A Plus
Hospice Care

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A Plus Hospice Care

Patient Safety Plan

INCIDENT REPORTING
Policy No. 3-004

PURPOSE

To define the reporting, follow-up, and feedback process for incidents involving patients and organization personnel.

POLICY

The organization will maintain a process for generating incident reports and follow-up corrective action, if applicable. The five (5) purposes of the incident report are:

1. To facilitate the early detection of problems or compensable events
2. To establish a foundation for early investigation of all potentially serious events
3. To develop a database for long-range problem detection analysis and correction
4. To enable cross-reference with other risk detection systems
5. To investigate and respond to serious adverse events, in accordance with accrediting bodies standards

All events or occurrences listed in "Examples of Specific Events or Occurrences That Must Be Reported" (see Addendum 3-004.A) must be reported, as well as any other occurrences presenting risks to patients.

The incident report is not a part of the patient's clinical/service record. No reference in the clinical/service record will be made indicating completion of an incident report.

The incident reporting system will be part of the organization's overall performance improvement and risk management plan.

Definitions

1. *Incident*: An unusual event involving organization personnel, a patient, and family/caregiver. The event is considered unusual if the result was unintended, undesirable, and/or unexpected. An incident is also any happening that is not consistent with the routine operation of the organization or the routine care of a patient. It may be actual or potential. (See "Examples of Specific Events or Occurrences That Must Be Reported" Addendum 3-004.A for further definition.)
2. *Serious Adverse Event*: An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or risk thereof" includes any process variation for which recurrence would carry a significant chance of a serious outcome.

PROCEDURE

1. When an incident occurs, the individual discovering the incident will:

   A. Notify your supervisor immediately with observations or identification of the incident.

   B. Follow-up with the patient and family/caregiver, and/or patient's physician, if indicated by your supervisor or designee.

   C. Maintain the confidentiality of the information. The report is for internal use only and is not available to physician or other agents outside the organization.

   D. Complete an incident report form within 24 hours of the incident.
   For personal care providers, the immediate supervisor should implement the form.

      1. The form should include the following:

         a. Pertinent patient information

         b. Type of incident

         c. Description of the incident or injury in narrative form; if no injury, state "no apparent injury"

         d. Name of the family/caregiver, organization personnel, or another witness of the incident

         e. Any drugs taken by the patient within eight (8) hours before the incident, including the dose, route, and time administered, especially for reporting falls

         f. Name of person(s) who requested follow-up or needed notification; indicate who was notified, the time, and by whom

         g. Whether organization personnel were injured, if applicable

         h. Any action taken by the physician, if applicable

         i. Nature of the injury; if other, please specify

         j. Names of any witnesses, the relationship to the patient or organization personnel, and title, when applicable

2. The Program Director or designee will review and sign the incident report form, request any necessary follow-up from appropriate personnel, and initiate incident report follow-up form, as required.

3. The Program Director or designee will forward the incident and follow-up forms to the Executive Director/Administrator. Copies of the incident reports will be forwarded to the Performance Improvement Coordinator for analysis, tracking, and trending.

4. The Performance Improvement Coordinator will review the incident reports and conduct follow-up as indicated. Corrective actions will be implemented and evaluated for effectiveness as indicated.

5. A summary of the analysis incident reports will go to the Executive Director/Administrator, who will review and forward report recommendations to the Governing Body on a quarterly basis.

6. Incidents that require reporting to the state and/or federal regulatory agencies must be reported within five (5) working days of becoming aware of the incident.

7. Incidents requiring reporting to state and/or federal regulatory agencies:

   A. All regulations and reporting forms will be available in the quality improvement department.

   B. The Performance Improvement Coordinator or designee will review incidents to determine if the event meets reporting criteria.

   C. As applicable, the Performance Improvement Coordinator or designee will complete and submit the necessary forms within the required time frame to the appropriate organization.

   D. The Performance Improvement Coordinator will prepare and submit any subsequent or summary reports that may be required.

   E. Reportable event files will be maintained according to applicable regulations.

7. Incidents that conform to A Plus Hospice Care's definition of serious adverse events will be immediately reported to the Executive Director/Administrator. Under the guidance of the Executive Director/Administrator, the Performance Improvement Coordinator will conduct a root cause analysis of the serious adverse event.

ADDENDUM 3-004.A
EXAMPLES OF SPECIFIC EVENTS OR OCCURRENCES THAT MUST BE REPORTED

1. Loss/Breakage

   - Patients and family/caregivers report missing articles from home after home visit
   - Organization personnel are involved in damage/breakage to a patient's personal belongings or equipment
   - Organization personnel's discovery of a patient's equipment or personal belongings missing from premises

2. Equipment/Medical Device

   - Failure to provide/receive orders
   - Non-delivery of an essential piece of equipment, whether the patient, vendor, or the referral source is responsible
   - Malfunctioning equipment resulting in actual or potential injury to the patient
   - Organization personnel or the patient and family/caregiver observes or reports injury resulting from equipment use

3. Endangerment—Building Security

   - Fire
   - Unidentified persons in the home/premises

4. Patient Endangerment

   - Suspected abuse by family/caregiver
   - The patient is confused and essentially helpless with inadequate care by others
   - Mentally competent adult chooses potentially unsafe home environment over institutionalization

   Note: For all above, notification to the state Elder-at-Risk program and/or Adult or Child Protective Services must be made by mandated reporters, per program requirements.

5. Organization Personnel Endangerment

   - Verbal and/or physical assault while on duty

6. Decubitus Ulcers

- Development of a new decubitus ulcer that reaches worsening Stage III after start of care

7. Refusal of Treatment

    - The patient and family/caregiver refuses treatment after start of care, against the professional advice of organization personnel

8. Problem with Procedure, Protocol Error

    - The patient and family/caregiver state the procedure/treatment has traumatized the patient
    - The patient and family/caregiver make an error in the procedure after they were evaluated as independent or competent to perform a procedure
    - Physician reports care that is inappropriate, unscheduled, provided without orders, or caused the family/caregiver to complain about the care provided
    - Attorney initiates telephone call to complain about or inquire about alleged patient injury
    - Staff member does not follow prescribed protocol, whether or not patient is injured
    - Staff member discovers difficulty in carrying out assigned orders
    - Staff member performs a procedure without patient authorization or appropriate physician (or other authorized licensed independent practitioner) orders
    - Patient care performed outside the scope of practice
    - Professional providing care not certified to perform specific procedure
    - Failure to provide ordered care for patient after a case has been accepted
    - Repeated complaints related to billing

9. Unanticipated Outcome

    - Drug reaction or toxic effect, immediate or delayed
        - Signs/symptoms of adverse or toxic effects
        - Anaphylaxis
    - Intravenous therapy complications
        - Extravasation
        - Infiltration (area of induration is in excess of 5 cm)
        - Hematoma

    - Phlebitis
    - Central venous catheter—elated sepsis
    - Questionable placement of central venous catheters
    - Vascular impairment of any extremity involving arteries/veins
    - Transfusion reaction (acute/non-acute systemic allergic, acute hemolytic or delayed)
- Treatment or procedure problems resulting in:
    - Aspiration of foreign matter into the respiratory tract, even if no problems are present at time
    - Loss of range of motion
    - Laceration of skin
    - Fracture, displaced, or un-displayed
    - Progressive worsening of decubitus ulcer, even though physician (or other authorized licensed independent practitioner) orders are being followed
    - Infection of any wound or organ, not present on admission to care
    - Bruise, abrasion, contusion, or pressure sore, not present on admission to care. Responsibility with reporting elder/child abuse.
    - Any hemorrhage
    - Neurological impairment, central or peripheral, not present on admission to care; i.e., convulsions, coma, loss of taste, sight, hearing, numbness, weakness, or paralysis
    - Retained foreign body, not intended
- Noncompliance by the patient and family/caregiver resulting in injury requiring emergency intervention or hospitalization
- Staff member neglects to report significant findings to the physician. In the case of non-licensed staff member, the reporting should be to the Clinical Supervisor who would then be responsible to the physician.

10. Consent Problems

- No consent obtained
- Wrong date on consent
- The patient withdraws consent by refusing treatment

11. Attended/Unattended Fall

    - The patient sustains injury subsequent to falling while organization personnel are present
    - The patient and family/caregiver reports a fall sustained by the patient during the course of his/her time on service

12. Medication Error

    - The patient and family/caregiver do not follow physician (or other authorized licensed independent practitioner) orders, nurse, or therapist instructions in administering medications; e.g., titrating IV opiates outside of physician's (or other authorized licensed independent practitioner's) ordered titration parameters
    - Medication errors that include errors in medication, time, dose, route of administration during intervention by the nurse
    - Missing scheduled administration of an IM/IV medication for any reason; e.g., staffing difficulties

13. Cardiac Arrest

    - Witnessed cardiac or respiratory arrest—unless "DNR/DNI" is in clinical record

14. Other

    - Staff member accepts separate compensation or private employment from the patient and family/caregiver
    - Any reference to legal action by a patient, family/caregiver, physician, or attorney
    - Any occurrence or observation that the organization personnel believe involves actual or potential injury to the patient, the company, or its organization personnel

SERIOUS ADVERSE EVENTS
Policy No. 3-005

PURPOSE

To have a positive impact in improving patient care.

To focus A Plus Hospice Care's attention after a serious adverse event on understanding the causes that underlie the event and on making changes in systems and processes to reduce the probability of such an event in the future.

To increase general knowledge about serious adverse events, their causes, and strategies for prevention.

To ensure maximum risk-prevention and loss-reduction activities on the part of A Plus Hospice Care in response to a serious adverse event.

POLICY

1. Incidents that conform to A Plus Hospice Care's definition of serious adverse events will be immediately reported to the Executive Director/Administrator or designee. Any member of the staff may report the incident.

2. Under the guidance of the Executive Director/Administrator, the Performance Improvement Coordinator will conduct a root cause analysis of the serious adverse event. The planning and preparing phase of the root cause analysis and action plan will be completed within 45 days of the event or of becoming aware of the event.

3. Undesirable patterns or trends in performance and serious adverse events will be intensively analyzed.

4. High-risk, high volume, and problem-prone areas related to the care and services provided will be correlated with the listing of frequently occurring serious adverse events identified in the organization's risk management data, and information about problematic processes generated by other professional organizations.

5. At a minimum, performance measures will be selected related to the following processes as appropriate to care and services:

   A. Medication use

   B. Use of blood and blood components

   C. Equipment malfunction

   D. Oxygen use

   E. Care or services provided to high-risk populations

Definitions

1. *Serious Adverse Event*: An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "serious adverse events" because they signal the need for immediate investigation and response.

2. *Root Cause Analysis*: A process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a serious adverse event. A root cause analysis focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in organizational processes, and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines, after analysis, that no such improvement opportunities exist. (See "Root Cause Analysis/Action Plan" Policy No. 3-006.)

3. *Action Plan*: The product of the root cause analysis is an action plan that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the action.

4. *Proximate Cause*: The obvious, direct cause of an accident, such as human error or equipment malfunction.

5. *Special Causes*: A cause that contributed to the accident but is outside the system and the organization, as it could not be foreseen or prevented.

6. *Common Causes*: Systematic problems that could lead to other accidents or injuries.

7. *Risk Points*: Procedures or a point of time when personnel could have averted the accident if they took extra care.

8. *Major Permanent Loss of Function*: Sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or lifestyle change. When "major permanent loss of function" cannot be immediately determined, applicability of the policy is not established until either the patient is discharged with continued major loss of function, or two (2) weeks have elapsed with persistent major loss of function, whichever occurs first.

PROCEDURE

Stage I: Immediately after the event, or hearing about the event (the first 48 hours)

1. Inform the Executive Director/Administrator or designee so he/she can provide information to any appropriate outside parties.

2. Make sure the organization is doing everything possible to provide follow-up care/services to ensure the best possible outcomes for injured parties/property and/or personnel.

3. Ensure that all parties involved in the event receive appropriate information to avoid miscommunication. Establish a mechanism for updates, as needed, using a designated spokesperson for consistency. The spokesperson should be someone familiar to and trusted by the patient and family. Personal rapport and concern are to be conveyed.

4. Follow any immediate regulator reporting requirement, such as the Occupational Safety and Health Administration in the case of an employee death, the Center for Missing and Exploited Children, adult/child protective services, etc.

5. Document appropriate information in occurrence reports and other risk management forms and submit to the Executive Director/Administrator or designee and the Performance Improvement Coordinator. Document objective clinical findings in the clinical record as necessary.

6. Document all confidential attorney patient communications and address to the corporate attorney.

7. Gather detailed information about the event.

8. Remind personnel of the confidentiality surrounding the event and the patient. Assure that personnel are aware of and communicate with the identified spokesperson/liaison, as appropriate.

Stage II: Within 45 days of the event or becoming aware of the event

1. The Performance Improvement Coordinator interviews all parties to the event, obtains written statements to gather an accurate description of the sequence of events.

2. Determine the root cause(s) of the event, including an analysis of all processes and systems related to its occurrence. Involve all appropriate personnel, as determined by the Executive Director/Administrator or designee in this analysis.

3. Determine potential improvements in processes or systems that would tend to decrease the likelihood of such events occurring in the future. Examples may include a change in communication, forms, training, equipment, policies, and procedures. If none exist, indicate in the conclusion of the analysis the determination that no such opportunities exist.

4. Establish a plan to address identified opportunities for improvement or formulation of a rationale for not undertaking such changes. Indicate time frame, person responsible, and criteria to evaluate effectiveness of the actions.

5. The Executive Director/Administrator or designee will notify all appropriate organization insurance carriers and plan for the proper handling and protection of the clinical record and other potential evidence (including log books, policies, procedures, or schedules) needed in anticipation of possible litigation.

Stage III: Post-event reporting

1. The Performance Improvement Coordinator will create a summary of all incidents managed through the serious adverse event intervention action plan.

2. The Executive Director/Administrator will review the summary and forward report recommendations to the Governing Body on a quarterly basis.

ROOT CAUSE ANALYSIS/ACTION PLAN

Policy No. 3-006

PURPOSE

To discover underlying causes and understand why a serious adverse event occurred. To discover what went wrong with the organization's systems and processes that can be altered to reduce the likelihood of reoccurrence.

POLICY

Root Cause Analysis

1. When a serious adverse event is discovered, a root cause analysis will be conducted to identify the basic or causal factors that underlie variation in performance.

2. The root cause analysis will focus primarily on systems and processes, not individual performance.

3. The analysis will progress from special causes in clinical/service processes, unusual circumstances or events that are difficult to anticipate, to common causes in organization processes. It will identify potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or determines, after analysis, that no such improvement opportunities exist.

4. Ordinarily, common cause variation can only be improved by redesigning a process. The intention will be not to accept an event as either human error or equipment breakdown, but to delve into what preceded the event or allowed it to occur.

Action Plan

1. An action plan will be initiated after the root cause analysis is completed.

2. The action plan will be the product of the root cause analysis, which identifies the strategies the organization intends to implement to reduce the risk of similar events occurring in the future.

3. The plan will address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.

PROCEDURE

Questions to be asked including:

1. What happened?

2. Why did it happen?

3. What processes were involved?

4. What systems underlie these processes?

5. How did the systems or processes fail?

Process for conducting a root cause analysis:

1. It is critical that the team understands the purpose of the investigation; keeping in mind that issues obvious to one member may not be to another.

2. Brainstorming is a good method to find the most likely contributing causes.

3. Following brainstorming, the team should further assess potential causes.

4. At this point, the team should be able to begin to determine the cause or causes of the problem and whether it is a special cause or a common cause issue.

5. It is important that the team not wait to finish the analysis before designing and implementing changes that may be appropriate and necessary to prevent recurrence.

6. During the process, it is important to determine progress and whether any course adjustments need to be made.

7. As redesign occurs, there may need to be changes in training, policies, procedures, forms, equipment, etc.

8. Monitoring for expected results from the redesign should be ongoing but completed no later than six (6) months from interventions.

A root cause analysis will be acceptable if it has the following characteristics:

1. The analysis focuses primarily on systems and processes, not individual performance.

2. The analysis progresses from special causes in clinical/service processes to common causes in organization processes.

3. The analysis repeatedly digs deeper by asking “Why?”

4. The analysis identifies changes, which could be made in systems and processes—either through redesign or development of new systems or processes—that would reduce the risk of such events recurring.

5. The analysis is thorough and credible.

The root cause analysis is thorough if it includes:

1. A determination of the precipitating human and other factors most directly associated with the serious adverse event, and the processes and systems related to its occurrence

2. Analysis of the underlying systems and processes through a series of “Why?” questions to determine where redesign might reduce risk

3. Identification of risk points and their potential contributions to this type of event

4. A determination of potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist

For the root cause analysis to be credible, it must:

1. Include participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review

2. Be internally consistent

3. Provide an explanation for all findings of “not applicable” or “no problem”

4. Include examination of any relevant literature

An action plan will be considered acceptable if it:

1. Identifies a resulting action plan that describes the organization’s risk reduction strategies or formulates a rationale for not undertaking such changes, and

2. Identifies who is responsible for implementing improvement actions, when the actions will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated

The organization will:

1. Document its analysis within 45 days of the serious adverse event or knowledge of the event, and begin the action plan.

2. Implement the recommended improvements.

3. Monitor the changes for effectiveness.

ADDENDUM 3-006.A
ROOT CAUSE ANALYSIS/ACTION PLAN FORM

This three (3)-page template will help to organize the steps in a root cause analysis. Not all possibilities and questions will apply in every case, and there may be others that will emerge in the course of the analysis. However, all possibilities and questions should be fully considered in your quest for "root causes" and risk reduction.

As an aid to avoiding "loose ends," the three (3) columns provided on the right are to be checked off for later reference:

"Root cause?" should be answered "yes" or "no" for each finding. A root cause is typically a finding related to a process or system that has a potential for redesign to reduce risk. If a particular finding that is relevant to the event is not a root cause, be sure that it is addressed later in the analysis with a "Why?" question. Each finding that is identified as a root cause should be considered for an action and addressed in the action plan.

"Ask why?" should be checked off whenever it is reasonable to ask why the particular finding occurred (or didn't occur when it should have) – in other words, to explore further. Each item checked in this column should be addressed later in the analysis with a "Why?" question. It is expected that any significant findings that are not identified as root causes will have check marks in this column. Also, items that are identified as root causes will often be checked in this column, since many root causes themselves have "roots."

"Take action?" Should be checked for any finding that can reasonably be considered a possible risk reduction strategy. Each item checked in this column should be addressed later in the action plan. It will be helpful to write the number of the associated action items on page 3 in the "Take Action?" column for each of the findings that require action.

Level of Analysis		Questions	Findings	Root Cause?	Ask "Why?"	Take Action?
What happened?	Sentinel event	What are the details of the event? (Brief description)				
		When did the event occur? (Date, day of week, time)				
		What area/service was impacted?				
Why did it happen? **What were the most proximate factors?** (Typically "special cause" variations)	The process or activity in which the event occurred	What was the intended flow process? (A flow diagram may be helpful here)				
		Were there any steps in the process that did not occur as intended?				
	Human factors	What human factors were relevant to the outcome?				
	Equipment factors	How did the equipment performance affect the outcome?				
	Controllable environmental factors	What factors directly affected the outcome?				
	Uncontrollable environmental factors	What uncontrollable external factors influenced this outcome?				
	Other	Are there any other factors that directly influenced this outcome?				
		What are the other areas in the organization where this could happen?				

Level of Analysis		Questions	Findings	Root Cause?	Ask "Why?"	Take Action?
Why did it happen? **What systems and processes underlie those proximate factors?** (Common cause variation here may lead to special cause variation in dependent processes.)	**Human resource issues**	Was the staff properly qualified and currently competent for their responsibilities at the time of the event?				
		How did actual staffing compare with ideal levels?				
		What is the plan for dealing with contingencies that would tend to reduce effective staffing levels?				
		To what degree is staff performance in the operant process(es) addressed?				
		How can orientation & inservice training be improved to reduce the risk of such events in the future?				
	Information management issues	To what degree was all necessary information available when needed? Accurate? Complete? Unambiguous?				
		To what degree was communication among participants adequate for this situation?				
	Environmental management issues	What systems are in place to identify environmental risks?				
		What emergency and failure-mode responses have been planned and tested?				
		To what degree was the physical environment appropriate for the processes being carried out for this situation?				
	Leadership issues: Corporate culture	How does the organization's culture support risk reduction?				
	Encouragement of communication	What are the barriers to communication of potential risk factors?				
	Clear communication of priorities	How is the prevention of adverse outcomes communicated as a high priority?				
	Uncontrollable factors	What can be done to protect against the effects of these uncontrollable factors?				
	Technology	Was available technology used as intended? How might technology be introduced or redesigned to reduce risk in the future?				

	Risk Reduction Strategies	MEASURES OF EFFECTIVENESS
For each of the findings identified in the analysis as needing an action, indicate the planned action, expected implementation date, and associated measure of effectiveness, OR . . . If, after consideration of such a finding, a decision is made not to implement an associated risk reduction strategy, indicate the rational for not taking action at this time. Check to be sure that the selected measure will provide data that will permit assessment of the effectiveness of the action. Consider whether pilot testing of a planned improvement should be conducted. Improvements to reduce risk should ultimately be implemented in all areas where applicable, not just where the event occurred. Identify where the improvements will be implemented.	Action item #1:	Measure:
	Action item #2:	Measure:
	Action item #3:	Measure:
	Action item #4:	Measure:
	Action item #5:	Measure:
	Action item #6:	Measure:
	Action item #7:	Measure:
	Action item #8:	Measure:
Cite any books or journal articles that were referenced when developing this analysis and action plan:		