SAMPLE – Response Plan – Minor Adverse, Non-Critical Events

I. Statement of Purpose:

To establish guidelines for managing minor adverse or non-critical events

II. Policy:

It is the policy of [name of hospital] to identify and effectively manage the risk(s) associated with minor adverse and non-critical events. The organization will conduct an investigation and implement an improvement plan.

III. Responsibility/scope:

All hospital services; all hospital staff members

IV. Definitions:

Minor adverse or non-critical event:
- Events that fall within the severity level categories zero through five and are determined not to be a reviewable “sentinel event” or “serious safety event”
- Circumstances or events that have the capacity to cause error or harm
- Errors that did not reach the patient
- Events that reached the patient, but did not cause harm
- Events that reached the patient and required monitoring to confirm that there was no harm and/or confirmed that no intervention was required to prevent harm
- Events that may have contributed to or resulted in temporary harm and required intervention
- Examples of events that are considered minor adverse or non-critical include the following:
  - Property damage, missing property, narcotic discrepancy
  - Missing medical record, inappropriate behavior, professional conflict, biohazard spills
  - Averted medication errors, “near miss” wrong medication (caught before patient administration), test ordered on wrong patient but not performed
  - Wrong medication not requiring any increased monitoring, dressing not changed, medication not given or started on time, procedure not initiated – without adverse outcome, wrong blood draw or X-ray on a patient, surgical or procedural delay because patient information not complete
  - Fall without noted injury, patient assessed post-fall for possible changes in condition (vital signs, neurological checks); vital signs/lab work after wrong med; lost specimens
  - Fall with abrasion(s), bump(s) scratch(es), or bruising, injury of any kind; wrong medication that impacted the patient’s condition (e.g., dropped BP or blood sugar); procedural complications

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V. Procedures

A. Determination of severity of event

1. If the severity of the event is above category five or is reviewable by The Joint Commission or other accrediting body, refer to the Critical Event Response Policy.
2. Follow this procedure if the severity of the event is within the severity level categories zero through five and is NOT one of the following (From The Joint Commission definition of Sentinel Event):
   - Death
   - Permanent harm
   - Severe temporary harm

An event is also considered sentinel if it is one of the following:

- Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital’s emergency department (ED)
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment, and services
- Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED), leading to death, permanent harm, or severe temporary harm to the patient
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the hospital
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital
- Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure
- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
- Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care
- Any intrapartum (related to the birth process) maternal death
- Severe maternal morbidity (not primarily related to the natural course of the patient’s illness or underlying condition) when it reaches a patient and results in any of the following: Permanent harm or severe temporary harm
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[Footnotes]

a. *Severe temporary harm* is critical, potentially life-threatening harm lasting for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition.

b. Sexual abuse/assault (including rape) as a sentinel event is defined as nonconsensual sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the hospital, including oral, vaginal, or anal penetration or fondling of the patient's sex organ(s) by another individual’s hand, sex organ, or object. One or more of the following must be present to determine that it is a sentinel event:
   - Any staff-witnessed sexual contact as described above
   - Admission by the perpetrator that sexual contact, as described above, occurred on the premises
   - Sufficient clinical evidence obtained by the hospital to support allegations of unconsented sexual contact

c. Invasive procedures, including surgery, on the wrong patient, or at the wrong site, or that is the wrong procedure are reviewable under the policy, regardless of the type of the procedure or the magnitude of the outcome.

d. If a foreign object (for example, a needle tip or screw) is left in the patient because of a clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a sentinel event to be reviewed. However, in such cases, the organization shall (1) disclose to the patient the unintended retention, and (2) keep a record of the retentions to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may identify opportunities for improvement.

e. *Fire* is defined as a rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities. A combustion process that results in smoldering condition (no flame) is still classified as fire. Source: National Fire Protection Association.

f. *Severe maternal morbidity* is defined, by the American College of Obstetrics and Gynecology, the US Centers for Disease Control and Prevention, and the Society of Maternal and Fetal Medicine, as patient safety event that occurs intrapartum through the immediate postpartum period (24 hrs), that requires the transfusion of 4 or more units of blood products (fresh frozen plasma, packed red blood cells, whole blood, platelets) and/or admission to the intensive care unit (ICU). Facilities are strongly encouraged to review all cases of severe maternal morbidity for learning and improvement. *Admission to the ICU* is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support.

B. Focus on the involved individuals, manage the situation and confirm that no one is in any “immediate” danger or exposed to practices not supported by professional standards.

C. Conduct an investigation and a timely focused quality review of the event (or a mini root cause analysis), as defined by the facility.
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1. A mini root cause analysis will include all of the steps involved in a full root cause analysis, but in an abbreviated manner. For example, the team may consist of one to three members, the number of disciplines involved may be only one or two, and the action plan may include only a few action items.
2. Handle all investigative materials as being protected by professional review statutes.
3. Determine from the event timeline what should be investigated. Consider the facts to determine the level of detail for the investigation (actual or potential risk of severity guides the scope of investigation).
4. Consider the following resources to support an informal investigation:
   - Site visit
   - Inquiry or interview of involved staff members and physicians
   - Review of medical records, lab results and X-ray results
   - Review of policies, guidelines, protocols, meeting minutes and audit reports
   - Examination of involved equipment and related service and maintenance records
   - Literature review to identify evidence-based best practices
5. Make a determination of the human and systems factors most directly associated with the event and the processes and systems related to and underlying its occurrence.

D. Initiate the Plan, Do, Study, ACT (PDSA) performance improvement model.

1. The goal of the PDSA improvement process is to answer these questions:
   - What are we trying to accomplish?
   - How will we know that a change is an improvement?
   - What changes can we make that still result in improvement?²
2. The steps in the PDSA improvement process are as follows:
   - Form a team. Composition and size of the team will vary depending on the improvement project.
   - Set an aim. The aim statement is specific, measurable, challenging, and will keep the team focused.
   - Establish measures. The measures will help answer the question, “How will we know that a change is an improvement?”
   - Choose and plan a change. Determine what changes will help reach the aim.
   - Test the change. Testing may be done in a limited way (e.g., one unit).
   - Implement the change. After testing and improving with several PDSA cycles, implement the change on a broader basis.
   - Spread the change. Extend the change to other areas of the system or other organizations.³

References

3. Ibid.