

CONFIDENTIAL

MEDICAL REVIEW FORM (RF2)

CASE No.

Directions:

- 1. Complete this form only if RF/1 completed by RN reviewers has identified that a screening criterion is present.***

- 2. Please read RF/1 Prior to reviewing the medical record of INDEX admission, prior to answering the specific questions on this form.***

- 3. Do not write the patients name or hospital record number on this form.***

- 4. "AE" means adverse event.***

- 5. Please print or write responses or notes legibly, in BLUE pen, RED for corrections or deletions.***

- 6. For all questions enter the appropriate number in the corresponding box.***

- 7. Please return this form to the team leader on completion of Review Session.***

DO NOT FILE IN THE MEDICAL RECORD

SECTION A – CLINICAL SUMMARY

1.

1a Reviewer ID Number: *1b* Case Number:

1c Country code: *1d* Hospital code:

1e Date of Review:
D D M M Y Y

1f Time Commenced Review: *1g* Time Review Finished:

1h Total time spent reviewing in minutes:

2.

2a Please give brief clinical summary focusing on the events leading to the AE in the context of the patient's disease

2b Do you confirm the RN reviewers criteria finding: 1=Yes (*Go to Q.3*)
 2=No (*Answer 2c*)

2c If you answered "NO" to Q.2b please indicate why by answering one of the following questions:

- i. No criteria present Yes
 No

Describe:

- ii. Wrong criterion indicated or other criterion present Yes
 No

Describe:

*FOR ALL QUESTIONS
ENTER APPROPRIATE
NUMBER IN BOX*

SECTION B – ADVERSE EVENT DETERMINATION

INJURY:

- 3.** Was there a patient injury or complications? YES NO (Then STOP)
(no AE)

3a If Yes to Q.3 please describe the injury:

DISABILITY:

3b Did the injury or complication result in a disability at the time of discharge and/or a prolonged hospital stay?

1=Disability/Death 2=Prolonged hospital stay/readmission 3=Both 4=Neither (Then STOP)
(no AE)

3c Describe the disability and/or prolonged hospital stay:

CAUSATION:

In your best judgement, is there evidence that HealthCare management caused the patient's injury?

In answering this question, consider when relevant the following questions and complete the appropriate boxes.

After due consideration of the clinical details of the patient's management, what level of confidence do you have that the HEALTHCARE MANAGEMENT caused the injury?

CONFIDENCE SCORE:

1. =Little or no evidence for management causation (Then STOP,no AE)
2. =Slight to modest evidence for management causation. (Then STOP,no AE)
3. =Management causation not likely; less than 50-50 but close call. (Then STOP,no AE)
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.

SCORE <input type="checkbox"/>

Did the patients HIV/AIDS status or its treatment contribute to the AE

YES

NO

If yes please describe in what way:

If an adverse event has been identified please proceed to complete all sections on the rest of the form.

SECTION C - CLASSIFICATION OF ADVERSE EVENT

PLEASE CHOOSE ONLY ONE OF SUBSECTIONS C1 - C10

C1 - DIAGNOSTIC ERROR:

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

YES

NO (If No skip to C2)

4a: If yes to Q.4 then describe:

4b: If yes to Q.4 choose one of the following that best describes the diagnostic error.

1. =There was a failure to take an adequate history and/or physical examination.
2. =There was a failure to employ indicated test.
3. =There was failure to act upon results of tests or findings.
4. =Inappropriate or outmoded diagnostic tests were used.
5. =There was avoidable delay in diagnosis.
6. =Doctors or other professionals were practising outside their area of expertise.

(GIVE DETAILS)

4c Were there other diagnostic errors? YES NO

4d If yes to Q.4c then describe:

C2 - OPERATIVE ADVERSE EVENT

5 Was the AE related to an operation or did it occur during the immediate (30 days) Postoperative period? YES NO (If No skip to C3)

5a If yes to Q5 select one of the following:

TECHNICAL

1=Technical problem. Specify: _____

2=Bleeding. Specify: _____

3=Wound Infection

4=Non-wound infection:

5=Other wound problem: Specify: _____

6=Other Specify: _____

6b Were there other operative problems? YES NO

6c If yes to 6b specify: _____

6d Choose one of the following that best describes the adverse event.

- 1=The operation was inefficacious (failed to relieve symptoms).
- 2=The patient was inadequately prepared before the operation.
- 3=There was delay in treatment.
- 4=There was inadequate monitoring/supervision of the patient after the operation.
- 5=Doctors or other professionals were practising outside their area of expertise.

(GIVE DETAILS)

- 6=Inappropriate or outmoded forms of therapy were used.
- 7=None of these apply.

NON-TECHNICAL

- 8=PE
- 9=CVA
- 10=CHF
- 11=DVT
- 12=AMI
- 13=PNEUMONIA
- 14= Other non-technical problem

C3 - FRACTURES

(Includes non-operative treatment)

6 Was the adverse event related to a fracture? YES NO (If No skip to C4)

6a If yes to Q.6 indicate the type of fracture: _____

6b If yes to Q.6 indicate one of the following:

1=Re-do: _____ (GIVE DETAILS)

2=Prosthesis Failure: _____ (GIVE DETAILS)

3=Operative Care: _____ (GIVE DETAILS)

4=Non-operative Care: _____ (GIVE DETAILS)

5=Other: _____ (GIVE DETAILS)

C4 - ANAESTHESIA RELATED INJURY:

7 Was the adverse event related to anaesthesia? YES NO (If No skip to C5)

7a If yes to Q.7 indicate the operation involved: _____

7b Please indicate the type of anaesthetic

- 1=General anaesthetic
- 2=Regional anaesthesia

3=Local anaesthesia

7c If yes to Q7 indicate one of the following:

1=Intubation

2=Anaesthetic agent complication

3=Equipment failure

4=Preop assessment

5=Difficulties in accessing blood for transfusion

6=Insufficient level of experience or qualifications of anaesthetic team

7=Other: _____

(GIVE DETAILS)

C5 -OBSTETRIC RELATED INJURY (Maternal)

8. Was the adverse event related to obstetric management? YES NO
(If No skip to C6)

8a If yes to Q.8 indicate at what stage the AE occurred.

1=Related to Antenatal care.

2=Related to care during Labour & Delivery

3=Related to care or supervision in the Post-partum period.

8b Describe the contributing factors to the adverse event:

8c Mode of Delivery

1=Normal Vaginal Delivery.

2=Instrumental Assisted Delivery.

3=Caesarean Section.

C6 - NEONATAL RELATED INJURY

9. Was the adverse event a neonatal injury? YES NO (If No skip to C7)

9a If yes go to Q.9 indicate one of the following.

1=Conduct of Delivery.

2=Pre Delivery Assessment.

3=Post-Delivery Care.

4=Other.Specify: _____

9b Describe the contributing factors to the adverse event:

C7 - NON-SURGICAL PROCEDURE

10. Was this procedure-related (Non-surgical) injury (such as endoscopy or cardiac catheterisation)? YES NO
(If No skip to C8)

10a If yes to Q.10 select one of the following:

TECHNICAL

1=Technical problem. Specify: _____

2=Bleeding. Specify: _____

3=Wound infection

4=Non wound infection

5=Other wound infection. Specify: _____

6=Other Specify: _____

NON-TECHNICAL

7=PE

8=CVA

9=CCF

10=DVT

11=AMI

12=PNEUMONIA

13=Other non-technical Specify: _____

10b Were there other procedure-related problems? YES NO

10c If yes to 10b specify: _____

10d Choose one of the following that best describes the adverse event.

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=Doctors or other professionals were practising outside their area of expertise.

6=Inappropriate or outmoded forms of therapy used.

7=None of these apply.

C8 - DRUG RELATED INJURY

11. Was this a drug related injury? YES NO (if NO skip to C9)

11a If yes please describe:

11b What was the drug?

1=anti-neoplastic

2=antibiotic

3=anti-malarial

4=antiretroviral

5=anti-seizure

6=diabetes

7=sedative or hypnotic.

8=anticoagulant

9=antihypertensive

10=narcotic/opiod

11=potassium

12=anti-tuberculosis antibiotics

13= other,please specify: _____

11c Name of medication(generic name if possible): _____

11d Describe the drug's side effect: _____

11e Choose one of the following that best describes the drug related injury.

1=The AE resulted from an error in the method of use or dose.

2=There was failure to recognise possible antagonistic or complementary drug-drug interaction.

3=There was inadequate monitoring of drug levels or other inadequate follow-up.

4=The drug was used inappropriately.

5=There was avoidable delay in treatment.

6=Doctors or other professionals were practising outside their area of expertise.

7=None of these apply.

11f Were there other drug treatment errors? YES NO

If yes please describe:

C9 - THERAPEUTIC ERROR

- 12.** Was this a therapeutic error (e.g. correct diagnosis but inappropriate therapy or delay in treatment)? YES NO (if NO skip to C10)

12a If yes please describe

C10 - FALLS

- 13.** Was the injury the result of a fall? YES NO

13a If yes please describe the circumstances

SECTION D - DISABILITY

- 14.** Was a portion of, or the entire hospitalisation, due to the adverse event?

1= No increase in hospital days.

2= Portion of hospital stay.

3= Entire hospital stay.

- 15.** How many days are attributable to the AE?
DAYS

- 16.** Would the patient at some time be able to return to pre-hospital state with regard to employment, independence and leisure? Yes No

16a: Based on evidence in the medical record what is the degree of disability attributable to the adverse event?

- 1= Minimal impairment and/or recovery in one month.
- 2= Moderate impairment, recovery in one to six months.
- 3= Moderate impairment, recovery in six months to a year.
- 4= Permanent impairment, disability 1-50%.
- 5= Permanent impairment, disability >50%.
- 6= Permanent nursing.
- 7= Institutional care.
- 8= Death
- 9= Cannot reasonably judge.

17. When did the Healthcare management and the consequent AE occur in relation to the index hospitalisation?

- 1= Healthcare management occurred during hospitalisation; AE discovered during hospitalisation.
- 2= Healthcare management occurred in outpatient treatment prior to hospitalisation; AE indication for hospitalisation or first discovered during hospitalisation.
- 3= Healthcare management occurred during hospitalisation at any institution 12 months prior to index hospitalisation; AE indication for hospitalisation or first discovered during hospitalisation.
- 4= Healthcare management occurred during index admission; AE discovered in subsequent hospitalisation.

SECTION E – CLINICAL CONTEXT OF AE

OUTSIDE HOSPITAL

18. Where did the HealthCare management causing the AE occur? (choose one)

- | | |
|--|-----------------------------------|
| 01=Physicians office | 04=Home, labour and delivery |
| 02=Ambulatory care unit
(inc.day surgery)outside hospital | 05=Nursing home |
| 03=Home | 06=Other site outside of hospital |
- Specify: _____

INSIDE HOSPITAL

- | | |
|---|---|
| 07=Patients hospital room | 17=Therapy/Rehabilitation |
| 08=OR | 18=Pathology |
| 09=ICU | 19=Laboratory (clinical) |
| 10=ER | 20=Blood bank |
| 11=Ambulatory care unit
(inc. Day surgery) inside hospital | 21=Pharmacy |
| 12=Recovery Room | 22=Hospital Bathroom |
| 13=Labour and Delivery | 23=Service Area (stairs, halls, elevator) |
| 14=Nursery | 24=Procedure room |
| 15=Radiology | 25=Other site in hospital |
| 16=Cardiac Catheterisation | Specify: _____ |

19. SPECIALTY responsible for AE (choose one)

SURGERY

- | | | |
|-------------------------|------------------------|-----------------------|
| 01=Anaesthesiology | 05=Gynaecology | 10=Plastic Surgery |
| 02=Cardiac Surgery | 06=Neurosurgery | 11=Thoracic Surgery |
| 03=Colon/Rectal Surgery | 07=Obstetrics | 12=Vascular Surgery |
| 04=General Surgery | 08=Orthopaedic Surgery | 13=Urological Surgery |
-

MEDICINE

- | | | |
|-----------------------|--|-------------------------|
| 14=Cardiology | 23=Intensive Care Unit (ICU) | 31=Pathology |
| 15=Dermatology | 24=Internal Medicine
(not otherwise classified) | 32=Paediatrics |
| 16=Emergency | 25=Medical Oncology | 33=Physical medicine |
| 17=Endocrinology | 26=Neonatology | 34=Psychiatry |
| 18=Family Practice | 27=Nephrology | 35=Pulmonary Disease |
| 19=Gastroenterology | 28=Neurology | 36=Radiation Therapy |
| 20=Haematology | 29=Ophthalmology | 37=Radiology |
| 21=Immunology | 30=Otorhinolaryngology | 38=Rheumatology |
| 22=Infectious disease | | 39=Other specify: _____ |
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- | | | |
|------------------------------|--|---------------------------|
| 40=Dentistry/Oral Surgery | 44=Nursing | 48=Podiatry |
| 41=Dietry | 45=Osteopathy | 49=Transportation support |
| 42=Hospital Psychiatry Plant | 46=Pharmacy | 50=Other specify: _____ |
| 43=Midwifery | 47=Physical or
Occupational Therapy | |
-

Traditional Non-doctor HealthCare YES NO

CONSIDER AND EVALUATE THE FOLLOWING QUESTIONS REGARDING THE CLINICAL CONTEXT OF THE AE

20. Is there general consensus about diagnosis or therapy regarding this type of case?

- 1=Very Little
- 2=Some
- 3=A great deal

20a How complex was this case?

- 1=Very complex
- 2=Moderately complex
- 3=Uncomplicated.

20b Was the management in question appropriate?

- 1=Definitely appropriate
- 2=Probably appropriate
- 3=Possibly inappropriate
- 4=Definitely inappropriate

- 20c** What was the co-morbidity of the case in which the adverse event occurred?
1=Very ill patient
2=Moderately ill patient
3=No co-morbidity
- 20d** What was the degree of deviation of management from the accepted norm?
1=Little
2=Moderate
3=Severe
- 20e** What was the degree of emergency in management of the case prior to the occurrence of adverse event?
1=Critical and very urgent
2=Moderate
3=Not urgent
- 20f** What potential benefit was associated with the intervention?
1=Life saving
2=Major quality of life
3=Minor quality of life
4=Not applicable
- 20g** What was the chance of benefit associated with the intervention?
1=High
2=Moderate
3=Low
4=Not applicable

SECTION F – CONTRIBUTORY FACTORS

21. Can you identify any factors contributing to this AE? Yes No

21a If yes to Q.21, choose as many of the following as apply: (please tick all that apply)

- 1=The AE resulted from defective equipment or supplies: _____
(GIVE DETAILS)
- 2=The AE resulted because equipment or supplies were not available: _____
(GIVE DETAILS)
- 3=There was inadequate reporting or communication: _____
(GIVE DETAILS)
- 4=There was inadequate training or supervision or doctors or other personnel: _____
(GIVE DETAILS)
- 5=There was a delay in the provision or scheduling of services (e.g. lab tests, xrays or follow up visits)
(GIVE DETAILS)

6=There was inadequate staffing:_____

(GIVE DETAILS)

7=There was inadequate functioning of hospital services (e.g. pharmacy,blood bank or housekeeping)

(GIVE DETAILS)

8=No protocol/policy or failure to implement protocol or plan:_____

(GIVE DETAILS)

21b Please describe any other contributing factors below

21c Was the patient receiving limited care as defined by Do Not Resuscitate status?

YES NO

21d Was the patient involved in an experimental protocol? YES NO

SECTION G – PREVENTABILITY

22. Rate on a 6 point scale the strength of evidence for preventability.

- 1= Virtually no evidence for preventability
- 2= Slight to modest evidence for preventability.
- 3=Preventability not quite likely; less than 50-50 but close call.
- 4= Preventability more likely than not; more than 50-50 but close call
- 5= Strong evidence for preventability.
- 6= Virtually certain evidence for preventability.

23. Describe briefly the manner in which the AE could have been prevented.

24. In the final analysis, was this an error of commission or omission?

1= Commission
2= Omission

25. Which areas should have efforts directed to avoid recurrence?
(you may choose more than one)

- 1= communication
 - 2= education
 - 3= record keeping
 - 4= more nursing staff
 - 5= more clerical staff
 - 6= protocol/treatment guidelines
 - 7= resources
 - 8= other _____
- | |
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