions that prevent the incident from recurring. If that is not possible, reduce the severity or consequences if it should recur.

(Please refer to Chapter 11 on Risk Reduction Strategies & Control Measure)

Step 8- Produce report and disseminate the report

- Report should be produced as soon as the investigation finishes.
- The content of the report should include the following:
 - i. Details of the incident
 - ii. Details of patient
 - iii. Details of Investigation team
 - iv. Person produced the report
 - v. Summary of the incident

- vi. Chronology of event
 - vii. Contributing factors, root cause(s)
 - viii. Action plan
 - ix. Lessons learnt
 - x. Attachment (if any)
- RCA² report need to be submitted to State Health Department and Ministry within **60 days following the incident.**
 - Present the report to top leaders/relevant officers in charge to get approval of the action plan and also for learning purposes

Step 9 – Implement action plan

- Recommended action plan should be implemented according to the plan

Step 10 – Evaluate effectiveness of actions

- Actions Implemented need to be monitored by specific officer and evaluated for effectiveness and problems that may occur.

What Are The Warning Signs of Ineffective RCA²

If any one or more of the following factors are true, then your specific RCA² review or your RCA² process in general needs to be re-examined and revised because it is failing:

- There are no contributing factors identified, or the contributing factors lack supporting data or information.
- One or more individuals are identified as causing the event; causal factors point to human error or blame.
- No stronger or intermediate strength actions are identified.
- Causal statements do not comply with the “Five Rules of Causation”
- No corrective actions are identified, or the corrective actions do not appear to address the system vulnerabilities identified by the contributing factors.
- Action follow-up is assigned to a group or committee and not to an individual.
- Actions do not have completion dates or meaningful process and outcome measures.
- The event review took longer than 45 days to complete.

- There is little confidence that implementing and sustaining corrective action will significantly reduce the risk of future occurrences of similar events.

(Source: National Patient Safety Foundation. Improving Root Cause Analyses and Actions to Prevent Harm. Version 2, 2016)

How To Measure Effectiveness & Sustainability Of RCA² Process?

National Patient Safety Foundation has come out with examples of measures that can be used to measure the effectiveness of RCA². These are:

- Percent of contributing factors written to meet the **Five Rules of Causation (Refer to Appendix 3)**
- Percent of RCA² reviews with at least one stronger or intermediate strength action
- Percent of actions that are classified as stronger or intermediate strength
- Percent of actions that are implemented on time
- Percent of actions completed
- Audits or other checks that independently verify that hazard mitigation has been sustained over time
- Staff and patient satisfaction with the RCA² review process (survey)
- Response to AHRQ survey questions pertinent to the RCA² review process
- Percent of RCA² results presented to the board

(Source: National Patient Safety Foundation. Improving Root Cause Analyses and Actions to Prevent Harm. Version 2, 2016)

□ **Chapter 10**

Multi Incident Root Cause
Analysis (MIRCA)

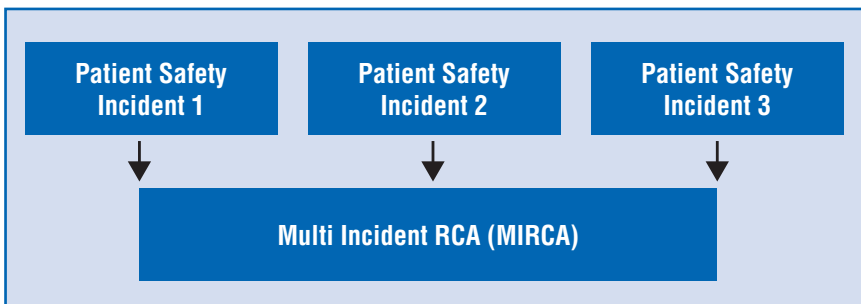


“FINDING COMMON ISSUES”

WHAT IS MIRCA?

- MIRCA is a process of investigating incidents with similar features using single Root Cause Analysis
- MIRCA can be used for incidents which **happen frequently** and result in no **harm, moderate or mild harm to patient** or **near misses** which **have not been investigated previously**.
- This combination of information is used to conduct a single RCA investigation to identify - contributing factors, root cause(s) and develop solutions.

CONCEPT OF MIRCA



WHAT IS THE BENEFIT OF MIRCA?

1. Reduce workload of the staff to conduct investigations
2. Saves time – only one RCA is done compared to multiple RCAs that address the same issue and requires more time.

WHAT ARE THE KEY STEPS IN MIRCA?

MULTI INCIDENT RCA (MIRCA)

Step 1 - Identify the subject and focus of investigation.

Step 2 - Form investigation team & plan the investigation

Step 3 - Review literature and gather expert views on the “area” being investigated.

Step 4 - Conduct RCA investigation

Step 5 - Determine actions

Step 6 - Write report and disseminate the report

Step 7 - Implement action plan

Step 8 - Evaluate actions

Step 1- Identify the subject and focus of investigation.

The subject can be “broad” or “narrow”.

- Broad theme (e.g: in-patient fall of all types combined together - fall in the toilet, fall at bedside, fall when mobilising)
- Narrow theme (e.g in-patient fall in the toilet only - which is more preferable)

Step 2- Form investigation team & plan the investigation

- Investigation team should be a mix of staff with knowledge of incidents, knowledge of RCA process and data analysis.

- All team members must have understanding of the incidents under review
- Plan the investigation- prepare relevant resources, gather relevant IR notification forms that need to be reviewed

Step 3- Review literature and gather expert views on the “area” being investigated.

- Evidence based practise (CPG), Standard Operating Procedure (S.O.P), other guidelines, policies, accreditation standards
- Expert opinion

Step 4 - Conduct RCA investigation

- Review timeline of each incidents
- Identify service delivery problems, contributing factors and root causes from the incident
- Ensure consistent investigation methods is used for each case
- Review, compare the - timelines, care and service delivery problems, contributory factors and root causes from all the incidents
- Look for cross-cutting or common issues that appear in most of the incidents

Step 5 - Determine actions

- Based on the issues identified, develop action plan to address the issues. (Please refer to Chapter 11- Risk Reduction Strategies and Action Plan)

Step 6- Write report and disseminate the report

- Present the report to top leaders/ relevant officers in charge to get agreement, approval and also for learning purposes

Step 7 – Implement action plan & evaluate action

- Implement of action plan to reduce the risk of harm to patients

- Monitor the implementation of action and evaluate for the effectiveness.
- Further actions need to be taken if actions are not effective and similar incident are still happening.

(Ammended from : National Patient Safety Agency. (2008). Root Cause Analysis Investigation Tool - A Guide to Aggregated and Multi-Incident RCA Investigation. UK: NHS.)

*Example of MIRCA is available in Appendix 2. Template of MIRCA

□ **Chapter 11**

Risk Reduction Strategies
& Action Plan



“LET’S DO IT EFFECTIVELY”

WHAT IS THE PRINCIPLE?

- The most important step in the Incident Reporting and Learning System is the process of taking ACTION in order to eliminate or reduce the probability of harm occurring to patients.
- Probability of harm occurring is what we called Risk
- Therefore, investigation team should strive to identify actions that is effective to reduce the risk and hence prevent recurrence of similar incidents.

WHAT IS RISK CONTROL?

- This the process of eliminating or reducing the risk to acceptable level.
- **Risk** can be controlled by eliminating the **hazard** or reducing the **exposure to hazard**
- In simple term:
 - o Risk is the probability of harm occurring
 - o Hazard is something which can cause harm
 - o Exposure is referring to exposure of a person to specific hazard.
- Simple equation which is important to understand is:

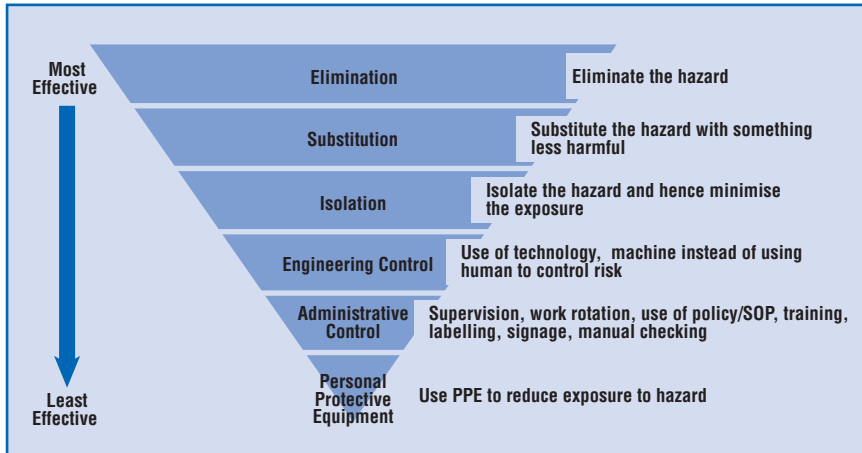
RISK = HAZARD X EXPOSURE

- Risk only arise when there is “hazard” and “exposure”

HOW TO CONTROL THE RISK IN HEALTHCARE?

- This can be done using similar approach which is used widely to manage occupational health and safety risk, using Hierarchy of Risk Control.

WHAT IS HIERARCHY OF RISK CONTROL?



- Hierarchy of risk control is a system of control measure based on the effectiveness of the control measure.
- The most effective or “stronger” control measure is the top most on the triangle which is elimination, followed by substitution, isolation, engineering control, administrative control and the use of Personal Protective Equipment.
- Examples are as follows:
 - o Elimination – Elimination of “High Alert Medication” from clinical area which are not using the medication. Hence, eliminate the hazard totally from patient
 - o Substitution – Substitute usual mattress with ripple mattress to prevent pressure ulcer among patient
 - o Isolation – Isolate highly infectious patient in an isolated room to prevent other patients from being infected
 - o Engineering Control – Use of computerised system to order medication rather than manual prescribing to reduce prescribing error and easy monitoring by the pharmacist. Use of safety needles to prevent needle stick injury. Use of non-slippery floor in the toilet.

- o Administrative Control – This include establishment of policy/guideline/ safe operating procedure, staff training, supervision of staff, work rotation, ensuring sufficient human resource to deliver care to patient, proper labelling, use of clear signage, use of 2 identifier to identify patient correctly, manual checking of prescription made by doctors.
- o Personal Protective Equipment – Use of mask/respirator, goggle, gloves, apron to protect patient or staff against various hazards in hospitals.
- Administrative control and PPE are “weaker” in controlling risk compared to engineering control because they depend very much on human factor such as human compliance in implementing the control.
- At times various types of control measures need to be used because one control measure is not sufficient to control the risk adequately. For instance staff need to be guided with CPG/SOP and undergo training.
- At times, “weaker” control measures need to be used while waiting for more effective control measures to be implemented.

HOW TO FORMULATE MORE EFFECTIVE ACTION PLAN?

- RCA² process emphasized very much on the most important step, which is “taking action”
- A tool called “Action Hierarchy” (i.e similiar to hierarchy of Risk Control) was developed by the US Department of Veterans Affairs National Centre for Patient Safety in 2001 to assist in strengthening of Action Plan. This approach is based on the Occupational Health and Safety “Hierarchy of Control” and has been customized for the use of healthcare organization.
- According to “ Action Hierarchy”, actions can be divided into three(3) categories:
 1. Stronger Actions - Which is “most effective”
 2. Intermediate Actions - Which is “moderately effective”
 3. Weaker Actions - Which is “less effective”
- In order to formulate effective Action plan, Investigation Team should identify **at least ONE (1) “STRONGER” or “INTERMEDIATE”** for each Action Plan formulated. At times, “weaker actions” need to be used while waiting for more effective or “stronger actions” to be implemented. This is only temporary measures.

Action Hierarchy

Incident	Definition	Definition
Stronger Actions (these tasks require less reliance on humans to remember to perform the task correctly)	Architectural/physical plant changes	Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.
	New devices with usability testing	Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.
	Engineering control (forcing function)	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/ fittings that can only be connected the correct way (e.g., IV tubing and connectors that cannot physically be connected to sequential compression devices or SCDs).
	Simplify process	Remove unnecessary steps in a process.
	Standardize on equipment or process	Standardize on the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.
	Tangible involvement by leadership	Participate in Patient Safety evaluations and interact with staff; support the RCA ² process; purchase needed equipment; ensure staffing and workload are balanced.

Incident	Definition	Definition
Intermediate Actions	Redundancy	Use two RNs to independently calculate high-risk medication dosages.
	Increase in staffing/ decrease in workload	Make float staff available to assist when workloads peak during the day.
	Software enhancements, modifications	Use computer alerts for drug-drug interactions.
	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.
	Education using simulation- based training, with periodic refresher sessions and observations	Conduct patient handoffs in a simulation lab/ environment, with after action critiques and debriefing.
	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fiber optic endoscopes.
	Eliminate look- and sound-alikes	Do not store look-alikes next to one another in the unit medication room.
	Standardized communication tools	Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handoff format.
	Enhanced documentation, communication	Highlight medication name and dose on IV bags.

Incident	Definition	Definition
Weaker Actions (these tasks require more reliance on humans to remember to perform the task correctly)	Double checks	One person calculates dosage, another person reviews their calculation.
	Warnings	Add audible alarms or caution labels.
	New procedure/ memorandum/ policy	Remember to check IV sites every 2 hours.
	Training	Demonstrate correct usage of hard-to-use medical equipment.

(Source: National Patient Safety Foundation. Improving Root Cause Analyses and Actions to Prevent Harm. Version 2, 2016; based on VA National Center for Patient Safety, http://www.patientsafety.va.gov/docs/joe/rca_tools_2_15.pdf.)

□ **Chapter 12**

Staff Responsibilities



No.	Staff	Responsibilities
01.	Staff who is involved in the incident or observed the incident	<ul style="list-style-type: none"> <li data-bbox="412 772 953 1002">I. Take immediate action to reduce risk to patient or others. For example, if the patient had allergic reaction due to wrong blood transfusion, the staff involved/ witnessed the incident should stop the transfusion immediately and gave immediate treatment to the patient. If necessary, senior officers need to be informed to assist in managing the situation. <li data-bbox="412 1034 953 1177">II. Report the incident using Incident Reporting 2.0 Form and send to the Risk Manager/ Quality Manager of the department within 48 hours from the time of incident. Ensure form is complete and description of incident is given. <li data-bbox="412 1209 953 1289">III. If possible, preserve the evidence which may assist in the investigation. Examples are photos of unsafe acts or unsafe conditions.

No.	Staff	Responsibilities
02.	Risk Manager/ Quality Manager of Hospital	<ol style="list-style-type: none"> <li data-bbox="412 280 954 363">I. Receive the I.R 2.0 Form. The form should be managed as “confidential record” and systematically. <li data-bbox="412 395 954 451">II. Notify the incident to Patient Safety Unit, MOH via e-IR within 5 working days of incident. <li data-bbox="412 483 954 627">III. Inform the Hospital Director, State Health Department and Patient Safety Unit (via email or telephone) immediately if the incident involved ‘severe/death’ outcome or potentially medico legal. <li data-bbox="412 659 954 742">IV. Determine the type and depth of investigation necessary (e.g RCA, MIRCA, record review & discussion, clinical audit etc) <li data-bbox="412 774 954 1002">V. Initiate, facilitate and coordinate process of investigation. Nevertheless, whenever the need arises, the process of coordinating specific investigation can also be given to “other officers who are suitable and competent”. However Risk Manager/ Quality Manager needs to be involved in following up the final outcome of the investigation and the implementation. <li data-bbox="412 1034 954 1233">VI. Only RCA report need to be submitted to the State Health Department and Patient Safety Unit (patientsafety@moh.gov.my), Medical Care Quality Section, Medical Development Division, Ministry of Health Malaysia. Submission of report is within 60 working days from the date of the incident. <li data-bbox="412 1265 954 1377">VII. Monitor progress of the recommended action plan. The Risk Manager/ Quality Manager should work closely with the person that has been appointed to implement the action plan.

No.	Staff	Responsibilities
		<p>VIII. Analyze trend of incidents, key issues and presented to hospital leaders and staff.</p> <p>IX. Coordinate training on Incident Reporting & Learning System</p> <p>X. Give feedback to the person who reports the incident or the relevant HOD using IR Prescription Slip .</p> <p>XI. Systematic and safe archiving of report need to be established and ensured. All investigation report must be managed and secured</p>
03.	State Health Department	<p>I. Review notification of incidents sent by hospitals within the relevant state.</p> <p>II. Monitor and improve the reporting quality (e-IR, RCA reports).</p> <p>III. Ensure investigation and necessary action is taken by hospitals</p> <p>IV. Provide technical assistance in implementation of IR & learning system such as capacity building.</p> <p>V. Conduct site visit to facilitate/ monitor action plan and improvement.</p> <p>VI. Facilitate in implementation of action to solve hospital issues (such as providing necessary resource etc)</p> <p>VII. Give feedback to Patient Safety Unit, MOH</p>
04.	Patient Safety Unit, Ministry of Health	<p>I. Receive notification of every incidents via e-IR</p> <p>II. Monitor and analyse e-IR data. Calculate and observe the rate of events over time. This might identify new changes or significant changes or even suggest a new problem</p>

No.	Staff	Responsibilities
		<p>III. Analyse national data of incidents and produce report regularly and timely. (Reports are accessible via Patient Safety Council of Malaysia & Patient Safety Unit, Ministry of Health website.)</p> <p>IV. Review RCA reports received from hospitals and give feedback to hospitals and states.</p> <p>V. Result of analysis and RCA findings are used to identify common patient safety issues in the country and is shared with relevant stakeholders for further actions or for new policy, programme development</p> <p>VI. Conduct training of the system implementation to the State Health Departments as well as the hospitals when required.</p> <p>VII. Give feedback to Director General of Health Malaysia, Patient Safety Council of Malaysia, State Health Departments.</p> <p>VIII. Continuously improving the Incident Reporting & Learning System based from feedback received.</p>

□ **Appendices**

Appendix 1

FRAMEWORK OF CONTRIBUTORY FACTORS INFLUENCING CLINICAL PRACTICE – LONDON PROTOCOL

Factor Types	Contributory Influencing Factor
Patient Factors	<ul style="list-style-type: none"> • Condition (complexity & seriousness) • Language and communication • Personality and social factors
Task and Technology Factors	<ul style="list-style-type: none"> • Task design and clarity of structure • Availability and use of protocols • Availability and accuracy of test results • Decision-making aids
Individual (staff) Factors	<ul style="list-style-type: none"> • Knowledge and skills • Competence • Physical and mental health
Team Factors	<ul style="list-style-type: none"> • Verbal communication • Written communication • Supervision and seeking help • Team structure (congruence, consistency, leadership, etc.)
Work Environmental Factors	<ul style="list-style-type: none"> • Staffing levels and skills mix Workload and shift patterns • Design, availability and maintenance of equipment • Administrative and managerial support • Environment • Physical
Organisational & Management Factors	<ul style="list-style-type: none"> • Financial resources & constraints • Organisational structure • Policy, standards and goals • Safety culture and priorities
Institutional Context Factors	<ul style="list-style-type: none"> • Economic and regulatory context • National Health service executive • Links with external organisations

Source: Vincent, C., Taylor-Adams, *Systems analysis of clinical incidents: The London Protocol, Clinical Risk J. 2004; Vol 10, Issue 6, 211 – 220.*

CONTRIBUTORY FACTORS FRAMEWORK – THE LONDON PROTOCOL (MODIFIED)

Patient Factors	
Clinical	<ul style="list-style-type: none"> • Known risk associated with treatment • Pre-existing co-morbidity • Complexity of condition • Seriousness of condition • Treatability of condition • Difficulty in diagnosis • Clinical / health history • Inexplicable / Unknown factors
Personal	<ul style="list-style-type: none"> • Personality • Physical state (e.g. malnourished, poor sleep pattern, • Cultural background • Religious beliefs • Language and communication • Social and family circumstances • External support • Stress • Disclosure of health history
Interpersonal	<ul style="list-style-type: none"> • Patient-staff relationship • Patient-patient relationship

Task and technology factors	
Availability and use of protocols (including guidelines)	<ul style="list-style-type: none"> • Availability of protocols to staff • Use of protocols • Poor quality of information included in the protocol • Procedures for reviewing and updating protocols • Inappropriate use of protocol
Availability and accuracy of health information, including medical record and test results	<ul style="list-style-type: none"> • Availability of information • Reliability of information • Information inaccessible to staff • Misinterpretation by staff • Disagreements regarding the interpretation of information

Task and technology factors	
	<ul style="list-style-type: none"> • Inadequately flagged information/ alert • Need to chase up information
Task design	<ul style="list-style-type: none"> • Relevance • Ease of task execution • Design deficiency
Decision making aids	<ul style="list-style-type: none"> • Availability, use and reliability of specific types of equipment e.g. CTG • Availability, use and reliability of specific types of tests, e.g. blood testing • Availability and use of a senior clinician
Medication- related	<ul style="list-style-type: none"> • Wrong medication • Adverse drug reaction • Miscalculation • Complicated dosage design • Mislabelling • Incorrect computer entry • Poor/ Similar packaging and labelling • Similar looking or sounding names
Radiotherapy related	<ul style="list-style-type: none"> • Miscalculation of dose • Error in execution of treatment • Delay in treatment

Staff Factors	
Competence	<ul style="list-style-type: none"> • Inadequate knowledge • Inadequate skills • Inadequate experience
Compliance	<ul style="list-style-type: none"> • Failure to comply with policy / Procedure / Protocol • Intentional violation • Unintentional violation
Personal	<ul style="list-style-type: none"> • Personality

Staff Factors	
	<ul style="list-style-type: none"> • Stress • Fatigue • Distraction • Attitude • Inadequate motivation • Lapse of concentration • Mental impairment (e.g. illness, drugs, alcohol, pain) • Specific mental health illness (e.g. depression)
Inter-personal	<ul style="list-style-type: none"> • Domestic issue • Staff-patient relationship • Staff-staff/ team relationship • Staff - organisation relationship • Other

Team Factors	
Verbal Communication	<ul style="list-style-type: none"> • Communication between junior and senior staff • Communication between professions • Communication outside of the ward/ department • Inadequate hand over • Communication between staff and patient • Communication between specialists and departments • Communication between staff of the same grade • Voicing disagreements and concerns • Communication between staff and relatives or carers
Written communication	<ul style="list-style-type: none"> • Incomplete/ absent information (e.g. test results) • Incomplete/ absent information (e.g. test results, handover) • Discrepancies in the notes/ documentation • Incomplete documentation • Illegible • Missing signature • Poor quality of information in the notes/ documentation • Inter-dept communication

Team Factors	
	<ul style="list-style-type: none"> • Communication with MoH/ other hospitals/ agencies • Misinterpretation
Supervision and seeking help	<ul style="list-style-type: none"> • Decision/willingness of staff to seek help • Unavailability of staff to help • Responsiveness of staff to help
Congruency/ consistency	<ul style="list-style-type: none"> • Definition of tasks between professions • Definition of tasks between different grades of staff • Definition of tasks between same grades of staff
Leadership & Responsibility	<ul style="list-style-type: none"> • Ineffective leadership in the team (e.g. by the Head of Department, Head of Nursing in the Department) • Unclear definitions of responsibility
Staff colleagues response to incident	<ul style="list-style-type: none"> • Inadequate support by peers after incident • Inadequate support by staff of comparable grades across professions e.g. senior nurse and junior doctor

Work and Care Environment	
Building and design	<ul style="list-style-type: none"> • Maintenance Management • Functionality (ergonomic assessment e.g. lighting, spaces, etc.)
Physical environment	<ul style="list-style-type: none"> • Housekeeping • Control of the physical environment (e.g. temp, light, etc.) • Movement of patient between wards/ sites • Storage
Equipment / supplies	<ul style="list-style-type: none"> • Malfunction/ Failure of equipment • Maintenance management • Functionality (e.g. ergonomic design, fail safe, standardisation) • System design

Work and Care Environment	
Staffing	<ul style="list-style-type: none"> • Unavailability/ Inadequate staff • Allocation of staff • Recruitment
Education and training	<ul style="list-style-type: none"> • Induction/ Orientation • Ongoing and refresher training
Workload / Hours of work	<ul style="list-style-type: none"> • Inadequate regular rest breaks • Heavy workload
Service delivery	<ul style="list-style-type: none"> • Long working hours • Delay • Missed • Inappropriate

Management and Organizational	
Leadership and governance	<ul style="list-style-type: none"> • High Level leadership presence at hospital level • Leadership style • Governance arrangement including clinical governance
Organisational structure	<ul style="list-style-type: none"> • Hierarchical arrangement of staff within the organizational context • Span of control • Unclear roles/ responsibility • Management arrangements (function)
Objectives, policies and standards	<ul style="list-style-type: none"> • Operation (e.g. Facility Management, Materials Management, Contract Management) • Human resources policy • Financial policy • Information policy • Risk management (e.g. incident reporting, Investigation and analysis, safety culture) • OSH management

Management and Organizational	
Resource & constraints	<ul style="list-style-type: none"> • Human resources • Financial
Safety culture & priorities	<ul style="list-style-type: none"> • Inadequate safety culture • Priorities in safety

External Factor	
Political	<ul style="list-style-type: none"> • Goals • Perceptions
Economic	<ul style="list-style-type: none"> • Climate
Regulatory	<ul style="list-style-type: none"> • Laws and regulations • Ministry of Health requirements • Requirements of other regulatory agencies/bodies
Partnership working with external organisation	<ul style="list-style-type: none"> • Governance arrangements • Management arrangements • Contractual arrangements • Communication

APPENDIX 2 EXAMPLE MIRCA REPORT

MIRCA FORMAT

- 1) Subject under investigation: Patient fall in the toilet of Hospital Cemerlang
- 2) Profile of Incident investigated & contributing factors

No.	Date of Incident	Brief summary of the incidents & the patient's outcome	Contributing Factors
01.	12/3/16	65 years old gentleman at Ward 10A (Medical Ward) with uncontrolled hypertension. He fell in the toilet at Day 1 of admission due to slippery floor of toilet. He sustained head injury with Left subdural haematoma He went to the toilet on his own although he felt dizzy. No risk assessment of fall conducted by staff. No education was given to patient on fall prevention. He was wearing slippers during the incident.	<ol style="list-style-type: none"> 1. Slippery floor- tiles used are not appropriate and wet flooring 2. No policy on fall prevention in the hospital, no education given 3. Patient was wearing slippers
02.	3/4/16	70 years old gentleman at Ward 10A (Medical Ward) with COAD. He fell in the toilet on Day 2 of admission. The floor was slippery. The patient sustained fracture of Right Ulnar. No risk assessment of fall conducted by staff. No education was given to patient on fall prevention.	<ol style="list-style-type: none"> 1. Slippery floor- tiles used are not appropriate and wet flooring 2. No policy on fall prevention in the hospital, no education given

No.	Date of Incident	Brief summary of the incidents & the patient's outcome	Contributing Factors
03.	27/4/16	67 years old gentleman at Ward 9A (Paliative Ward) with cancer of prostate. He fell in the toilet at Day 3 of admission due to slippery floor. He was not accompanied by his wife as he has been in the hospitals for 3 days and so far he went to toilet on his own without any difficulty. He had laceration wound at his forehead. No education was given to patient on fall prevention.	<ol style="list-style-type: none"> 1. Slippery floor- tiles used are not appropriate and wet flooring 2. No policy on fall prevention in the hospital, no education given
04.	9/5/16	30 years old lady from Ward 7A (Surgery) with breast cancer. Admitted for mastectomy. Fell in the toilet at Day 1 due to slippery floor. She had soft tissue injury. No risk assessment of fall conducted by staff. No education was given to patient on fall prevention. She was wearing safe footwear during the incident	<ol style="list-style-type: none"> 1. Slippery floor- tiles used are not appropriate and wet flooring 2. No policy on fall prevention in the hospital

3) References used

No.	Resource
01.	Guideline on Fall Prevention In Hospital By Patient Safety Agency
02.	Fall prevention checklist By Patient Safety Agency
03.	A guide to Safe Hospital Environment By XYZ
04.	National Accreditation Standard by MSQH
05.	Patient admission checklist of Hospital Cemerlang
06.	Patient education leaflet of Hospital Cemerlang
07.	S.O.P of nursing care of Hospital Cemerlang

4) Team members

No.	Name	Designation
01.	Dr. Aireen J	Consultant Geriatrician
02.	Dr. Mahmood Y	Medical Officer Ward 1A
03.	Matron Aliah T	Matron Paediatrics Ward
04.	Sr Normah M	Quality Officer of Hospital XYZ

5) Significant problems identified:

No.	Problem
01.	Floor is slippery , tiles used are not suitable & Wet flooring
02.	No policy on patient fall prevention in the hospital
03.	No patient education on fall prevention was given

6) Action Plan:

No.	Problem	Action	Resources Needed	Person Responsible	Date commenced	Date review
01.	Floor is slippery	<ul style="list-style-type: none"> - Change tiles of toilet to non slippery flooring. - Cleaner to increase frequency of toilet cleaning from twice a day to 4 times a day 	<ul style="list-style-type: none"> -Budget for new toilet flooring RM... -More time hours needed for Hospital Support Service Cleaner... hours; RM..... 	<p>Dr. Nasrul Nizar (Deputy Director of Hospital Cemerlang)</p> <p>Mr. Reh (Manager of Hospital Support Service)</p>	<p>1/8/2016</p> <p>1/7/2016</p>	<p>31/12/2016</p> <p>7/7/2016</p>
02.	No policy on Fall Prevention	<ul style="list-style-type: none"> - Develop policy and guideline on fall prevention - Training for staff need to be planned & implemented 	<ul style="list-style-type: none"> • Time need to be allocated for Task Force involved... hours • Printing of policy for circulation RM..... • Time hours required for training of staff 	Dr Adleena Wong (Geriatrician)	1/7/2016	1/9/2016
03.	Patient was not given education on fall prevention and the use of proper footwear to toilet	Develop education material for patient and start patient education on fall prevention	<ul style="list-style-type: none"> • Time need to be allocated for Task Force involved to formulate the 	Dr Zarith Nazham (Rehab Registrar)	1/7/2016	1/8/2016

No.	Problem	Action	Resources Needed	Person Responsible	Date commenced	Date review
			education material... hours <ul style="list-style-type: none"> • Printing of education material RM... • Time hours required for training of staff... hours 			

APPENDIX 3 THE FIVE RULES OF CAUSATION

THE FIVE RULES OF CAUSATION

The wording of the rules below is based on The Five Rules of Causation developed by the Department of Veterans Affairs, Veterans Health Administration, and appearing in their NCPS Triage Cards™ for Root Cause Analysis (version October 2001, see <http://cheps.engin.umich.edu/wp-content/uploads/sites/118/2015/04/Five-Rules-of-Causation.pdf>) and their document Root Cause Analysis (RCA), http://nj.gov/health/ps/documents/va_triage_questions.pdf. The rules were adapted from the Federal Aviation Administration technical report “Maintenance Error Causation,” by David A. Marx, June 9, 1999.

After the RCA² team has identified system vulnerabilities, these need to be documented and written up to comply with the Five Rules of Causation. Applying the rules is not a grammar exercise. When the rules are met, causal statements will be focused on correcting system issues. Causal statements also have to “sell” why the corrective actions identified by the team are important. Using the format described in this appendix will increase the likelihood that the corrective actions will be supported. Causal statements are written to describe (1) Cause, (2) Effect, and (3) Event. Something (Cause) leads to something (Effect) which increases the likelihood that the adverse event will occur.

Example: A high volume of activity and noise in the emergency department led to (cause) the resident being distracted when entering medication orders (effect) which increased the likelihood that the wrong dose would be ordered (event).

Rule 1. Clearly show the “cause and effect” relationship.

INCORRECT : A resident was fatigued.

CORRECT : Residents are scheduled 80 hours per week, which led to increased levels of fatigue, increasing the likelihood that dosing instructions would be misread.

Rule 2. Use specific and accurate descriptors for what occurred, rather than negative and vague words. Avoid negative descriptors such as: Poor; Inadequate; Wrong; Bad; Failed; Careless.

INCORRECT : The manual is poorly written.

CORRECT : The pumps user manual had 8 point font and no illustrations; as a result nursing staff rarely used it, increasing the likelihood that the pump would be programmed incorrectly.

Rule 3. Human errors must have a preceding cause.

INCORRECT : The resident selected the wrong dose, which led to the patient being overdosed.

CORRECT : Drugs in the Computerized Physician Order Entry (CPOE) system are presented to the user without sufficient space between the different doses on the screen, increasing the likelihood that the wrong dose could be selected, which led to the patient being overdosed.

Rule 4. Violations of procedure are not root causes, but must have a preceding cause.

INCORRECT : The techs did not follow the procedure for CT scans, which led to the patient receiving an air bolus from an empty syringe, resulting in a fatal air embolism.

CORRECT : Noise and confusion in the prep area, coupled with production pressures, increased the likelihood that steps in the CT scan protocol would be missed, resulting in the injection of an air embolism from using an empty syringe.

Rule 5. Failure to act is only causal when there is a pre-existing duty to act.

INCORRECT : The nurse did not check for STAT orders every half hour, which led to a delay in the start of anticoagulation therapy, increasing the likelihood of a blood clot.

CORRECT : The absence of an assignment for designated RNs to check orders at specified times increased the likelihood that STAT orders would be missed or delayed, which led to a delay in therapy.

References

1. Farhad Peerally, M., Carr, S., Warring, J., & Dixon-Woods, M. (2017). The Problem with Root Cause Analysis. (1-6), *BMJ Quality & Safety*, 26(5), 417-422.
2. Imogen, M., Anne, S., Smith, K., Pronovost, P., & Wu, A. (2015). Patient Safety Reporting : A Qualitative Study of Thoughts and Perceptions of Experts 15 Years After 'To Err is Human'. *BMJ Quality & Safety*, *Published Online First: 27 July 2015*. doi: 10.1136/bmjqs-2015-004405.
3. Johnson, C. (2002). Reason for The Failure of Incident Reporting in the Healthcare and Rail Industries. (pp. 31 - 57), *In Proceedings of the Tenth Safety-Critical Systems Symposium*, Southampton, UK.
4. Leape, L. L. (2002). Reporting of Adverse Events. 347(20), *The New England Journal of Medicine*, 347(20), 1633.
5. Macrae, C. (2015). The Problem with Incident Reporting. 25(71-75), *BMJ Quality & Safety* Published Online First: 07 September 2015. doi: 10.1136/bmjqs-2015-004732.
6. Ministry of Health Malaysia. (1999). *Quality Manual : Incident Reporting*.
7. Ministry of Health Malaysia. (2013). *Incident Reporting & Learning System From Information to Action Manual*.
8. National Patient Safety Agency. (2008). *Root Cause Analysis Investigation Tool - A Guide to Aggregated and Multi-Incident RCA Investigation*. National Patient Safety Agency, NHS UK.
9. National Patient Safety Foundation. (2015). *RCA²: Improving Root Cause Analyses and Actions to Prevent Harm*. Boston
10. Taylor-Adams, S., & Vincent, C. (2004). *System Analysis of Clinical Incidents : The London Protocol*. *Clinical Risk*, 10(6), 211-220.
11. Western Australia Department of Health, The Patient Safety Surveillance Unit. (2016). *Clinical Incident Management Toolkit*. Perth
12. World Health Organisation. (2009). *The Conceptual Framework for the International Classification for Patient Safety*. Geneva

