

## A TWO-STEP APPROACH TO IDENTIFYING INPATIENT ADVERSE EVENTS

### TOOL II – ADVERSE EVENT ASSESSMENT TOOL

- Include all potential injuries or complications noted in Tool IA/B.
- Complete one form for each identified potential injury or complication.
- If the patient has more than one, use as many of these forms and fill Q.4 and 5 accordingly.
- Answer *all* questions, unless otherwise indicated.

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Q.1 Case Number (same as in screening tool) : \_\_\_\_\_

Q.2 Reviewer ID : \_\_\_\_\_

Q.3 Date of data collection (*dd/mm/yyyy*) : \_\_\_\_\_

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Q.4 Form No \_\_\_\_\_ out of a total of \_\_\_\_\_ potential injury or complications noted on the last page of the screening tool of the corresponding Case Number.

Q.5 Briefly describe the adverse event (AE).

Q.6 Did the patient experience any unintended injury or complication?

**(1 = Yes, 2 = No)**

***(The questionnaire is complete if the answer is 'No')***

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Q.6.1 When did this event occur? (*DD/MM/YY*) \_\_\_\_\_

Q.7 Adverse event – Briefly state the '*what, who, when, where, how*'. Give any relevant laboratory/imaging results. Continue at the end of the tool if needed.

7.1 What? \_\_\_\_\_

7.2 Who? \_\_\_\_\_

7.3 When? \_\_\_\_\_

7.4 Where? \_\_\_\_\_

- 7.5 How? \_\_\_\_\_
- 7.6 Other info \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

### **ADVERSE EVENT DETERMINATION**

#### **SEVERITY** (1 = Yes, 2 = No)

- Q.8 Did the injury or complication cause the hospitalization?
- Q.9 Was the injury or complication associated with death of the patient?
- Q.10 Was the injury or complication associated with disability/deficit at the time of discharge? (*Physical or mental disability, or increased financial cost to the patient for treatment during or after admission*)
- Q.11 Was the injury or complication associated with prolonged hospital stay?

\_\_\_\_\_ **(The questionnaire is complete if the answer to all four items is 'No')** \_\_\_\_\_

#### **CAUSATION**

In your best judgement, is there evidence that healthcare management caused the adverse event? In answering this question, consider, when relevant, the following questions and complete the appropriate boxes.

- Q.12 Could the event be expected, given the disease or the health status of the patient? (1 = Yes, 2 = No, 3 = Don't know)
- Q.13 Are there indications that health care management caused the injury? (1 = Yes, 2 = No, 3 = Don't know)
- Q.14 Does the timing of events suggest that the injury was related to the treatment or lack of treatment? (1 = Yes, 2 = No, 3 = Don't know)
- Q.15 Are there other reasonable explanations for the event? (1 = Yes, 2 = No, 3 = Don't know)
- Q.16 Was there an opportunity prior to the occurrence of the injury for intervention which might have prevented it? (1 = Yes, 2 = No, 3 = Don't know)

Q.17 Was the unintended injury or complication recognized during this admission?

(1 = Yes, 2 = No)

Q.18.1 Was appropriate action taken? (1 = Yes, 2 = No, 3 = Not applicable)

Q.18.2 Did the unintended injury or complication respond to the appropriate action?

(1 = Yes, 2 = Probably, 3 = Too early to know, 4 = No, 5 = Don't know, 6 = Not applicable)

**Carefully consider questions 12 – 18.2 before continuing**

Q.19 After considering the clinical details of the patient's management, *irrespective of preventability*, what level of confidence do you have that *health care management* caused the injury?

1 = Virtually no evidence for management causation

2 = Slight to modest evidence for management causation

3 = Management causation not likely; less than 50-50

4 = Management causation more likely than not, more than 50-50

5 = Moderate/strong evidence for management causation

6 = Virtually certain evidence for management causation

**Confidence Score**

\_\_\_\_\_ **(The questionnaire is complete if your score is three or less)** \_\_\_\_\_

### **LOCATION OF OCCURRENCE**

Q.20 Where did the healthcare management causing the AE occur?

(1 = Outside this hospital 2 = Inside this hospital)

(If you chose 1, proceed to Q.21 and then directly to Q.25. If you chose 2, proceed to Q.22)

Q.21 What type of hospital was it?

01 = Public hospital

02 = Private hospital

03 = Home with professional healthcare management

04 = Home without professional healthcare management

05 = Primary healthcare facility outside this hospital

06 = Other \_\_\_\_\_

Q.22 Specify the service line in which the AE occurred.

- |   |                               |
|---|-------------------------------|
| 1 = Heart, Lung and Vascular (SL-01)          | 6 = Mind and Brain (SL-07)    |
| 2 = Musculoskeletal & Sports Medicine (SL-03) | 7 = Oncology (SL-09)          |
| 3 = Pediatric Department (SL-04)              | 8 = Internal Medicine (SL-10) |
| 4 = Women's Health Care (SL-05)               | 9 = Eye and ENT (SL-11)       |
| 5 = Kidney and Bladder (SL-06)                | 10 = GI and Surgery (SL-12)   |

Q.23 Specify the clinical unit in which the AE occurred.

- |                              |                              |                            |
|------------------------------|------------------------------|----------------------------|
| 1.1 = Cardiology             | 5.2 = Fetomaternal Unit      | 10.1 = Internal Medicine   |
| 1.2 = Cardiothoracic Surgery | 5.3 = Urogynecology          | 10.2 = Infectious Diseases |
| 1.3 = Pulmonology            | 5.4 = Gynecological Oncology | 10.3 = Endocrinology       |
| 1.4 = Vascular Surgery       | 6.1 = Urology                | 10.4 = Critical Care       |
| 3.1 = Orthopedics            | 6.2 = Nephrology             | 11.1 = Ophthalmology       |
| 3.2 = Rheumatology           | 7.1 = Neurosurgery           | 11.2 = Otorhinolaryngology |
| 4.1 = Pediatric Medicine     | 7.2 = Neurology              | 12.1 = General Surgery     |
| 4.2 = Pediatric Surgery      | 7.3 = Neurophysiology        | 12.2 = Plastic Surgery     |
| 4.3 = Pediatric ICU          | 7.4 = Psychiatry             | 12.3 = Breast Surgery      |
| 4.4 = Neonatal ICU           | 9.1 = Medical Oncology       | 12.4 = Trauma Surgery      |
| 4.5 = Neonatology            | 9.2 = Radiation Oncology     | 12.5 = Gastroenterology    |
| 5.1 = Obs & Gyn              | 9.3 = Clinical Hematology    |                            |

Q.24 Specify the exact clinical area where the AE occurred.

- |  |   |
|--|---|
| 01 = Operating Room                    | 08 = Labor and Delivery                     |
| 02 = Recovery Room                     | 09 = Radiology                              |
| 03 = ICU/CCU/SCU                       | 10 = Emergency Department                   |
| 04 = Catheterization/Endoscopy unit    | 11 = Service area (stairs, halls, elevator) |
| 05 = Consultation, out-patients clinic | 12 = Other site in hospital                 |
| 06 = Physiotherapy/Rehabilitation      | 13 = Don't know                             |
| 07 = Patient's room                    |   |

### **CLASSIFICATION OF ADVERSE EVENT**

Q.25 What type of care management was the AE mainly related to?

**(1 = Prevention or prophylaxis, 2 = Diagnosis, 3 = Therapeutic, 4 = Rehabilitation)**

Q.26 What was the main cause of AE (the *most important* one).

1 = Error in the choice of management

2 = Delayed or no implementation (especially due to financial unaffordability)

3 = Error during its implementation

4 = Other (mainly unavoidable events)

5 = Don't know

Q.27 Was the AE related to a procedure? **(1 = Yes 2 = No)**

(If no, proceed to Q.28)

Q.27.1 If yes, which procedure?

1 = Surgery

9 = Urinary catheter

2 = Anesthesia management

10 = Gastric

3 = Surgical intervention during radiology

11 = Intubation

4 = Radiology using contrast product

12 = Dialysis

5 = Endoscopy

13 = Radiotherapy

6 = Biopsy

14 = Instrument assisted delivery

7 = Puncture or tapping

15 = Physiotherapy

8 = Catheter, perfusion, or injection

16 = Other \_\_\_\_\_

Q.28 Was the AE related to a substance or health product? **(1 = Yes, 2 = No)**

(If no, proceed to Q.29)

Q.28.1 If yes, which product?

1 = Drug

2 = Blood product

3 = Medical device

4 = Equipment (laser, diathermy)

5 = Dietetic product

6 = Local preparation (e.g., chemotherapy product)

7 = Other \_\_\_\_\_

**PATIENT-RELATED CONTRIBUTING FACTORS** **(1 = Yes, 2 = No)**

Q.29 Patient's global health status and disease

Q.30 Patient's behavior

Q.31 Patient unable to afford correct recommended care

Q.32 Family's behavior

Q.33 Other \_\_\_\_\_

**SYSTEM-RELATED CONTRIBUTING FACTORS** (1 = Yes, 2 = No)

Q.34 Inadequate or defective premises

Q.35 Equipment or supplies not available or defective

Q.36 Inadequate staffing at the time of the AE (not merely in terms of numbers; take account of balance among different competences and experience, at weekend and during holidays)

Q.37 Inadequate reporting or communication

Q.38 Delay in the provision or scheduling of services (lab tests, x-rays, follow-up visits, etc.)

Q.39 Failure to implement protocol or plan

Q.40 Inadequate monitoring of patient

Q.41 Inadequate discharge procedure

Q.42 Other \_\_\_\_\_

Q.43 Describe the most important factor contributing to the adverse event.

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**PREVENTABILITY**

Consider and evaluate the following questions before making a judgement on preventability.

Q.44 How serious was the clinical condition *prior* to the occurrence of the AE?  
**1 = Very serious**                      **2 = Moderately serious**   
**3 = Not very serious**                **4 = Not serious**

Q.45 How complex was the clinical condition (co-morbidity, global health status)?  
**1 = Very complex**                      **2 = Moderately complex**   
**3 = Not very complex**                **4 = Uncomplicated**

Q.46 What was the degree of emergency in the management of the case prior to the occurrence of the adverse event?  
**1 = Critical and very urgent**        **2 = Moderate**   
**3 = Low**                                      **4 = Not urgent**

Q.47 Was the choice of actual management of the disease appropriate?

**1 = Definitely****2 = Likely****3 = Unlikely****4 = Inappropriate****5 = Don't know***(If you answer with 3, 4 or 5, go to Q.49)*

Q.48 If the choice was appropriate, was there a deviation in the implementation of the intended management?

**1 = None****2 = Slight deviation****3 = Moderate deviation****4 = Marked deviation****5 = Don't know**

Q.49 What was the chance of benefit associated with the actual management of the disease which led to the AE?

**1 = High****2 = Moderate****3 = Low****4 = Absent**

Q.50 What was the risk associated with the actual management of the disease which led to the AE?

**1 = Virtually absent****2 = Low****3 = Moderate****4 = High**

Q.51 Upon reflection, would a reasonable doctor or health professional have managed the care in a similar manner?

**1 = Definitely would****2 = Probably would****3 = Probably would not****4 = Definitely would not**

**Consider questions 44 – 51 above before continuing**

Q.52 Rate your confidence on the evidence for preventability on the following 6-point scale:

1 = Virtually no evidence for preventability

2 = Slight to modest evidence for preventability

3 = Preventability not really likely; less than 50-50

4 = Preventability more likely than not; more than 50-50

5 = Strong evidence for preventability

6 = Virtually certain evidence for preventability

**Confidence Score**

Q.53 Please describe a way in which the adverse event may have been prevented.

Q.54 Was an increased length of hospital stay caused by the adverse event?

**(1 = Yes, 2 = No)**

Q.54.1 If yes, how many days were added due to the adverse event? \_\_\_\_\_

Q.55 Were any procedures or treatments added as a result of the AE?

**(1 = Yes, 2 = No)**

Q.55.1 If yes, please write the relevant procedure codes \_\_\_\_\_