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STANDARD OPERATING PROCEDURE (SOP)

FOR THE MANAGEMENT OF PATIENT SAFETY INCIDENT REPORTING AND LEARNING

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1. INTRODUCTION

This procedure describes the steps to be taken in managing Patient Safety Incident (PSI) reporting and to ensure that learning takes place from the data that has been collected at Vikhe Patil Memorial Hospital.

PSI is an event or circumstance that could have resulted, or did result in harm to a patient as a result of the health care services provided, and not due to the underlying health condition. These are considered incidents. An incident can be a near miss, no harm incident or harmful incident (adverse event).

Near miss is an incident which did not reach the patient. **No harm incident** is an incident which reached a patient but no discernible harm resulted. **Harmful incident (adverse event)** is an incident that results in harm to a patient that is related to medical management, in contrast to disease complications or underlying disease.

The purpose of this Standard Operating Procedure:

- Prevent and or reduce harm to patients whilst undergoing medical care
- Ensure that statistical data on PSIs are readily available for planning and decision making
- Learn from data collected on PSIs to prevent reoccurrence to ensure that patient safety, quality of care and health outcomes of patients are improved
- Ensure that preventive measures are put in place to reduce the incidence of PSIs and prevent their reoccurrence
- Continuously improve quality of care through the identification of all missed opportunities in ensuring optimal patient outcomes
- Ensure appropriate communication with patients who have been harmed due to a PSI, including an apology if indicated

2. SCOPE

All staff working in the hospital is responsible to:

- Report and record all patient safety incidents
  - Report all incidents that resulted in serious harm or death (Severity Assessment Code 1 incidents) within 24 hours to management and district/provincial office
- Commence and/or participate in the open disclosure process as appropriate
- Participate in the investigation of incidents as required
- Finalise Severity Assessment Code 1 incident reports within sixty working days
- Participate in the implementation of recommendations arising from the investigation of incidents
- encourage colleagues to report incidents that have been identified

3. PRINICIPLES OF PSI MANAGEMENT

All PSIs will be managed according to the following principles:

- Just Culture
- Confidential
- Timely
- Responsive
- Openness about failures
- Emphasis on learning

4. PATIENT SAFETY COMMITTEE

The Patient Safety Committee will ensure that PSIs are managed effectively. The Committee's main objective is to oversee the effective management of PSIs. The Terms of Reference and composition of the committee is set out below.

4.1 Terms of reference of Committee

- Develop a Standard Operating Procedure (SOP) to manage PSIs
- Designate a staff member that is responsible to manage and coordinate PSIs.
- Monitor that the hospital adhere to the SOP for the management of PSIs.
- Management must report all Severity Assessment Code 1 incidents to the respective district/provincial office within 24 hours.
- Review PSI reports for all Severity Assessment Code 1 incidents that are reported. In cases where further investigation is required, investigate incident.
- Monitor that all Severity Assessment Code 1 incidents reports are finalised within 60 days.
- Monitor that recommendations are implemented to prevent reoccurrence of the incident.
- Conduct monthly meetings of which the minutes will be recorded.
- Compile and analyse statistical reports to identify trends.
- Submit monthly statistical reports to the respective district/provincial office or Verification of web-based application data will be done at the end of each month to ensure that reports that are generated at district/provincial level from the web-based application are accurate
- Make recommendations to improve patient safety according to trends identified.
- Disseminate lessons learned from PSI management.
- Implement guidelines and protocols that support staff and encourage an environment where incident notification and active management of incidents is fostered.
- Attend district/provincial Patient Safety Committee meetings when required.
- Ensure that regular training of staff on the management of PSIs takes place.
- Identify education needs emerging from PSI management.

4.2 Designation of members of the Committee

- Chief Executive Officer
- Clinical Manager (Chairperson)
- Quality Assurance manager
- Nursing manager/s
- Representative of the Infection and prevention control section
- Complaints manager/ Public relations officer
- Head of corporate services
- Representative of the Occupational health and Safety division
- On an ad-hoc basis:
    - Nursing Managers of areas where the incidents took place
    - Clinical Heads of areas where the incidents took place
    - Specialist expertise as applicable to the case discussed

5. PROCESS TO MANAGE PSIs

Once a PSI has been identified a series of action steps should be followed to ensure the effective management of PSIs. These action steps are as follows:

5.1 Step 1: Identifying patient safety incidents

The following methods will be used to detect PSIs:

- Patient safety incident reporting by health professionals
- Medical record / retrospective patient record review
- Focus teams
- External sources
- Review of record on follow-up of patients
- Surveys on patients' experience of care
- Safety walk rounds
- Use data to identify and guide management of PSIs
- Research studies and findings

5.2 Step 2: Immediate action

Following identification of a PSI, it may be necessary to take immediate actions to mitigate the harmful consequences of the incident. These actions may include:

- Providing immediate care to individuals involved in the incident (patient, staff or visitors) to prevent the harm from becoming worse
- Making the situation/scene safe to prevent immediate recurrence of the event
- Gathering basic information from staff while the details are still fresh in the minds of the involved clinicians

5.3 Step 3: Prioritisation

The purpose of prioritisation is to ensure that a standardised, objective measure of severity is allocated to each incident. The Severity Assessment Code (SAC) should be used to prioritise all notifications. The key purpose of the SAC is to determine the level of investigation and action required. Therefore the degree of harm suffered should be the key consideration.

There are three classes in the SAC, classes 1, 2 and 3. SAC 1 includes incidents where serious harm or death occurred; SAC 2 includes incidents that caused moderate harm and SAC 3 includes incidents that caused minor or no harm. See Annexure A that describes the SAC.

5.4 Step 4: Notification

All PSI data will be recorded and analysed in the following manner:

- **Record keeping**

All PSIs will be recorded on a PSI reporting form, see annexure B. Section A (notification) of the form will be completed by the manager of the section where the incident took place. In cases where the PSI was identified by making use of one of the methods as described in section 5.1 (retrospective reviews), the PSI reporting form must also be completed. Section 9 of the PSI form makes provision for selecting the method by which the PSI was detected. In some of these cases staff will not be able to complete section B (statements of staff involved) of the form if the staff involved have left the service or could not be identified. If the incident is a SAC1 incident, submit section A and B to the district/provincial office for notification. Section B (statements by staff patient or significant other) of the form will be completed by the staff, patients or significant others that were present while the incident took place. Section C (investigation) of the form will be completed by the staff member(s) that has investigated the incident, in most cases this would be the manager(s) of the section where the incident took place.

- A summary of all PSIs will be populated into a PSI register, see annexure C.

Incident notification to Management

All SAC 1 incidents will be reported within 24 hours to the district/provincial office. PSIs with SAC rating of 2 or 3 will be reported to the executive management.

Initial notification to patient

Initial disclosure will take place as early as possible after the incident. Information should be a provided to the patient and family in a clear and simple language, and the occurring error recognised and explained. The provider should share with the patient and/or their family or carer what is known about the incident and what actions have been taken to immediately mitigate or remediate the harm to the patient. The discussion should focus on the condition as it currently exists i.e. no assumptions and uncertain future actions should be communicated at this stage. It is the obligation of the health care organization to provide support or assistance as required to patients,

family and health professionals involved. Patients, family and healthcare professionals often also require psychological support.

The following, depending on careful assessment of circumstances, may be communicated to the patient or representative:

- The facts of the harm and incident known at that time
- Steps taken for ongoing care of the patient
- An expression of sympathy by the health care provider or organisation
- A brief overview of the investigative process that will follow including time lines and what the patient should expect from the analysis
- An offer of future meetings as well as key contact information
- Time for patients and or representative to ask questions. Provide answers that you are sure of at the time. Where uncertain, promise to and seek answers for the patient
- Where necessary offer practical and emotional support
- Plan for future investigation and treatment required
- Remedial action taken
- The relevant health professional involved can at this stage convey their apology in a sincere manner
- Systems to support the health professionals involved should also be in place

5.5 Step 5: Investigation

All notified incidents require investigation at an appropriate level. The SAC applied in the prioritisation stage guides the level of investigation.
An investigative report should include:

- A detailed chronology of circumstances leading to the incident
- A summary of the interviews conducted with staff, patient or significant other
- Root cause analysis that includes the actions to be taken
- Conclusions by Patient Safety committee
- Recommendations arising from the investigation.

PSIs should be investigated by means of systems Root Cause Analysis (RCA) to determine cause and then to ensure prompt improvement to prevent the same PSI from reoccurring. Underlying causes should be explored and solutions or corrective actions to improve the system should be identified. Remedial actions can include but is not limited to, appropriated training or education of staff members, correction of system failures and appropriate disciplinary action in cases where reckless behaviour was identified. Incidents where a health professional displayed reckless behaviour should also be referred to the relevant professional body for further management. See Annexure B; section C, number 2b of the PSI reporting form for a framework for RCA and action plans.

In cases where staff was found to be the cause of the incident the just culture should be applied. A just culture recognises that:

- human error and faulty systems can cause an error
- individual practitioners should not be held accountable for system failings over which they have no control
- competent professionals make mistakes
- even competent professionals will develop unhealthy norms (shortcuts, "routine rule violations").

Although the Just Culture does not support the punishment of staff that made mistakes, it has zero tolerance for reckless behaviour. It supports coaching and education if the mistake was inadvertent, or occurred in a system that was not supportive of safety.

The Just Culture is founded on three behaviours, Human error, At-risk Behaviour and Reckless behaviour. The hospitals should console those who commit human error, coach those who are guilty of at-risk behaviour and discipline those with reckless behavior, see table 1. In some cases where an incident is reported as a PSI the outcome of the investigation can also conclude that no error occurred.

Human Error	**At-Risk Behaviour**	**Reckless Behaviour**
Product of our current system design and behavioural choices	A Choice: Risk believed insignificant or justified	Conscious disregard of substantial and unjustifiable risk
Manage through changes in:	Manage through:	Manage through:
• Choices • Processes • Procedures • Training • Design • Environment	• Removing incentives for at risk behaviours • Creating incentives for healthy behaviours • Increasing situational awareness	• Remedial action • Disciplinary action
Console	**Coach**	**Discipline**

Table 1: Just culture Model

The following algorithm can be used by managers to determine the type of behaviour according to the Just Culture:

- Did the employee intend to cause harm?
- Did the employee come to work under the influence or equally impaired?
- Did the employee knowingly and unreasonably increase risk?
- Would another similarly trained and skilled employee in the same situation act in a similar manner?

If the first three answers are "No" and the last "Yes" the origin of the unsafe act lies in the organisation, not the individual.

Investigation of PSIs will be concluded within 60 working days from the occurrence of the incident. A PSI is viewed as concluded under the following circumstances:

- The case has been investigated and the committee for review of PSIs has **concluded** an outcome with recommendations.
- Written confirmation has been received that the hospital is being sued and therefore the case will be further **managed by a court of law**.
- The case has been referred to the **Labour Relations** section for further management.

In the last two instances although the case will be closed on the PSI Management Reporting System, the outcome of the investigations conducted by the relevant organisations/sections should be noted in the PSI reporting form once it has been concluded by either a court of Law or the Labour Relations section.

5.6 Step 6: Classification

All PSIs will be classified according to the following classes:

- agents (contributing factors), see annexure D
- incident type, see annexure E
- incident outcome, see annexure F

5.7 Step 7: Analysis

All data on PSIs will be analysed and recommendations will be made for change to prevent reoccurrence.

Three indicators will be monitored as set out in table 2.

Indicator name	Calculation of Indicator	
Patient Safety Incident case closure rate	Total number of PSI case closed in the reporting month	X 100
	Total number of PSI cases reported in the reporting month	
Severity assessment code (SAC) 1 incident reported within in 24 hours rate	Total number of SAC 1 incidents that were reported within 24 hours in the reporting month	X 100
	Total number of SAC 1 incidents in the reporting month	
Patient Safety Incident case closure within 60 working days rate	Total number of PSI cases closed within 60 days in the reporting month	X 100
	Total number of PSI cases closed in the reporting month	

Table 2: Calculation of Indicators for patient safety incidents

Monthly reports will be submitted to the district/provincial office or Verification of web-based application data will be done at the end of each month to ensure that reports that are generated at provincial level from the web-based application are accurate.

The following statistical data will be recorded and submitted or will be printed from the web-based application and filed:

- Data on classifications of agents involved, see annexure G
- Data on classifications of incident type, see annexure H
- Data on classifications of incident outcome, see annexure I
- Indicators for PSIs, see annexure J

Statistical data for SAC 1 incidents should be kept separate from statistical data on SAC 2 and SAC 3 incidents.

5.8 Step 8: Implementation of recommendations

Recommendations from the investigations and reviews should be implemented to ensure the development of better systems to ensure improved practices. The Root Cause Analysis indicates the time frames as well as the staff responsible for implementation, see annexure B, section C, number 2b (Framework for RCA and actions).

5.9 Step 9: Learning

The fundamental role of PSI reporting systems is to enhance patient safety by learning from failures of the health-care system. Learning to improve patient safety will be done through:

- The generation of alerts regarding significant new hazards,
- Feedback to relevant departments, staff and patients
- Annual reports distributed to all departments.

Feedback to the patient post analysis is very important that all avenues related to the occurrence of adverse events be fully investigated and made known to the patient, relatives or legal representative/s. Giving wrong information is dangerous and where there is suspicion of litigation, the hospital should consult the legal representative of the provincial health department.

The management of the relevant section will be responsible to ensure that feedback to patients do take place. Where needed the provincial legal unit will be approach to assist.

The following will be included in post analysis disclosure:

- The patient should be informed of improvements made to prevent similar events from recurring
- Continued practical and emotional support should be provided as required
- Re-enforcement, correction or update of information provided in previous meetings should be provided
- The patient/representative should be promised to be informed of further additional information as it unveils

- Further expression of sympathy and, where necessary, regret that may include an apology with acknowledgement of responsibility for what has happened
- Actions taken as a result of internal analysis that might have resulted in system improvement.

Other disclosure methodologies such as multi-patient and multi-jurisdictional disclosures, in instances where PSIs affected more than one patient, can be used to convey the message. Information provided should be as selective as possible to ensure that privacy and confidentiality of the patients is realised. Where PSIs involve more than one institution, representatives of both institutions from affected should collaborate throughout the process and send one common message.

The series of action steps that should be followed to ensure the effective management of PSI is set out in figure 1.

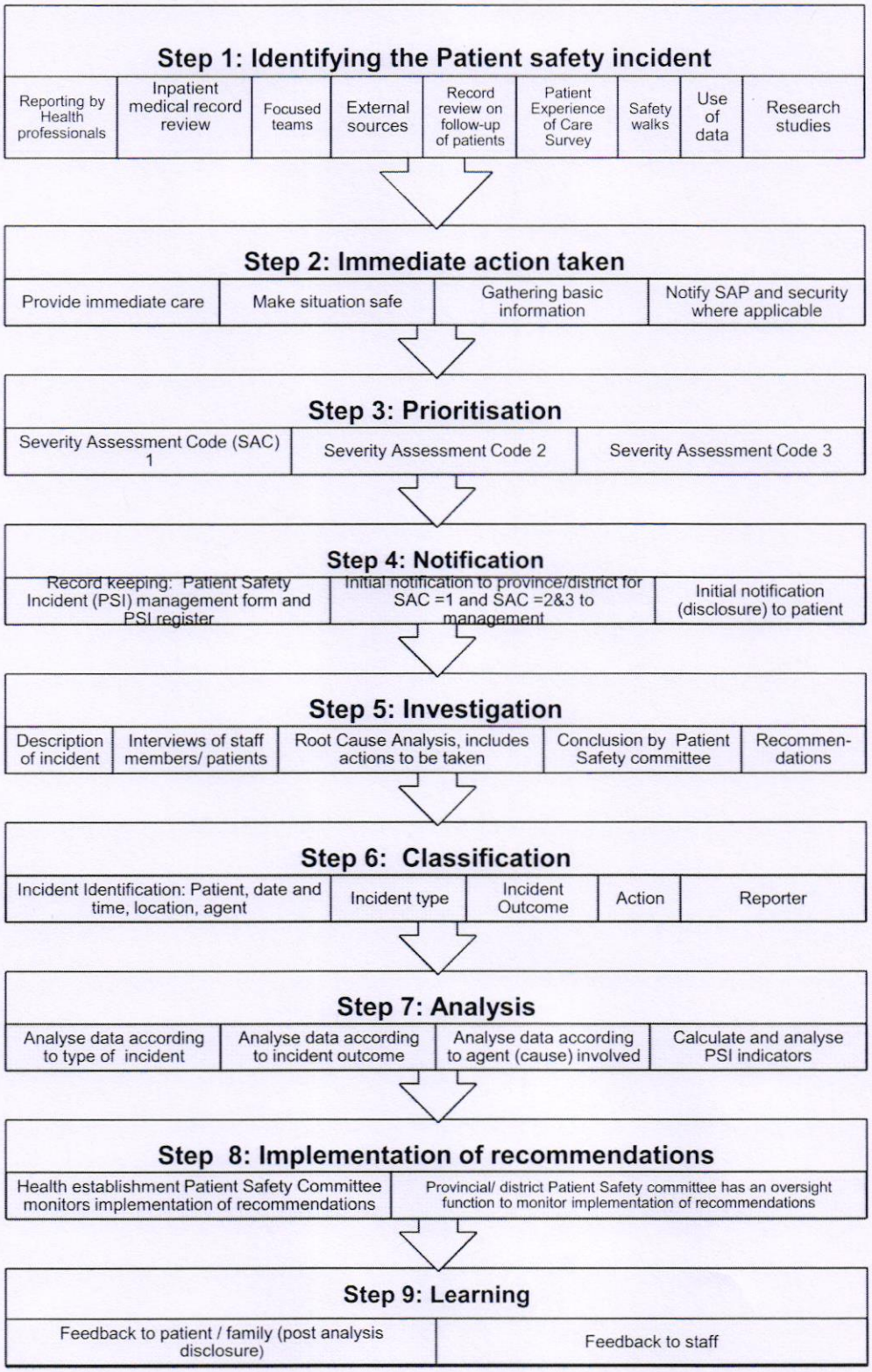

Figure 1: Action steps for the management of Patient Safety Incidents

Annexure A: Prioritisation - Severity Assessment Code (SAC)

	SAC 1	SAC 2	SAC 3
Actual/potential consequence to patient	**Serious harm or death** that is/could be specifically caused by health care rather than the patient's underlying condition or illness	**Moderate harm** that is/could be specifically caused by health care rather than the patient's underlying condition or illness	**Minor or no harm** that is/could be specifically caused by health care rather than the patient's underlying condition or illness
Type of event/incident	• Procedure involving the wrong patient or body part resulting in death or major permanent loss of function • Retained instruments or other material after surgery • Wrong surgical procedure • Surgical site infections that lead to death or morbidity • Suicide of a patient in an inpatient unit • Death or serious morbidity due to assault or injury • Nosocomial infections resulting in death or neurological damage • Blood transfusion that caused serious harm or death • Medication error resulting in death of a patient • Adverse drug reaction (ADR)that results in death or is life-threatening • Maternal death or serious morbidity • Neonatal death or serious morbidity • Missing/swopped/abscond patient and assisted or involuntary mental health care user/mental ill prisoner/State patient • Any other clinical incident which results in serious harm or death of a patient	Incidents include but are not limited to the following: • Moderate harm resulting in increased length of stay (More than 72 hours to 7 days) • Additional investigations performed • Referral to another clinician • Surgical intervention • Medical intervention • Moderate harm caused by a near miss • ADR that resulted in moderate harm • Blood transfusion reaction that resulted in moderate harm	Incidents include but are not limited to the following: • Minor harm resulting in increased length of stay of up to 72 hours • No harm • Only first aid treatment required • Near miss that could have resulted in minor harm • ADR that resulted in minor or no harm • Blood transfusion reaction that resulted in minor or no harm
Action required	• Notify management immediately • Submit a notification to provincial/district office within 24 hours • Conduct a formalised investigation • In cases of unnatural deaths, report it to the South African Police Service and refer to Forensic Pathological Services • In cases where an assisted or involuntary mental health care user, mentally ill prisoner or State patient has absconded, notify and request the South African Police Service to locate, apprehend and return the patient to the relevant hospital. Complete MHCA 25 (annexure L) and submit to the relevant authority as indicated on the form • In cases where a Mental Health Care user was subjected to physical or other abuse, was exploited, neglected or received degrading treatment. Complete MHCA 02 (annexure M) • In cases of an ADR notify the National Adverse Drug Event Monitoring Centre of the Medicines Control Council (see annexure N, form ARF1). If the ADR was caused by Anti-retroviral drugs or medicines for the treatment of tuberculosis, it must also be reported to the National Pharmacovigilance Centre for Public Health Programs (see annexure O, form 31a). • In cases of blood transfusion reactions notify the blood transfusion service where the blood was ordered from and submit the required documentation and samples, see annexure P	• Notify management within 24 hours • Conduct a formalised investigation • In cases of an ADR notify the National Adverse Drug Event Monitoring Centre of the Medicines Control Council (see annexure N, form ARF1). If the ADR was caused by Anti-retroviral drugs or medicines for the treatment of tuberculosis, it must also be reported to the National Pharmacovigilance Centre for Public Health Programs (see annexure O, form 31a). • In cases where a Mental Health Care user was subjected to physical or other abuse, was exploited, neglected or received degrading treatment. Complete MHCA 02 (annexure M) • In case of a blood transfusion reaction that did not cause serious harm or death, notify the blood transfusion service and submit the required documentation and samples, see annexure P	
Reporting requirement	• Complete investigation and actions taken within 60 working days Submit report to provincial/district office	• Complete investigation and actions taken within 60 working days Submit report to management	

Annexure B: Patient Safety Incident Reporting form

Section A (notification) - to be completed by manager of section where incident took place. Submit section A and B to next level for notification for SAC 1 incidents

Section B(Statement by staff, patient or significant other)– to be completed by staff, patients or significant other that were directly involved while the incident took place

Section C(investigation) - to be completed by investigator(s) of the incident, in most cases this would be the manager(s) of section where the incident took place

SECTION A - Notification

1. Type of Patient Safety Incident (PSI): Mark with an X		
No Harm	Near miss	Harmful (Adverse Event)

2. Patient information		3. Staff involved		
Patient Name and surname		Name and Surname	Contact detail	Department
Patient file number				
Location (department/ward)				
Age				
Gender				
Final Diagnosis				

4. Date of PSI		5. Time of PSI	

6. SAC rating: mark with an X	1	2	3	7. Date reported to next level if SAC = 1		8. No of days to report PSI with SAC = 1	

9. Method of detecting PSI: mark with an X	Reported by health professional	Research studies	Surveys on patient experience of care	Inpatient medical review	Review of record on follow-up	External sources			Safety walk rounds	Focused teams	Use of data
						Complaints	Media	Public			

10. Short description of Patient Safety Incident (detailed information available under section B as reported by staff)

11. Immediate resulting action taken to minimise harm

12. Short description of Initial disclosure

Compiled by:	Designation:	Signature:	Date:

SECTION B- Statement by staff, patient or significant other

1. Statement by staff, patient or significant other: (Add sections for additional statements and information as needed)			
Statement 1:			
Compiled by:	**Designation:**	**Signature:**	**Date:**

SECTION C - Investigation

1. Category according to type – mark appropriate one with an X					
1.Clinical Admini-stration	**2.Clinical process/ procedure**	**3. Health Care associated infections**	**4. Medication / IV fluids**	**5. Blood and blood products**	**6. Medical device**
Medical procedure performe d without valid consent	Not performed when indicated	Central Line Associated Blood Stream Infection	Wrong dispensing	Acute transfusion reactions	Lack of availability
	Performed on wrong patient	Peripheral Line Infection	Omitted medicine or dose	Delayed transfusion reactions/ events (including Transfusion Transmitted Infections)	Failure / malfunction
	Wrong process/ procedure/ treatment performed	Surgical site	Medicine not available	Errors- wrong blood/ blood products	**8. Patient Accidents**
	Retention of foreign object	Hospital Acquired Pneumonia	Adverse Drug Reaction	**7. Behaviour**	Falls
	Pressure ulcers acquired during admission	Ventilator Associated Pneumonia	Wrong medicine	Suicide	**9. Infrastructure/ Buildings/ Fixtures**
	Performed on wrong body part/ site/side	Catheter Associated Urinary Tract infection	Wrong patient	Attempted suicide	Non-Existent/ inadequate
	Maternal death	Communicable diseases	Wrong frequency	Self-inflicted injury	Damaged/ faulty/ warn
	Neonatal death		Wrong route	Sexual assault by staff member	**10. Other**
	Fresh still born		Prescription error	Sexual assault by fellow patient or visitor	Any other incident that does not fit into categories 1 to 9
			Wrong dose/ strength administered	Physical assault by staff member	
				Physical assault by fellow patient or visitor	
				Exploitation, abuse, neglect or degrading treatment by fellow patient or visitor	
				Exploitation, abuse, neglect or degrading treatment by staff member	
				Wandering/ Abscond	
				Refusal of hospital treatment	
2. Framework for Root Cause Analysis and implementation of action plans					

a. Contributing factors – Mark with an X								
1. Staff	Cognitive	Performance	Behaviour	Communication	Patho-Physiological/ Disease			
2. Patient	Cognitive	Behaviour	Communication	Patho-Physiological/ Disease		Emotional	Social	
3. Work / Environment	Physical Environmental / Infrastructure	Remote/ long distance from service	Equipment	Consumables	Environmental risk	Current Code/ Specifications/ Regulations	Security/ safety	
4. Organisational/Service	Protocols/Policies/ procedures	Processes	Organisational Management/Decisions/Culture			Organisation of teams	Staff establishment	
5. External	Natural Environment	Equipment, Products,			Services, systems and policies			
6. Other								

b. Root Cause Analysis

Contributing Factor	Describe the factor that contributed to the event	Describe the action plan to rectified the identified problem	Person responsible for implementing the action plan	Date for implementation

3. Findings and recommendations by Patient Safety Committee

4. Conclusion

Type of behaviour according to Just Culture: mark with a X	No error	Human Error	At – Risk Behaviour	Reckless Behaviour

5.	**Summary of Final disclosure to patient/family**																		
6.	**Date of closure of PSI case**		**7.**	**No days to close PSI case**				**8.**	**Type of closure: mark with an X**			**PSI case concluded**		**Litigation**		**Referred to Labour relations**		
9.	**Patient Outcome according to degree of harm: Mark with an X**							None		Mild		Moderate		Severe		Death			
10.	**Organisational Outcome: Mark with an X**		Property damage			Increase in required resource allocation for patient			Media attention		Formal complaint		Damaged reputation		Legal ramifications			Other	
Compiled by:				Designation:				Signature:						Date:					

Annexure C: Patient Safety Incident (PSI) register

HOSPITAL NAME: _____ **MONTH/YEAR**_____

Ref No.	Date and time of Incident	Patient's Name& Surname	Location (ward/ department/area)	Type of PSI	SAC score	Reporting date of SAC 1 incidents	working days to report SAC 1 incident	Summary of incident	Finding (all incidents) and recommendations by Patient Safety Committee	Class according to Incident type	Class according to agent	Patient outcome	Organisational outcome	Date PSI closed	Type of closure	# of working days to close PSI	Type of Behaviour

Annexure D: Classification for agents (Contributing factors)

Main classification	Sub classification
1.Staff Factors	Cognitive Factors (e.g not competent due to lack of knowledge, not able to resolve a problem with available knowledge obtained through training, experience, induction and orientation programmes)
	Performance Factors (e.g technical errors made while performing procedures or not performing the procedure as required (act of omission))
	Behaviour (e.g risky, reckless (due to forgetfulness, fatigue, overconfidence), criminal act
	Communication Factors (amongst staff, family members and patients eg. language difficulties, communication methods, health literacy)
	Patho- Physiologic/ Disease Related Factors (e.g problems with substance abuse other mental illness)
	Emotional Factors
	Social Factors
2. Patient Factors	Cognitive Factors (e.g perception, understanding, knowledge)
	Behaviour (risky, reckless, criminal act, attention issues (absentmindedness/forgetfulness, distraction), fatigue/exhaustion)
	Communication Factors (eg. language difficulties, communication methods, health literacy)
	Patho-Physiologic/ Disease Related Factors (problems with substance abuse other mental illness)
	Emotional Factors
	Social Factors
3. Work/Environment Factors	Physical Environment/Infrastructure
	Equipment (e.g not available or not functioning as maintenance plans were not executed)
	Consumables (e.g not available or insufficient)
	Remote/Long Distance from Service
	Environmental Risk (e.g ventilations systems not functioning)
	Security/safety
	Current Code/Specifications/ Regulations
4. Organisational/Service Factors	Protocols/Policies/Procedures/
	Processes e.g insufficient record keeping, patient not referred
	Organisational Management /Decisions/Culture
	Organisation of Teams
	Staff establishment (e.g vacant posts, absenteeism)
5. External Factors	Natural Environment (e.g floods, fire spreading from nearby areas to the health establishment)
	Equipment, Products, (e.g malfunctioning of equipment due to manufacturer's fault)
	Services, Systems and Policies of external providers (e.g equipment procured not delivered)
Other	Not specified in classification 1 to 5

Annexure E: Classification for Incident Type

Main classification	Sub classification
1. Clinical Administration	Medical procedure performed without valid consent
2. Clinical process/ procedure	Not performed when indicated
	Performed on wrong patient
	Wrong process/ procedure/ treatment performed
	Performed on wrong body part/ site/ side
	Retention of foreign object during surgery
	Pressure ulcers acquired during admission
	Maternal death
	Neonatal death
	Fresh still birth
3. Health Care associated infections	Central Line Associated Blood Stream Infection
	Peripheral Line Infection
	Surgical Site
	Hospital Acquired Pneumonia
	Ventilator Associated Pneumonia
	Catheter Associated Urinary Tract Infection
	Communicable diseases
4. Medication/ IV fluids	Wrong dispensing
	Omitted medicine or dose
	Medicine not available
	Adverse Drug Reaction
	Wrong medicine
	Wrong dose/ strength administered
	Wrong patient
	Wrong frequency
	Wrong route
	Prescription Error
5. Blood or blood products	Acute transfusion reactions
	Delayed transfusion reactions/ events (including Transfusion Transmitted Infections)
	Errors- wrong blood/ blood products
6. Medical device/ equipment/	Lack of availability
	Failure/ malfunction
7. Behaviour	Suicide
	Attempted suicide
	Self-inflicted injury
	Sexual assault by staff member
	Sexual assault by fellow patient or visitor
	Physical Assault by staff member
	Physical assault by fellow patient or visitor
	Exploitation, abuse, neglect or degrading treatment by fellow patient or visitor
	Exploitation, abuse, neglect or degrading treatment by staff member
	Wandering/Absconding/Missing
	Refusal of hospital treatment
8. Patient accidents	Falls
9. Infrastructure/ Buildings/ Fixtures	Damaged/Faulty/Worn
	Non-Existent/Inadequate
10. Other	Any other incident not listed in classification 1 to 9

Annexure F: Classification for incident outcome

Class	Description
PATIENT OUTCOME	
1.None	Patient outcome is not symptomatic or no symptoms detected and no treatment is required.
2.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.
3.Moderate	Patient outcome is symptomatic, requiring intervention (e.g., additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long-term harm or loss of function.
4.Severe	Patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long-term harm or loss of function.
5.Death	On balance of probabilities, death was caused or brought forward in the short term by the incident.
ORGANISATIONAL OUTCOME	
1.Property damage	
2.Increase in required resource allocation for patient	Increased length of stay, admission to special care area, additional treatment/tests, disrupted workflow/delays for other patients, additional staff required, additional equipment required
3.Media attention	
4.Formal complaint	
5.Damaged reputation	
6. Legal ramifications	
7. Other	

Annexure G: Statistical data on classification for agents (contributing factor)

Hospital name:	**Financial Year:** Q=Quarter																		
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
	Apr	May	Jun	Q1	Jul	Aug	Sept	Q2	Oct	Nov	Dec	Q3	Jan	Feb	Mar	Q4	TOT	AVG	% *
1.Staff Factors																			
Cognitive factors																			
Performance																			
Behaviour																			
Communication factors																			
Patho- Physiologic/ Disease related Factors																			
Emotional factors																			
Social factors																			
2. Patient factors																			
Cognitive factors																			
Behaviour																			
Communication factors																			
Patho- Physiologic/ Disease related factors																			
Emotional factors																			
Social factors																			
3. Work/ Environment factors																			
Physical environment/ infrastructure																			
Security/Safety																			
Remote/long distance from service																			
Environmental risk																			
Current code/ specifications/ regulations																			
Equipment																			
Consumables																			
4.Organisational/ Service factors																			
Protocols/Policies/ Procedures/																			
Processes																			
Organisational Management/ Decisions/ culture																			
Organisation of teams																			
Staff establishment																			
5. External Factors																			
Natural environment																			
Equipment, Products,																			
Services, systems and policies																			
6. Other																			
Other																			
GRAND TOTAL																			

Total of agent in Column Q ÷ Grand Total of Column Q

Annexure H: Statistical data on classification according to type of Incident

Hospital name:	Financial Year:*Q=Quarter																		
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
Type	Apr	May	Jun	Q1	Jul	Aug	Sept	Q2	Oct	Nov	Dec	Q3	Jan	Feb	Mar	Q4	TOT	AVG	% *
1.Clinical Administration																			
Medical procedure performed without consent																			
2. Clinical process/ procedure																			
Not performed when indicated																			
Performed on wrong patient																			
Wrong process/procedure/treatment performed																			
Performed on wrong body part/ site/ side																			
Retention of foreign object during surgery																			
Pressure sores acquired during admission																			
Maternal death																			
Neonatal death																			
Fresh still born																			
3. Health care associated infections																			
Central Line Associated Blood Stream Infection																			
Peripheral Line Infection																			
Surgical site																			
Hospital Acquired Pneumonia																			
Ventilator Associated Pneumonia																			
Catheter Associated Urinary Tract Infection																			
Communicable diseases																			
4. Medication/ IV Fluids																			
Wrong dispensing																			
Omitted medicine or dose																			
Medicine not available																			
Adverse Drug Reaction																			
Wrong medicine																			
Wrong dose/ strength administered																			
Wrong patient																			
Wrong frequency																			
Wrong route																			
Prescription Error																			
5. Blood or blood products																			
Acute transfusion reactions																			

Delayed transfusion reactions/ events (including Transfusion Transmitted Infections)																			
Errors- wrong blood/ blood products																			
6. Medical devises/ equipment/ property																			
Lack of availability																			
Failure / malfunction																			
7. Behaviour																			
Suicide																			
Attempted suicide																			
Self-inflicted injury																			
Sexual assault by staff																			
Sexual assault by fellow patient or visitor																			
Physical Assault by staff																			
Physical assault by fellow patient or visitor																			
Exploitation, abuse, neglect or degrading treatment by fellow patient or visitor																			
Exploitation, abuse, neglect or degrading treatment by staff member																			
Wandering/Abscondi ng																			
Refusal of hospital treatment																			
8. Patient accidents																			
Falls																			
9. Infrastructure/ Buildings/ fixtures																			
Damaged/ Faulty/ Worn																			
Non-Existent/ Inadequate																			
10. Other																			
Any other incident that does not fit into category 1 to 9																			
GRAND TOTAL																			

*** Total of type in Column Q ÷ Grand Total of Column Q**

Annexure I: Statistical data on classification according to incident outcome

PATIENT OUTCOME																			
Hospital name:	**Financial Year:** Q=Quarter																		
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
	Apr	May	Jun	Q1	Jul	Aug	Sept	Q2	Oct	Nov	Dec	Q3	Jan	Feb	Mar	Q4	TOT	AVG	%*
None																			
Mild																			
Moderate																			
Severe																			
Death																			
GRAND TOTAL																			

ORGANISATIONAL OUTCOME																			
Hospital name:	**Financial Year:** Q=Quarter																		
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
	Apr	May	Jun	Q1	Jul	Aug	Sept	Q2	Oct	Nov	Dec	Q3	Jan	Feb	Mar	Q4	TOT	AVG	%*
Property damage																			
Increase in required resource allocation for patient																			
Media attention																			
Formal complaint																			
Damaged reputation																			
Legal ramifications																			
Other																			
GRAND TOTAL																			

*** Total of outcome in Column Q ÷ Grand Total of Column Q**

Annexure J: Statistical data on Indicators for Patient Safety Incidents

Hospital name: _____

Financial Year: _____

Column Name	A	B	C	D	E	F	G	H
Month:	# PSI cases	#PSI cases closed	% PSI cases closed (Column B/ Column A)	# PSI cases closed within 60 working days	% of PSI cases closed within 60 working days (Column D/ Column B)	# PSI SAC 1	# SAC 1 incidents reported within 24 hours	%of SAC 1 incidents reported within 24 hours (Column F/ Column G)
April								
May								
June								
Quarter 1								
July								
Aug								
Sept								
Quarter 2								
Oct								
Nov								
Dec								
Quarter 3								
Jan								
Feb								
March								
Quarter 4								
TOTAL								
AVG								

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Documents Pertaining to Quality of Care and Patient Safety Practices followed by the Teaching Hospital

- **Faculty and Student Support in Relation to Patient:-**

⇒ At the time of admission to the medical course at the Institution, all undergraduate and postgraduate students are advised to have Hepatitis B Vaccination and Tetanus Toxoid prophylaxis at the earliest.

⇒ The Hepatitis B Vaccination and Tetanus Toxoid prophylaxis is advised for the newly joined teaching and non-teaching staff.

⇒ A three days orientation programme called as MEDKNOW is organized for the newly admitted undergraduate students.

⇒ MEDKNOW workshop is conducted for postgraduate students after their joining to the course and practice is followed every year.

⇒ Also yearly same above programme is repeated for new faculty who has joined newly including nursing and supportive staff involved in infection prevention and control practices.

⇒ Department of Microbiology regularly conducts the safety measure training especially to interns, UG, PG, Nursing students in the form of theory lectures as well as hands on training.

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➢ Hospital Infection Control and Hygiene Measures:-

- Hand washing technique & steps are emphasized for all those concerned with patient care. Charts, display material, social media awareness are used for infection prevention and control practices in our hospital.
- Infection ward segregates patient from non-infectious ones.
- In our hospital Central Sterile Supply Department (CSSD) unit is very well operated by department of Anaesthesia for infection prevention and control practices for infection control.
- Practice of collecting regular swabs from operation theatres and various intensive care units and fumigation practices in association with department of Microbiology with special emphasis on infection prevention and control practices for infection control.
- The Institution has strict guidelines for infection prevention and control practices for infection control and the standard operating procedures are followed strictly.
- Hospital infection control committee under Microbiology department. If any student or staff gets accidental exposure to infection, all the required treatment or medications are provided free of cost by institute along with the sick leave or special leave.

➢ Patient Safety Infrastructures Measures:-

A. Fire Safety.

B. Patient Transport Facilities.

C. Patient Care Givers Support Facilities.

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