National Guideline for Patient Safety Incident Reporting and Learning in the Health Sector of South Africa

Version 2 - 2022

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Foreword

One of the greatest challenge today is delivering safer and quality care in complex, pressurised and fast-moving healthcare environments. In such environments, things can often go wrong. Patient Safety Incident Reporting and Learning Systems (RLS) are used to identify patient safety issues and therefore forms the cornerstone of patient safety strategies. By learning from these systems, errors can be corrected to prevent reoccurrence and ensure that patient safety, quality of care and health outcomes of patients are improved.

The World Health Organization's (WHO) World Alliance for Patient Safety developed the first draft guidelines for adverse event reporting in 2005 with the vision that one day it may be possible for the bad experience suffered by a patient in one part of the world to be a source of transmitted learning that will benefit future patients in many other countries. These guidelines were updated and revised in 2020 as the *WHO Guidelines for patient safety incident RLS*. The recommendation from the WHO's *Global patient safety action plan 2021-2030* is that all countries should develop an effective and sustainable national level patient safety incident RLS (Strategy 6.1).

To this end, the national Department of Health developed the first *National Guideline for Patient Safety Incident Reporting and Learning* that was implemented on 1 April 2018 to guide the health system to report patient safety incidents. After three years of implementation there was a need to revise the Guideline, specifically the classification systems to enable meaningful analysis of the incidents reported, and to enable the country to report on the indicators set out in the *Global Patient Safety Action Plan*. The emphasis should not only be on reporting as it is only one part of implementing an efficient RLS, but should include individuals and the whole health sector learning from the incidences to prevent reoccurrence. Sir Liam Donaldson, WHO Envoy for patient safety stated that: "To err is human, to cover up is unforgivable, but to fail to learn is inexcusable". I believe that Version two of this Guideline is essential to allow meaningful analysis of incidents to identify trends in system failures to improve the quality of care provided to patients. The Guideline will further guide health facility to comply with the Norms and Standards Regulations applicable to different categories of health establishments (2018).

Director-General for Health
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This Guideline will be reviewed as the need arise.

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ABBREVIATIONS AND ACRONYMS

ADR	Adverse Drug Reaction
ICPS	International Classification for Patient Safety
MHCA	Mental Health Care Act
MIM	Minimum Information Model
NDoH	National Department of Health
PSI	Patient Safety Incident
RCA	Root Cause Analysis
RLS	Reporting and Learning Systems
SAC	Severity Assessment Code
SANBS	South African National Blood Service
SAPS	South African Police Service
SOP	Standard Operating Procedure
WHO	World Health Organization

INTRODUCTION

Lapses in patient safety are a major healthcare quality problem. These lapses in patient safety are referred to as patient safety incidents (PSI). In the context of this guideline, a 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).[1]

An incident may have been caused:

- Because something has gone wrong during the patient's episode of care – an event has occurred that was unplanned or unintended.
- From a recognised risk inherent to an investigation or treatment – for example, a patient's bowel is perforated during a routine colonoscopy.
- Because the patient did not receive his/her planned or expected treatment – for example, he/she did not receive his/her medications as ordered.[2]

The occurrence of patient harm due to such lapses is remarkably common, causing many avoidable deaths each year. A large majority of these lapses are the unintended results of highly complex and imperfect healthcare delivery systems in which minor mishaps sometimes combine to cause harmful or disastrous results. Most of the unintended occurrences are related to whole system challenges.

Professional errors, at risk behaviour, and reckless misconduct or negligent behaviour contribute to PSIs. Identifying where, when, and how in the care process lapses occur and changing processes of care to reduce the chance of reoccurrence requires a reliable PSI reporting system.

All healthcare professionals should report PSIs as soon as they become aware of it to ensure that optimal learning take place. Other methods to detect incidents should also be used as underreporting by staff is the norm, although its degree varies. Studies have found that reporting systems detects only 7–15% of incidents.[3] PSIs should be

[1] World Health Organization. The *Conceptual Framework for the International Classification for Patient Safety, Version 1.1 Final Technical Report Technical Annex 2,* WHO, Geneva, 2009.
[2] NSW Health Incident Management Policy PD2014_004. Clinical Excellence Commission Open disclosure handbook – chapter 2.
[3] World Health Organization. Incident Reporting and Learning Systems. Technical Report and Guidance. 2020

recorded and analysed to identify whether improvements in the delivery system can be made.

Improved patient safety is demonstrated by, among others, improved patient satisfaction with health services, reduction of avoidable mortality, harm encountered during care, litigations, and reduced healthcare costs.

The first *National Guideline for Patient Safety Incident Reporting and Learning* was implemented on 1 April 2018. A national web-based PSI RLS was developed and rolled out at the same time to assist health facilities to implement the National Guideline. The revision of the Guideline, specifically the classification system for PSI was prompted by two documents:

- The 2020/2021 Annual PSI report that included an analysis of the data reported on the National PSI RLS over a two-year period (2018/2019 and 2019/2020)
- The WHO's *Global Patient Safety Action Plan 2021-2030.* The plan contains core and advanced indicators that countries must report on.

The revised classifications for type of PSI, contributing factors, outcome and severity assessment code (SAC) were outlined in the Annual PSI report that was shared with Provincial Heads of Health with a request for inputs. The inputs received were reviewed and amendments were made to the classifications which were shared with Provincial Quality Assurance Managers and National Programme managers for final inputs before finalising the classifications.

The review of the classifications also prompted the review of the following:

- The PSI definition. The definition was reviewed to ensure that everyone has the same understanding of what a PSI is. A decision tree to guide staff to correctly identify a PSI was added.
- The PSI reporting form. The form was rearranged to allow for a logic flow for collection of information. The classifications were updated according to the revised classification and prompts were added into some fields to guide staff on the content to be completed for those fields.
- Addition of an algorithm to guide a just assessments of individual acts of staff based on the just culture. This was added to the existing section of the just culture in the guideline.
- Updated the Adverse Drug Reaction and Blood transfusion reporting form.

PURPOSE

The purpose of this Guideline is to provide direction to the health sector of South Africa regarding the management of PSI reporting, including the provision of appropriate feedback to patients, families/support persons and clinicians, as well as the sharing of lessons learned to prevent patient harm. This Guideline describes a national standardised system for managing PSIs to ensure that various levels of care in the health system respond effectively to PSIs. By doing so, patient safety is improved by learning from failures of the healthcare system so that the likelihood of a reoccurrence of the same event is significantly reduced.

The objectives of this Guideline are to:

- create a framework to guide the implementation of a PSI RLS
- assist facilities to comply with the norms and standards regulations applicable to different categories of health establishments (2018)
- prevent and or reduce harm to patients whilst undergoing medical care
- standardise the definitions for PSIs
- standardise the degree of severity classification
- standardise the classification for PSIs by type, contributing factors, and outcomes
- standardise the methodology for reporting, investigating, and responses to PSIs
- ensure that statistical data on PSIs is readily available for planning and decision making
- learn from data reported 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

SCOPE

This Guideline:

- applies to all incidents affecting patient safety that occur in all health establishments of South Africa
- is applicable to clinical staff and non-clinical staff
- describes roles and responsibilities in the incident management process
- articulates reporting requirements
- defines the timeframes within which incidents, and the results of the investigation of these incidents, are to be reported
- identifies the facility/district/provincial and national level processes for aggregation, analysis, learning, and action on incidents

All staff working in healthcare establishments are responsible to:

- report and record all patient safety incidents
- report all incidents that resulted in serious harm or death (SAC 1 incidents) within 24 hours to management or sub-district/district and provincial office
- commence and/or participate in the open disclosure process as appropriate
- participate in the investigation of incidents as required
- finalise SAC 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

DEFINITION OF TERMS AS USED

Degree of harm: The severity and duration of any harm, and any treatment implications that result from an incident.

Detection: An action or circumstance that results in the discovery of an incident.

Error: The failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (error of planning). Errors may be errors of commission of omission, and usually reflect deficiencies in the systems of care.

Hazard: A circumstance, agent or action with the potential to cause harm.

Harm: Implies impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological.

Harmful incident (adverse event): An incident that results in harm to a patient that is related to medical management, in contrast to disease complications or underlying disease.

Incident type: A descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features.

Incident outcomes: The impact upon a patient or an organisation wholly or partially attributable to an incident.

Minimal information model: Refers to a minimal common architecture for the core concepts considered to be essential for information and comparison purposes of PSI reports[4].

Mitigating factor: An action or circumstance that prevents or moderates the progression of an incident towards harming a patient.

Near miss: An incident which did not reach the patient.

No harm incident: An incident which reached a patient, but no discernible harm resulted.

Organisational outcome: The impact upon an organisation which is wholly or partially attributable to an incident.

Patient safety: The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.

Patient outcome: The impact upon a patient which is wholly or partially attributable to an incident

Patient safety incident: 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)

Resulting actions: Identify immediate or indirect action taken that relates to the patient or the organisation to improve the situation or prevent the reoccurrence of an incident.[5,6]

[4] WHO Working Paper. Preliminary version of Minimal Information Model for Patient Safety, Spring 2014: 4
[5] World alliance for patient safety WHO draft guidelines for adverse event reporting and learning systems – from information to action 2005:7
[6] Conceptual framework for the International Classification for Patient Safety, WHO, 2009: 15-16

Root cause analysis: A systematic iterative process whereby the factors that contribute to an incident are identified by reconstructing the sequence of events and repeatedly asking why, until the underlying root causes have been elucidated.[7]

Severity Assessment Code 1: Serious harm or death that is/could be specifically caused by healthcare rather than the patient's underlying condition or illness.

Severity Assessment Code 2: Moderate harm that is/could be specifically caused by healthcare rather than the patient's underlying condition or illness.

Severity Assessment Code 3: Minor harm that is/could be specifically caused by healthcare rather than the patient's underlying condition or illness.

Severity Assessment Code 4: No harm.

System: A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim.

LEGAL AND POLICY FRAMEWORK

The constitutional, legislative and policy framework for the Guideline is as follows:

5.1 National Health Act, 2003 (Act 61 of 2003)

Section 47, subsection 1 of the National Health Act stipulates that all health establishments should comply with the quality requirements and standards prescribed by the minister after consultation with the National Health Council. The quality requirements and standards contemplated in subsection 1 may relate to human resources, health technology, equipment, hygiene, premises, delivery of health services, business practices, safety, and the manner in which users are accommodated and treated.

5.2 The National Health Amendment Act, 2013 (Act 12 of 2013)

Section 78 of the Act states that one of the objectives of the Office of Health Standards Compliance is to protect and promote the health and safety of users of health services. The Norms and Standards Regulations applicable to different categories of health establishments were published in 2018 to realise this objective.

[7] World Health Organization. Incident Reporting and Learning Systems. Technical Report and Guidance. 2020.

5.3 Ethical rules for health practitioners

All healthcare practitioners are bound by ethical rules in their specific professional practice. As the gist of these rules has to do with the protection of their patients and the public at large, health professionals are thus held accountable for their professional acts and omissions.

A healthcare practitioner should always regard concern for the best interests or well-being of their patients as their primary professional duty. Healthcare practitioners must treat patients with respect, keep information confidential and provide information to patients as required to ensure that they can make an informed decision when they have to give consent for procedures. Healthcare practitioners must also work with and respect other healthcare professionals in pursuit of the best healthcare possible for all patients. The ethical rules guide judgment against unethical practices of health professionals.[8]

Public health workers are also subject to the Code of *Conduct for Public Servants* in which the expected relationship of the employee with the public is clearly defined.

5.4 The national *Patients' Rights Charter*

The *Patients' Right Charter* stipulates that users of health services have the right to a healthy and safe environment.

5.5 The Health Professions Amendment Act, 2007 (Act 29 of 2007)

The Act regulates the mandatory reporting of procedure-related deaths. The Act stipulates that the death of a person undergoing, or as a result of, a procedure of a therapeutic, diagnostic or palliative nature, or of which any aspect of such a procedure has been a contributory cause, shall not be deemed to be a death from natural causes as contemplated in the Inquest Act, 1992 (Act 145 of 1992), or the Births, Marriages and Deaths Registration Act, 1992 (Act 51 of 1992).

[8] Health Professions Council of South Africa, General ethical guidelines for health care professions, May 2008: 5-8.

5.6 The Births and Deaths Registration Act, 1992 (Act 51 of 1992)

The Act provides for the notification of death by medical practitioners and authorised nursing practitioners in cases of death. A notice of death must be given within 72 hours of the death by the informant. The cause of death must be recorded as –

(i) "natural causes", if satisfied that the death was due to natural causes,

(ii) "unnatural causes", if satisfied that the death was due to unnatural causes, or

(iii) "under investigation" and the case number, if the death is still under investigation in terms of Section 3 of the Inquests Act.

5.7 The Inquest Act, 1992 (Act 145 of 1992), as amended

The Act regulates procedures in unnatural deaths by making provision for the holding of inquests in cases of deaths or alleged deaths apparently occurring from other than natural causes and for matters incidental thereto. Any person who has reason to believe that any other person has died, and that death was due to other than natural causes, shall as soon as possible report to the South African Police Service (SAPS), unless he has reason to believe that a report has been or will be made by any other person.

By definition it also requires referral to Forensic Pathology Services and the performance of an autopsy. The consent of family members is not required in such cases; however, the family/relatives of the deceased should be informed prior to the performance of the autopsy.

5.8 The Mental Health Care Act, 2002 (Act 17 of 2002)

The act regulates procedures regarding assisted and involuntary mental healthcare users, mentally ill prisoners and State patients that have absconded from a health establishment.

In cases where an assisted and involuntary mental healthcare user, State patient or mentally ill prisoner has absconded or is deemed to have absconded the head of the health establishment may request assistance from the SAPS to apprehend and return the user to the health establishment concerned using Mental Health Care Act form number 25 (MHCA 25).

The health establishment must inform the SAPS of the estimated level of dangerousness of the mental healthcare user, State patient or mentally ill prisoner. If the mental healthcare user, State patient or mentally ill prisoner is apprehended in the vicinity of the health establishment, the SAPS must return the user immediately to the health establishment. Should the apprehension by the SAPS not take place in the vicinity of that health establishment, the mental healthcare user may be held in custody at the police station for a period of not more than 24 hours. During this time the head of the health establishment should take steps to ensure that a mental healthcare practitioner from a health establishment nearest to the police station provides treatment to the mental healthcare user.

Section 11, subsection one of the Mental Health Care Act prescribes that every person, body, organisation or health establishment providing care, treatment and rehabilitation services to a mental healthcare user must take steps to ensure that: i) users are protected from exploitation, abuse and any degrading treatment, ii) users are not subjected to forced labour, and iii) care, treatment and rehabilitation services are not used as punishment or the convenience of other people. A person witnessing any form of abuse set in subsection one against a mental healthcare user must report this fact in the prescribed manner.

5.9 Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended

This Act refers to the reporting of adverse drug reactions received by pharmaceutical manufacturers (license holders) from health professionals. Regulations 34 and 37 of the Act stipulates that that license holders must report all adverse drug reactions (ADRs) associated with the use of registered medicines and any other safety data which arise during post-registration and post-marketing clinical trials to the office of the Registrar of Medicines via their pharmacovigilance unit. Health professionals are encouraged to report suspected adverse drug reactions directly to the National Adverse Drug Event Monitoring Centre using the prescribed ADR form. An ADR is defined as any reaction to medicine which is noxious (harmful or unpleasant) and unintended, and which occurs at doses normally used for the prevention, treatment or diagnosis of disease.

The minimum information required when reporting an ADR is:

- an identifiable source (reporter) of the information. This should include the name or initials and address of the reporter, reporter's qualification and contact details
- an identifiable patient. A patient may be identified by surname and forenames(s) or initials of surname and forenames, or by reference number
- age and gender of patient
- suspected product(s)
- suspected reaction(s)
- name of health establishment

Information additional to the minimum should be actively sought and submitted as soon as it becomes available.

5.10 National Health Act, 2003 (Act 61 of 2003) - Regulations relating to blood and blood products (no.r.179)

Sub-regulation (10) of the National Health Act states that the South African National Blood Service (SANBS) must inform the Director-General: Health or a person specifically designated by him or her, verbally immediately of any report received in terms of a blood transfusion that resulted in any serious or life-threatening reaction or death and confirm such report in writing as soon as possible.

In order for SANBS to report the blood transfusion reactions that resulted in any serious or life-threatening reaction or death to the director-general, the Standards of Practice for Blood Transfusion in South Africa, 6th edition, September 2013, section 60.1.3 further states that the medical practitioner at the health establishment shall report any blood transfusion reactions as soon as possible in writing to the SANBS where the blood was obtained from. In the event of mortality or major morbidity, the report may be verbal initially and then subsequently in writing. A labelled blood sample must be obtained from the recipient and sent together with the blood container, any attached transfusion set and intravenous solutions to the SANBS where the blood was ordered from. The prescribed form must be completed and sent together with aforementioned.

The SANBS will investigate the incident and submit a report on the outcome of the investigation to the responsible medical practitioner or clinical manager at the health establishment who reported the incident to the SANBS.

SITUATIONAL ANALYSIS

6.1 Internationally

Approximately two thirds of the global burden of adverse events resulting from unsafe care, including the disability-adjusted life years lost from them, occurs in low- and middle-income countries. Patient harm due to adverse events is one of the top 10 causes of death and disability in the world. Available evidence suggests that annually 134 million adverse events due to unsafe care occur in hospitals in low- and middle-income countries, contributing to 2.6 million deaths.[9]

In high-income countries, it is estimated that one in every 10 patients is harmed while receiving hospital care.[10] The harm can be caused by a range of adverse events, with nearly 50% of them being preventable.[11] Globally, as many as four in 10 patients are harmed in primary and outpatient health care. Up to 80% of harm is preventable. The most detrimental errors are related to diagnosis, prescription and the use of medicines.[12]

In OECD countries, 15% of total hospital activity and expenditure is a direct result of harmful incidents.[13]

6.2 Public health service in South Africa

The 2020/2021 National Annual Patient Safety Incident Report sets out the analysis of incidents reported on the national web-based RLS since its inception in 2018. The Compliance Report generated from the web-based information system is used as a proxy to measure progress made with implementation of the National PSI guideline. For South Africa, the Compliance rate for PSIs has increased from 34% since inception of the guideline (2018/2019) to 51% at the end of the 2020/2021 financial year. While some provinces have improved much, others have not.

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[9] World Health Organisation – Global patients safety action plan 2021-2030
[10] Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017.
[11] de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. Qual Saf Health Care. 2008;17(3):216–23.
[12] Slawomirski L, Auraaen A, Klazinga N. The Economics of Patient Safety in Primary and Ambulatory Care: Flying blind. Paris: OECD; 2018
[13] Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017

The number of PSI cases reported nationally increased from 17 341(2018/2019) to 21 777 (2019/2020) and decreased slightly to 21 726 in the 2020/2021 financial year. It is important to recognise that high levels of PSI reporting are not necessarily indicative of a less safe environment for the patient, but instead could highlight a good reporting culture.

When analysing indicator and classification data for the 2020/2021 financial year, the number of PSIs reported must always be taken in consideration. When interpreting the classifications for the type of PSIs, it must be kept in mind that there are currently other information systems used by provinces to report specific types of PSIs, i.e. Perinatal Problem Identification Programme, Child Problem Identification Programme, and the reporting of adverse drug reaction to the NDoH and the South African Health Products Regulatory Authority. Some provinces have taken a decision to report these types of PSIs on these auditing systems, therefore data for these types of PSIs will not reflect on the national PSI reporting system. Attempts have been made to consolidate all the data, but it is a complicated process and consensus could not be reached on how to best manage it.

For South Africa the case closure rate (86%) and the case closure rate within 60 working days (99%) is high. A similar trend is seen in all provinces. The percentage of SAC 1 PSIs that are reported within 24 hours to the next level is much lower nationally (73%) and range from 46% to 80% in provinces.

Most PSIs reported were classified as SAC 3 (49%), while SAC 2 and SAC 3 PSIs were more or less equal at 23% and 27%. The top three main categories for type of PSIs that were reported nationally for the 2020/21 financial year is behaviour (27%), clinical processes/procedures (27%) and patient accidents (12%). The top four sub-categories for type of PSIs nationally are falls (12%), wandering/absconding (10%), neonatal death (10%), refusal of treatment (10%) and pressure sores acquired during admission (6%). The classification for ‘Other’ type of PSIs should be less than 10%. Nationally, 25% of the PSIs were logged under the category for ‘Others’, with some provinces classifying up to 44% of PSIs under the same classification. Analysis of the data indicated that most PSI cases categorised under the category for ‘Other’ were misclassified as there were either an existing category under which it could have been categorised or it did not fall within the definition of a PSI as defined in the National Guideline. For example, cases where standard care was provided were reported like

stillbirths that occurred due an underlying health condition and not as a result of the healthcare that was provided.

For South Africa, the top four main categories for contributing factors for the 2020/2021 financial year were: patient factor (81%), staff factors (30%), work/environment (13%), and organisational/service factors (12%). Similar to the type of PSIs, one must drill down on the sub-classification for contributing factors to better pick up trends. For South Africa, the top four sub-classifications for contributing factors are patient factors: patho-physiologic/ disease related factors (45%), patient factors: behaviour (32%), staff factors: performance (20%), and patient factors: cognitive factors (11%). Trends differed widely in provinces. The top three categories for patient outcome for the 2020/2021 financial year that were reported nationally were: death (27%), mild (27%) and none (24%). The trend is similar in most provinces with a few provinces having recorded more ‘mild’ and ‘moderate’ outcomes. The top three categories for organisational outcome nationally are: none (59%), increased in required resources (23%) and other (10%). The trend is similar at provincial level.

PRINICIPLES OF PATIENT SAFETY INCIDENT MANAGEMENT

All health facilities should have a system in place to manage PSIs according to the following principles:

7.1 Just Culture

Staff that report patient safety incidents should be free from fear of victimisation solely for reporting PSIs. The Just Culture supports a “learning organisation” that investigates incidents instead of blaming individuals. See Section 9.5 for a detailed explanation of the Just Culture.

7.2 Confidentiality

The identities of the patient, reporter or institution should be kept anonymous and only known to staff directly involved in the management of a PSIs as well as managerial staff that are indirectly involved in the further management of the incident.

7.3 Timeliness

Reports are analysed promptly. Once the organisation is notified of PSIs, investigation should be conducted immediately.

7.4 Responsiveness

Participating organisations commit to the immediate implementation of recommendations.

7.5 Openness about failures

Patients and their families/support persons are offered an apology and told what went wrong and why.

7.6 Emphasis on learning

The system is oriented towards learning from mistakes and consistently employs improvement methods for achieving this.

MINIMUM INFORMATION MODEL

One of the long standing aspirations of the WHO was to turn the failures of healthcare into global learning opportunities to accelerate and expand patient safety improvement. Weak patient safety cultures, together with the fear of punishment, prevent to some extent the reporting of PSIs. In addition, the scarcity of universally applicable and common standards for collecting, storing, classifying, analysing and interpreting incident reports as well as other clinical data is a significant barrier to effective reporting and learning. Therefore, the WHO developed a tiered classification system in the form of an information model. There are three tiered classification models:

- first tier - Minimal Information Model (MIM)
- second tier - Intermediate Information Model
- third tier - Full Information Model

The detail of the data collected increases as the tiers progresses. The Minimal Information Model may be seen as the first layer of a fuller local reporting system tailored to its own context.

For the South African context, the MIM will be used as a starting point to strengthen effective reporting by identifying the key data features that can provide maximum meaningful learning.

In general, reporting systems aim to satisfy three main objectives:

- description (what happened)
- explanation (why it happened)
- remedial (what were the reactions)

The MIM includes these three main objectives into the following classifications:

- incident identification
    - patient (a person who is a direct or indirect recipient of healthcare and involved directly or indirectly in the PSI)
    - time (date and time of day when the incident occurred)
    - location (physical environment in which a PSI occurs)
    - contributing factor (factor with the potential to cause harm. It refers to the product, device, person, or any elements involved in the incident with the potential to influence it)
- incident type (a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features)
- incident outcomes (the impact an incident had upon a patient or an organisation that was wholly or partially caused by an incident)
- resulting actions (identify immediate or indirect action taken that relates to the patient or the organisation to improve the situation or prevent the reoccurrence of an incident)
- reporter (person who collects and writes information about the incident)[14]

The classes for the contributing factor, incident type and incident outcome are defined by the WHO's framework for the International Classification for Patient Safety (ICPS).[15] The classes as set out by the WHO are very extensive, therefore the rapid assessment of the contents of provincial patient safety or adverse event policies/protocols/guidelines that were collected by the NDoH in June 2014 were used to reduce the concepts of each of the three classes for the South African context.

[14] WHO Working Paper. Preliminary version of Minimal Information Model for Patient Safety, Spring 2014: 4-7
[15] Conceptual framework for the International Classification for Patient Safety, WHO, 2009: 32-47 and 90-95

Table 1 sets out the classification of the MIM and provides a description of the classifications.

Classification	Description of classification
a. Incident identification	
Patient	Name, surname, patient file, gender, age
Date and time	Specific date and time when incident took place
Location	Ward, department, section where incident took place
Contributing factors	See **Appendix A**
b. Incident type	See **Appendix B**
c. Incident outcomes	See **Appendix C**
d. Resulting actions	Note down action implemented to prevent a similar incident from re-occurring
e. Reporter	Name and surname, designation, contact details. Note that the anonymity of reporting should be considered at all levels to increase adherence to the procedure. It is not recommended in cases where the incident result in legal action.

Table 1: Classification and description for MIM

MANAGEMENT OF PATIENT SAFETY INCIDENTS

Once a PSI has been identified, a series of action steps should be followed to ensure effective management of PSIs.[16] 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 9.1 to 9.9 and set out in **Figure 2** as a flow diagram.

[16] New South Wales Incident Management policy, 2014: 7-14

9.1 Step 1: Identifying patient safety incidents

It is essential that only incidents that falls within the definition of a PSI are reported. **Figure 1** sets out a decision tree to give guidance to staff in the decision-making process to identify a PSI.[17]

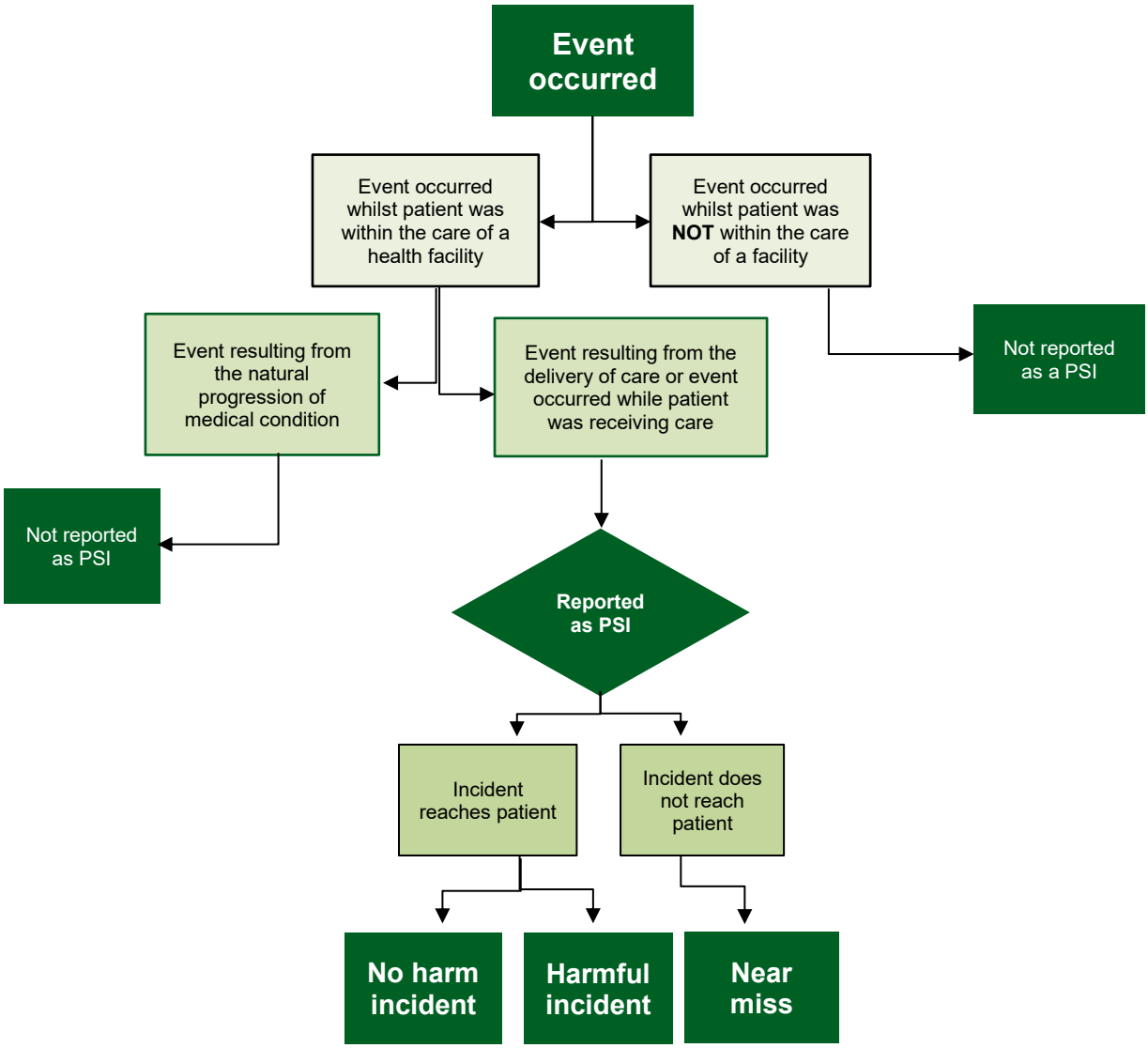


Figure 1: Decision tree to identify PSIs

PSI prevention and or management can only happen if PSIs are detected in time. Although there are different mechanisms that may be used to detect PSIs, most managers get to know about PSIs in their own health establishments from tip-offs, media publications and lawsuits or from complaints by patients and members of the public.

[17] New South Whales Health Incident Management Policy PD2014_004. Clinical Excellence Commission Open disclosure handbook – chapter 2.

There are various ways that are used to detect PSIs without the need for additional costs. All PSIs should be reported in one central Patient Safety Incident Management Systems irrespective of the manner in which they were detected/identified. The following are some of the well-known PSI detection methods:

9.1.1 Patient safety incidents reporting by health professionals

Most Patient Safety Incident Management Systems rely on detecting patient safety incidents through reporting by health professionals even though only a small number of PSIs are reported in this manner. Health researchers have established that only 10 to 20 per cent of errors are ever reported and, of those, 90 to 95 per cent cause no harm to patients.[18] Therefore, information on PSIs is scanty in most establishments. The reasons for under-reporting vary, hence the need for seeking alternative options of detecting PSIs. The Just Culture philosophy should be developed within health establishments to enable a conducive environment to report PSIs.

9.1.2 Medical record/retrospective patient record review

Medical records of a sample size of patients admitted or treated at a specified service area (at a specified time) are reviewed by a selected team. The process of reviewing medical records follows a defined inpatient event. The inpatient event may comprise of five to eight outcomes i.e. death, return to operating theatre within seven days, transfer from a general ward to an intensive care unit, unplanned readmission within six weeks after discharge, increased average length of stay in hospital, patient dissatisfaction, litigation cases, etc. The intended outcome of disease intervention is agreed upon i.e. delivery of a healthy neonate, full recovery from current illness, complete alleviation of pain, improved functionality of the body part or organ, etc. Once the outcome of disease (treatment or stay in health facility) has been identified by the team, all criteria related to treatment of the condition are examined. Health professionals' notes are examined and compared among one another.

Another example of a structured tool that can be used to review records is the *Institute for Healthcare Improvement (IHI) Global Trigger Tool for Measuring Adverse Events*

[18] IHI Global Trigger Tool for Measuring Adverse Events (Second Edition). Cambridge, Massachusetts: Institute for Healthcare Improvement; Griffin FA, Resar RK. 2009: 2.
(Available on www.IHI.org)

developed by the Cambridge Institute for Healthcare Improvements. The Trigger Tool methodology is a retrospective review of a random sample of inpatient hospital records using "triggers" (or clues) to identify possible adverse events. It is important to note, however, that the IHI Global Trigger Tool is not meant to identify every single adverse event in an inpatient record. The methodology, recommended time limit for review, and random selection of records are designed to produce a sampling approach that is sufficient to determine harm rates and observe improvement over time.[19]

9.1.3 Focus teams

Focus teams offer an opportunity for a very rich learning environment as members within teams discuss and develop ideas. Examples of focus teams are morbidity and mortality review committees, clinical audit teams, quality assurance committees, etc.

9.1.4 External sources

Patients' families and representatives, any concerned member of public member (who may have not been a patient but has observed an incident happening or heard about it) and the media, can also report adverse events. Reporting of incidents may be through Speak Up campaigns, complaint management system, public representatives (e.g. hospital boards or clinic committees), etc. Once the PSI is reported, the health department is obliged to initiate proper investigations into the allegation.

9.1.5 Review of record on follow-up of patients

Bearing in mind that PSIs may occur or be recognised after patient is discharged from healthcare facility, a specially formulated patient's progress form is attached to a discharge summary report. Once the PSI is detected by the health professional during patient's follow up, the form is completed and returned to the healthcare facility that initially treated the patient. The alleged PSI is investigated then appropriate corrective measures are implemented. Corrective measures may include recalling patient to a facility for further treatment.

9.1.6 Surveys on patients' experience of care

Regular, well-structured surveys on patients' perception of care provide valuable information on issues related to PSIs. Although they may seem to be generic and not pinpoint the actual location of incidents, surveys on patients' perception of care help to

[19] IHI Global Trigger Tool for measuring Adverse Events (UK version) Institute for Healthcare Improvement, 2008

direct and guide managers towards critical focus area (within the healthcare system) that should be improved.

9.1.7 Safety walk rounds

Safety walk rounds consist of a core group of senior managers walking through the health facility on a regular basis. The rounds take place in six to eight service areas of a health facility. Overall rounds should last for 60 or more minutes. During the rounds, operational staff members, excluding their immediate managers, are asked questions about their knowledge of any PSIs using a safety rounds 'toolbox' – see **Appendix D**. All comments by the staff are recorded. The management team conducts its own observations across all the service areas. After each walk round, the team meets for debriefing. All responses are collated, categorised, and prioritised according to severity and impact. Managers are delegated to resolve the identified safety concerns. The best way is to use an action plan to guide progress and evaluation. The managers at health facilities are expected to keep hospital executives or district managers informed of their progress and challenges that demand the intervention of senior managers. The summary of the safety walk rounds, including results of interventions, is presented at the monthly management meeting or any other regular platform designed by the health facility. The presentation of interventions may be done in a narrative format or graphically.

9.1.8 Use data to identify and guide the management of patient safety incidents

Many organisations have local, provincial and national information systems e.g., the District Health Information System from which analysis can be made. It is imperative that managers investigate negative trends using statistical data on PSIs and subsequently improve such performance. In addition to identifying PSIs, various important issues other than PSIs, e.g. technical expertise of data capturers, can be identified.

9.1.9 Research studies and findings

Research studies may include any patient safety related research studies that may have been conducted over time. An individual, group or the health facility may have conducted the research. Research findings and recommendations are considered in quality improvement projects and are then implemented.

9.2 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 reoccurrence of the event
- gathering basic information from staff while the details are still fresh in the minds of the involved clinicians
- notifying the SAPS, health establishment's security or other institution where applicable

9.3 Step 3: Prioritisation

The purpose of prioritisation is to ensure that a standardised, objective measure of severity is allocated to each incident. The 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. Experience has demonstrated that predicting the likelihood of reoccurrence is not helpful as it can be unreliable.[20]

There are four 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 no harm. See **Appendix E** that describes the four SAC classes.[21]

9.4 Step 4: Notification

[20] New South Wales Incident Management policy, 2014: 9
[21] Government of Western Australian Health Department: Clinical Incident management toolkit, 2012 (updated Feb 2014): 6

According to the WHO, PSI data should be recorded and analysed to improve patient safety. It is equally important to develop a response system and a reporting system to improve patient safety.[22]

9.4.1 Record keeping

All PSIs should be recorded as recordkeeping is crucial in the effective management of PSIs. Data on PSIs can be reported in unstructured or structured reports.

Unstructured reports on PSIs are more narrative and the format of the report is not defined (headings and fields names are not defined). The contents of reported PSIs are determined by the reporter's discussion with the person receiving the report. Although unstructured reports carry more information and clarity, more time is needed to make some inferences before deciding on the applicable action to be taken. The unstructured reports are therefore labour intensive and time consuming when compared to the highly structured reporting systems.

Structured reporting is usually done on an electronic information system. These types of reports are conducted in a highly structured manner and require both specific information (field names and heading defined) and a detailed narrative description of the incident. The highly structured reporting format may require a reporter to select options from pre-defined fields. The system ensures that reports are quickly entered, readily classified, aggregated, analysed and recommendations made available within a few minutes of reporting. The preliminary findings and recommendations are made available to the head of the facility in question for further investigation and responsive measures. Countries such as Australia, Japan, England, and some health organisations in South Africa have successfully implemented structured PSI reporting on electronic information systems.

Structured PSI reporting has proven to be more effective to manage PSIs than unstructured reporting especially when data is captured on an electronic information system. Therefore, for the South African health sector structured reporting is prescribed by means of using various prescribed forms and templates to record data on PSIs.

[22] World alliance for patient safety WHO draft guidelines for adverse event reporting and learning systems – from information to action 2005: 54

All PSIs should be recorded on a PSI reporting form, see **Appendix F** as an example. Section A (notification) of the form should be completed by the staff who witnessed the incident. In cases where the PSI was identified by making use of one of the methods as described in section 9.1.2 to 9.1.9 (retrospective reviews), the PSI reporting form must also be completed. Section A, point 3 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 (patient, staff or other who witnessed the incident) of the form if the staff involved have left the service or could not be identified. If the incident is a SAC 1 incident, section A and B is submitted to the district or provincial office for notification. Section B (statements by staff patient or significant other) of the form should be completed by the staff, patients or significant others that were present while the incident took place. Section C (investigation) of the form should 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.

To enable health facilities to keep statistical data on PSIs, all PSIs should be recorded in a PSI register, see **Appendix G**. The register is a written record that contains information on PSIs. The register can be in the form of a book or separate pages kept in a file that is clearly marked that it contains PSI registers. In cases where an electronic information system is used, the minimum dataset should include all data fields as indicated in the PSI register to enable the automated generation of the PSI register.

9.4.2 Incident notification to management

All SAC 1 incidents should be reported to the provincial or district office within 24 hours depending on the line of reporting as determined by the specific province. The reporting of SAC 1 incidents is mandatory. PSIs with a SAC rating of 2, 3, and 4 should be reported to executive management within the facility. The provincial, district and facility protocol or standard operating procedure to manage PSIs should include a flow diagram that details the process flow to be followed when reporting PSIs.

9.4.3 Initial notification to patient

Initial disclosure should take place as early as possible after the incident. Information should be a provided to the patient and family in 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 healthcare organisation to provide support or assistance as required to patients, family and healthcare professionals involved. Patients, family, and healthcare professionals often require psychological support.

Disclosure involves healthcare providers as well as patients. Depending on the severity and impact of the PSI, people to be called and the venue for disclosure should be carefully decided on. The healthcare provider at the service site may disclose some of the less serious PSIs, such as close calls. More serious PSIs may be communicated in designated areas such as the duty room or manager's office.

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 healthcare 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 healthcare professional involved can at this stage convey their apology in a sincere manner
- systems to support the healthcare professionals involved should be in place

9.5 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[23]

PSIs should be investigated by means of systems Root Cause Analysis (RCA) to determine the 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 are 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 healthcare professional displayed reckless behaviour should be referred to the relevant professional body for further handling. See **Appendix F**, Section C, section 2b of the PSI reporting form for a framework for RCA and action plans. Various methods to conduct a RCA are outlined in the National Quality Improvement Guide (2012).

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 failures 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 model fosters increased safety in the delivery of healthcare by promoting transparency, fairness, communication, and learning.[24]

[23] The Pan American Health Organization adverse events policy and guidelines, December 2011: 7-8
[24] Patient Safety handbook, Barbary J Youngberg, 2012, Chapter 13:178

The Just Culture is founded on three behaviours: human error, at-risk behaviour, and reckless behaviour. Health facilities should console those who commit human error, coach those who are guilty of at-risk behaviour and discipline those with reckless behaviour (**Table 2**).[25] In some cases where an incident is reported as a PSI, the outcome of the investigation can 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: • choices • processes • procedures • training • design • environment	Manage through: • removing incentives for at-risk behaviours • creating incentives for healthy behaviours • increasing situational awareness	Manage through: • remedial action • disciplinary action
Console	**Coach**	**Discipline**

Table 2: Just Culture Model

It is a key component of work to move away from asking 'Who was to blame?' to asking, 'Why did the individual act in this way?' when things went wrong. The PSI decision tree (**Appendix H**) was created to 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 user is guided through a series of structured questions about the individual's actions, motives, and behaviour at the time of the incident. The questions move through four sequential "tests". These questions may need to be answered on the balance of probability - i.e. determining the most likely explanation (considering the information available at the time), although the importance of pausing to gather data is emphasised:[26]

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

[25]The ABC of the Just Culture: The path to building a dependable organization. Alejandro Alfonso Díaz, September 2011
[26] United Kingdom National Patient Safety Agency. Sandra Meadows, Karen Baker, Jeremy Butler. The Incident Decision Tree: Guidelines for action following patient safety incidents. Sept 2019.

- 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 facility 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.

9.6 Step 6: Classification

A classification comprises of a set of concepts linked by semantic relationships. It provides a structure for organising information to be used for a variety of other purposes, including health facilities, district, provincial and national statistics, descriptive studies, and evaluative research.

A uniform classification system according to the Minimal Information Model as described in section 5.6 ensures accurate data analysis. All PSIs should be classified according to the following classes:

- contributing factors, see **Appendix A**
- incident type, see **Appendix B**
- incident outcome, see **Appendix C**

9.7 Step 7: Analysis

Regardless of the objective of the Patient Safety Incident Management Reporting System neither the act of reporting nor the collection of data will reduce the occurrence of PSIs unless the data is analysed and recommendations are made for change and these changes are implemented.

There are three indicators to monitor PSIs: PSI case closure rate, SAC 1 incident reported within 24 hours rate, and PSI case closure within 60 working days rate. The data for these indicators should be collected from the PSI registers that are completed monthly. The calculation of the indicators is set out in **Table 3**

Indicator name	Calculation of indicator
Patient safety incident case closure rate	$\frac{\text{Total number of PSI case closed in the reporting month}}{\text{Total number of PSI cases reported in the reporting month}} \times 100$
Severity assessment code (SAC) 1 incident reported within in 24 hours rate	$\frac{\text{Total number of SAC 1 incidents that reported within 24 hours in the reporting month}}{\text{Total number of SAC 1 incidents in the reporting month}} \times 100$
Patient safety incident case closure within 60 working days rate	$\frac{\text{Total number of PSI cases closed within 60 days in the reporting month}}{\text{Total number of PSI cases closed in the reporting month}} \times 100$

Table 3: Calculation of indicators for patient safety incidents

Health facilities should submit reports to their district/provincial departments monthly. Where a web-based application is in place at provincial level, hospitals, community health centres, sub district and district offices do not need to submit reports as the provincial department will be able to generate reports from the web-based application. Provincial departments should report to the national department quarterly. The data for the prescribed reporting templates can be submitted manually or electronically in cases where a web-based application is available.

The following statistical data should be recorded and submitted:

- data on classifications of contributing factors, see **Appendix I**
- data on classifications of incident type, see **Appendix J**
- data on classifications of incident outcome, see **Appendix K**
- indicators for PSIs, see **Appendix L**

Statistical data on SAC 1 incidents should be kept separate from statistical data on SAC 2, SAC 3 and SAC 4 incidents.

In cases where an electronic information system is used to capture the data on PSIs, the data fields as indicated in the patient safety register should be used to populate the data onto Appendices I to K, this will include the automatic calculation of the indicators.

9.8 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 RCA indicates the timeframes as well as the staff responsible for implementation, see **Appendix F**, Section C, Section 2b (Framework for RCA and actions).

Patient safety committees at various levels in the health system are responsible for ongoing monitoring that is required to ensure recommendations are addressed in a timely manner and to evaluate the success of any action taken to achieve improvement.

9.9 Step 9: Learning

The fundamental role of PSI reporting systems is to enhance patient safety by learning from failures of the healthcare system. Reporting can lead to learning and improved safety through:

- the generation of alerts regarding significant new hazards
- feedback
- analysing reports[27]

9.9.1 Alerts

Reports can provide sufficient data to enable analysts to recognise a significant new hazard and generate an alert. These alerts should be published as widely as possible to prevent the reoccurrence of the newly identified hazard.

9.9.2 Feedback

[27] World alliance for patient safety WHO draft guidelines for adverse event reporting and learning systems – from information to action 2005: 13

Feedback on the progress and outcome of the PSI is an important component of a successful Patient Safety Incident Management System. The patient as well as the staff should receive feedback on the management of PSIs.

9.9.2.1 Feedback to staff

To ensure that learning takes place, it is essential that feedback is given to all staff on the results/outcomes of investigations in a timely manner. Feedback should be provided to staff involved in the incident and should happen as soon as possible, including after the completion of the RCA. The information to be provided is limited to that which is included in the final RCA report. This way staff involved in the incident will be informed of the conclusions reached by the team and the recommendations arising from any investigation.

To close the loop and ensure learning, feedback should be given to the broader group of clinical providers and managers within the organisation. This feedback will focus on the lessons to be learned by the organisation and system amendments that will provide a greater chance that the incident will not happen again. Such feedback and discussion could take place at, for example, ward meetings, mortality, and morbidity review meetings.

Feedback should include updates as the changes are made and improvements achieved because of these changes. This will provide a level of accountability for implementation of the recommendations that come from the RCA.

9.9.2.2 Feedback to the patient – post analysis disclosure

Achieving a culture of patient safety requires open, honest, and effective communication between the healthcare providers and patients. It is 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 facility should consult the legal representative of the provincial health department.

Patients lose trust, become anxious, fearful, and angry when they sense that information is being withheld. Post analysis disclosure is reached when additional facts have been identified and the reasons for the adverse events are better understood.

Management may likely have a greater role to play at this stage and healthcare providers involved should be updated about the results of the analysis and encouraged to continue to participate in the discussions. Leadership or the legal counsel has to decide what information should be disclosed.

The following should 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 because 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 maintained. Where PSIs involve more than one institution, representatives of both affected institutions should collaborate throughout the process and send one common message.

Patients and or family members should not be sent from pillar to post while seeking answers on PSIs. Managers should not apportion blame and refer a patient/representative to other levels of care without assisting one to do so.

9.9.3 Analysing reports

Analysing reports can reveal unrecognised trends and hazards requiring attention. Regular reports on trended aggregated data and outcomes of RCAs should be provided to the management team and clinical staff.

The most important function that a large reporting system can perform is to use the results of investigations and data analysis to formulate and disseminate recommendations for systems changes.

The series of action steps that should be followed to ensure the effective management of PSI is set out in **Figure 2**

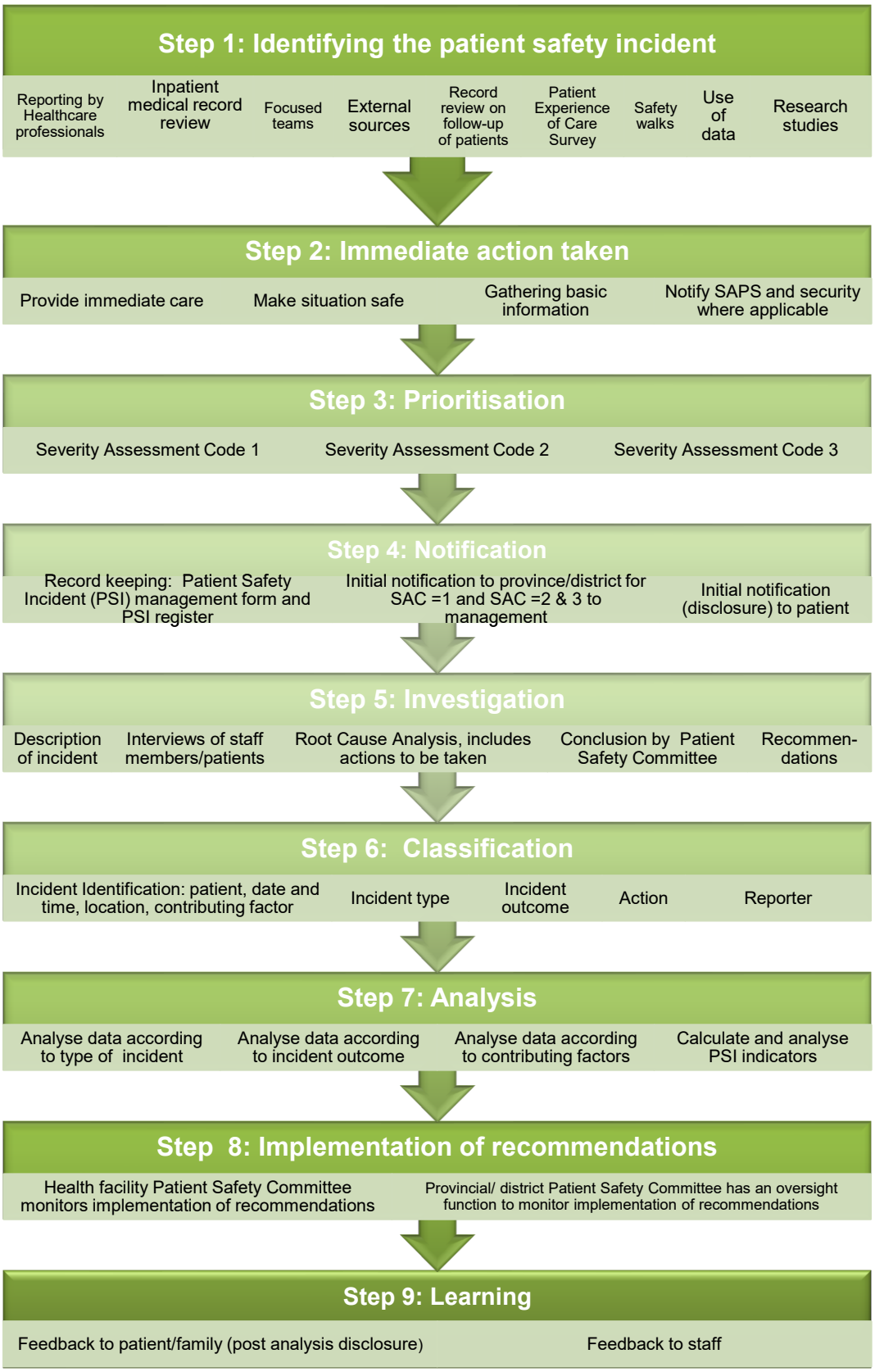


Figure 2: Action steps for the management of patient safety incidents

IMPLEMENTATION BY PATIENT SAFETY COMMITTEES

To ensure that PSIs are managed effectively according to the nine action steps as described in Section 9; hospitals, community health centres, sub-district/district offices, provincial departments and the national department should establish Patient Safety Committees.

The committees' main objective is to oversee the effective management of PSIs. These committees do not need to be stand-alone committees but can form part of other committees that deal with clinical governance. The terms of reference of such combined committees should stipulate in detail the functions to be performed managing PSI reporting. This Guideline only gives direction on the terms of reference of the committees as well as who can be appointed as members, but is remains the relevant authority's prerogative to decide on the actual terms of reference and appointment of members.

10.1 Hospital, community health centres (CHCs), and sub-district/district Patient Safety Committees

10.1.1 Terms of reference

- 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.
- 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.

10.1.2 Designation of members for hospital

Committee can be constituted, but not limited to, staff members with the following designations:

- Chief Executive Officer
- Clinical Manager (chairperson)
- Quality Assurance Manager
- Nursing Manager(s)
- Representative of the infection and prevention control section
- Complaints' manager or public relations officer
- Head: Corporate Services
- Representative of the occupational health and safety division
- On an *ad hoc* basis:
    - Nursing manager(s) of areas where the incidents took place

- Clinical head(s) of areas where the incidents took place
- Specialist expertise as applicable to the case discussed

10.1.3 Designation of members for Community Health Centres

Committees can be constituted, but not limited to, by staff members with the following designations:

- Manager of the Community Health Centre (chairperson)
- Medical practitioner
- Professional nurse assigned to manage the infection and prevention control section

10.1.4 Designation of members for sub-district/district offices committees

Committees can be constituted, but not limited to staff members with the following designations:

- District Quality Assurance Manager (chairperson)
- District Manager
- Representative from district hospitals and community health centres
- Member(s) of District Specialist Teams
- On an *ad hoc* basis:
  - facility managers of health establishment where incidents took place
  - programme managers
  - specialist expertise as applicable to the case discussed

10.2 Provincial Patient Safety Committees

10.2.1 Terms of reference

- Develop a provincial protocol/guideline to manage PSIs.
- Monitor that SOPs of health facilities and sub-district/ district offices are aligned with the provincial PSI protocol/guideline.
- Assist health facilities and sub-district/ district offices to mitigate immediate consequences of PSIs.
- Monitor the reporting of Severity Assessment Code 1 incidents within 24 hours.

- Review PSI reports for all Severity Assessment Code 1 incidents that are reported. In cases where further investigation is required, conduct investigation.
- Monitor that all incident reports are finalised within 60 days.
- Monitor the implementation of recommendations 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 at least quarterly meetings of which the minutes should be recorded. *Ad hoc* meeting can be scheduled as needed.
- Submit quarterly statistical reports to the national 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.
- Compile an annual report to identify trends and make recommendations to improve patient safety according to trends identified.
- Disseminate lessons learned from PSI management.
- Develop guidelines and protocols that encourage an environment in health facilities where incident notification and active management of incidents is fostered.
- Implement provincial system-wide initiatives to prevent similar future incidents.
- Identify training needs emerging from PSI management and conduct training for staff at health facilities.
- Facilitate the transformation of knowledge obtained through the statistical analysis of PSIs into protocols, guidelines and standard operating procedures.

10.2.2 Designations of members

Committee can be constituted, but is not limited to, staff members with the following designations

- Head of Quality Assurance division and or designated person (chairperson)
- Clinical specialists to be co-opted according to expertise required to give an opinion on the adverse event cases that will be presented
- Nurse expert
- Representative from the legal advisor’s division

- on an *ad hoc* basis:
    - Chairperson of district/ sub district Patient Safety Committees where the incident took place
    - Chairperson from hospital Patient Safety Committees where the incident took place

The committee can co-opt members as required based on the need.

10.3 National Patient Safety Committee

10.3.1 Terms of reference

- Review the national guideline to manage PSI as the need arise.
- Conduct quarterly meetings of which the minutes should be recorded.
- Monitor that provincial departments adhere to the guideline to manage PSIs.
- Review PSI registers to assess data quality
- Compile and analyse quarterly national PSI statistical reports.
- Implement national system-wide initiatives to prevent similar future incidents.
- Provide advice to the Minister of Health on issues of public concern and media or public attention.
- Provide an appropriate national response to new risks as they are identified.

10.3.2 Designations of members

- Chief Director or Director for Hospital services
- Chief Director or Director for Primary Healthcare
- Chief Director or Director for Quality Assurance (Chairperson)
- Chief Director or Director for Legal Services
- Chief Director or Director for Monitoring and Evaluation
- Chief Director or Director for Policy Coordination and Integrated Planning

The committee can co-opt members as required based on the need.

Appendix A: Classification for contributing factors

Main/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
2. 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/not maintained 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 and poor leadership
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	Delays in Emergency medical services transport
6. Other	
6.1 Not specified in classification 1 to 5	

Appendix B: Classification for incident type

Main/Sub Classification	Explanations/Examples
1. Clinical administration	
1.1 Medical procedure performed without valid consent	Medical procedure was performed without obtaining informed consent from the patient or family (in cases where patient is unable to give consent).
1.2 Communication/ confidentiality	• Harm occurred because there was lack of communication between the patient and care provider, e.g. patient did not inform staff that he/she is allergic to penicillin and or staff did not ask specifically about any allergies to medicines. • Psychosocial harm occurred because the HIV status of a patient was shared with family members or unrelated individuals without the patient's consent.
1.3 Patient incorrectly identified and recorded	• Patient record was incorrectly labelled with another patient's sticker and therefore received incorrect medication that resulted in an adverse event. • Physician dictating a note into the wrong patient's chart.
1.4 Missing patient record	• Entire patient record could not be found, therefore historical and current treatment plans not available resulting in inappropriate dose of potassium and diuretic administered for pulmonary oedema causing cardiac arrhythmia and possible death. • Patients' prescription charts not found - similar scenario: full drug history unknown causing drug interactions with serious life threatening consequences.
1.5 Unclear/ Ambiguous/ Illegible / Incomplete Information in patient record	• Nurse's notes recorded that patient was on anti-depressants that was totally contraindicated for the drug prescribed by the doctor because the doctor could not read the notes. • Doctors' instructions not legible thus mobilization instructions not understood resulting in patient with serious neuropathy following spinal surgery as he /she was mobilized too early.
2. Clinical process/ procedure	
2.1 Not performed when indicated	Clinical process/procedure not performed resulting an unplanned/unintended event that could have or did result in harm **Note**: This excluded failure to act on test results or reports as there is a separate sub-classification for it. • Did not do a test or put up a drip when indicated. • Caesarian not performed when indicated as no doctor was on duty, resulted in brain damage due to fetal distress. • Not stabilizing a gurney prior to patient transfer and patient falls off gurney. • Delay in calling for expert assistance/transfer to higher level of care resulted in neonatal death-delay is due to not being aware and monitoring for signs of neonatal distress. • CVP line not removed before patient was discharged • Vaginal tampon left in patient after vaginal delivery (found 2 months after delivery).
2.2 Performed on wrong patient	Clinical and surgical procedure performed on the wrong patient because patient identity not checked with clinical instructions • Blood transfusion done on wrong patient. • Patient received IV drug that was not prescribed for the patient. • Lumbar puncture performed on the wrong patient.

	• Two patients have the same surname. Senior doctor did not give clear instructions on which patient the procedure should be performed on. Resulted in wrong procure on patient without clinical indication.
2.3 Clinical procedure errors	Preventable error made during a clinical procedure (any procedure performed on a patient that requires an intervention using a device (excluding surgical procedures and procedure performed on wrong body part/ site/ side as there is a separate sub-classification for it) • Patient had a colonoscopy, colon was accidentally perforated. • Lumbar puncture was performed, spinal cord was injured, patient was paralysed. • Third degree perineal tears as an episiotomy were not performed. • Unsafe injection practices resulting in harm e.g. wrong gauge needle causing severe localized bruising. • Subcutaneous medication administered as intradermal. • Overexposure to radiation while receiving radiation therapy causing severe internal and external burns. • Infiltration of the subcutaneous tissue by an intravenous line which turns septic. • Patient intubated too deeply into one bronchus resulting in loss of lung function and ultimately brain hypoxia.
2.4 Surgical procedure errors	Preventable error made during the entire surgical procedure (pre-operative, peri-operative and immediate post operative care) **Note:** Excludes identification of wrong body part/ site/ side and retention of foreign object during surgery as there are separate sub-classifications for it. • An anterior and posterior repair of prolapse uterus was performed; bladder was accidently damaged. • Incorrect anaesthesia administered resulting in brain damage/death. • Preoperative swab count was incorrect, and no verification took place prior to wound closure. • Burn inflected by cautery machine during surgery. • Incorrect mixture of gases during anaesthesia resulting in hypoxic brain damage.
2.4 Clinical treatment error (Incorrect clinical management)	Clinical management protocol not followed • Woman in labour not assessed according to labour management protocol, therefore gave birth in the bathroom even though she was fully dilated. • Neonate with meconium staining and intrapartum asphyxia not done according to neonate resuscitation procedure resulting in aspiration pneumonia and death. • Patient with haemoptosis not fully evaluated for liver cirrhosis and developed liver failure.
2.5 Clinical assessment error (Missed, delayed, wrong diagnosis)	**Missed** • Cancer missed despite symptoms. • Sepsis not diagnosed early enough to save a patient's life. • Pre-eclampsia that was missed in a pregnant woman that resulted in a maternal death. • Fetal distress missed/not detected; no intervention done for prolonged second stage of labour resulted in neonatal death. **Wrong** • Patients incorrectly diagnosed when there is evidence of another diagnosis.

	Delayed • Abnormal test result suggestive of cervical/prostate cancer, but patient not recalled and informed on the next steps.
2.6 Failure to act on test results or reports	Failure to act on results of investigation undertaken • Blood results filed in patient record, without appropriate action being taken, resulting in harm e.g. patient's condition deteriorated. • Doppler shows a deep vein thrombosis, warfarin not administered resulting in an embolus to the brain and permanent disability.
2.8 Procedure performed on wrong body part/ site/ side	Clinical and surgical procedures performed on wrong body part/site/side • Wrong limb amputated e.g. right arm was amputated instead of left arm due to nursing identification error. • Radiation treatment given on the right breast instead of the left breast.
2.9 Retention of foreign object during surgery	• Post operatively theatre nurse found a swab was missing on recount after skin closure. Patient required further surgery to remove swab. • Drill bit broke off in the bone of a patient, patient required further surgery • Staple used for anastomosis of healthy end of colon falls into abdominal cavity and is not retrieved, resulting in puncture of healthy small intestines when patient is mobilized. **Note:** 1) Foreign object must be left in the patient. 2) Only incidents where patient went for surgery is included in this sub-classification.
3. Health care-associated infections	
3.1 Central line associated blood stream infection	See Manual for the Implementation of the National Infection Prevention and Control Strategic Framework for the definitions of HAI
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	
4. Medication/ IV fluids	
4.1 Incorrect dispensing	Script was written correctly but the medicine on the script was issued incorrectly.
4.2 Omitted medicine or dose	Medicine was not given at the intervals as prescribed or not given at all.
4.3 Medicine not available	Medicine prescribed is not available, patient not treated at all. Pharmacist substitute medicine but the substitution is inappropriate for this patient.
4.4 Adverse drug reaction	Any reaction to medicine which is noxious (harmful or unpleasant) and unintended, and which occurs at doses normally used for the prevention, treatment or diagnosis of disease.
4.5 Incorrect medicine	Incorrect medicine administered. This error often occurs with medicine that look alike/sound alike. Medicine A is prescribed but medicine B is administered.
4.6 Incorrect dose/ strength administered	Dosage/strength of medicine is not administered according to the prescription.
4.7 Incorrect patient	Medicine prescribed is administered to incorrect patient. Medicine prescribed for patient A is administered to patient B.
4.8 Incorrect frequency	Medicine is not administered according to the frequency /times prescribed.

4.9 Incorrect route	Medicine not administered according to the prescription e.g. subcutaneous injection is administered intramuscularly resulting in muscular necrosis at injection site.
4.10 Prescription error	Prescription was not written correctly by doctor e.g. doctor wrote 200mg instead of 20mg for a child.
4.11 Incorrect dispensing label	Label is not according to prescription, e.g. prescription stated a tablet once a day. Label reads 3 tablets 3 times a day resulting in an overdose.
4.12 Medicine expired	Medicine administered has expired
4.13 Incorrect technique	Inappropriate crushing of tablets or dilution of IV fluids
4.14 Inappropriate polypharmacy	Irrational prescribing of too many medications that often occur when existing prescriptions was not reviewed at every point of initiation of a new treatment for the patient, and when the patient moves across different health care settings.
5. Blood or blood products	
5.1 Acute transfusion reactions	Blood reaction happens within 24 hours of transfusion e.g. while patient was receiving blood transfusion, he started to develop a fever, hypertension and had rigors, action was not taken, patient went into shock.
5.2 Delayed transfusion reactions/ events (including transfusion transmitted Infections)	Occur after 24 hours following a transfusion of blood or components. It usually occurs two weeks after but can go up to 30 days post transfusion.
5.3 Errors- wrong blood/ blood products	Patient with type A blood receives transfusion of type B resulting in an ABO incompatibility reaction.
6. Medical device/equipment	
6.1 Not available	• Intubation equipment not available to resuscitate a patient, patient demised. • No accessible intensive care unit (ICU) bed with ventilator results in neonatal death. • Patient with history of alleged sexual assault missed 72 hour window to test as crime collection kit was locked in an administrator's office.
6.2 Failure/ malfunction	Medical device/equipment is available, but it is not functional. **Note:** this excludes equipment that is not functional due to the unavailability of back-up electricity supply as there is a separate sub-classification for it. • Defibrillator was not working; patient could not be resuscitated. • Suction apparatus not functional, therefore no suction vacuum present when a baby needed to be resuscitated. • Baby needed to be resuscitated in the resus room but there was no oxygen supply flow from the oxygen regulator.
6.3 Not used correctly	Medical device/equipment is available, but it is not used according to manufacturer's specifications • Single-use syringes used repeatedly. • Ventilator circuits being reused even though it is strictly for single use.
6.4 Incorrect medical device/equipment used	Incorrect medical device/equipment is used to perform a procedure • Incorrect size endotracheal tube used for resuscitation; patient's trachea was perforated.
7. Behaviour	
7.1 Sexual assault by staff member	Staff member sexually violates a patient without their consent.
7.2 Sexual assault by fellow patient or visitor	A patient sexually violates another fellow patient without their consent.
7.3 Physical assault by staff member	Physical harm or unwanted physical contact inflicted by a staff member upon a patient.
7.4 Physical assault by fellow patient or visitor	Physical harm or unwanted physical contact inflicted by a patient or visitor upon a fellow patient.

7.5 Exploitation, verbal abuse, aggression, neglect or degrading treatment by fellow patient or visitor	All forms of emotional ill-*treatment of a patient by a fellow patient that resulted in emotional and/or psychological harm to the patient.*
7.6 Exploitation, verbal abuse, aggression, neglect or degrading treatment by staff member	All forms of emotional ill-treatment of a patient by a staff member that resulted in emotional and/or psychological harm to the patient.
7.7 Missing patient	In-patient (patient was registered for admission (folder allocated)) that has unwilling left the health facility.
7.8 Patient abscond	In-patient (patient was registered for admission (folder allocated)) who absconded (willingly) from a health facility.
7.9 Abscond while under 72-hour admission	In-patient (patient was registered for admission (folder allocated)) who absconded (willingly) from a health facility while under 72-hour observation.
8. Patient accidents and self-inflicted injury	
8.1 Falls – Bed	An event that occurred when a patient fell of the bed (e.g. cot sides not secured) on the floor which results in a person coming to rest inadvertently on the ground or floor.
8.2 Falls – Toilet/bathroom	An event that occurred at the toilet/bath/shower which results in a person coming to rest inadvertently on the ground or floor.
8.3 Falls – Stretcher	An event that occurred while patient was lying on a stretcher which results in a person coming to rest inadvertently on the ground or floor.
8.4 Falls – Therapeutic equipment	An event that occurred while the patient received therapy (e.g. physical therapy (during ambulation, rehabilitation)) which results in a person coming to rest inadvertently on the ground or floor.
8.5 Falls – Other	An event that occurred which results in a person coming to rest inadvertently on the ground or floor that is not included in any of the sub-classifications for falls e.g. patient walking from bed to bathroom in the ward or patient fell off the radiology bed.
8.6 Patient injury	An injury sustained by a patient while in the care of a health facility. **Note:** it excludes injuries caused by dilapidated/non existing building infrastructure or lack of water/electricity as there is a separate sub-classification for it. i.e. 'Infrastructure/ Buildings/ Fixtures' • Cleaner was polishing the floor, patient's toe was scrapped with the machine resulting in a laceration. • Patient accidently kicked the window with his foot and sustained a deep laceration on his right toe.
8.7 Self-inflicted injury/Self-harm	Act of injuring oneself intentionally as a result of emotional *pain*, intense anger and frustration by various methods such as self-laceration, self-battering, taking overdoses or exhibiting deliberate recklessness but with no intent to die. • Patient banged his head on the wall intentionally and sustained a laceration. • Patient made laceration on her wrist.
8.8 Suicide	Inpatient death caused by injuring oneself with the intent to die.
8.9 Attempted suicide	When an inpatient harm themselves with any intent to end their life, but they do not die as a result of their action.
9. Pressure ulcers acquired during / after admissions	
9.1 Pressure ulcers – Grade I	Ulcers that feel **warm to the touch, discolouration of the skin (has not yet broken),** occurred during/after admission on areas of the skin that are under pressure from lying in bed, sitting in a wheelchair, or wearing a cast for a prolonged time.
9.2 Pressure ulcers – Grade II	Ulcers that look **more damaged (break in the top two layers of skin (epidermis and/or dermis)) and may have an open sore, scrape, abrasion or blister,** that occurred during/after admission on areas of the skin that are under pressure from lying in bed, sitting in a wheelchair, or wearing a cast for a prolonged time.

9.3 Pressure ulcers – Grade III	Ulcers that have a **crater-like appearance due to damage/necrosis to the top two layers of skin, as well as fatty tissue,** that occurred during/after admission on areas of the skin that are under pressure from lying in bed, sitting in a wheelchair, or wearing a cast for a prolonged time.
9.4 Pressure ulcers – Grade IV	Ulcers where the area is **severely damaged/destructed, and a large wound is present, it may impact muscle, tendons, ligaments, and bone,** that occurred during/after admission on areas of the skin that are under pressure from lying in bed, sitting in a wheelchair, or wearing a cast for a prolonged time.
10. Infrastructure/ Buildings/ Fixtures	
10.1 Damaged/faulty/poor maintenance	• Dilapidated ceiling board falls on patient. • Handrail of an access ramp is loose, and patient falls off the side.
10.2 Non-existent	• Patient falls of a ramp as there was no handrail fixed to the ramp. • Patient falls in the shower as there is no grab rail.
10.3 Inadequate/inappropriate	• Orthopaedic ward only has baths and a patient who had a hip replacement fall trying to get into the bath. • Patient in a wheelchair falls from the chair as the ramp is too steep.
10.4 Back-up electricity not functional/available	• Ventilator not working resulting in patient's death. • Incubator not working resulting in death of a premature neonate.
10.5 Back-up water supply not available	• Back-up water supply was not available, therefore suction compressors and water-cooled medical gas not functional resulting in harm to patient. • Autoclave not functioning to sterilize correctly, patient died due to sepsis.
11. Laboratory / Pathology	
11.1 Delayed laboratory results	Specimens submitted in-time by the facility but not processed according to turnaround times of the laboratory. • Patient was scheduled for surgical procedure, could not be performed as laboratory results were not processed according to turnaround time for the processing of the specific test. • Patient is taken to theatre for emergency procedure, urgent specimen sent to laboratory abnormal results not communicated to attending clinician immediately, resulting in death of patient.
11.2 Processing error by laboratory	Incorrect technique performed to process specimen resulting in error in results or malfunction/calibration not done of test machine. • False positive COVID test, patient is sent to COVID isolation ward where he actually contracts COVID. • Blood grouping test incorrectly performed, thus incorrectly matched blood given to patient, resulting in shock.
11.3 Incorrect labelling of results	Hospital submitted correctly labelled specimen, but laboratory attached the incorrect patient information on the report. • Specimen for patient X was submitted to perform INR, results for INR for patient X was submitted for patient Y, resulting in Warfarin overdose as INR for patient X was low.
12. Other	
12.1 Any other incident not listed in classification 1 to 11	

Appendix C: Classification for incident outcome

CLASSIFICATION FOR PATIENT OUTCOME	Examples
1. No harm	Patient outcome is not symptomatic, or no symptoms detected, and no treatment is required.
2. Mild harm	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 harm	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 harm	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. Stillbirth	A fetus that had at least 26 weeks of intra-uterine existence but showed no sign of life after complete birth
6. Neonatal death	Death of a neonate (birth to 28 days inclusive (first four weeks after birth))
7. Child death under 5 years	Death of a person from 29 days to the age of 4 years and 364 days
8. Child death 5 years and above	Death of a person from 5 years to the age of 17 years and 364 days
9. Adult death	Death of a person 18 years and above
10. Maternal death	Death of a woman at any time between the conception of her infant and 42 days after the delivery of the infant
11. Deaths due to hospital associated venous thromboembolism	Death due to venous thromboembolism up to 90 days post discharge
12. Deaths due to health care associated sepsis	Deaths due to health care associated sepsis
13. Perioperative death	Death after surgery occurring up to 30 days after surgery
14. Neonatal trauma	An impairment of the neonate's body function or structure due to an error that occurred at birth. Injury may occur during labour, delivery, or after delivery, especially in neonates who require resuscitation in the delivery room, e.g.: • Brachial palsy • Bruising or forceps marks • Cephalohematoma • Facial paralysis • Fractures
15. Obstetric trauma	Injury relating to childbirth and the processes associated with it, e.g.: • Uterine rupture • Anal fissures • Episiotomy • Preeclampsia • Placenta abruption
16. No longer classified as a PSI after investigation	A PSI was recorded but after a full investigation, it was concluded that the harm occurred was not due to the healthcare provided.

ORGANISATIONAL OUTCOME	Examples
1.Property damage	Patient was psychotic and broke windows etc.
2. Increased length of stay	Patient's length of stay increased due to the harm that occurred, e.g.: • Patient had a HAI and therefore took longer to recover.
3. Admission to special care area (e.g., high care or ICU)	Patient required admission in a special care unit due to the harm that occurred, e.g.: • Patient has a surgical site infection, developed sepsis and had to be transferred to ICU. • Patient fell due to negligence in the ward and had to have a hip fracture repair, therefore require ICU care.
4. Additional treatment/tests	Patient required additional treatment/tests e.g.: • Patient received an overdose of medication due to a prescription error and had to be treated for overdose and had to have renal and liver function tests to ensure no damage to liver or kidneys
5. Additional staff required	Additional staff required a shortage of a specific category of staff resulted in harm e.g.: • The single surgeon consultant appointed, is ill and therefore unable to perform surgery for bowl obstruction and patient dies.
6. Additional equipment required	Additional equipment required as the lack of functional equipment resulted in harm e.g.: • Preterm baby died because there were not enough incubators available • Defibrillator was not available, as patient could not be resuscitated manually
7. Media attention	Incident resulted in negative media attention of the health facility
8.Formal complaint	Incident resulted in a formal complaint (written or verbal lodged by the patient/family/ support person
9.Damaged reputation	Reputation of facility was damaged e.g.: • Standard clinical practice not followed, e.g. multiple suicides within a psychiatric hospital, state of neonatal deaths in neonatal ICU in one facility in three months.
10. Legal ramifications	Incident resulted in patient/family/support person taking the legal route, the patient/facility sued the facility.
11. None	No organisational outcome, this is often the case with near misses
12. No longer classified as a PSI after investigation	A PSI was recorded but after a full investigation, it was concluded that the harm occurred was not due to the healthcare provided.
13. Other	Any other organisational outcome not covered in classifications 1 to 12

Appendix D: Safety walk around toolkit

AREA	FOCUS
Care delivery	• Any special training needs • Missed or delayed orders • Any missing care delivery issue
Communication	• Missing test results • Delayed tests results • Availability of policies or procedures
Environment	• Cleanliness • Hand washing facilities • Sanitary facilities • Exposed electrical wires / broken glasses / broken walls / pilling paint • Waste bins with plastic lining and lid
Equipment	• Availability of resuscitation / lifesaving equipment • Functionality of resuscitation / lifesaving equipment • Proper storage of resuscitation / lifesaving equipment • Control list of resuscitation / lifesaving equipment
Intra-departmental transport	• Adequate communication between the departments e.g. porters, radiology, wards to wards, operating theatre and wards, etc. • Availability of processes for providing staff to accompany and or stay with patient
Medication	• Consistence in naming of medications (generic vs trade names) • Proper identification of patients • Procedure for medicine administration • Procedure for safekeeping of medication
Security	• Ability to distinguish patients from visitors • Ability to distinguish different staff categories among disciplines • Ability to control / monitor visitors and patients' movement in / out of care areas
Staffing	• Staff patient ratio (consider acuity levels) • Appropriate skill mix

Appendix E: Prioritisation - Severity Assessment Code (SAC)[28]

	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	• Notify management within 24 hours • Conduct a formalised investigation		• Notify management within 24 hours

[28] **Government of Western Australian Health Department: Clinical Incident management toolkit, 2012 (updated Feb 2014), page 6.**

	SAC 1	SAC 2	SAC 3	SAC 4
	• 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**	• 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.**		• 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

Appendix F: 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		**2. Time PSI identified**								
3. 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			

4. Provide a short overview of the Patient Safety Incident
What happened/went wrong?
What is the initial outcome or harm?

5. 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?

6. 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)

		2		**4**	**9. Date SAC 1 reported to next level**			

8. SAC rating: Mark with an X	1 Serious	Moderate	3 Minor	None	10. Time SAC 1 reported to next level		11. No of days to report PSI with SAC = 1	

12. Patient and ward information		13. 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	**11. 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

2. Framework for root cause analysis and implementation of action plans

a. 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							

b. 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

3. 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.)

4. Type of behaviour according to Just Culture: mark with a X	No error	Human error	At–risk behaviour	Reckless behaviour

5. 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)

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	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)

10. 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	

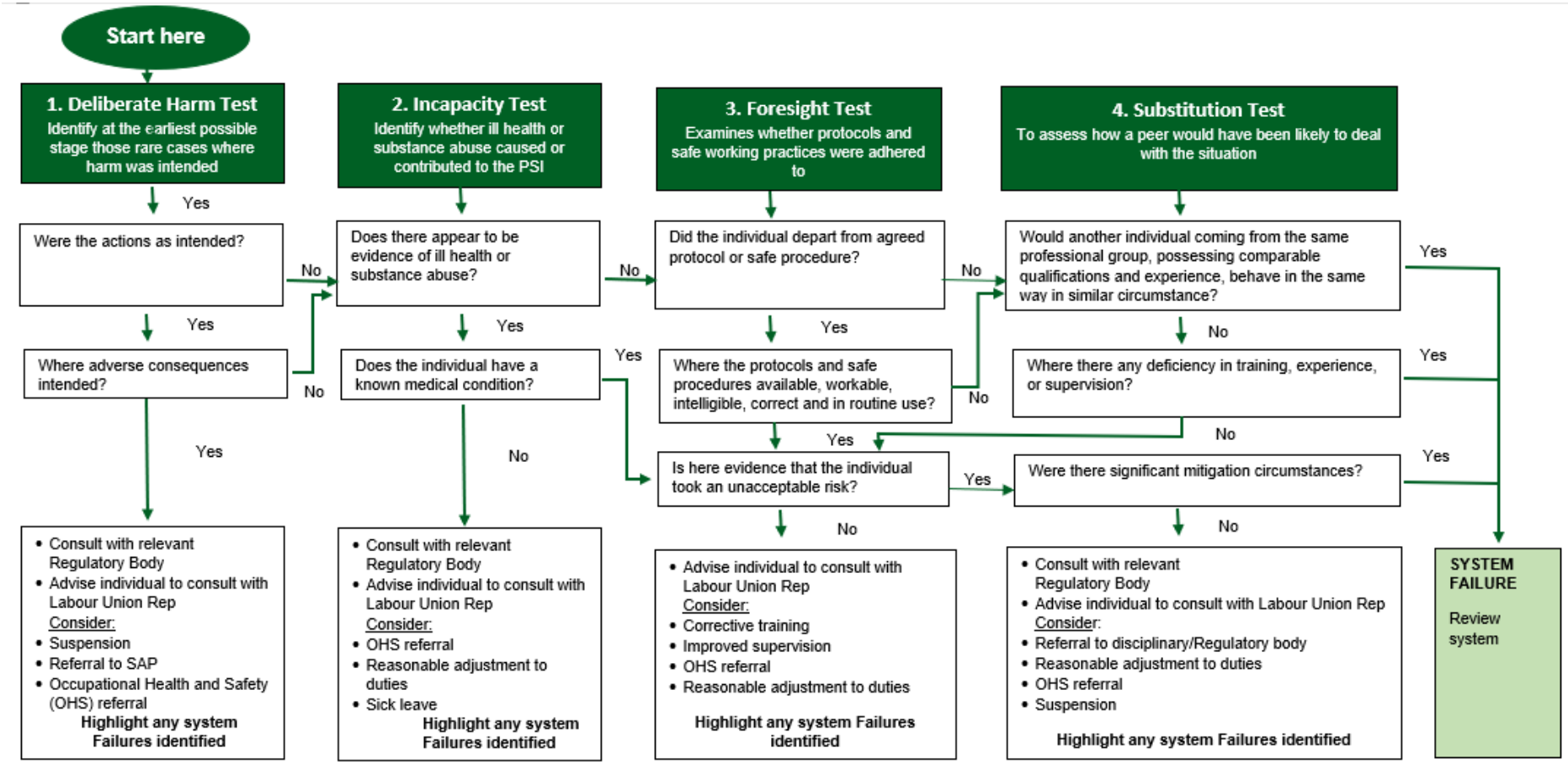
Compiled by: Designation: Signature: Date:

Appendix G: Patient Safety Incident register

HEALTH ESTABLISHMENT NAME: _____ MONTH/YEAR_____

Ref No.	Date and time of incident	Patient's name and surname	Age	Gender	Location (ward/ department/ area)	Type of PSI	SAC score	Reporting date of SAC 1 incidents	Number 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 contributing factor	Patient outcome	Organisational outcome	Date PSI closed	Type of closure	# of working days to close PSI	Type of Behaviour

Appendix H: Patient Safety Incident decision tree to assess staff based on the Just Culture



Appendix I: Statistical data on classification for contributing factor

Establishment Name/Province:	**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

Appendix J: Statistical data on classification according to type of Incident

Establishment Name/Province:	**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 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																			

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																			
12. Other																			
Any other incident that does not fit into category 1 to 11																			
GRAND TOTAL																			

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

Appendix K: Statistical data on classification according to incident outcome

PATIENT OUTCOME																			
Establishment Name/Province:	**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																			
Neonatal trauma																			
Obstetric trauma																			
No longer classified as a PSI after investigation																			
GRAND TOTAL																			

ORGANISATIONAL OUTCOME																			
Establishment Name/Province:	**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**

Appendix L: 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								

Appendix M: Mental Health Care Act Form 25

GOVERNMENT GAZETTE, 23 DECEMBER 2016 No.40515 343

FORM MHCA 25

DEPARTMENT OF HEALTH

NOTICE OF ABSCONDMENT TO SOUTH AFRICAN POLICE SERVICE (SAPS) AND REQUEST FOR ASSISTANCE TO LOCATE, APPREHEND AND RETURN USER

[Sections 40(4), 44(1) or 57(1) of the Act]

Surname of assisted user/involuntary user/state patient/mentally ill prisoner: .....

First name(s) of assisted user/involuntary user/state patient/mentally ill prisoner: .....

Date of birth..... or estimated age.....

Gender: Male ☐ Female ☐

Occupation: ..... Marital status: S ☐ M ☐ D ☐ W ☐

Date if admission to health establishment: .....

The above assisted user/involuntary user/state patient/mentally ill prisoner absconded from:

……. (name of health establishment)

Address: .....

.....

.....

.....

Date of abscondment: .....

Absconder is: (mark with across)

Assisted user ☐ Involuntary user ☐ State patient ☐ Mental ill prisoner ☐

Diagnosis on medical condition:

.....

.....

.....

Estimation of likelihood of doing harm to self or others: (mark with a cross)

Little chance ☐ Reasonable chance ☐ High likely ☐ Extremely likely ☐

Circumstances of abscondment:

.....

.....

.....

.....

Attach full report (if available)

Your assistance in locating and apprehending the above assisted user/involuntary user/state patient/mentally ill prisoner is appreciated

Print initials and Surname: .....

Signature: .....

(Head of health establishment)

Date: .....

Place: .....

[In case of an assisted or involuntary User: copy of this notice to be submitted to head of provincial department]

[In case of a state patient: copy of this notice to be submitted to Registrar or Clerk of the relevant Court official *curator ad litem* and head of national department]

[In the case of a mentally ill prisoner: copy of this notice to be submitted to head of the prison from where the User was initially transferred and to head of national department]

Appendix N: Mental Health Care Act Form 02

FORM MHCA 02

DEPARTMENT OF HEALTH

REPORT ON EXPLOITATION, PHYSICAL OR OTHER ABUSE, NEGLECT OR DEGRADING TREATMENT OF A MENTAL HEALTH CARE USER
[Section 11(2) of the Act]

(All the information contained in this Form will be held strictly confidential).

I.....
(name/s)

……..
(address)

☐ hereby declare that I have witnessed exploitation, physical or other abuse, neglect or degrading treatment of the following mental health care user:

☐ hereby declare that I have been through exploitation, physical or other abuse, neglect or degrading treatment

A. Details of User (where known)
First Name and Surname of User.....
Date of birth ..... or estimated age .....

Gender: Male ☐ Female ☐

Occupation ..... Marital status: S ☐ M ☐ D ☐ W ☐
Residential address: .....
.....
.....
.....
.....

B. Name of health establishment or other place where the alleged incident occurred
.....
Address: .....
.....
.....
.....

C. Date of incident .....

D. Brief description of the User:
E. Description of the alleged incident:

.....
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.....

Print initials and surname .....
Contact number: …….
Signature under oath: ……
(person who witnessed alleged incident)
Date: .....……

OATH/AFFIRMATION

I certify that:

i. The deponent acknowledged to me that:
   a. He/she knows and understands the contents of this declaration;
   b. He/she has no objection to taking the prescribed oath;
   c. He/she considers the prescribed oath to be binding on his/her conscience;
ii. The deponent signed this declaration in my presence at …… on this …… day of …… 20…….

_____
Signature: Commissioner of Oath: Ex-Officio
Name: …….
Rank / Designation: …….

[Original to be submitted to the relevant Mental Health Review Board]

Appendix O: Adverse Drug Reaction / Product Quality Problem Report Form

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

NDoH Pharmacovigilance Centre for Public Health Programmes (NPC)
Adverse Drug Reaction (ADR) / Product Quality Problem Report Form
This report will be shared with the
South African Health Products Authority (SAHPRA)
adr@sahpra.org.za or call 012501031

Reporting Health Care Facility/Practice

Tel: 012 395 9506 (NPC)	Facility/Practice				
Fax: 086 241 2473	District		Tel		
Email: npc@health.gov.za	Province		Fax		

Patient Details

Patient Initials		File/Reference Number		Weight (kg)		Date of Birth/Age			
Sex	□M □F □Unk	Race		Weight (kg)		Height (cm)		Pregnant?	□N □Y
Allergies				Estimated Gestational Age at time of reaction					

Suspect Medicine(s) **[Medicines suspected to have caused the ADR]**

Trade Name [Generic Name if Trade Name is unknown]	Name of Manufacturer	Route	Dose (mg) and Interval	Date Started	Date Stopped	Reason for use	Batch Number / Expiry Date

All other Medicines Patient was taking at time of reaction [Including over-the-counter and herbal products]

Trade Name [Generic Name if Trade Name is unknown]	Name of Manufacturer	Route	Dose (mg) and Interval	Date Started	Date Stopped	Reason for use	Batch Number / Expiry Date

Adverse Drug Reaction/Product Quality Problem

Date and time of onset of reaction		Date reaction resolved/duration	

Please describe Adverse Reaction/Product Quality Problem: (kindly add as much clinical information as possible)

Intervention [tick all that apply]	**Patient Outcomes** [tick all that apply]
□ No intervention	□ Patient recovered □ Patient recovering
□ Intervention unknown	□ Patient not recovering □ Outcome unknown
□ Patient counselled/non-medical treatment	□ Patient died; Date of death:_____
□ Discontinued Suspect Drug; **Replaced with**:_____	□ Impairment/Disability □ Congenital Anomaly
□ Decreased Suspect Drug Dosage; **New Dose**:_____	□ Patient hospitalised or hospitalisation prolonged
□ Treated ADR with:_____	□ Life threatening □ Other:_____
□ Referred to hospital; **Hospital Name**_____	□ ADR reappeared after restarting suspect drug/similar drug (rechallenge)?: □N □Y □ Not done □ Unknown
□ Other Intervention (e.g. dialysis): _____	

Laboratory Results

Lab Test	Test Result	Test Date	Lab Test	Test Result	Test Date

Co-morbidities/Other Medical Condition(s) **[tick all that apply]**

□ Hypertension □ Diabetes □ Asthma □ Tuberculosis □ HIV/AIDS □ Other:

Reported by

Name		E-mail	
Designation	□ Nurse □ Pharmacist □ Doctor □ Other:	Date Reported	
Telephone	Signature	**VERSION 35.0 May 2021**	

Appendix P: Blood transfusion reaction form

South African National Blood Service

2 Constantia Boulevard, Constantia Kloof Extension 22, Roodepoort 1709
Toll Free: 080011 9031

SANBS
South African National Blood Service
Registration No. 2000/026390/08

TRANSFUSION REACTION FORM

Important: Please read this pamphlet before commencing the transfusion

Responsibilities of the Doctor Transfusing a Patient with Blood or a Blood Component:

1. Discuss the benefits and the potential risks of blood transfusion and obtain informed consent from the patient. All transfusions must be medically justifiable and alternatives to a blood transfusion need to be considered.
2. Check that the certificate of compatibility on the container has been completed correctly.
3. Ensure that the patient is satisfactorily identified as the correct patient for whom the blood or blood component in each unit is intended.
4. Verify that a pre-transfusion compatibility test has been carried out and ensure that a record is kept thereof. In case of extreme emergency, blood may be transfused without a pre-transfusion compatibility test provided that such a test is performed when possible, unless the doctor considers such a test impractical or unnecessary.
5. Inspect the container and the blood therein for any abnormalities before it is transfused, in order to ensure that the hermetic seal of the container is intact and shows no evidence of having been pierced. A container of blood shall not be entered/spiked by piercing the hermetic closure for preparing a suspension of packed red cells or removing a sample for testing or for any other purpose unless:
   - the entering/spiking of the container is carried out under conditions which conform with acceptable methods of asepsis;
   - the container of blood is kept at a temperature of 2 - 6°C from the time of entering/spiking until immediately prior to transfusion;
   - the transfusion is completed with 6 hours of the container being entered.
6. Check the expiry date on the unit of blood or blood component to ensure that it has not lapsed.
7. Ensure that each infused blood unit is retained at a storage temperature of 2 - 6°C for at least 48 hours after the completion of the transfusion.
8. In the event of a suspected transfusion reaction deliver a fully completed transfusion reaction form with the empty packs and administration set to the Blood Bank for the purpose of investigating the cause of an untoward reaction or death following the transfusion. (Refer to 8 below)
9. **Report promptly to the Blood Bank any untoward reaction, or death of the patient as an apparent result of the transfusion.**
10. Storage and transportation temperature:
    - Blood must be transported at (1 - 10°C)
    - Blood must be stored at 2 - 6°C until immediately before transfusion.
    - FFP must be transported and stored at less than - 18°C (minus).
    - Blood and blood products must **NOT** be immersed in hot water or heated except by using an approved warming device, the temperature of which must not exceed 37°C.
    - Blood must be infused within 4 – 6 hours of warming.
    - Blood must not be frozen
    - Platelets to be transported and stored at 20 - 24°C and continuously agitated until transfusion.

NB! All issued products must be transfused within 72 hours, if unused/not transfused, must be returned to the blood bank.

IN THE EVENT OF TRANSFUSION REACTION

1. Stop the transfusion immediately
2. Keep the vein open with normal saline using new administration set
3. Confirm if unit was intended for same patient
4. Contact the doctor in charge
5. Monitor temperature, pulse rate, BP, respiratory rate and urine output
6. Perform a dipstix on urine sample for haemoglobinuria
7. Contact the transfusion service for advice
8. **Send to the Blood Bank as soon as possible:**
   - This form fully completed
   - The suspect donor pack (and other previous blood or plasma packs, if any), the administration set and drip filter. (Do not empty the pack or remove drip set).
   - At least 5ml EDTA venous blood taken from the patient from a different site to the infusion, with precautious to avoid haemolysis and bacterial contamination.

TRANSFUSION REACTION CATEGORIES

REACTION	SIGNS / SYMPTOMS
ANAPHYLACTIC REACTION Severe, usually due to IgA immunoglobulin, less frequently severe reactions to other plasma proteins.	Sudden onset. Symptoms include dyspnoea, hypotension/shock, facial and/or glottal oedema plus explosive GI symptoms. May lead to cardiac arrest/death.
ACUTE HAEMOLYTIC REACTION (AHTR) Caused by exposure of patient to incompatible donor red cells (usually ABO mismatched blood). Apparently similar reactions can result from incorrectly heated/stored/administered red cells products.	Usually abrupt in onset and within 15- 20 minutes after initiation of any red cell containing blood products. Fever, chills, nausea, vomiting, pain – flank back, chest, dyspnoea, hypertension, tachycardia, unexpected degree of anaemia, renal failure, DIC.
BACTERIAL CONTAMINATION Caused by any contaminated blood product most frequently associated with platelet concentrates.	Usually rapid onset, about one hour post transfusion. Chills, fever, abdominal, cramps, vomiting or diarrhoea, renal failure, renal failure, flushed dry skin, hypertension and shock.
FEBRILE NON HAEMOLYTIC TRANSFUSION REACTION Cause: Usually recipient leucocyte or platelet antibodies to transfused donor cells.	Onset usually with 1 – 2 hours after start of transfusion. Headache, myalgia, malaise, fever, chills, tachycardia and hypertension. Commonly found in multiparous or multi-transfused patients. Isolated fever > 38°C or, a rise of 1°C from the pre-transfusion value.
TRANSFUSION – RELATED ACUTE LUNG INJURY (TRAIL) Severe, usually caused by leucoagglutinins in the plasma of the donor. Generally under-recognised and under reported.	No lung injury prior to the transfusion. Dyspnoea, hypotension, fever, bilateral pulmonary oedema usually occurring within 4 hours of a transfusion.
TRANSFUSION – ASSOCIATED CIRCULATORY OVERLOAD (TACO) This is usually due to rapid or massive transfusion of blood in patients with diminished cardiac reserve or chronic anaemia	Dyspnoea, orthopnoea, cyanosis, tachycardia, increased blood pressure and pulmonary oedema usually occurring within 4 hours of a transfusion.
DELAYED TRANSFUSION REACTION Extravascular Haemolytic Reaction: Caused by exposure to incompatible red cells in the presence of an atypical IgG antibody such as anti-Kell, anti-Duffy, etc. Severity variable ranging from mild to severe.	Signs and symptoms may appear within hours in a severe reaction (often anti-Kell) & is characterized by a drop in haemoglobin and jaundice. In some cases there may be additional complications, e.g. renal failure and DIC. However most cases are mild and are only noticed 2 – 10 days after the transfusion with mild jaundice &anaemia. Often the reaction goes unnoticed if mild.
ALLERGIC REACTION Caused: Allergens to plasma proteins	Usually mild. NO FEVER. Itching, hives, urticaria, erythema. Limited to muco-cutaneous symptoms only.

ACCOUNT NUMBER	LAB NUMBER	HOSPITAL LABEL

PATIENT INFORMATION

NAME OF PATIENT:			AGE:
SURNAME:	OTHER INITIALS:	FEMALE	MALE
HOSPITAL NAME:	HOSPITAL NUMBER:		
DIAGNOSIS (BEFORE TRANSFUSION):			
INDICATION FOR TRANSFUSION:			
PRODUCTS TRANSFUSED:	UNIT/PACK NUMBERS:		
WAS THE BLOOD WARMED:	HOW?		
BRIEF MEDICAL HISTORY:			

REACTION DETAILS

DATE OF TRANSFUSION:	D	D	M	M	Y	Y	Y	Y	TIME:	VOLUME TRANSFERRED BEFORE REACTION:

ONSET OF REACTION: ☐ IMMEDIATE ☐ <1HR ☐ 1-2HRS ☐ < 6 HRS ☐ > 6 HRS ☐ >24 HR DATE:

CLINICAL SIGNS AND SYMPTOMS (Compulsory fields, please complete in full)

PRE-TRANSFUSION		POST-TRANSFUSION	
Temp: _______°C Hb:____________ BP: Pulse: Sats:		Temp: _______°C Hb:____________ BP: Pulse: Sats:	
RESTLESSNESS/ANXIETY		RESTLESSNESS/ANXIETY	
FLUSHING/SWEATING		FLUSHING/SWEATING	
FEVER		FEVER	
DIZZINESS		DIZZINESS	
PRURITIS (ITCHING)		PRURITIS (ITCHING)	
URTICARIA (RASH)		URTICARIA (RASH)	
RIGORS (INVOLUNTARY SHAKING)		RIGORS (INVOLUNTARY SHAKING)	
HYPOTENSION (SBP DROP ≤ 30MM HG)		HYPOTENSION (SBP DROP ≤ 30MM HG)	
HYPERTENSION		HYPERTENSION	
BACK PAIN		BACK PAIN	
HEADACHE		HEADACHE	
DYSPNOEA(SHORTNESS OF BREATH)		DYSPNOEA(SHORTNESS OF BREATH)	
CHEST PAIN		CHEST PAIN	
CYANOSIS		CYANOSIS	
DECREASE IN OXYGEN SATURATION		DECREASE IN OXYGEN SATURATION	
TACHYCARDIA (HR RISE > 40BMP)		TACHYCARDIA (HR RISE > 40BMP)	
SHOCK		SHOCK	
WHEEZING		WHEEZING	
COLLAPSE		COLLAPSE	
JOINT/MUSCLE PAIN		JOINT/MUSCLE PAIN	
HAEMATURIA		HAEMATURIA	
FACIAL/TONGUE SWELLING		FACIAL/TONGUE SWELLING	
JAUNDICE		JAUNDICE	
OLIGURIA		OLIGURIA	
OTHER SYMPTOMS			

TREATING DOCTOR AND / OR NURSE IN CHARGE OF PATIENT

DOCTOR'S NAME:	CONTACT NUMBER	SIGNATURE
NURSE'S NAME:	WARD NO:	DATE:
TREATMENT/MEDICATION GIVEN:		
CHEST X-RAY RESULTS:		
PATIENT OUTCOME		
IF DEMISED STAT DATE AND TIME OF DEATH:		