

Appendix: Adverse Event Analysis Form

STUDY ID NUMBER: _____

MEDICAL RECORD REVIEW FORM

Instructions: Please carefully complete all of the following sections

1. Medical Record Number:

2. Reviewer ID Number: _____

3. Date of Admission: ___/___/___ 4. Date of Discharge: ___/___/___

5. Disposition:

- 1. Discharged to Home
- 2. Transferred to another institution
- 3. Expired

6. Date of Review: ___/___/___

CAUSATION

<input type="checkbox"/>	1 =
Yes	

7. Was there a medical injury?

7a. If yes then describe:

7b. Did the injury result in a disability at the time of discharge and/or prolong the hospital stay?

- 1 = Disability
- 2 = Prolonged Hospital Stay
- 3 = Both

7c. Please rate the severity of the disability

1. Up to 1 day of symptoms

2. Laboratory abnormality requiring only change in therapy
3. More days of symptoms
4. Non-permanent disability
5. Permanent disability
6. Death

Determination of Adverse Event

In your best judgment, is there evidence that medical management caused the patient's injury? In answering this question, consider when relevant the following questions and complete the appropriate boxes.

8a. Is there a note in the medical record, which indicates or suggests that medical management caused the injury?

<input type="checkbox"/>	1 =
Yes	

8b. Is there a note in the medical record which predicts the possibility of an injury from the patient's disease?

<input type="checkbox"/>	1 =
Yes	

8c. Does the timing of events suggest that the injury was related to the treatment?

<input type="checkbox"/>	1 =
Likely	2 =

8d. Are there other reasonable competing explanations for the cause of the injury?

<input type="checkbox"/>	1 = Few
Some	2 =

8e. Was there an opportunity prior to the occurrence of the injury for intervention, which might have prevented it?

<input type="checkbox"/>	1 = Yes
Possibly	2 =

8f. Is there recognition that the intervention in question causes this kind of injury?

<input type="checkbox"/>	1 = Widely recognized
Specialists	2 = Recog. by other

8g. Did the adverse event respond to new management to neutralize or modify the effects of former management?

<input type="checkbox"/>	1 = Convincing response
	2 = Suggestive response
	3 = No response

8h. After due consideration of the clinical details of the patient's management, and your response to the questions above, what level of confidence do you have that the medical management caused the injury?

Confidence Score:

1 = Little or no evidence for management causation

2 = Slight to modest evidence for management causation

Score

3 = Management causation not likely; less than 50-50 but close call

4 = Management causation more likely than not, more than 50-50 but close call

5 = Moderate/strong evidence for management causation

6 = Virtually certain evidence for management causation

Classification of Adverse Event

DIAGNOSTIC ERROR

9. Was the adverse event the result of a diagnostic error (wrong/delayed diagnosis)?

Yes

1 =

9a. If yes then describe: _____

9b. If yes, choose one of the following that best describes the diagnostic error:

- 1. There was a failure to employ indicated test
- 2. There was failure to act upon results of tests or findings
- 3. Inappropriate or outmoded diagnostic tests were used
- 4. There was avoidable delay in diagnosis.
- 5. Physicians or other professionals were practicing outside their area of expertise.

9c. Were there other diagnostic errors?

Yes 1 =

9d. If yes, then describe:

9e. Reasons for error are not apparent?

Yes 1 =

OPERATIVE COMPLICATIONS

10. Was the AE related to an operation or did it occur during The immediate (30 days) postoperative period?

Yes 1 =

10a. If yes then select on of the follow

1 = Technical problem. Specify: _____

2 = Bleeding. Specify: _____

3 = Wound infection

4 = Non-wound infection

5 = Other wound problem. Specify: _____

technical Specify:

6 = Other technical problem. Specify _____

7 = PE

8 = CVA

9 = CHF

10 = DVT

11 = AMI

12 = Pneumonia

13 = Dysrhythmia

Type:

14 = Other non-

10b. Were there other operative problems?

1 =
 Yes

10c. If yes specify:

10d. Choose one of the following that best describes the complications:

- 1. The operation was inefficacious (failed to relieve symptoms)
- 2. The patient was inadequately prepared before the operation
- 3. There was avoidable delay in treatment.
- 4. There was inadequate monitoring of the patient after the operation.
- 5. Physicians or other professionals were practicing outside their area of expertise.
- 6. Inappropriate or outmoded forms of therapy
- 7. None of these apply.

10e. Were there other performance errors?

1 =
Yes

POST-PARTUM RELATED INJURY (Maternal)

11. Was the adverse event a post-partum injury?

1 =
Yes

11a. If yes indicate one of the following:

- 1. Infection
- 2. Hemorrhage
- 3. Other. Specify _____

NEONATAL RELATED INJURY

12. Was the adverse event a neonatal injury?

1 =
Yes

12a. If yes indicate one of the following:

- 1 = Forceps-induced palsy
- 2 = Fractured clavicle
- 3 = RSD
- 4 = Other. Specify: _____

MEDICAL RELATED INJURY

13. Was this a procedure-related (non-surgical) injury (such as endoscopy or cardiac catheterization)?

1 =
Yes

13a If yes then select on of the follow

- 1 = Technical problem. Specify: _____
- 2 = Bleeding. Specify: _____
- 3 = Wound infection
- 4 = Non-wound infection
- 5 = Other wound problem. Specify: _____
- technical Specify: _____

- 7 = PE
- 8 = CVA
- 9 = CHF
- 10 = DVT
- 11 = AMI
- 12 = Pneumonia
- 13 = Dysrhythmia Type:
- 14 = Other non-

6 = Other technical problem. Specify _____

13b. Were there other procedure-related problems?

<input type="checkbox"/>	1 =
Yes	

13c. If yes specify:

13d. Choose one of the following that best describes the complication.

1. The procedure was inefficacious (failed to relieve symptoms)
2. The patient was inadequately prepared before the procedure
3. There was avoidable delay in treatment.
4. There was inadequate monitoring of the patient after the procedure.
5. Physicians or other professionals were practicing outside their area of expertise.
6. Inappropriate or outmoded forms of therapy
7. None of these apply.

13e. Were there other performance errors?

<input type="checkbox"/>	1 =
Yes	

13f. If yes describe:

DRUG RELATED INJURY

13. Adverse drug event?
 1 = ADE
 2 = potential ADE
 3 = Exclude

14. Severity of ADE (select only one)
 1.= Fatal ADE
 2.= Life-threatening ADE
 3.= Serious

4 = Significant ADE

15. Disability/injury associated with ADE (select only one)
- 1 = Up to 1 day of symptoms
 2 = Laboratory abnormality requiring only change in therapy
 3 = More days of symptoms
 4 = Non-permanent disability
 5 = Permanent disability

16. Core components of event (check all that apply)

- | | | |
|--|---|---|
| <input type="checkbox"/> Anorexia | <input type="checkbox"/> Anticholinergic | <input type="checkbox"/> |
| Cardiovascular | | |
| <input type="checkbox"/> Dermatologic/allergic | <input type="checkbox"/> Electrolytes/fluid balance | <input type="checkbox"/> EPS/ TD |
| <input type="checkbox"/> Fall | <input type="checkbox"/> Fall + Injury | <input type="checkbox"/> Functional Decline |
| <input type="checkbox"/> Gait problems | <input type="checkbox"/> Gastrointestinal | <input type="checkbox"/> |
| Hemorrhagic | | |
| <input type="checkbox"/> Hematologic | <input type="checkbox"/> Hepatic | <input type="checkbox"/> Infection |
| <input type="checkbox"/> Metabolic/endocrine | <input type="checkbox"/> Neuropsychiatric | <input type="checkbox"/> Renal |
| <input type="checkbox"/> Respiratory | <input type="checkbox"/> Syncope/dizziness | |
| <input type="checkbox"/> Other, specify: | | |
-

17. Severity of potential ADE (select only one)
- 1 = Potential for fatal or life-threatening ADE
 2 = Potential for serious ADE
 3 = Potential for significant ADE

18. Categories of drugs involved (check all that apply)

- | | | |
|--|--|---------------------------------------|
| <input type="checkbox"/> Analgesics | <input type="checkbox"/> Anti-Alzheimer | <input type="checkbox"/> Anti- |
| coagulants, | | |
| <input type="checkbox"/> Anti-depressants | <input type="checkbox"/> Anti-epileptic | <input type="checkbox"/> Anti- |
| histamine | | |
| <input type="checkbox"/> Anti-hyperlipidemic | <input type="checkbox"/> Anti-infectives | <input type="checkbox"/> Anti- |
| neoplastics | | |
| <input type="checkbox"/> Anti-Parkinsonian | <input type="checkbox"/> Anti-psychotics | <input type="checkbox"/> |
| Cardiovascular | | |
| <input type="checkbox"/> Diuretic | <input type="checkbox"/> Gastrointestinal | <input type="checkbox"/> Gout |
| <input type="checkbox"/> Hypoglycemics | <input type="checkbox"/> Muscle relaxants | <input type="checkbox"/> Nutrients |
| <input type="checkbox"/> Ophthalmic | <input type="checkbox"/> Opioids | <input type="checkbox"/> Osteoporosis |
| <input type="checkbox"/> Respiratory | <input type="checkbox"/> Sedatives/hypnotics | <input type="checkbox"/> Steroid |
| <input type="checkbox"/> Topical, non-ophthalmic | | |
| <input type="checkbox"/> Other, specify: | | |
-

19. Naranjo Algorithm : Attribution

	Yes	No	Do Not Know
19.1 Are there previous conclusive reports on this reaction?		+1	0 0
19.2 Did the adverse event appear after the suspected drug was administered?		+2	-1 0
19.3 Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?		+1	0 0
19.4 Did the adverse reaction reappear when the drug was readministered?		+2	-1 0
19.5 Are there alternative causes (other than the drug) that could on their own have caused the reaction?		-1	+2 0
19.6 Did the reaction reappear when a placebo was given?		-1	+1 0
19.7 Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?		+1	0 0
19.8 Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?		+1	0 0
19.9 Did the patient have a similar reaction to the same or similar drugs in any previous exposure?		+1	0 0
19.10 Was the adverse event confirmed by any objective evidence?		+1	0 0

TOTAL SCORE = _____

THERAPEUTIC ERROR

20 Was this a therapeutic error (e.g. correct diagnosis But inappropriate therapy or delay in treatment)?

<input type="checkbox"/>	1 =
Yes	

20a. If yes then describe:

FALLS

<input type="checkbox"/>	1 =
Yes	

21 Was the injury the result of a fall?

21a. If yes then describe:

SYSTEM ERROR

22 Was the injury the result of a system error?

1 =
Yes

22a. If yes , choose one of the following to describe the system error

1. The AE resulted from defective equipment or supplies
2. The AE resulted because equipment or supplies were not available
3. There was inadequate reporting or communication
4. There was inadequate training or supervision of MDs or other personnel
5. There was a delay in the provision or scheduling of services (e.g. lab tests, x-rays)
6. There was inadequate staffing
7. There was inadequate functioning of hospital services (e.g pharmacy, blood bank or housekeeping)

22b. Were there other system errors?

1 =
Yes

22c. If yes then describe:

23 Preventability – Implicit (select only one)

- 1 = No error
- 2 = Error intercepted
- 3 = Definitely preventable
- 4 = Probably preventable
- 5 = Probably not preventable
- 6 = Definitely not preventable
