	Quality Management Systems Procedure	
	Title: Reporting of adverse events policy	
	Document Number- 05/QA/TVVP/2017	
	Issue Number- 01	
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Review and Approved by: Smt. Karuna Vakati, IAS (Signed)		

Policy:

Reporting of adverse incident's policy underpins the key principles of TVVP hospitals incident reporting procedure in order to mitigate and minimise the incidents of adverse events and to ensure that patients receive appropriate, safe and effective care in accordance with the National Quality Assurance Standards.

An adverse incident is any unexpected / unintended incident, occurrence or accident which may result in injury / harm / unnecessary risk, adverse legal or medical position, loss or damage of property / assets, or to a patient, visitor, staff. These can be clinical or non-clinical events.

Purpose:

The purpose of TVVP incident reporting policy is:

- To create a framework for managing adverse events that defines the processes of prevention, identification, reporting, disclosure, investigating, analysing and managing adverse events which occur in healthcare facilities in the State of Telangana.
- A learning and non-blame culture is fostered.
- To minimize the Loss of reputation or assets of TVVP hospitals.
- To help support effective implementation of the TVVP Hospitals risk Management Policy.
- To fulfils the statutory requirements for incident and accident reporting.

Scope:

This policy applies to all personnel directly and indirectly employed, and patients / visitors coming to the TVVP hospitals. All heads of facilities shall be responsible for ensuring implementation of this policy.

Definitions:

1. **Near Miss and No Harm incidents** - A '**near miss'** is an unplanned event that did **not** result in injury, illness, or damage - **but had the potential to do so**. Only a fortunate break in the chain of events prevented an injury, fatality, loss or damage.

2. A **'near miss by intervention'** incident is an unplanned event that did **not** result in injury, illness, or damage, due to intervention and action at the time of the incident.

These must be reported as an incident as a 'near miss' or 'near miss by intervention' incident. Reporting this type of incident is as important as reporting incidents resulting in identified harm. Although no harm was caused at this time, the potential for re- occurrence is likely to exist and this needs to be managed effectively to prevent any future harm. These should be reported on same day or next day morning.

3. **Adverse Incidents:** An adverse incident is any unexpected / unintended incident, occurrence or accident which may result injury / harm / unnecessary risk, adverse legal or media position, loss or damage of property / assets, or financial loss to a patient, visitor or staff of TVVP. These can be clinical or non-clinical. These should be reported on same day within 4 to 6 hours.

Examples of adverse incidents:

- Accidental injury
- Work-related ill-health
- Unusual or dangerous occurrences, such as a fire or electrical malfunction
- Medication incidents
- Adverse drug reactions
- Incidents involving violence or aggression to people, plant equipment or property
- Equipment failure or misuse involving clinical and non-clinical equipment
- Information governance / data security incidents
- Infection Control incidents

This list is **not** exhaustive and is a guide only. **If in doubt – report it!**

4. **High Risk Incidents:** High Risk Incident is an incident that occurred in relation to services and care resulting in one of the following:

    - Unexpected or avoidable death
    - Serious harm
    - A scenario that prevents or threatens to prevent a provider's ability to continue to deliver healthcare services

- Allegations of abuse
- Adverse media coverage or public concern about

In the case of a High Risk Incident, the MS and RMO of the facility should alert the Senior Management like Supervising Officer at HO-TVVP, Commissioner-TVVP. This should happen without delay and **within 24 hours**. In order '*to ensure that the needs of individuals affected by the incident are attended to which may reduce the harmful impact* 'and also that all identified High Risk Incidents are notified to relevant authorities without delay and within **two working days**.

5. **Hazard** - A hazard is something with the potential to cause harm, or a situation/factor that may cause an incident or make it more likely to happen. The process of reporting the Hazard is same like High Risk Incidents and is notified to relevant authorities immediately.

Statutory obligation:

Under the Occupational Safety and Health Act- India, in 1989 and other associated legislation, both management and staff have legal obligations, including obligation to report, investigate and keep a record of events that have caused injury or which have the potential to do so.

It is vital to report all incidents and near-misses in order to prevent / mitigate the risk and to minimize the future occurrences.

Roles & Responsibilities:

- The Medical Superintendent has ultimate responsibility for all aspects of risk management, including the management of reported incidents. This includes ensuring services are adequately resourced to comply fully with this policy.
- The RMO and Nursing Superintendent and the in-charges of allied departments have responsibility to ensure the adequate arrangements are in place to facilitate compliance with the policy, and monitor the quality and effectiveness of incident reporting and subsequent investigations by receiving and commenting on incident trend analysis and investigation reports.
- The clinical departmental heads are responsible to ensuring local implementation and compliance of this policy in their respective areas, and ensuring appropriate support is given to the patients involved in reporting incidents.

The Head Nurse of the department is responsible for:

- Be aware and comply with this policy.
- Investigate all reported incidents and inform the outcomes to MS/RMO/NS.
- Develop action plans and risk reduction measures to reduce the likelihood and recurrence of incidents.
- Ensure that all incident forms from are completed with all relevant details of the incident occurring to the designated reviewer(s) for review without any delay.

- Ensure all staff attends risk management training as detailed in this policy.

Process of Reporting an Incident:

Any member of staff, who witnesses, discovers or is involved in, an incident / accident / near miss should complete and submit an Incident Report Form. This should be brought to the attention of the person in-charge at that time without delay.

It is acceptable for staff to submit an incident report form on behalf of another member of staff who is unable to complete the form personally.

Contracted staff also shall complete and submit an incident report for any incidents that occur on TVVP Hospital property during the course of their work.

With regards to an adverse incident, the immediate safety and well-being of the patient, staff member or visitor affected or involved, remedial first aid or emergency treatment must be given. In the case of a medication incident where the patient has been given the wrong drug / dosage, the treating doctor must formally review the patient's condition and the results of any examination recorded in the patient's case sheet.

If possible, where an adverse incident has occurred involving plant, machinery, equipment or furniture and fittings, label it for the attention of the Medical Superintendent / RMO but do not alter it in any way until it has been seen by the MS / RMO except to move it to a safe place if it is causing a hazard to others. If the incident is rated as major or catastrophic the 'scene' must not be altered. It may be advisable to check other pieces of similar equipment and label them as unsafe if necessary until they are able to be checked for safety. If the incident involves a medical device it must be quarantined.

Key requirements in filling the Incident Report Form:

- The entries must be clear and legible and if possible in block capitals.
- All sections should be completed.
- Facts only should be reported, not opinion. In the event of litigation, the form could be requested for disclosure and therefore should be accurate and factual.
- A severity grading of this incident should be made.
- Any factors that could have led up to the incident should be determined and completed in the relevant section. These could be lack of signage of a wet floor, lack of training, alcohol abuse by the patient, low staffing levels, illegible documentation etc.

The completed form should be submitted to the person in charge, for review, identification of Lessons Learnt, completion of the action plan and risk assessment where appropriate. The person in charge or reviewer should ensure that all sections have been completed (both the report and the reviewer fields) and submits the reviewed report to Medical Superintendent without delay.

In the event of High Risk / Hazardous incident resulting in a death or which is otherwise suspicious, the police and other relevant departments may need to be informed immediately by the person in-charge at the time of the incident.

Protocol for reporting of an event:

1	Time Frame for Reporting the Event	
Near Miss Event	**Adverse Event**	**High Risk / Hazardous Event**
Same day, may be next morning	Same day, within 4-6 hours	Immediate, within 2 hours
Should be reported at the earliest so that investigation/action can be taken without delay. If delay is likely, the matter can be reported on telephone, followed by writing.		
2	**Suggested Format for Reporting the Event**	
Following details shall be provided in case of occurrence of an adverse event (A format can be developed for this or an online mechanism can be developed for		

reporting these details)

REPORTING OF HIGH RISK / HAZARDOUS/ADVERSE/NEAR MISS EVENT

(By the Victim/Staff/Anyone Present on the spot)

Particulars of the person reporting				
Name/designation/address/telephone No.				
Brief description of the event				
Place of occurrence				
Date/Time of occurrence				
Details of the Victim, if any	**Name**	**Address**	**Patient/Public /Staff**	**Condition**
Cause of event				
Details of Event				
Reporting to (Designation of) the Official				
Date and Time				
Signature and Name				

Process by which to raise concern:

Staff members must be aware that anything they notice at work that appears to be unusual practice or behaviour or causes them to feel uncomfortable should be raised.

External Reporting Procedure:

Adverse drug reactions must be reported to DRUGS CONTROL ADMINISTRATION, Telangana and TSMSIDC by the fastest means available, preferably on-line,and follow-up by a confirmatory telephone call.

Incidents involving building fabric, equipment (Medical & Non-Medical) etc must be reported to the respective engineer, TSMSIDC.

DM&HO will receive reports on outbreaks of communicable diseases.

Report on dangerous occurrences like death at work / major injury will be reported Commissioner-TVVP by the quickest available means with the duly filled adverse incident reporting form.

Staff Training:

All employees will receive relevant ongoing training on incident reporting.

All the nursing staff required to undertake identification and investigation of Adverse Drug Reactions will receive appropriate training.

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