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##### **GUIDELINE TO DEVELOP A HOSPITAL SPECIFIC**

#####  **STANDARD OPERATING PROCEDURE**

##### **FOR THE MANAGEMENT OF PATIENT SAFETY INCIDENT REPORTING AND LEARNING**

#####

This is a guideline to assist hospitals to develop their own Standard Operating Procedure (SOP) to manage patient safety incident reporting and learning that is in line with the National Guideline for Patient Safety Incident Reporting and Learning in the Health Sector of South Africa.

Hospitals can use this document as a guideline to develop their own hospital specific SOP by amending or choosing from the options (highlighted in red) in the sections as indicated in the guideline.

  **April 2022**

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**STANDARD OPERATING PROCEDURE FOR THE**

**MANAGEMENT OF PATIENT SAFETY INCIDENT REPORTING AND LEARNING**

**FOR**

**............. HOSPITAL (fill in hospital’s name)**

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Mr/Ms/Dr....................................... Date approved

Chief Executive Officer

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Date for next review: ........................

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# 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 ........hospital (fill in hospital’s name).

**PSI** is an unplanned or unintended event or circumstance that could have resulted or did result in harm to a patient while in the care of a health facility. This event is thus not due to the underlying health condition or natural progression of disease. 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 (SOP) is:

* 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 preventative 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
1. **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 (choose one applicable)
* 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
1. **PRINICIPLES OF PATIENT SAFETY INCIDENT MANAGEMENT**

All PSIs will be managed according to the following principles:

* Just Culture
* Confidential
* Timely
* Responsive
* Openness about failures
* Emphasis on learning
1. **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. (If the committee is not a standalone committee, change accordingly to indicate which committee it will form part of). The Committee will meet \_\_\_\_\_\_\_(complete the time frame). The Terms of Reference and composition of the committee is set out below.

## Terms of reference of Committee (amend if needed)

* Hospitals should develop a standard operating procedure (SOP) to manage PSIs.
* Sub-district/districts should develop SOP to manage PSIs for the health facilities within their district.
* Identify staff members in every health facility that will be responsible for the management of PSIs. These staff members should be trained on the management of PSIs.
* Monitor that health facilities adhere to the SOP for the management of PSIs.
* Management must report all Severity Assessment Code 1 incidents to the respective 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, it should be conducted.
* 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.
* Review PSI registers to assess data quality (e.g. incidents reported falls within the PSI definition, classifications done correctly, summary description of PSI and investigation outcome is clear and understandable).
* Conduct monthly meetings of which the minutes should be recorded.
* Submit monthly statistical reports to the respective provincial department. Where a web-based application is used by the province, reports do not need to be submitted as the provincial department can generate reports from the web-based application. (Choose one applicable)
* Compile an annual report to identify trends and 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 provincial Patient Safety Committee meetings when required.
* Identify education needs emerging from PSI management and schedule training accordingly.

## 4.2 Designation of members of the Committee (change accordingly to be in line with the hospital’s structure)

* 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
1. **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:

Step 1: Identifying PSIs

Step 2: Immediate action taken

Step 3: Prioritisations

Step 4: Notification

Step 5: Investigation

Step 6: Classification

Step 7: Analysis

Step 8: Implementation of recommendations

Step 9: Learning

The action steps are explained in detail in sections 5.1 to 5.9 and set out in figure 1 as a flow diagram.

##

## Step 1: Identifying patient safety incidents

It is essential that only incidents that falls within the definition of a PSI are reported. The figure below sets out a decision tree to give guidance to staff in the decision-making process to identify a PSI



The following methods will be used to detect PSIs: (amend as needed)

* 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 patient safety incidents
* Research studies and findings

## 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
* notify South African Police Service (SAP), hospital’s security or other institution where applicable

## 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, 3 and 4. SAC 1 - incidents that have or could have caused serious harm or death, SAC 2 - incidents that caused or could have caused moderate harm, SAC 3 - incidents that have or could have caused minor harm, and SAC 4 – incidents that caused not harm. See **Annexure A** that describes the SAC.

## 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 (choose one applicable). 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**. (describe here who will be responsible for capturing and collating the PSI data for the hospital).

PSIs classified under the main classification for Medication/ IV fluids (sub classification, **Adverse drug reaction**), **Blood or blood products** and Behaviour (sub classification, **Wandering/absconding**) must be reported to the National Department of Health’s Pharmacovigilance unit, the South African National Blood Services and provincial Mental Health Review Board respectively (describe here how these forms must be processed within the hospital to reach the various organizations as indicated).

**Incident notification to Management**

All SAC 1 incidents will be reported within 24 hours to the district/provincial office (change here if needed depending on the line of reporting as determined by the specific province. Best to also stipulate the specific department who will be responsible). PSIs with SAC rating of 2, 3 or 4 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 (describe who should conduct the investigations).

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 PSI decision tree (**Appendix D**) can assist managers and senior clinicians to assess individual acts of staff involved in a serious PSI and to identify appropriate management action. The aim is to promote a Just Culture by managing staff in a fair and consistent manner within healthcare organisations. The following algorithm can be used by managers to determine the type of behaviour according to the Just Culture.

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 E**
* incident type, see **Annexure F**
* incident outcome, see **Annexure G**

## 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 (Select the applicable one).

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 H**
* data on classifications of incident type, see **Annexure I**
* data on classifications of incident outcome, see **Annexure J**
* indicators for PSIs, see **Annexure K**

Statistical data for SAC 1 incidents should be kept separate from statistical data on SAC 2, SAC 3 and 4 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 (amend according to what the hospital will do):

* 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** | **SAC 4** |
| --- | --- | --- | --- | --- |
| Actual/potential consequence to patient | Incidents that have or could have caused **serious harm or death**  | Incidents that have or could have caused **moderate harm**  | Incidents that have or could have caused **minor harm**  | Incidents that caused **no harm** |
| 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 healthcare 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 seven 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
* Only first aid treatment required
* ADR that resulted in minor or no harm
* Blood transfusion reaction that resulted in minor harm
 | Incidents include but are not limited to the following:* No harm
* Near miss that could have resulted in minor 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 healthcare 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 health establishment. Complete MHCA 25 (**Appendix M**) and submit to the relevant authority as indicated on the form
* In cases where a mental healthcare user was subjected to **physical or other abuse, was exploited, neglected or received degrading treatment. Complete MHCA 02, see Appendix N.**
* In cases of an ADR notify the South African Health Products Regulatory Authority (see **Appendix O**, ADR form). If the ADR was caused in a HIV or TB patient, it must also be reported to the National Pharmacovigilance Centre for Public Health Programs (NPC), using the same form. This may be done on a single email using the different email addresses.
* 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 **Appendix P**
 | * Notify management within 24 hours
* Conduct a formalised investigation
* In cases of an ADR notify the South African Health Products Regulatory Authority (see **Appendix O**, ADR form). If the ADR was caused in a HIV or TB patient, it must also be reported to the National Pharmacovigilance Centre for Public Health Programs (NPC), using the same form. This may be done on a single email using the different email addresses.
* In cases where a mental healthcare user was subjected to **physical or other abuse, was exploited, neglected or received degrading treatment. Complete MHCA 02, see Appendix N.**
* 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 **Appendix P.**

In cases  | * Notify management within 24 hours
* Conduct a formalised investigation
 |
| Reporting requirement | * Complete investigation and actions taken within 60 working days Submit report to provincial department/district office
 | * Complete investigation and actions taken within 60 working days
* Submit report to management
 | * 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 the staff who witnessed the incident that occurred. Submit section A and B to next level for notification for SAC 1 incidents.

**Section B:** (Account of the event by patient, staff or other witnesses) – to be completed by staff, patients or 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 of event**

**Ref no:**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Date PSI identified**
 |  | 1. **Time PSI identified**
 |  |
| 1. **Event identified by**
 | Reported by health professional | Research studies | Patient experience of care surveys | Inpatient medical review | Review of record on follow-up | External sources | Safety walk rounds | Focused teams | Use of data |
| Complaints | Media | Public |
| 1. **Provide a short overview of the Patient Safety Incident**
 |
| What happened/went wrong? |
|  |
| What is the initial outcome or harm? |
|  |
| 1. **Describe immediate actions taken to minimise harm**
 |
| What action was taken to minimise harm? |
|  |
| Who led that action? |
|  |
| What was the outcome of the minimising action? |
|  |
| 1. **Provide a description of communication and escalation (initial disclosure)**
 |
| What and how was the incident communicated with patient? (if appropriate) |
|  |
| What and how was the incident communicated with patient’s family? (if appropriate) |
|  |
| What and how was the incident escalated to management within the facility? (if appropriate) |
|  |
| **7. Type of patient safety incident (PSI): Mark with an X (review this once the investigation has been finalised)** |
| No harm | Near miss | Harmful (Adverse Event) |
| **8. SAC rating: Mark with an X** | **1 Serious** | **2****Moderate** | **3 Minor** | **4** **None** | **9. Date SAC 1 reported to next level** |  | **11. No of days to report PSI with SAC = 1**  |  |
| **10. Time SAC 1 reported to next level** |  |
| 1. **Patient and ward information**
 | 1. **Staff witnesses**
 |
| Patient name and surname |  | Name and surname | Contact detail | Department |
| Patient file number |  |  |  |  |
| Patient Id number |  |  |  |  |
| Location (department/ward) |  |  |  |  |
| Age |  |  |  |  |
| Gender |  |  |  |  |
| Final diagnosis  |  |  |  |  |
| Number of patients in the ward/head count |  |  |  |  |
| Name of facility patient was referred from (where applicable) |  |  |  |  |
| Name of facility patient was down referred to (where applicable)  |  | **14. Number of staff on duty** |  |
| **Compiled by: Designation: Signature: Date:** |

**SECTION B- Account of the event by patient, staff or other witnesses**

|  |
| --- |
| 1. **Account by staff, patient or significant other: (Add sections for additional statements and information as needed)**
 |
| **Account 1:**  |
|  |
|  |
|  |
|  |
|  |
|  |
| **Account 2:** |
|  |
|  |
|  |
|  |
|  |
| **Compiled by: Designation: Signature: Date:** |

**SECTION C – Investigation including classification**

|  |
| --- |
| 1. **Classification according to incident type – mark appropriate one with an X**
 |
| **1.Clinical administration** | **3. Healthcare-associated infections** | **5. Blood and blood products** | **8. Patient accidents and self-inflicted injury** |
| Medical procedure performed without valid consent | Central line associated Blood Stream Infection | Acute transfusion reactions | Falls – Bedside |
| Falls – Toilet/bathroom |
| Communication/ confidentiality | Non-device related (Primary) blood line blood infection | Delayed transfusion reactions/ events (including Transfusion Transmitted Infections) | Falls – Stretcher |
| Falls – Therapeutic equipment |
| Patient incorrectly identified and recorded | Peripheral line blood infection | Errors- wrong blood/ blood products | Patient injury |
| Missing patient record | Surgical site infection | **6. Medical device/equipment** | Self-inflicted injury |
| Unclear/ ambiguous/ illegible/ incomplete information in patient record | Hospital acquired pneumonia | Not available  | Suicide  |
| Ventilator associated pneumonia | Failure / malfunction | Attempted suicide |
| Catheter associated urinary tract infection | Not used correctly | **9. Pressure ulcers acquired during/after admission** |
| Communicable diseases |
| **2. Clinical process/ procedure** | **4. Medication / IV fluids** | Incorrect medical device/ equipment used | Grade I |
| Not performed when indicated | Incorrect dispensing | **7. Behaviour** | Grade II |
| Performed on wrong patient | Omitted medicine or dose | Sexual assault by staff member | Grade III |
| Clinical procedure errors | Medicine not available | Sexual assault by fellow patient or visitor | Grade IV |
| Surgical procedure errors | Adverse drug reaction | Physical assault by staff member | **10. Infrastructure/ Buildings/ Fixtures** |
| Clinical treatment error (incorrect clinical management) | Incorrect medicine | Physical assault by fellow patient or visitor | Damaged/ faulty/ poor maintenance |
| Incorrect dose/ strength administered | Non-existent |
| Clinical assessment error (Missed, delayed, wrong) | Incorrect patient | Exploitation, verbal abuse, aggression, neglect or degrading treatment by fellow patient or visitor | Inadequate/inappropriate |
| Incorrect frequency | Back-up electricity not functional/available |
| Incorrect route | Back-up water supply not available |
| Failure to act on test results or report | Prescription error | Exploitation, verbal abuse, aggression, neglect or degrading treatment by staff member | 1. **Laboratory / Pathology**
 |
| Performed on wrong body part/ site/ side | Incorrect dispensing label | Delayed laboratory results |
| Retention of foreign object during surgery  | Medicine expired | Patient abscond | Processing error by laboratory |
| Incorrect technique  | Missing patient Abscond while under 72-hour observation | Incorrect labelling of results |
| Inappropriate polypharmacy | **12. Other** |
|  | Any other incident that does not fit into categories 1 to 11 |
| 1. **Framework for root cause analysis and implementation of action plans**
 |
| * 1. **Contributing factors – Mark with an X**
 |
| **1. Staff**  | Lack of knowledge of clinical processes/ guidelines/ protocols | Human error- clinical  | Human error - Admin | Risky/reckless behaviour | Communication Factors | Condition/ disease related factor | Social factors | Leadership |
| **2. Patient**  | Behaviour | Communication factor | Condition/ disease related factor | Social factors |
| **3. Work/ environment** | Physical environmental / infrastructure | Remote/ long distance from service | Equipment (faulty due to no maintenance) | Consumables | Environmental risk  | Current Code/ specifications/ regulations | Security/safety |
| **4. Organisational/ service**  | Clinical Protocols/ policies/ procedures not available/ up to date/ approved | Non - Clinical Protocols/ policies/ procedures not available/ up to date/ approved | Organisational management/ decisions/culture | Organisation of teams | Staffing | Political unrest | Package of service  | Bed utilisation  |
| **5. External** | Natural event or disaster | Equipment, products malfunctioning due to manufacturer’s fault | Services, systems and policies of external providers | Delays in emergency medical services transport |
| **6. Other** | Not specified in classification 1 to 5 |
| * 1. **Root cause analysis -** These are the most fundamental underlying factors contributing to the incident that can be addressed
 |
| **Contributing factor** | **Describe the factor that contributed to the event**  | **Describe the action plan to rectify the identified problem** | **Person responsible for implementing the action plan** | **Date for implementation** |
|  |  |  |  |  |
|  |  |  |  |  |
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|  |  |  |  |  |
| 1. **Findings and recommendations of the investigation**
 |
| What were the key findings (why did the incident occur)? |
|  |
| What are the key recommendations? (Note: Recommendations should address all the root causes and lessons learned, be designed to significantly reduce the likelihood of recurrence and/or severity of outcome; be clear and concise and kept to a minimum wherever possible; be Specific, Measurable, Achievable, Realistic and Timed (SMART) so that changes and improvements can be evaluated; be prioritised wherever possible; be categorised as: those **specific** to the area where the incident happened; those that are **common** only to; the organisation involved; those that are **universal** to all and, as such, have provincial/district significance.) |
|   |
|  |
|  |
| 1. **Type of behaviour according to Just Culture: mark with a X**
 | **No error** | **Human error** | **At–risk behaviour** | **Reckless behaviour** |
| 1. **Provide a description of final communication to patient/family (final disclosure)**
 |
| What and how was the incident communicated with patient? (if appropriate) |
|  |
| What and how was the incident communicated with patient’s family? (if appropriate) |
|  |
|  |
| 1. **Date of closure of PSI case**
 |  | 1. **No days to close PSI case**
 |  | 1. **Type of closure: mark with an X**
 | **PSI case concluded**  | **Litigation** | **Referred to labour relations** |
| 1. **Patient outcome according to degree of harm: Mark with an X**
 | No harm  | Mild | Moderate | Severe | Neonatal trauma | Obstetric trauma | No longer classified as a PSI after investigation |
| Child death under 5 years | Child death 5 years and above | Adult death | Neonatal death | Maternal death | Still birth | Deaths due to hospital associated venous thromboembolism | Deaths due to health care associated sepsis | Perioperative death (30 days after surgery) |
| 1. **Organisational outcome: Mark with an X**
 | Property damage  | Increased length of stay | Admission to special care area (e.g., high care or ICU) | Additional treatment/tests | Additional staff required | Additional equipment required | Media attention |
| Formal complaint | Damaged reputation | Legal ramifications | None | Other | No longer classified as a PSI after investigation |
| Compiled by: Designation: Signature: Date: |

Annexure C:Patient Safety Incident (PSI) register

**HOSPITAL NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ MONTH/YEAR\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Ref No.** | **Date and time of Incident** | **Patient’s Name& Surname** | **Age** | **Gender** | **Location (ward/ department/area)** | **Type of PSI** | **SAC score** | **Reporting date of SAC 1 incidents** | **# of 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** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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Annexure D: Patient Safety Incident decision tree to assess staff based on the Just Culture



Annexure E: Classification for contributing factors

| **Main classification** | **Sub classification**  | **Example** |
| --- | --- | --- |
| 1. **Staff factors**
 | 1.1 Lack of knowledge of clinical processes/guidelines/ protocols | Lack of knowledge, not able to resolve a problem with available knowledge obtained through training, experience, induction and orientation programmes |
| 1.2 Human error – Clinical | Technical errors made while performing clinical procedures or not performing the clinical procedure as required (act of omission) |
| 1.3 Human error -Administrative | Technical errors made while performing administrative procedures or not performing the administrative procedure as required (incomplete/ poor record keeping) |
| 1.4 Risky/reckless behaviour | Risky, reckless (due to forgetfulness, fatigue, overconfidence), criminal act |
| 1.5 Communication factors | Amongst staff, family members and patients e.g., language difficulties, poor communication, health literacy |
| 1.6 Condition/disease related factor | Problems with substance abuse other mental illness |
| 1.7 Social factors | Stress, lack of motivation, high workload, fatigue |
| 1.8 Leadership | Lack of supervision, Delegation of duties outside of scope of practice  |
| 1. **Patient factors**
 | 2.1 Behavior | Risky, reckless, overconfident, criminal act, attention issues (absentmindedness/forgetfulness, distraction), fatigue/exhaustion) |
| 2.2 Communication factors | Language difficulties, communication methods, health literacy |
| 2.3 Condition/disease related factor | Problems with substance abuse other mental illness, spasticity, cognitive fall outs post Cerebral Vascular Accident (CVA), existing comorbidities |
| 2.4 Social factors | Living conditions, support structures, education  |
| 2.1 Behavior | Risky, reckless, overconfident, criminal act, attention issues (absentmindedness/forgetfulness, distraction), fatigue/exhaustion) |
| **3. Work/ environment factors** | 3.1 Physical environment/ infrastructure | Damaged/faulty/worn/ as maintenance plans were not executed, or infrastructure is inadequate/ inappropriate |
| 3.2 Equipment | Not available or not functioning as maintenance plans were not executed |
| 3.3 Consumables | Not available or insufficient |
| 3.4 Remote services | Long distance from service |
| 3.5 Environmental risk | Ventilation systems not functioning |
| 3.6 Security/safety | Security systems insufficient |
| 3.7 Current Code/ specifications/ regulations | Not available/outdated/up to standard |
| **4. Organisational / Service factors** | 4.1 Clinical protocols/policies/procedures  | Not available/up to date/ approved/signed |
| 4.2 Non-clinical protocols/policies/ procedures | Not available/up to date/ approved/ signed |
| 4.3 Organisational management  | Decisions, culture of organisation |
| 4.4 Organisation of teams | Poor/non-existing teamwork |
| 4.5 Staffing  | Staffing shortages |
| 4.6 Political unrest | Disruption of services due to riots |
| 4.7 Package of services | Package of service not offered. Cancellation/ unavailability of services |
| 4.8 Bed utilisation | Unavailability of beds |
| **5. External factors** | 5.1 Natural event or disaster  | Fire/smoke/Flood |
| 5.2 Equipment/products  | Malfunctioning due to manufacturer’s fault) |
| 5.3 Services, systems and policies of external providers  | Equipment procured not delivered |
| 5.4 Emergency medical services (EMS) | Delays in EMS transport |
| **6. Other** | 6.1 Not specified in classification 1 to 5 |  |

Annexure F: Classification for incident type

| **Main classification** | **Sub classification** |
| --- | --- |
| 1. **Clinical administration**
 | 1.1 Medical procedure performed without valid consent |
| 1.2 Communication/confidentiality |
| 1.3 Patient incorrectly identified and recorded |
| 1.4 Missing patient record |
| 1.5 Unclear/Ambiguous/Illegible/Incomplete Information in patient record |
| 1. **Clinical process/ procedure**
 | 2.1 Not performed when indicated  |
| 2.2 Performed on wrong patient |
| 2.3 Clinical procedure errors |
| 2.4 Surgical procedure errors |
| 2.5 Clinical assessment error (missed/delayed/wrong diagnoses) |
| 2.6 Failure to act on test results or report  |
| 2.7 Clinical treatment error (incorrect clinical management)  |
| 2.8 Performed on wrong body part/ site/ side |
| 2.9 Retention of foreign object during surgery |
| 1. **Healthcare-associated infections\***
 | 3.1 Central line associated blood stream infection |
| 3.2 Non-device related (Primary) blood stream infection |
| 3.3 Peripheral line blood stream infections infection |
| 3.3 Surgical Site infection |
| 3.4 Hospital acquired pneumonia |
| 3.5 Ventilator associated pneumonia |
| 3.6 Catheter associated urinary tract infection |
| 3.7 Communicable diseases |
| 1. **Medication/ IV fluids**
 | 4.1 Incorrect dispensing  |
| 4.2 Omitted medicine or dose |
| 4.3 Medicine not available |
| 4.4 Adverse drug reaction |
| 4.5 Incorrect medicine |
| 4.6 Incorrect dose/ strength administered |
| 4.7 Incorrect patient |
| 4.8 Incorrect frequency |
| 4.9 Incorrect route |
| 4.10 Prescription error |
| 4.11 Incorrect dispensing label |
| 4.12 Medicine expired |
| 4.13 Incorrect technique (e.g. inappropriate crushing of tablets or dilution of IV fluids) |
| 4.14 Inappropriate polypharmacy |
| 1. **Blood or blood products**
 | 5.1 Acute transfusion reactions |
| 5.2 Delayed transfusion reactions/ events (including transfusion transmitted Infections) |
| 5.3 Errors- wrong blood/ blood products |
| 1. **Medical device/equipment**
 | 6.1 Not available  |
| 6.2 Failure/ malfunction |
| 6.3 Not used correctly |
| 6.4 Incorrect medical device/equipment used |
| 1. **Behaviour**
 | 7.1 Sexual assault by staff member |
| 7.2 Sexual assault by fellow patient or visitor |
| 7.3 Physical assault by staff member |
| 7.4 Physical assault by fellow patient or visitor |
| 7.5 Exploitation, verbal abuse, aggression, neglect or degrading treatment by fellow patient or visitor |
| 7.6 Exploitation, verbal abuse, aggression, neglect or degrading treatment by staff member |
| 7.7 Missing patient |
| 7.8 Patient absconding |
| 7.9 Abscond while under 72-hour admission |
| 1. **Patient accidents and self-inflicted injury**
 | 8.1 Falls – Bedside |
| 8.2 Falls – Toilet/bathroom |
| 8.3 Falls – Stretcher |
| 8.4 Falls – Therapeutic equipment |
| 8.5 Falls – Other |
| 8.6 Patient injury |
| 8.7 Self-inflicted injury/Self-harm |
| 8.8 Suicide |
| 8.9 Attempted suicide |
| 1. **Pressure ulcers acquired during/ after admission**
 | 9.1 Grade I |
| 9.2 Grade II |
| 9.3 Grade III |
| 9.4 Grade IV |
| 1. **Infrastructure/ Buildings/ Fixtures**
 | 10.1 Damaged/faulty/worn |
| 10.2 Non-existent |
| 10.3 Inadequate/inappropriate |
| 10.4 Back-up electricity not functional/available |
| 10.5 Back-up water supply not available |
| 1. **Laboratory / Pathology**
 | 11.1 Delayed laboratory results |
| 11.2 Processing error by laboratory |
| 11.3 Incorrect labelling of results |
| 1. **Other**
 | 12.1 Any other incident not listed in classification 1 to 11 |

\* Definitions for healthcare-associated infections is set out in the National Infection Prevention and Control Manual, 2020.

Annexure G: Classification for incident outcome

|  |
| --- |
| **CLASSIFICATION FOR PATIENT OUTCOME** |
| 1. No harm (Patient outcome is not symptomatic, or no symptoms detected, and no treatment is required).
 |
| 1. 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.)
 |
| 1. 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.)
 |
| 1. 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
 |
| 1. Child death under 5 years
 |
| 1. Child death 5 years and above
 |
| 1. Adult death
 |
| 1. Neonatal death
 |
| 1. Maternal death
 |
| 1. Still birth
 |
| 1. Deaths due to hospital associated venous thromboembolism (up to 90 days post discharge)
 |
| 1. Deaths due to healthcare associated sepsis
 |
| 1. Perioperative death (occurring 30 days after surgery)
 |
| 1. Neonatal trauma
 |
| 1. Obstetric trauma
 |
| 1. No longer classified as a PSI after investigation
 |
| **ORGANISATIONAL OUTCOME** |
| 1. Property damage
 |
| 1. Increased length of stay
 |
| 1. Admission to special care area (e.g. high care or ICU)
 |
| 1. Additional treatment/tests
 |
| 1. Additional staff required
 |
| 1. Additional equipment required
 |
| 1. Media attention
 |
| 1. Formal complaint
 |
| 1. Damaged reputation
 |
| 1. Legal ramifications
 |
| 1. None
 |
| 1. No longer classified as a PSI after investigation
 |
| 1. Other
 |

Annexure H: Statistical data on classification for contributing factor

|  |  |
| --- | --- |
| **Establishment 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** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Lack of knowledge of clinical processes/guidelines/protocols  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Human error – clinical |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Human error – administrative |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Risky/reckless behaviour |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Communication factors  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Condition/disease related factors |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Social factors |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Leadership |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **2. Patient factors** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Behaviour |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Communication factors  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Condition/disease related factors |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Social factors |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **3. Work/environment factors** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Physical environment/ infrastructure |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Equipment |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Consumables |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Remote/long distance from service |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Environmental risk  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Security/safety |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Current code/ specifications/regulations |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **4.Organisational/service factors** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Clinical protocols/policies/procedures |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Non-clinical protocols/policies/procedures |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Organisational management/decisions/ culture |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Organisation of teams |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Staffing |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Political unrest |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Package of service  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Bed utilisation  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **5. External factors** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Natural event or disaster  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Equipment/products malfunctioning due to manufacturer’s fault |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Services, systems and policies of external providers  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Delays in emergency medical services transport |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **6. Other** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Other |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **GRAND TOTAL**Total of contributing factors in Column Q ÷ Grand Total of Column Q |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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

|  |  |
| --- | --- |
| **Facility/District office 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** | **% \*** |
| **Type** |
| **1.Clinical administration** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Medical procedure performed without valid consent |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Communication/confidentiality |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Patient incorrectly identified and recorded |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Missing patient record |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Unclear/ambiguous/illegible/incomplete Information in patient record |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **2. Clinical process/procedure** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Not performed when indicated |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Performed on wrong patient |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Clinical procedure errors |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Surgical procedure errors |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Clinical treatment error  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Clinical assessment error  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Failure to act on test results or reports |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Performed on wrong body part/site/side |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Retention of foreign object during surgery |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **3. Healthcare-associated infections** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Central line associated blood stream infection |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Non-device related (Primary) blood stream infection |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Peripheral line blood stream infection |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Surgical site infection |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 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 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Incorrect dispensing label |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Medicine expired |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Incorrect technique |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Inappropriate polypharmacy |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **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** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Not available  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Failure/malfunction |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Not used correctly |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Incorrect medical device/equipment used |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Not available  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Failure/malfunction |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **7. Behaviour** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 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, verbal abuse, aggression, neglect or degrading treatment by fellow patient or visitor |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Exploitation, verbal abuse, aggression, neglect or degrading treatment by staff member |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Missing patient |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Patient abscond |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Abscond while under 72-hour admission |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **8. Patient accidents and self-inflicted injury** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Falls – Bedside |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Falls – Toilet/bathroom |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Falls – Stretcher |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Falls – Therapeutic equipment |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Falls – Other |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Patient injury |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Self-inflicted injury/self-harm |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Suicide |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Attempted suicide |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **9. Pressure ulcers acquired during/after admissions** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Grade I |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Grade II |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Grade III |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Grade IV |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **10. Infrastructure/ buildings/ fixtures** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Damaged/faulty/worn |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Non-existent |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Inadequate/inappropriate |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Back-up electricity not functional/available |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Back-up water supply not available |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **11. Laboratory / Pathology** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Delayed laboratory results |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Processing error by laboratory |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Incorrect labelling of results |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **11. Other** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Any other incident that does not fit into category 1 to 10 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **GRAND TOTAL** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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

Annexure J: Statistical data on classification according to incident outcome

|  |
| --- |
| **PATIENT OUTCOME** |
| **Establishment 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** | **%\***  |
| No harm |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mild |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Moderate |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Severe |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Child death under 5 years |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Child death 5 years and above |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Adult death |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Neonatal death  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Maternal death |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Still birth |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Deaths due to hospital associated venous thromboembolism (up to 90 days post discharge) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Deaths due to healthcare associated sepsis |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Perioperative death (occurring 30 days after surgery) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Neonatal trauma |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Obstetric trauma |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| No longer classified as a PSI after investigation |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **GRAND TOTAL** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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| --- |
| **ORGANISATIONAL OUTCOME** |
| **Establishment 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 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Increased length of stay |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Admission to special care area (e.g. high care or ICU) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Additional treatment/tests |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Additional staff required |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Additional equipment required |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Media attention |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Formal complaint |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Damaged reputation |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Legal ramifications |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| None |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| No longer classified as a PSI after investigation |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Other |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **GRAND TOTAL** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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

Annexure K: Statistical data on indicators for patient safety Incidents

**Name of establishment/province: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**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** |  |  |  |  |  |  |  |  |