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

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Preamble

One of the greatest challenges today is to delivering safer and quality care in complex, pressurized and fast-moving healthcare environments. In such environments, things can often go wrong. Patient Safety Incident Reporting and Learning systems is used to identify these patient safety issues and therefore forms the cornerstone of patient safety strategies. By learning from these systems errors can be corrected to prevent reoccurrence to 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 are currently being updated and revised as WHO Guidelines for Patient Safety Incident Reporting and Learning Systems. Several initiatives are undertaken by the WHO to obtain inputs for these guidelines. One of the initiatives were to create an international platform for presenting and discussing experiences and the role of reporting and learning systems for patient safety by hosting the Inter- Regional consultation workshop on patients safety incident reporting and learning systems in Africa and Asia Pacific that was held in Colombo, Sri Lanka in March 2016. South Africa was privilege to attend this workshop. The recommendation from this workshop was that all countries should develop an effective and sustainable National level Patient Safety Incident Reporting and Learning System.

The Ministerial medico-legal Committee was established in 2014 as South Africa is currently experiencing an explosion in medical malpractice litigation which is not in keeping with the generally known trend of negligence in malpractice. The impact of medico-legal litigations threatens the vision of Government of achieving a long and healthy life for all South Africans The Committee held a medico-legal summit on 9 and 10 January 2015, one of the recommendations of this summit was that a uniform National reporting System of adverse events related to patient safety must be implemented, this is in line with the recommendations of the WHO.

I believe that this policy is essential for realising the vision of the WHO as well as the Ministerial Medico-Legal committee. Every public health establishment must have a Patient Safety Incident Reporting and Learning system as stipulated in this policy. The emphasis should not only be on reporting as it is only one part of implementing an efficient system, if learning does not take place the data collected through reporting is of no use. 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”.

Once the national Patient Safety Incident Reporting and Learning system is established, data from the system will be used to develop National action plans to improve patient safety to ensure that all South Africans receive safe health care.

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Ms P Matsoso
Director General of Health
Date:

Acknowledgements

Developing the National Policy for Patient Safety Incident Reporting and Learning required specific technical expertise that was provided by a range of organisations.

My sincere gratitude to the committee members of the Ministerial Medico-legal Committee for organizing and hosting the first Medico-legal summit in January 2015 that set the background for this policy to be developed. These members also gave valuable inputs on the draft versions of the policy.

Being well aware that mentioning by name those that have contributed always carries the risk of also unknowingly excluding important names, the Department of Health nether the less would like to extend special thanks dr. Valentina Hafner, consultant of the WHO on patient safety who volunteered to provide inputs on the first draft of the policy. She also provided valuable literature on the minimal information model for patient safety as well as highlighting new developments in the world of patient safety. Dr Neelam Dingra-Kumar, the WHO's coordinator for Patient Safety and Quality Improvement, for inviting South Africa to attend the Inter- Regional consultation workshop on patients safety incident reporting and learning systems in Africa and Asia Pacific held in Colombo, Sri Lanka, where valuable lessons were learned.

Also a vote of thanks to the National Blood Service of South Africa, the Mental Health Directorate and the Pharmocovigilence unit within the National Department of Health for providing inputs on the various sections pertaining to the services that they govern.

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POLICY FOR PATIENT SAFETY INCIDENTS REPORTING AND LEARNING

1. PURPOSE

The purpose of this policy is to provide direction to the public health sector of South Africa regarding the management of patient safety incident reporting, including the provision of appropriate feedback to patients, families/support persons and clinicians, and the sharing of lessons learned to prevent patient harm. A patient safety incident (PSI) is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. The use of the word “unnecessary” in this definition recognizes that errors, violation, patient abuse and deliberately unsafe acts occur in healthcare. These are considered incidents. In the context of this policy the term PSI will be referred to as an incident. This policy describes a national standardised system for managing PSIs to ensure that health facilities, district offices, provincial offices and the national office respond effectively to PSIs.

2. SCOPE

This Policy Directive:

- applies to all incidents that occur in public health establishments of South Africa
- is applicable to clinical staff and non-clinical staff
- describes roles and responsibilities in the incident management process
- articulates mandated reporting requirements from legal and policy perspectives, see section 5.4
- 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

Compliance with this Policy Directive is mandatory for all Health Professionals working in public Primary Health Care establishments and Hospitals in South Africa.

3. MANDATORY REQUIREMENTS

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

3.1 Just Culture

Staff that reports 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.

3.2 Confidential

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.

3.3 Timely

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

3.4 Responsive

Participating organisations commit to the immediate implementation of recommendations.

3.5 Openness about failures

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

3.6 Emphasis on learning

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

4. IMPLEMENTATION

All staff working in Primary Health Care Facilities and Hospitals are responsible to:

- report and record all patient safety incidents **in line with the procedures to as stipulated in the procedural manual for Patient Safety Incident Reporting and Learning**
- report all incidents that resulted in serious harm or death (Severity Assessment Code 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 Severity Assessment Code 1 incident reports within sixty working days
- participate in the implementation of recommendations arising from the investigation of incidents
- encourage colleagues to notify incidents that have been identified

All hospitals, district offices, provincial offices and national office must have a Patient Safety Committee.

The Committee's 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 deals with clinical governance. The Terms of Reference of such combined committees must indicate in detail the functions the Committee will be performing in regard to the management of PSI reporting.

4.1 Terms of Reference for Hospital and Sub-district/ District Patient Safety Committees

- Develop a Standard Operating Procedure (SOP) to manage PSIs that is **in line with the procedures as stipulated in the procedural manual for Patient Safety Incident Reporting and Learning.**
- 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, investigate incident.
- Monitor that all Severity Assessment Code 1 incidents reports are finalised within 60 days.
- Monitor that recommendations are implemented to prevent reoccurrence of the incident.
- Conduct monthly meetings of which the minutes must be recorded.
- Compile and analyse statistical reports to identify trends.
- Submit monthly statistical reports to the respective provincial office.
- Make recommendations to improve patient safety according to trends identified.
- Disseminate lessons learned from PSI management.
- Sub-district/ district Patient Safety Committees must identify a staff member in all Primary Health Care facilities that will be responsible for the management of PSIs. These staff members must be trained on the management of PSIs.
- 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.
- Ensure that regular training of staff on the management of PSIs takes place.
- Identify education needs emerging from PSI management.

4.2 Terms of Reference for Provincial Patient Safety Committees

- Develop a provincial protocol to manage PSIs that is **in line with the procedures as stipulated in the procedural manual for Patient Safety Incidents Reporting and Learning**
- Monitor that health facilities and sub-district/district offices adhere to provincial PSI protocol.
- Assist health facilities and sub-district/ district offices to mitigate immediate consequences of PSI.
- Monitor that Severity Assessment Code 1 incidents are reported within 24 hours.
- Review PSI reports for all Severity Assessment Code 1 incidents that are reported. In cases where further investigation is required, investigate the incident.
- Monitor that all Severity Assessment Code 1 incident reports are finalised within 60 days.
- Monitor the implementation of recommendations to prevent reoccurrence of the incident.
- Conduct at least quarterly meetings of which the minutes must be recorded. Ad hoc meeting can be scheduled as needed.
- Compile and analyse provincial statistical reports to identify trends.
- Submit quarterly statistical reports to the national office.
- 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 are fostered.
- Implement provincial system-wide initiatives to prevent similar future incidents.
- Facilitate the transformation of knowledge obtained through the statistical analysis of PSIs into protocols, guidelines and standard operating procedures.

4.3 Terms of Reference for National Patient Safety Committee

- Develop a national policy to manage PSI.
- Conduct quarterly meetings of which the minutes must be recorded.
- Monitor that provinces adhere to the policy to manage PSIs.
- Compile and analyse quarterly national PSI statistical reports.
- Implement national system-wide initiatives to prevent similar future incidents.
- Provide advice to the Minister for Health on issues of public concern and media or public attention.
- Provide an appropriate national response to new risks as they are identified.

5. Procedural manual for Patient Safety Incidents Reporting and Learning

The procedures to manage patient incident reporting and ensure learning are set out in the following procedural manual (see section 5.1 to 5.8) for patient safety incident reporting and learning.

PROCEDURAL MANUAL FOR PATIENT SAFETY INCIDENTS REPORTING AND LEARNING

5.1 Rationale for patient safety incident reporting and learning

Lapses in patient safety are a major health care quality problem. 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 health care 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 also contribute to PSI. Appropriate preventative measures will reduce the number and severity of incidents.

The aim of PSI reporting is to improve patient safety by learning from failures of the health-care system so that the likelihood of a recurrence of the same event is significantly reduced.

All health-care professionals must report PSIs as soon as they become aware of it to ensure that optimal learning take place. PSIs must be 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 health care costs.

5.2 Objectives for patient safety incidents reporting and learning

The objectives of the procedures for PSI reporting and learning are to:

- create a framework to guide the implementation of a PSI Management Reporting System
- standardise the definitions for PSIs
- standardise the degree of severity classification

- standardise the classification for PSIs by type, agent (cause) and outcome
- standardise the methodology for reporting, investigating and responses to PSIs
- ensure that statistical data on PSIs are readily available for planning and decision making
- prevent and or reduce harm to patients whilst undergoing medical care
- 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

5.3 Definition of terms as used

Patient Safety: is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.

Incident: An incident can be a near miss, no harm incident or harmful incident (adverse event).

Near miss: is an incident which did not reach the patient.

No harm incident: is one in which an event reached a patient but no discernible harm resulted.

Harmful incident (adverse event): is an incident that results in harm to a patient that is related to medical management, in contrast to disease complications or underlying disease. Medical management includes all aspects of care from interaction with health care provider to discharge of a patient from medical treatment or health care facility.

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

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.

Degree of harm: is the severity and duration of any harm, and any treatment implications, that result from an incident.
Severity Assessment Code 1: Serious harm or death that is/could be specifically caused by health care rather than the patient's underlying condition or illness

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

Severity Assessment Code 3: Minor or no harm that is/could be specifically caused by health care rather than the patient's underlying condition or illness

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: is a circumstance, agent or action with the potential to cause harm

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

Incident outcomes: all impacts upon a patient or an organisation wholly or partially attributable to an incident

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

Patient outcome: is the impact upon a patient which is wholly or partially attributable to 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.[1],[2]

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[3].

5.4 Legal and policy framework

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

5.4.1 National Health Act no 61 of 2003

Section 47, subsection 1 of the National Health Act stipulates that all health establishments must 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, the delivery of health services, business practices, safety and the manner in which users are accommodated and treated.

5.4.2 The National Health Amendment Act 12 of 2013

Section 78 of the Act states that one of the objectives of the Office of Health Standards Compliance (OHSC) is to protect and promote the health and safety of users of health services. A set of National Core Standards for Health Establishments were developed to realise this objective. The standards are structured into seven cross-cutting domains. The various standards relating to PSI are set out in domain 2 (Patient Safety, Clinical Governance and Clinical Care).

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[1] **World alliance for patient safety WHO draft guidelines for adverse event reporting and learning systems – from information to action 2005:7**

[2] **Conceptual framework for the International Classification for Patient Safety, WHO, 2009: 15-16**

[3] **WHO Working Paper. Preliminary version of Minimal Information Model for Patient Safety, Spring 2014: 4**

5.4.3 Ethical rules for health practitioners

All health care 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 health care practitioner should always regard concern for the best interests or well-being of their patients as their primary professional duty. Health Care 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. Health care practitioners must also work with and respect other health-care professionals in pursuit of the best health care possible for all patients. The ethical rules guide judgment against unethical practices of health professionals[4].

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.

5.4.4 The National Patients' Rights Charter

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

5.4.5 The Health Professions Amendment 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 No. 145 of 1992), or the Births, Marriages and Deaths Registration Act, 1992 (Act No. 51 of 1992).

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

5.4.6 The Births and Deaths Registration 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;

5.4.7 The Inquest Act (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, 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 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.

5.4.8 The Mental Health Care Act 17 of 2002

The act regulates procedures in regard to assisted and involuntary mental health care users, mentally ill prisoners and State patients that have absconded from a health establishment.

In cases where an assisted and involuntary mental health care 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 South African Police Services 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 South African Police Services of the estimated level of dangerousness of the mental health care user, State patient or mentally ill prisoner. If the mental health care user, State patient or mentally ill prisoner is apprehended in the vicinity of the health establishment, the South African Police Service must return the user immediately to the health establishment. Should the apprehension by the South African Police Service not take place in the vicinity of that health establishment, the mental health care 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 health care practitioner from a health establishment nearest to the police station provides treatment to the mental health care user.

Section 11, subsection one of the Mental Health Care Act also prescribes that every person, body, organisation or health establishment providing care, treatment and rehabilitation services to a mental health care 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 health care user must report this fact in the prescribed manner.

5.4.9 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 also encouraged to report suspected adverse drug reactions directly to the National Adverse Drug Event Monitoring Centre using the prescribed ADR reporting form.

Adverse drug reaction means a response to a medicine in humans or animals, which is noxious and unintended, including lack of efficacy, and which occurs at any dosage and can also result from overdose, misuse or abuse of a medicine.

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 and the reporter's qualification
- an identifiable patient. A patient may be identified by surname and forenames (s) or initials of surname and forenames, or by reference number, or by age or gender
- suspected product(s)
- suspected reaction(s)

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

5.4.10 National Health Act No. 61, 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 of 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 also 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 SANBS.

5.5 Situational analysis

5.5.1 Internationally

European data from the World Health Organization consistently show that medical errors and health-care related adverse events occur in 8% to 12% of hospitalisations.

Strategies to reduce the rate of adverse events in the European Union alone would lead to the prevention of more than 750 000 harm-inflicting medical errors per year, leading in turn to over 3.2 million fewer days of hospitalisation, 260 000 fewer incidents of permanent disability, and 95 000 fewer deaths per year[5].

In the United States of America between 210 000 and 440 000 patients who go to the hospital for care suffer some type of preventable harm that contributes to their death yearly. That would make medical errors the third-leading cause of death in America, behind heart disease, which is the first, and cancer, which is second[6].

In an Eastern Mediterranean and African study, almost one third of patients who suffered a harmful incident died. Another 14% sustained permanent disability, 16% sustained moderate disability, 30% were left with minimal disability and 8% of the patients' harm could not be specified. The study also concluded that 34% of the observed incidents resulted from therapeutic errors. Others came from diagnostic errors (19%), surgical mistakes (18%), obstetrics (9%), neonatal procedures (8%), non-surgical procedures (5%), drug-related incidents (4%), fractures (2%), anaesthesia (0.5%) and falls (0.5%).[7]

[5] World Health Organisation – Regional Office for Europe Office: http://www.euro.who.int/en/health-topics/Health-systems/patient-safety/data-and-statistics, 2016
[6] How many die from medical mistakes in U.S hospitals, Patient Safety exploring quality of care in the US, Sept 2013
[7] Patient safety in developing and transitional countries, New insights from Africa and the Eastern Mediterranean , WHO, 2011: 5-6

5.5.2 Public Health Service in South Africa

National data on the occurrence of PSIs in public health establishments is not currently available. Therefore rapid assessment of the contents of provincial policies/ protocols/ guidelines to manage PSIs was conducted by the National Department of Health (NDOH) in June 2014. Eight of the nine provinces responded on the request by NDOH to avail their provincial policies/guidelines. One of the eight provinces that responded did not have an official approved provincial policy to manage PSIs as the province was still in the process of developing the policy. Wide variations were found in the management of PSIs amongst provinces. Categories of incident types also varied widely. Although some provinces used a few similar categories, no province used the same set of categories. There were also differences in the processes followed to manage PSIs as well as the forms used to capture PSIs. Some similarities were found in the manner in which adverse events were escalated to District and Provincial Offices if the PSIs were of a serious nature, had legal implications or appeared in the media. Five of the provinces used the "Safety Assessment Code (SAC)" matrix to risk rate PSIs. The majority of the provinces did not include templates to collect statistical data on PSIs in their policies/protocols/guidelines to manage PSIs.

5.6 Minimum Information Model

One of the long standing aspirations of the World Health Organization (WHO) was to turn the failures of health-care 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)
    - Agent(s) involved (agent 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 (all impacts upon a patient or an organisation wholly or partially attributable to 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)[8]

The classes for the agents (contributing factor), incident type and incident outcome are defined by the WHO's framework for the International Classification for Patient

[8]**WHO Working Paper.Preliminary version of Minimal Information Model for Patient Safety, Spring 2014: 4-7**

Safety (ICPS)[9]. 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.

Table 1 set out the classification of the MIM and also provide 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
Agents involved	See annexure A
b. Incident type	See annexure B
c. Incident outcomes	See annexure 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 level 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

5.7 Designation of members of Patient Safety Committees

The National policy to manage PSIs stipulates the terms of reference of the Patient Safety Committees that must be established at hospital, sub-district/ district, provincial and national level. Sub district/district offices must identify a designated Patient Safety Champions in every Primary Health Care establishment.

[9] **Conceptual framework for the International Classification for Patient Safety, WHO, 2009: 32-47 and 90-95**

The members of these committees as set out in section 8.1 to 8.4 gives guidance to Patient Safety Committees on the designation of the members to include in their committees.

5.7.1 Designation of members for hospital Patient Safety Committees

Members of the Patient Safety Committee should be constituted by, 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/ Public relations officer
- Head of corporate services or representative of the Labour Relations division
- Representative of the Occupational health and Safety division
- On an ad-hoc basis:
    - Nursing Managers of areas where the incidents took place
    - Clinical Heads of areas where the incidents took place

5.7.2 Designation of members for sub-district/district offices Patient Safety Committees

Members should be constituted by, but not limited to, staff members with the following designations:

- District Quality Assurance manager (Chairperson)
- District manager
- Representative from district hospitals
- Member(s) of District Specialist Teams
- Representative of the Labour Relations division
- On an ad-hoc basis:
    - Facility Managers of health establishment where incidents took place
    - Managers of programmes

5.7.3 Designations of Patient Safety Committee members for provincial offices

Members should constitute, 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 Advisors division
- Representative from the Labour Relations division
- On an ad-hoc basis:
    - Chair persons of district/ sub district Patient Safety committees where the incident took place
    - Chair persons from hospital Patient Safety committees where the incident took place

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

5.7.4 Designations of Patient Safety Incident Committee members for national office

- Chief Director or Director for Hospital services
- Chief Director or Director for Primary Health Care
- 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.

5.8 Management of patient safety incidents

Once a PSI has been identified a series of action steps must be followed to ensure the effective management of PSIs[10]. These action steps are as follows:

Step 1: Identifying PSIs
Step 2: Immediate action taken
Step 3: Prioritisations
Step 4: Notification
Step 5: Investigation
Step 6: Classification
Step 7: Analysis
Step 8: Implementation of recommendations
Step 9: Learning

The action steps are explained in detail in sections 5.8.1 to 5.8.9 and set out in figure 1 as a flow diagram.

5.8.1 Step 1: Identifying patient safety incidents

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 law-suits or from complaints by patients and members of the public.

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

5.8.1.1 Patient safety incident 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. Public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent

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

cause no harm to patients[11].Therefore information on PSIs are scanty in most establishments. The reasons for under-reporting vary, hence the need for seeking alternative options of detecting PSIs. The Just Culture philosophy must be developed within health establishments to enable a conducive environment to report PSIs.

5.8.1.2 Inpatient medical record review / retrospective patient record review (Clinical Audit).

Medical records of all 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 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[12].

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[11] ***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)**

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

5.8.1.3 Focus teams

Focus teams offer an opportunity for a very rich learning environment as members within the team discuss and develop ideas. Examples of focus teams are Morbidity and Mortality review committees, clinical audit teams, Quality Assurance committees, etc. conduct focused audit on patient safety.

5.8.1.4 External sources

Patients' families and representatives, any concerned 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 committees), etc. Once the PSI is reported, the health department is obliged to initiate proper investigations into the allegation.

5.8.1.5 Review of record on follow-up of patients

Bearing in mind that PSIs may occur or be recognized after patient's discharge from health care 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 health care 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.

5.8.1.6 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 direct and guide managers towards critical focus area (within the health care system) that should to be improved.

5.8.1.7 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 the health facility. Overall rounds should last for 60 or more minutes. During rounds, operational staff members, excluding their immediate managers, are asked questions about their knowledge of any PSIs using a safety rounds 'toolbox' – see Annexure D. All comments by the staff are recorded. The management team also conducts its own observations across all the service areas. After each walk round, the team meets for debriefing. All responses are collated, categorised into categories 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 are also expected to keep hospital executives 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 presented in a narrative format or graphically.

5.8.1.8 Use data to identify and guide management of patient safety incidents

Many organizations have local, provincial and national information system e.g. 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.

5.8.1.9 Research studies and findings

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

5.8.2 Step 2: Immediate action

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

- providing immediate care to individuals involved in the incident (patient, staff or visitors) to prevent the harm from becoming worse

- making the situation/scene safe to prevent immediate recurrence of the event
- gathering basic information from staff while the details are still fresh in the minds of the involved clinicians
- notify South African Police Service (SAP), health establishment's security or other institution where applicable

5.8.3 Step 3: Prioritisation

The purpose of prioritisation is to ensure that a standardised, objective measure of severity is allocated to each incident. The Severity Assessment Code (SAC) must 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 recurrence is not helpful as it can be unreliable[13]

There are three classes in the SAC, classes 1, 2 and 3. SAC 1 includes incidents where serious harm or death occurred; SAC 2 includes incidents that caused serious harm and SAC 3 includes incidents that caused mild or no harm. See Annexure E that describes the SAC [14].

5.8.4 Step 4: Notification

According to the WHO PSI data must be recorded and analysed in order to improve patient safety. It is equally important to develop a response system and a reporting system to improve patient safety[15].

[13] New South Wales Incident Management policy, 2014: 9
[14] Government of Western Australian Health Department: Clinical Incident management toolkit, 2012 (updated Feb 2014): 6
[15] World alliance for patient safety WHO draft guidelines for adverse event reporting and learning systems – from information to action 2005: 54

5.8.4.1 Record keeping

All PSIs must 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. The contents of reported PSIs are determined by the reporters' discussion with the person receiving the report. Although unstructured reports carry more information and clarity, more time is needed to make some inferences then decide on the applicable action to be taken. The unstructured reports are therefore, labour intensive and time consuming as 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 specific information or narrative description of incidents. 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 public health sector structured reporting is prescribed by means of using various prescribed forms and templates to record data on PSIs.

All PSIs must be recorded on a PSI reporting form, see annexure F as an example. Section A (notification) of the form must be completed by the manager of the section where the incident took place. If the incident is a SAC1 incident, submit section A to the district or provincial office for notification. Section B (statements by staff patient or significant other) of the form must be completed by the staff, patients or significant others that were present while the incident took place. Section C (investigation) of the form must 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 establishments to keep statistical data on PSIs, all PSIs must be recorded in a PSI register, see annexure 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 filed in a file that is clearly marked that it contains PSI registers. In cases where an electronic information system is used the minimum dataset must include all fields as indicated in the patient safety register.

5.8.4.2 Incident notification to Management

All SAC 1 incidents must be reported within 24 hours to the Provincial or District office 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 or 3 must be reported to executive management within the facility. The provincial, district and facility protocol or standard operating procedure to manage PSIs must include a flow diagram that details the process flow to be followed when reporting PSIs.

5.8.4.3 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 a clear and simple language, and the occurring error recognised and explained. The provider should share with the patient and/or their family or carer what is known about the incident and what actions have been taken to immediately mitigate or remediate the harm to the patient. The discussion should focus on the condition as it currently exists i.e. no assumptions and uncertain future actions should be communicated at this stage. It is the obligation of the health care organization to provide support or assistance as required to patients, family and health professionals involved. Patients, family and healthcare professionals often also require psychological support.

Disclosure involves health care 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 health care provider at the service site may

disclose some of the less serious PSI, 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 health care provider or organisation
- a brief overview of the investigative process that will follow including time lines and what the patient should expect from the analysis
- an offer of future meetings as well as key contact information
- time for patients and or representative to ask questions. Provide answers that you are sure of at the time. Where uncertain, promise to and seek answers for the patient
- where necessary offer practical and emotional support
- plan for future investigation and treatment required
- remedial action taken
- the relevant health professional involved can at this stage convey their apology in a sincere manner
- systems to support the health professionals involved must also be in place

5.8.5 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[16].

[16] **The Pan American Health Organization adverse events policy and guidelines, December 2011: 7-8**

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

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

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

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

The Just Culture is founded on three behaviours, Human error, At-risk Behaviour and Reckless behaviour. Health Establishments should console those who commit human error, coach those who are guilty of at-risk behaviour and discipline those with reckless behaviour (see Table 2)[17]. In some cases where an incident is reported as a PSI the outcome of the investigation can also conclude that there no error occurred.

[17]**The ABC of the Just Culture: The path to building a dependable organization. Alejandro Alfonso Díaz, September 2011**

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

A mechanism to assess individual versus system accountability has been developed by James Reason in his "Unsafe Acts" algorithm (Reason 1997), and is a practical method of ensuring a just assessments of individual acts based on the Just Culture. This algorithm was put into practical use for managers of health establishments by streamlining the process to four simple questions:

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

If the first three answers are "No" and the last "Yes" the origin of the unsafe act lies in the organisation, not the individual[18].

The Just Culture model fosters increased safety in the delivery of healthcare by promoting transparency, fairness, communication and learning[19].

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

- The case has been investigated and the committee for review of PSIs has concluded an outcome with recommendations.
- Written confirmation has been received that the establishment is being sued and therefore the case will be further managed by a court of law.

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[18] **Fair and Just Culture, Team Behavior, and Leadership Engagement: The Tools to Achieve High Reliability. Health Services Research, August 2006**

[19] **Patient Safety handbook, Barbary J Youngberg, 2012, Chapter 13:178**

- 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 must me noted in the PSI reporting form once it has been concluded by either a court of Law or the Labour Relations section.

5.8.6 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 establishment, 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 must be classified according to the following classes:

- agents (contributing factors), see annexure A
- incident type, see annexure B
- incident outcome, see annexure C

5.8.7 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 are 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 must be collected from the PSI registers that must be completed on a monthly basis. The calculation of the indicators is set out in table 3

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

Table 3: Calculation of Indicators for patient safety incidents

Health establishments must on a monthly basis submit reports to their district/provincial office. Provincial offices must report to the National Office 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 must be recorded and submitted:

- data on classifications of agents involved, see annexure H
- data on classifications of incident type, see annexure I
- data on classifications of incident outcome, see annexure J
- indicators for PSIs, see annexure K

Statistical data for SAC 1 incidents must be kept separate from statistical data on SAC 2 and SAC 3 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 must be used to populate the data onto annexures H to K.

5.8.8 Step 8: Implementation of recommendations

Recommendations from the investigations and reviews must be implemented to ensure the development of better systems to ensure improved practices. The Root Cause Analysis indicates the time frames as well as the staff responsible for

implementation, see annexure F, section C, number 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.

5.8.9 Step 9: Learning

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

- the generation of alerts regarding significant new hazards,
- feedback and
- analyzing reports[20].

5.8.9.1 Alerts

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

5.8.9.2 Feedback

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 must receive feedback on the management of PSIs.

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 must be provided to staff involved in the incident and should occur as soon as possible,

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

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 of the recommendations arising from any investigation.

In order to close the loop and ensure learning, feedback must also 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 also include updates as the changes are made and improvements achieved as a result of these changes. This will also provide a level of accountability for implementation of the recommendations that come from the RCA.

Feedback to the patient – post analysis disclosure

Achieving a culture of patient safety requires open, honest and effective communication between the health care 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 health care 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 improvement made to prevent similar events from recurring
- continued practical and emotional support should be provided as required
- re-enforcement, correction or update of information provided in previous meetings should be provided
- the patient/representative should be promised to be informed of further additional information as it unveils
- further expression of sympathy and, where necessary, regret that may include an apology with acknowledgement of responsibility for what has happened
- actions taken as a result of internal analysis that might have resulted in system improvement.

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

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.

5.8.9.3 Analysing reports

Analysing report can reveal unrecognised trends and hazards requiring attention. Regular reports on trended aggregated data and outcomes of RCAs must 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 analyses to formulate and disseminate recommendations for systems changes.

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

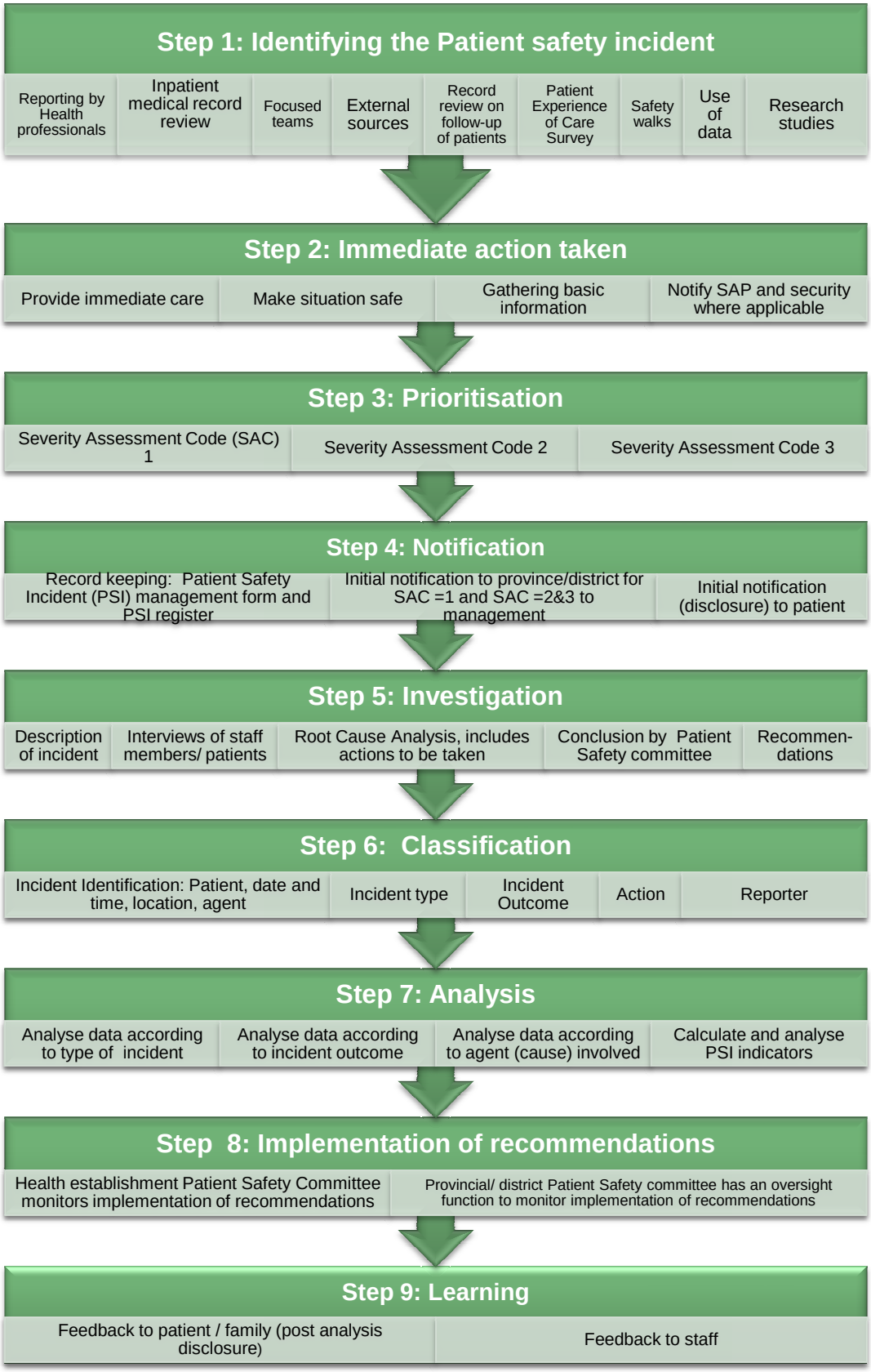

Figure 1: Action steps for the management of Patient Safety Incidents

Annexure A: Classification for agents (Contributing factors)

Main classification	Sub classification
1.Staff Factors	Cognitive Factors (e.g Perception/understanding, knowledge based/problem solving(Failure to synthesise/action on available information), halo effects(is the cognitive bias where staff seen as knowledgeable or highly respected, opinions' are followed blindly
	Performance Factors (e.g Technical error in execution(physical – skill based), , rule based (misapplication of good rules or application of bad rules, bias)
	Behaviour (e.g risky, reckless, sabotage/criminal act, attention issues(absentmindedness/ forgetfulness, out of sight, out of mind, distraction), fatigue/exhaustion, , overconfidence)
	Communication Factors (eg. language difficulties, communication methods, health literacy)
	Patho- Physiologic/ Disease Related Factors (e.g problems with substance abuse other mental illness)
	Emotional Factors
	Social Factors
2. Patient Factors	Cognitive Factors (e.g perception, understanding, knowledge based/problem solving (Failure to Synthesise/Action on available information), , halo effects(is the cognitive bias where staff seen as knowledgeable or highly respected, opinions' are followed blindly)
	Performance Factors (Technical error in execution(physical – skill based), rule based (misapplication of good rules or application of bad rules), bias)
	Behaviour (risky, reckless, sabotage/criminal act, attention issues(absentmindedness/forgetfulness, out of Sight, out of mind, distraction), fatigue/exhaustion, , overconfidence)
	Communication Factors (eg. language difficulties, communication methods, health literacy)
	Patho-Physiologic/ Disease Related Factors (problems with substance abuse other mental illness)
	Emotional Factors
	Social Factors
3. Work/Environment Factors	Physical Environment/Infrastructure
	Remote/Long Distance from Service
	Environmental Risk Assessment/ Safety Evaluation
	Current Code/Specifications/ Regulations
4. Organisational/Service Factors	Protocols/Policies/Procedures/
	Processes
	Organisational Decisions/Culture
	Organisation of Teams
5. External Factors	Natural Environment
	Products, Technology and Infrastructure
	Services, Systems and Policies
Other	Not specified in classification 1 to 5

Annexure B: Classification for Incident Type

Main classification	Sub classification
1. Clinical Administration	Medical procedure performed without valid consent
2. Clinical process/ procedure	Not performed when indicated
	Performed on wrong patient
	Wrong process/ procedure/ treatment performed
	Performed on wrong body part/ site/ side
	Retention of foreign object during surgery
	Pressure sores acquired during admission
	Maternal death
	Neonatal death
	Fresh still birth
3. Health Care associated infections	Bloodstream
	Surgical Site
	Pneumonia
	Urinary drain/tube
	Communicable diseases
4. Medication/ IV fluids	Wrong dispensing
	Omitted medicine or dose
	Medicine not available
	Adverse Drug Reaction
	Wrong medicine
	Wrong dose/ strength administered
	Wrong patient
	Wrong frequency
	Wrong route
	Prescription Error
5. Blood or blood products	Acute transfusion reactions
	Delayed transfusion reactions/ events (including Transfusion Transmitted Infections)
	Errors- wrong blood/ blood products
6. Medical device/ equipment/	Lack of availability
	Failure/ malfunction
7. Behaviour	Suicide/Intended Self Harm
	Attempted suicide
	Sexual assault by staff member
	Sexual assault by fellow patient or visitor
	Physical Assault by staff member
	Physical assault by fellow patient or visitor
	Exploitation, abuse, neglect or degrading treatment by fellow patient or visitor
	Exploitation, abuse, neglect or degrading treatment by staff member
	Wandering/Absconding/Missing
8. Patient accidents	Falls
9. Infrastructure/ Buildings/ Fixtures	Damaged/Faulty/Worn
	Non-Existent/Inadequate
10. Resources/ Organisational Management	Bed/Service Availability/Adequacy
	Human Resource/Staff Availability/Adequacy
	Protocols/Policy/Procedure/Guideline/ Availability/Adequacy
11. Other	Any other incident not listed in classification 1 to 10

Annexure C: Classification for incident outcome

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

Annexure D: Safety Walk around toolkit.

AREA	FOCUS
Care Delivery	• Any special training need • 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 / life saving equipment • Functionality of resuscitation / life saving equipment • Proper storage of resuscitation / life saving equipment • Control list of resuscitation / life saving 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 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

Annexure E: Prioritisation - Severity Assessment Code (SAC)[21]

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

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

	treatment. Complete MHCA 02 (annexure M) • In cases of an ADR notify the National Adverse Drug Event Monitoring Centre of the Medicines Control Council (see annexure N, form ARF1). If the ADR was caused by Anti-retroviral drugs or medicines for the treatment of tuberculosis, it must also be reported to the National Pharmacovigilance Centre for Public Health Programs (see annexure O, form 31a). • In cases of blood transfusion reactions notify the blood transfusion service where the blood was ordered from and submit the required documentation and samples, see annexure P	the required documentation and samples, see annexure P
Reporting requirement	• Complete investigation and actions taken within 60 working days Submit report to provincial/district office	• Complete investigation and actions taken within 60 working days Submit report to management

Annexure F: Patient Safety Incident Reporting form

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

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

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

SECTION A - Notification

Ref no:	

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

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

4. Date of PSI		**5. Time of PSI**	

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

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

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

11. Immediate resulting action taken to minimise harm
12. Short description of Initial disclosure
Compiled by: Designation: Signature: Date:

SECTION B- Statement by staff, patient or significant other

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

SECTION C - Investigation

1. Category according to type – mark appropriate one with an X

1.Clinical Admini-stration	2. Clinical process/ procedure	3. Health Care associated infections	4. Medication / IV fluids	5. Blood and blood products	8. Patient Accidents
Medical procedure performed without valid consent	Not performed when indicated	Bloodstream	Wrong dispensing	Acute transfusion reactions	Falls
	Performed on wrong patient	Surgical site	Omitted medicine or dose	Delayed transfusion reactions/ events (including Transfusion Transmitted Infections)	**9.Infrastructure/ Buildings/ Fixtures**
	Wrong process/ procedure/ treatment performed	Pneumonia	Medicine not available	Errors- wrong blood/ blood products	Damaged/ faulty/ warn
		Urinary drain/tube	Adverse Drug Reaction	**7. Behaviour**	Non-Existent/ inadequate
	Retention of foreign object	Communicable diseases	Wrong medicine	Suicide/Intended self harm	**10.Resources/ Organisational**
	Pressure sores acquired during admission	**6. Medical device**	Wrong patient	Attempted suicide	Bed/Service availability/ adequacy
			Wrong frequency	Sexual assault by staff member	Human Resources/ Staff Availability/ Adequacy
	Performed on wrong body part/ site/side	Lack of availability	Wrong route	Sexual assault by fellow patient or visitor	
		Failure / malfunction	Prescription error	Physical assault by staff member	
	Maternal death	**11. Other**	Wrong dose/ strength administered	Physical assault by fellow patient or visitor	Protocols/Policy/procedure/guideline available/ adequate
	Neonatal death	Any other incident that does not fit into categories 1 to 10		Exploitation, abuse, neglect or degrading treatment by fellow patient or visitor	
	Fresh still born			Exploitation, abuse, neglect or degrading treatment by staff member	
				Wandering/ Abscond	

2. Framework for Root Cause Analysis and implementation of action plans

a. Contributing factors – Mark with an X

1. Staff	Cognitive	Performance	Behaviour	Communication	Patho-Physiological/ Disease			
2. Patient	Cognitive	Performance	Behaviour	Communication	Patho-Physiological/ Disease	Emotional	Social	
3. Work / Environment	Physical Environmental / Infrastructure		Remote/ long distance from service		Environmental risk assessment/safety Evaluation	Current Code/ Specifications/ Regulations		
4. Organisational/Service	Protocols/Policies/ procedures		Processes		Organisational decisions/Culture	Organisation of teams		
5. External	Natural Environment				Products, Technology and Infrastructure			
6. Other								

b. Root Cause Analysis

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

3. Findings and recommendations by Patient Safety Committee

4. Conclusion					
Type of behaviour according to Just Culture: mark with a X	**No error**	**Human Error**	**At – Risk Behaviour**	**Reckless Behaviour**	
Patient outcome: mark with a X	**None**	**Mild**	**Moderate**	**Severe**	**Death**

5. Summary of Final disclosure to patient/family

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

Compiled by: Designation: Signature: Date:

Annexure G: Patient Safety Incident (PSI) register

HEALTH ESTABLISHMENT NAME: _____ MONTH/YEAR_____

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

Annexure H: Statistical data on classification for agents (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																			
Cognitive factors																			
Performance																			
Behaviour																			
Communication factors																			
Patho- Physiologic/ Disease related Factors																			
Emotional factors																			
Social factors																			
2. Patient factors																			
Cognitive factors																			
Performance																			
Behaviour																			
Communication factors																			
Patho- Physiologic/ Disease related factors																			
Emotional factors																			
Social factors																			
3. Work/ Environment factors																			
Physical environment/ infrastructure																			
Remote/long distance from service																			
Environmental risk assessment/ safety evaluation																			
Current code/ specifications/ regulations																			
4.Organisational/ Service factors																			
Protocols/Policies/ Procedures/																			
Processes																			
Organisational decisions/ culture																			
Organisation of teams																			
5. External Factors																			
Natural environment																			
Products, technology and infrastructure																			
Services, systems and policies																			
6. Other																			
Other																			
GRAND TOTAL																			

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

Annexure I: 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 consent																			
2. Clinical process/ procedure																			
Not performed when indicated																			
Performed on wrong patient																			
Wrong process/procedure/treatment performed																			
Performed on wrong body part/ site/ side																			
Retention of foreign object during surgery																			
Pressure sores acquired during admission																			
Maternal death																			
Neonatal death																			
Fresh still born																			
3. Health care associated infections																			
Bloodstream																			
Surgical site																			
Pneumonia																			
Urinary drain/ tube																			
Communicable diseases																			
4. Medication/ IV Fluids																			
Wrong dispensing																			
Omitted medicine or dose																			
Medicine not available																			
Adverse Drug Reaction																			
Wrong medicine																			
Wrong dose/ strength administered																			
Wrong patient																			
Wrong frequency																			
Wrong route																			
Prescription Error																			
5. Blood or blood products																			
Acute transfusion reactions																			
Delayed transfusion reactions/ events																			

(including Transfusion Transmitted Infections)																			
Errors- wrong blood/ blood products																			
6. Medical devises/ equipment/ property																			
Lack of availability																			
Failure / malfunction																			
7. Behaviour																			
Intended Self Harm/Suicide																			
Attempted suicide																			
Sexual assault by staff																			
Sexual assault by fellow patient or visitor																			
Physical Assault by staff																			
Physical assault by fellow patient or visitor																			
Exploitation, abuse, neglect or degrading treatment by fellow patient or visitor																			
Exploitation, abuse, neglect or degrading treatment by staff member																			
Wandering/Absconding																			
8. Patient accidents																			
Falls																			
9. Infrastructure/ Buildings/ fixtures																			
Damaged/ Faulty/ Worn																			
Non-Existent/ Inadequate																			
9. Resources/ Organisational																			
Bed/Service Availability/Adequacy																			
Human Resource/Staff Availability/Adequacy																			
Protocols/Policy/Procedure/Guideline Availability/Adequacy																			
11. Other																			
Any other incident that does not fit into category 1 to 10																			
GRAND TOTAL																			

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

Annexure J: Statistical data on classification according to incident outcome

PATIENT OUTCOME																			
Establishment Name/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	%*
None																			
Mild																			
Moderate																			
Severe																			
Death																			
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																			
Increase in required resource allocation for patient																			
Media attention																			
Formal complaint																			
Damaged reputation																			
Legal ramifications																			
Other																			
GRAND TOTAL																			

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

Annexure K: Statistical data on Indicators for Patient Safety Incidents

Name of Establishment/Province: _____

Financial Year: _____

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

Annexure L: Mental Health Care Act form 25

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 user.....

First name(s) of user.....

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

Gender: Male ☐ Female ☐

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

Date if admission to health establishment :.....(name of establishment)

Address: .....

.....

.....

.....

Date of abscondment: .....

User 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 user 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]

Annexure M: 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]

Annexure N: Adverse Drug reaction and Product Quality Problem report form

ARF1

ADVERSE DRUG REACTION AND PRODUCT QUALITY PROBLEM REPORT FORM

(Identities of reporter and patient will remain strictly confidential)

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL ADVERSE DRUG EVENT MONITORING CENTRE
NADEMC

The Registrar of Medicines
Private Bag X 828
Pretoria , 0001

Fax: (021) 448-6181
Tel : (021) 447-1618

In collaboration with the WHO International Drug Monitoring Programme

PATIENT INFORMATION

Name (or initials): ..... **Patient Reference Number:** ……..

Sex: | M | F | **Age:** ..... **DOB:** ..... / ...../ ..... **Weight (kg)** ..... **Height (cm)** .....

ADVERSE REACTION / PRODUCT QUALITY PROBLEM (tick appropriate box)

Adverse reaction ☐ **and/or Product Quality problem** ☐

Date of onset of reaction: ...../...../.....
Time of onset of reaction: ……hour……min

Description of reaction or problem (Include relevant tests/lab data, including dates):

1. MEDICINES / VACCINES / DEVICES (include all concomitant medicines)

Trade Name & Batch No. (Asterisk Suspected Product)	Daily Dosage	Route	Date Started	Date Stopped	Reasons for use

ADVERSE REACTION OUTCOME (Check all that apply)

☐ death
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage

☐ life-threatening
☐ hospitalisation
☐ Other.....
.....
.....
.....
……

Reaction abated after stopping medicine:
Y **N** **N/A**

Event reappeared on rechallenge:
Y **N** **Rechallenge not done**

Recovered: **Y** **N**
Sequelae: **Y** **N**
Describe Sequelae:.....
.....
.....
.....
.....

COMMENTS: (e.g. Relevant history, Allergies, Previous exposure, Baseline test results/lab data)

2. PRODUCT QUALITY PROBLEM:

Trade Name	Batch No	Registration No	Dosage form & strength	Expiry Date	Size/Type of container

Product available for evaluation?: **Y** **N**

REPORTING HEALTHCARE PROFESSIONAL:

NAME: ..... QUALIFICATIONS:.....

ADDRESS: .....

Postal Code: …… TEL: (.....)..... ……. ……..
Signature Date

This report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:

- medications (drugs, vaccines and biologicals)
- medical devices (including in-vitro diagnostics)
- complementary / alternative medicines (including traditional, herbal remedies, etc)

Please report especially:

- adverse drug reactions to newly marketed products
- serious reactions and interactions with all products
- adverse drug reactions which are not clearly reflected in the package insert.

Report Product Quality Problems such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labelling
- therapeutic failures

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Important numbers:

Investigational Products and Product Quality Problems:

- fax: (012) 395-9201
- phone: (012) 395-9341

Adverse Events Following Immunisation:

- fax: (012) 395 8905
- phone: (012) 395 8914/5

Confidentiality: Identities of the reporter and patient will remain strictly confidential.

Your support of the Medicine Control Council's adverse drug reaction monitoring programme is much appreciated. Information supplied by you will contribute to the improvement of medicine safety and therapy in South Africa.

PLEASE USE ADDRESS PROVIDED BELOW - JUST FOLD IN THIRDS, TAPE and MAIL

Postage will be paid by the Addressee
Posgeld sal deur die geadresseerde betaal word

No Postage stamp necessary if posted in the Republic of South Africa
Geen posseël nodig nie indien in die Republiek van Suid-Afrika gepos

BUSINESS REPLY SERVICE
BESIGHEIDSANTWOORDDIENS

Free Mail Number: **BNT 178**
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DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

REGISTRAR OF MEDICINES
REGISTRATEUR VAN MEDISYNE

PRIVATE BAG / *PRIVAATSAK* X828
PRETORIA
0001

Annexure O:
Suspected ADR report HIV/AIDS and TB treatment programme

SUSPECTED ADVERSE DRUG REACTION REPORT
HIV/AIDS AND TB TREATMENT PROGRAMME

(For assistance in completing the form please see back of page.)

health
Department: Health
REPUBLIC OF SOUTH AFRICA

NATIONAL PHARMACOVIGILANCE CENTRE (NPC)
TEL: 012 395 9506/ 8099
Fax2email: 086 241 2473 Email: npc@health.gov.za

PATIENT DETAILS:

Patient Initials		**Reference No**		**Age/ Age range**		**Gender**	☐M ☐F	**Pregnant**	☐Yes ☐No
Allergy		**Weight (kg)**		**Height (cm)**		**Estimated Gestational Age**			
Race	☐Black	☐ Coloured	☐Asian	☐White					
Facility		**Sub district**				**DISTRICT**			

Adverse Drug Reaction

Date of onset of reaction (dd/mm/yyyy)

Description of reaction or problem (tick all that apply) – Attach additional information if required

☐Abdominal pain	☐Dizziness	☐Hyper pigmentation	☐ Persistent muscle pain	☐Vision changes
☐Abnormal behavior	☐Enlarged breast/s	☐Impaired concentration	☐Problems with breathing	☐Vomiting
☐Anxiety	☐Fat gain	☐Impotence	☐Psychosis/hallucinations	☐Weight loss
☐Back pain	☐Fat loss	☐Insomnia/sleep issues	☐Rash	☐Other
☐Chills	☐Fat redistribution	☐Lactic acidosis	☐ Ringing in the ears	
☐Confusion	☐Fever	☐Loss of appetite	☐Unusual bleeding	
☐Constipation	☐Headache	☐Nausea	☐Unusual bruising	
☐Depression	☐ Hearing loss	☐Pain/tingling/numbness in extremities	☐ Unusual fatigue	
☐Diarrhoea	☐Heartburn	☐Pancreatitis	☐Violent behavior	

ADVERSE REACTION OUTCOME/INTERVENTION (TICK ALL THAT APPLY):

☐ Patient Counseled
☐ Referred to expert
☐ Additional visit request
☐ Hospitalization
☐ Additional lab request _____

☐ ADR subsided after removing suspected drug
☐ ADR reappeared after restarting drug
☐ Discontinued suspected drug
Replaced by _____
☐ Decreased dose
☐ Treated ADR with _____
☐ Other

LABORATORY RESULTS: (PREV; CUR=CURRENT)

	Date	*K+*	*Creat*	*eGFR*	*ALT*	*AST*	*Hb*	*Platelets*	*CD4*	*Viral Load*	*Lact*	*Other:*
Prev												
Prev												
CUR												

MEDICINES (AND CONCOMITANT MEDICINES, INCLUDING HERBAL PRODUCTS)

Medicine	**Suspect drug/ Trade Name**	**Dose**	**Interval**	**Route**	**Date started**	**Date stopped**	**Prescriber (Dr/Pharm/Nurse)**

CONCOMITANT MEDICAL CONDITION(S) (TICK ALL THAT APPLY):

☐ HTN ☐ DM ☐ KS ☐Hep B ☐ PCP ☐ Esophageal Candidiasis ☐Oropharyngeal Candidiasis
☐Cryp Meningitis ☐ Renal dysfunction ☐ Hepatic dysfunction ☐TB ☐ Other/s

REPORTED BY:

Name				Highest Qualification	
Designation	☐ Doctor ☐ Nurse ☐ Pharmacist ☐ Other			Email	
Tel		Signature		Date	

THIS REPORT IS NOT AN ADMISSION THAT THE REPORTER OR THE SUSPECTED DRUG(S) CAUSED THE ADR.

Version 31a

THE IDENTITY OF THE PATIENT, REPORTER AND THE FACILITY WILL REMAIN CONFIDENTIAL.

Instructions on filling the ADR Report

A) Patient Details – All fields to be completed

B) Medicines (and Concomitant medicines, including herbal products) – All fields to be completed as per the example below:

MEDICINES (AND CONCOMITANT MEDICINES, INCLUDING HERBAL PRODUCTS, IF KNOWN)							
Medicine	**Suspect drug/ Trade Name**	**Dose**	**Interval**	**Route**	**Date started**	**Date stopped**	**Prescriber (Dr/Pharm/Nurse)**
AZT	Retrovir	300mg	BID	PO	16-Oct-2014	NA	Doctor
Paracetamol	Panado	1g	TDS	PO	16-Oct-2014	19-Oct-2014	Nurse
St John's Wort		2 drops	TDS	PO	16-Sep-2014		Pharmacist

In the first column, please insert the accepted abbreviation of the name of the medicine or the name of the medicine the patient is taking (1 or AZT or zidovudine in the example), in the second column, insert the name of the drug suspected of causing the ADR, preferably its trade name(In this case the Trade name is Retrovir). You should then enter the dose, route of administration, the date started and stopped (where applicable) and the professional category of the prescriber namely, Doctor, pharmacist or nurse.

C) Adverse Drug Reaction – Please report any suspected ADR. Report even if you do not have all the details. Please tick ADRs presented in the form as appropriate. If they do not appear on the list, please complete in the section labelled other. Please provide as much detail as possible.

D) Laboratory Results – Please select the laboratory results and write the value. (BL = Basline; Cur = Current). If they are not among the ones listed, there is a section provided for other lab results. Please complete in as much detail as possible.

E) Adverse Drug Reaction Outcome – Please complete the Intervention, action taken and patient outcome in all fields. A section is provided in cases where interventions, actions and outcomes other than those provided occur.

F) Relevant Clinical History – Please complete all fields in this section

G) Concomitant Medical Conditions – Please complete all fields in this section. If they are not among the ones listed, there is a section provided for other lab results. Please complete in as much detail as possible.

H) Reported by – Please complete all fields. Your contact details may be required in case of follow up to clarify information

Abbreviations

AZT = Zidovudine **3TC** = lamivudine **ABC** = Abacavir **APV** = amprenavir **ATV** = atazanavir **d4T** = stavudine **ddC** = zalcitabine **ddI** = didanosine **DLV** = delavirdine	**DRV** = darunavir **ETR** = etravirine **FPV** = fosamprenavir **FTC** = Emtricitabine **IDV** = indinavir **MVC** = maraviroc **NFV** = nelfinavir **NVP** = Nevirapine	**RAL** = raltegravir **SQV** = saquinavir **TDF** = Tenofovir **TPV** = tipranavir **R** = Rifampicin **H** = Isoniazid **E** = Ethambutol **Z** = Pyrazinamide	**Km** = Kanamycin **Lzd** = Linezolid **TRD** = Terizidone **Pto** = Protionamide **Cs** = cycloserine **Cfx** = Ciprofloxacin **AZI** = Azithromycin **Clr** = Clarithromycin	**Cm** = Capreomycin **Mfx** = Moxofloxacin **LFX** = Levofloxacin **Gfx** = Gatifloxacin **Eto** = Ethionamide **EFV** = efavirenz **ENF** = enfuvirtide	**RTV**=ritonavir/r=ritonavir,low dose **LPV/r** = lopinavir/ritonavir **PAS**=*para*-aminosalicylic acid **PAS**=Para-Aminosalicylic Acid **Amx/Clv** =Amoxicillin/Clavulanic Acid **PA824**=Experimental Nitroimidazole drug

Annexure 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℃ from the time of entering/spiking until im mediately 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℃ 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℃)
    - Blood must be stored at 2 - 6℃ until immediately before transfusion.
    - FFP must be transported and stored at less than - 18℃ (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℃.
    - 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℃ or, a rise of 1℃ from the pre-transfu sion 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, eg. 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, urticari, erythema. Limited to muco-cutaneous symptoms only.

ACCOUNT NUMBER	LAB NUMBER	HOSPITAL LABEL

PATIENT INFORMATION

Name of patient: _____ Age: _____

Surname: _____ Gender: M ☐ F ☐

Hospital name: Hospital number:

Diagnosis (before transfusion)

Indication for transfusion:

Products transfused: Unit/Pack numbers:

Was the blood warmed: How?

CATEGORY: ☐ Haematology ☐ Oncology ☐ Medical ☐ Obstetrics/Gyn/Perinatal ☐ Anaesthetics

☐ Trauma ☐ Surgical ☐ Paediatric ☐ Orthopaedics

Brief medical history: _____

REACTION DETAILS

Date of transfusion: ____/____/____ Time: _____ Volume transfused: _____

Onset of reaction: ☐ Immediate ☐ < 1hr ☐ 1-2hrs ☐ < 6 hrs ☐ > 6 hrs ☐ >24 hrs Date: / /

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

Symptoms (tick all that apply)					
	Pre-transfusion	Temp: ℃	BP:	Pulse:	Hb:
	Post-transfusion	Temp: ℃	BP:	Pulse:	Hb:

☐ Urticaria (rash)	☐ Joint/muscle pain	☐ Dyspnoea(shortness of breath)	☐ Pruritis (Itching)
☐ Back pain	☐ Wheezing	☐ Facial/tongue swelling	☐ Chest pain
☐ Hypertension	☐ Fever	☐ Dizziness	☐ Hypotension (SBP drop ≤ 30mm Hg)
☐ Headache	☐ Jaundice	☐ Tachycardia (Hr rise > 40bmp)	☐ Rigors (involuntary shaking)
☐ Oliguria	☐ Flushing/sweating	☐ Collapse	☐ Cyanosis
☐ Shock	☐ Restlessness/anxiety	☐ Nausea/vomiting	☐ Decrease in oxygen saturation
☐ Haematuria	Other relevant clinical information:		

Treating doctor information

Name: _____ Contact no: _____ Date: _____

Ward no: _____ Signature: _____

INCIDENT (For SANBS staff only)

☐ Patient misidentification ☐ Product related ☐ Near miss event ☐ Other (Specify) _____

Transfusion Reaction	☐ FNHTR ☐ Minor allergic ☐ Severe allergic ☐ Anaphylactic shock	
	☐ Acute haemolytic reaction ☐ Delayed haemolytic reaction	
Incompatible transfusion	Cause:	
Delayed Serological Transfusion Reaction: Specify new all antibody(ies) within 28 days of transfusion		
Specify:		
☐ TACO ☐ TAD ☐ Hypertensive ☐ PTP ☐ TA-GVHD		
Bacterial Contamination	☐ Positive culture product	Organism (specify): _____
	☐ Positive culture recipient	Organism (specify): _____
TRALI	☐ Possible TRALI risk factors: _____	
	☐ Unknown ☐ Other (specify): _____	

RELATIONSHIP AND GRADING (HAEMOVIGILANCE – OFFICE ONLY)

Relationship of reaction to transfusion	☐ Definite	☐ Probable	☐ Possible	☐ Doubtful	☐ Ruled out	☐ Not determined
Severity (Grade)	☐ 1.(non-severe)	☐ 2. (severe)	☐ 3.(Life-threatening)	☐ 4. Death	☐ Not determined	

Conclusion (Based on IHN definitions) _____