ADVERSE EVENTS MONITORING AND REPORTING GUIDELINES

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i. Table of Contents

ii. List of Tables

iii. List of Figures

iv. Acknowledgements

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1. Background

The mission of the National Department of Health is to improve health status through prevention of ill-health and promotion of healthy lifestyles and to consistently improve the health care delivery system by focusing on access, equity, efficiency, quality and sustainability. In order to achieve the overall mission, one of the strategic objectives is to contribute towards human dignity by improving quality of care. Quality of care is multifaceted of which the reduction in medical errors and other adverse events is an important aspect

The adverse event monitoring system is consistent with the vision of the Kwa Zulu-Natal Department of Health to achieve optimal health status for all persons in the province and at a specific level with the vision and mission of the Quality Control, Monitoring and Evaluation Unit which is to promote an optimal level of compassionate quality health care for all persons in the Province of Kwa Zulu-Natal, by empowering all health facilities in Kwa Zulu-Natal to achieve and maintain service excellence.

The adverse event reporting and monitoring system is continuous and permits access to information on a real time basis. Furthermore, the Health Charter enshrines the right of every person to complain about health care services and to have such complaints investigated and to receive a full response on such investigation. It is therefore important for institutional and provincial mangers to have management tools that will enable them to deal with any complaints that may arise. The adverse event reporting and monitoring system is a passive surveillance system that does not solely depend on complaints from patients and permits institutional and departmental managers to have relevant information for proactive decision making. So in fact managers are able to anticipate problems and take action to prevent them from occurring before they become problematic. The system is intended to be supportive in a stressful environment where life and death decisions have to be taken on a minute by minute basis. Under such exacting circumstances where it is always possible for errors to occur, an The adverse event reporting and monitoring system offers the opportunity to reduce the incidence of these errors and achieve the vision of the KwaZulu-Natal Department of Health.

Definition of Terms

Clinical incident: A clinical incident is defined as "any event that has caused harm, or has the potential to harm, a patient, visitor or staff member, or any event which involves malfunction, damage or loss of equipment or property, and any event which might lead to a complaint

Medical Error: The failure of a plan of action to be completed as intended or the use of a wrong plan to achieve an aim." Errors can include problems in practice, products, procedures and systems.

Patient Safety: Patient safety applies to initiatives designed to prevent adverse outcomes from medical errors. Enhancements of patient safety include activities in preventing errors known and visible, and mitigate the effect of errors.

Adverse Event: Unintended incidents in care that may result in adverse outcomes and may require additional care efforts.

Near Miss: Events in which unwanted consequences were prevented.

Sentinel Event: Event in which death or serious harm to a patient has occurred.

2. Introduction

An adverse event is a happening, incident, or set of circumstances which exhibits three key characteristics to some degree:

- *Negativity*: it must be an event which is, by its very nature, undesirable, untoward, or detrimental to the healthcare process or to the patient. This is a theme which is common to all definitions
- *Patient involvement/impact:* it must in some way involve or have some negative impact or potential impact on a patient or patients. The wider definitions of adverse events include occurrences in which there is no actual effect on any patient, though there is the potential for harm. More restrictive definitions often only include events where the patient has suffered some definable and identifiable ill effect from the event
- *Causation*: there must be some indication that the event is a result of some part of the healthcare process (either through commission or omission), rather than a result of events outside the healthcare process, such as the patient's own actions or the natural progression of the disease. Again, definitions vary, with some accepting events as adverse events with little or no evidence of causation, while others insist on strong and direct evidence of causation.[1]

Some adverse events are not preventable and they reflect the risk associated with treatment, such as a life-threatening allergic reaction to a drug when the patient had no known allergies to it. However, the patient who receives an antibiotic to which he or she is known to be allergic, goes into anaphylactic shock, and dies, represents a preventable adverse event.

Among the problems that commonly occur during the course of providing health care are adverse drug events and improper transfusions, surgical injuries and wrong-site surgery, suicides, restraint-related injuries or death, falls, burns, pressure ulcers, and mistaken patient identities. High error rates with serious consequences are most likely to occur in intensive care units, operating rooms, and emergency departments.

This guideline prepared by the Health Outcomes Research Unit and the Evaluation Unit of the KwaZulu Natal Department of Health is directed at creating a standardized methodology of determining the nature, incidence and causes and reporting of Adverse Health Events at Hospitals in KwaZulu Natal and the design of standard operating procedures for preventative actions.

3. Methodological Approach

The approach to be adopted to create a framework for identifying, monitoring and correcting risks associated with the adverse health outcomes is schematically represented in figure 1 below;[2]

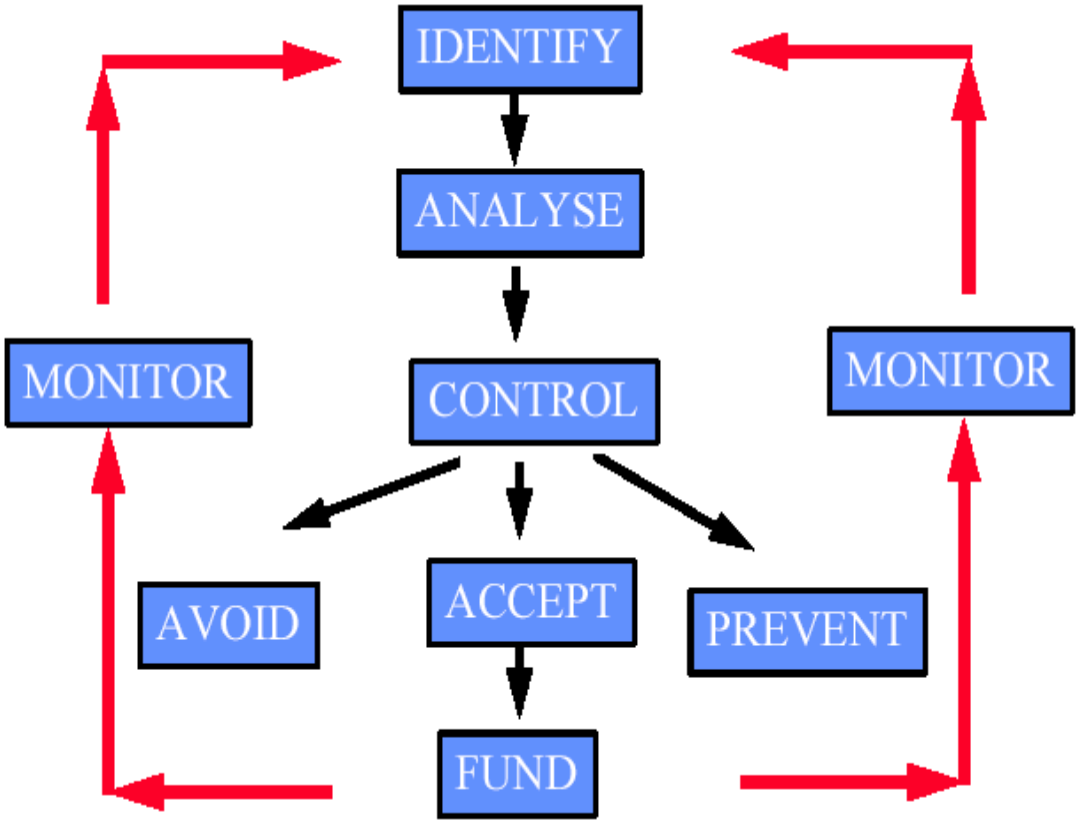

Figure 1: Risk Management Cycle

The process begins with identifying the adverse event so that it can be analyzed in terms of its nature and cause. The adverse event after identification can be stratified according to its consequences so that control measures can be instituted. Once accepted, steps can be taken to either avoid or prevent its occurrence in the future. The methodological approach to be adopted will be based on the above conceptual framework and will include the following steps:

1) Development of a risk management culture through the creation of a Hospital Clinical Risk Management Team or Clinical Governance team
2) Standardized approach to identification and stratification of adverse events.
3) Analysis of the root causes of the identified adverse events
4) Classification of adverse health events
5) Development of action plans to prevent or avoid the recurrence of adverse events.
6) Standardized reporting mechanisms for adverse health events.

3.1. Creation of Clinical Risk Management Team

The Chief Executive Officer is personally responsible for corporate governance within the organization, which includes risk management activities. All of the senior management team has a role in setting the strategic direction of the hospital and overseeing the implementation of policies and objectives including those relating to risk management. However, certain members of the senior management team have a particular role in assisting the Chief Executive with risk management and these are:

The **Nursing Service Manager** is responsible for risk management, including quality assurance, complaints, nursing professional conduct and clinical effectiveness.

The **Medical Manager** is responsible for clinical governance including clinical risk management and medical professional conduct

The **Systems Manager** is responsible for Health & Safety, security, fire safety, management of the estate, catering and environmental health and emergency planning.

In order to support the above managers in their roles, the following staff has designated risk management responsibilities:

- Infection Control Manager
- Health & Safety Manager
- Quality Assurance Manager
- Complaints Manager/ Client Relationship Officer

In addition, each clinical department is required to appoint a clinical risk manager (doctor) as well as nursing risk manager on to the clinical risk management team.

3.2. Identification of Adverse Health Events

All adverse events should be recorded retrospectively. Adverse events will recorded at different levels. These should include all inpatient and emergency department clinical/incident reporting records, laboratory records, and patient complaints. The screening of clinical records for adverse events should be performed by the doctor responsible for the clinical care of the patient, the ward sister responsible for patient care as well as the hospital client liaison officer. (PRO)

3.2.1. Screening of Clinical Records

The medical records of all patients admitted to the hospital should be reviewed, in accordance with the following standard operating procedure. Patients admitted to the ward and fulfill any one of the following criteria (Table 1)[3], should be required to be risk assessed.

Table 1: Risk Assessment Screening Criteria

1. Death	
Unnatural death (suicide, homicide, maternal, neonatal, procedure related)	
Death associated with a nosocomial infection	
Procedure related	
2. Procedure related events	
Surgery on the wrong body part	
Surgery on the wrong patient	
Wrong surgical procedure performed on patient	
Unplanned return to operating room on this admission	
3. Patient care events	
Transfer from general care unit to a higher level e.g. High care or ICU	
Length of stay greater than 10 days	
Unplanned re-presentation to department within 48 hours for same condition	
Return to emergency department or outpatients department for complication related to the last hospital admission	
Disability associated with labour related event or procedure. E.g. CVP/LP	
4. Medication related events	
Allergic Reaction (Steven Johnson syndrome)	
Drug Interaction	
5. **Blood Product Related events**	
Blood transfusion reaction (Fever, Jaundice, urticaria)	
Incorrect blood administered (Blood to wrong patient)	
6. Hospital Related events	
Multi drug resistant organism (organism resistant to 3 or more antibiotics)	
IV site inflammation/ Catheter related infections	
Post operative wound infection	
Hospital incurred patient incident, such as fall	
Development of pressure sores	
Patient abscondment	
Infant discharged to wrong person or missing infant	
Patient with needle stick injury	

Records with at least one of the criteria should be sent to a designated nursing unit manager to estimate its likelihood of occurrence and consequences based on Australia/ New Zealand Risk Management Standard [4] (Table 2).These events are ranked according to their risk severity (risk severity = consequence score x likelihood score). Events with high risk severity (score >10) will be should be reviewed within 48 hours. A clinical incident report form will be required to be completed and submitted together with the risk assessment tool and patients medical records to the designated practitioner. If the nature of the incident is purely a system or predominantly a nursing issue then the risk assessor should be the designated nursing practitioner from the department. However, should the nature of the event be a clinical issue then the risk assessment is to be conducted by the designated medical practitioner.

The designated risk assessor should undertake a root cause analysis and the adverse event analysis forms together with the relevant recommendations should be forwarded to the hospital manager and medical manager for immediate action.

For adverse events with a low risk priority, a clinical incident form as well as the risk assessment tool should be submitted and discussed at the clinical risk management meeting, where a decision as whether to take action or to accept the risk and continue monitoring for that event will be made.

3.2.2 Patients complaints

All complaints received by the client liaison officer should be reviewed and classified in terms of the above stipulated criteria. If a high risk event is documented the necessary documentation should be completed and forwarded to the medical manager for review. Administrative, systemic and human resource complaints received should be documented and discussed at the risk management meetings.

Table 2: Qualitative measures used to determine risk severity of adverse events (modified from Australian/New Zealand Standard 43:60)

Measures of consequence or impact		
1	Insignificant	No injuries, low financial loss
2	Minor	Minor treatment required, no increase in length of stay or readmission, minor financial loss
3	Moderate	Major temporary injury, increased length of stay or readmission, medium financial loss
4	Major	Major permanent injury, increased length of stay or readmission, major financial loss
5	Catastrophic	Death, huge financial loss or threat to goodwill
Measures of likelihood		
1	Rare	May occur only in exceptional circumstances
2	Unlikely	Could occur at some time
3	Possible	Might occur at some time
4	Likely	Will probably occur in most circumstances
5	Almost certain	Is expected to occur in most circumstances

Clinical/Incident Report Form

This form is to be accompanied by Clinical Risk Assessment Tool

Ward: **Department:**

Date of Incident: **Time of Incident:**

Name of Patient:

Date of Admission:

Admitting Diagnosis:

Brief Description of Incident/Clinical Event:

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Notified by: **Date:**

3.3. Root cause analysis

Once the preliminary adverse event analysis is completed, a root cause analysis must be performed which identifies the main reason that led to the event as well as the contributing factors.

The steps followed in the root cause analysis are: [5]

a) Description of the event: Using medical records the adverse event and activities leading up to it must be described in detail. When did it occur? Did it happen over the weekend or during off hours? What service areas were affected? Specify the injury or potential injury to the patient.

b) Identification of the proximate cause(s) that led to the event: The proximate cause explains why the event occurred. For example, an adverse drug reaction (the event) occurred because the doctor wrote an order for a tenfold overdose of antibiotic (proximate cause) that the pharmacy dispensed (proximate cause) and a nurse administered (proximate cause). These proximate causes of the adverse event are deficiencies in the processes of care, and hence errors. It may be helpful to construct a diagram of the event, showing the steps in the current process of care and the steps where the process failed.

c) Identification of the contributing factors (or latent errors) that led to the proximate cause(s): Contributing factors permit errors to occur. For instance, a nurse who forgot to administer a dose of medication may have been required to do a double shift. Fatigue and staff shortages were the contributing factors to this medication error. Contributing factors to adverse events often fit into the following categories:

- **Human resource issues:** Was the staff adequately trained? Was the staffing adequate? Was there appropriate supervision?
- **Information availability:** Was necessary information available, accurate, and complete?
- **Environmental issues:** Did the physical environment contribute to the event? Are safeguards in place to minimize and address environmental risks?

- **Leadership and culture:** Did the organizational culture impair safe care?
- **Communication among clinicians:** Was communication among staff adequate?

The root cause analysis will be summarized in a tabular format as follows:

Adverse Event	**Proximate Causes**	**Contributing Factors**
		Human resources:
		Communication
		Systems:
		Information:

3.4. Classification of Adverse Events

The adverse events will be classified according to the National Quality Forum standard measures that were developed for Serious Reportable Adverse Events. The detailed classification system is attached in Appendix 1. The adverse events can be can be categorized as follows[6]:

a) Surgical Events

b) Product or Device Events

c) Patient Protective Events

d) Care management events

e) Environment events

f) Criminal events

3.5 Action Plans Development

This is the most important step. The goal is to develop improvements that can be implemented and tested. How could one prevent this problem from happening again? Although education and training are important, improvements that rely on exhortation, education, and reliance on memory are unreliable. The best action plans change the process of care itself.

The broad categories of action plans that can be implanted are listed in Table 3.[7]

Table 3: Actions taken to reduce the frequency of adverse events
Changes to clinical and administrative protocols
Focused audits to investigate specific adverse events
Discussion with staff involved
Education (including presentation of adverse events at postgraduate education meetings and clinical risk management presentations)
Creation of worksheets containing details of clinical policy, space to write clinical notes and a patient management checklist
Developing checklists for complex procedures
Increasing the supervision of junior hospital medical officers
Introduction of patient risk assessment tools to determine risk of falling, developing a pressure ulcer or thrombo-embolus and difficulty with discharge home
Regular feedback to clinical staff about adverse events and the results of actions taken to reduce risk

The management action undertaken needs to be recorded below the action plans.

3.6. Reporting system

Once all the relevant documentation has been completed, the unit manager or sister in charge of the ward must collate the documents. A photocopy of these documents should be made. A hard copy will need to be kept in an Adverse Event file in the sister's office. The copy of the documents then needs to be forwarded to the Quality Manager at the hospital who will then enter this information onto the Adverse Health Event Monitoring database. The completed adverse event notification, analysis, classification and recommendations must then be forwarded to the clinical risk management teams electronically.

The software programme is designed to generate a tabular report which will provide a summary of the adverse events as well as recommendations implemented. This can be discussed at the bimonthly clinical risk management meetings.

The quality coordinator will be required to generate a monthly report for onward transmission to the District Quality coordinator for monitoring and evaluation of the implementation of action plans.

A quarterly report will be required to be forwarded to the Quality Control, Monitoring and Evaluation Unit at the Department of Health.

In the event of a catastrophic adverse event occurring, immediate notification needs to be provided to the District and Provincial offices.

4. Conclusion

Adverse events can, as individual instances of care, provide an information-rich and compelling case for action and improvement, and in aggregate they can be used to identify and explore important variations in performance. Adverse events are important to healthcare organizations, not only because of their impact on patients but also because they can provide an insight into the quality of health care and an opportunity for improvement because of the direct connection between adverse events, patients' healthcare experience, and the process of care itself. Clinicians recognize the importance of adverse events and see the opportunities for improvement that they present.

Although adverse events in health care provide important and useful insights into the healthcare process which can certainly be used to great effect in promoting quality and performance improvements, some caution should be exercised. The negativity of adverse events which makes them a powerful tool in quality improvement also makes it important that quality measurement does not solely focus on such events.

5. References

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5) Massachusetts Medical Society. Patient Safety: Conducting a Root Cause Analysis of Adverse Events. Available online from: http://www.massmed.org/AM/Template.cfm?Section=Patient_Safety_Conducting_a_Root_Cause_Analysis_of_Adverse_Events

6) National Quality Forum. Serious Reportable Events in Healthcare. A Consensus Report. Washington D.C; National Quality Forum. 2002

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6. Appendices

6.1. Appendix 1: Classification of Adverse Events

EVENT	ADDITIONAL SPECIFICATIONS
1. SURGICAL EVENTS	
A. Surgery performed on the wrong body part	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
B. Surgery performed on the wrong patient	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures.
C. Wrong surgical procedure performed on a patient	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
D. Retention of a foreign object in a patient after surgery or other procedure	Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
E. Intraoperative or immediately post-operative death in an ASA Class I patient	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.
2. PRODUCT OR DEVICE EVENTS	
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
3. PATIENT PROTECTION EVENTS	
A. Infant discharged to the wrong person	
B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	Excludes events involving competent adults.
C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.

EVENT	ADDITIONAL SPECIFICATIONS
4. CARE MANAGEMENT EVENTS	
A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)	Excludes reasonable differences in clinical judgment on drug selection and dose.
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinimia in neonates	Hyperbilirubinimia is defined as bilirubin levels >30 mg/dl. Neonates refers to the first 28 days of life.
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
G. Patient death or serious disability due to spinal manipulative therapy	
5. ENVIRONMENTAL EVENTS	
A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	Excludes events involving planned treatments such as electric countershock.
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	
D. Patient death associated with a fall while being cared for in a healthcare facility	
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	
6. CRIMINAL EVENTS	
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	
B. Abduction of a patient of any age	
C. Sexual assault on a patient within or on the grounds of a healthcare facility	
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility	

6.2 Appendix 2: Adverse Events Monitoring Tools

6.2.1. Risk Assessment Tool

1. Death	
Unnatural death (suicide, homicide, maternal, neonatal, procedure related)	
Death associated with a nosocomial infection	
Procedure related	
2. Procedure related events	
Surgery on the wrong body part	
Surgery on the wrong patient	
Wrong surgical procedure performed on patient	
Unplanned return to operating room on this admission	
3. Patient care events	
Transfer from general care unit to a higher level e.g. High care or ICU	
Length of stay greater than 10 days	
Unplanned re-presentation to department within 48 hours for same condition	
Return to emergency department or outpatients department for complication related to the last hospital admission	
Disability associated with labour related event	
4. Medication related events	
Allergic Reaction (Steven Johnson syndrome)	
Drug Interaction	
5. **Blood Product Related events**	
Blood transfusion reaction (Fever, Jaundice, urticaria)	
Incorrect blood administered (Blood to wrong patient)	
6. Hospital Related events	
Multi drug resistant organism (organism resistant to 3 or more antibiotics)	
IV site inflammation/ Catheter related infections	
Post operative wound infection	
Hospital incurred patient incident, such as fall	
Development of pressure sores	
Patient abscondment	
Infant discharged to wrong person or missing infant	
Patient with needle stick injury	

6.2.2. Clinical/Incident Report Form

This form is to be accompanied by Clinical Risk Assessment Tool **Ward:**

Department:

Date of Incident: **Time of Incident:**

Name of Patient:

Date of Admission:

Admitting Diagnosis:

Brief Description of Incident/Clinical Event:

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Notified by: **Date:**

Section 2: Measure the risk severity of the adverse event

Choose the appropriate score for each of the following categories

Measures of consequence or impact		
1	Insignificant	No injuries, low financial loss
2	Minor	Minor treatment required, no increase in length of stay or readmission, minor financial loss
3	Moderate	Major temporary injury, increased length of stay or readmission, medium financial loss
4	Major	Major permanent injury, increased length of stay or readmission, major financial loss
5	Catastrophic	Death, huge financial loss or threat to goodwill
Measures of likelihood		
1	Rare	May occur only in exceptional circumstances
2	Unlikely	Could occur at some time
3	Possible	Might occur at some time
4	Likely	Will probably occur in most circumstances
5	Almost certain	Is expected to occur in most circumstances

b) Determine the Risk Adversity Score

Consequence of Impact: _____

Measures of Likelihood: *_____

Risk Adversity Score: _____

Score > 10 requires immediate action

Section 3: Root Cause Analysis:

Adverse Event	**Proximate Causes**	**Contributing Factors**
		Human Resources
		Communication
		Systems
		Information

Section 4: Recommendations

Please tick appropriate box:

Actions taken to reduce the frequency of adverse events	
Changes to clinical and administrative protocols	
Focused audits to investigate specific adverse events	
Discussion with staff involved	
Education (including presentation of adverse events at postgraduate education meetings and clinical risk management presentations)	
Creation of worksheets containing details of clinical policy, space to write clinical notes and a patient management checklist	
Developing checklists for complex procedures	
Increasing the supervision of junior hospital medical officers	
Introduction of patient risk assessment tools to determine risk of falling, developing a pressure ulcer or thrombo-embolus and difficulty with discharge home	
Regular feedback to clinical staff about adverse events and the results of actions taken to reduce risk	

6.3. Appendix 3: Summary Report

6.3. Summary Report

Date	Ward	Classification of Event	Nature of Event	Root cause	Action plans	Management Decision	Current status

* Example of a summary report that can be manually generated at facility level to monitor adverse events and track the progress regarding action plans.