

Appendix 1: Modular Review Form: Dr Assessment of Harm from the Harvard Method

CONFIDENTIAL

MODULAR REVIEW FORM (MRF2)

for

Retrospective Case Record Review

Directions:

1. Complete stage A in full
2. Complete stage B in full
3. Complete the relevant subsection(s) in Stage C (as identified in A7)
4. Complete the relevant subsection(s) in Stage D (as identified in Stage C)
5. Complete stage E in full
6. "AE" means adverse event
7. Please print or write responses or notes legibly
8. Please return this form to the team leader on completion
9. A manual is available with definitions

Stage A: PATIENT INFORMATION AND BACKGROUND TO ADVERSE EVENT**A1 REVIEWER INFORMATION**
 Reviewer ID Number:
 Case Number:

 Date of Review:
d d m m y y
 Time Commenced Review:
 Time Review Finished:
(use 24 hour clock)
A2 PATIENT INFORMATION
 Patient's age: Sex: M/F Pregnancy: Yes/No
 Date of Admission:
 Date of Discharge:
 or Date of Death d d m m y y
 Degree of emergency at time of admission
 1 Critical (life at risk) 3 Semi-urgent
 2 Urgent (emergency) 4 Routine (non-urgent / waiting list)
A3 NATURE OF ILLNESS**Primary diagnosis**
Prognosis from the primary illness? To answer tick relevant **Yes** or **No** responses to **3A**, **3B** and **3C**
3A Complete recovery back to patient's normal health **Yes** **No**
 If **yes**, then complete recovery is:
 1 Probable
 2 More likely than not
 3 Possible (20-50% chance)
 4 Unlikely

3B Recovery with residual disability **Yes** **No**
 If **yes**, then recovery is:
 1 Non-progressive
 2 Slowly progressive
 3 Rapidly progressive

3C Terminal illness **Yes** **No**
 If **yes**, the prognosis is:
 1 Likely to die this admission
 2 Likely to die within 3 month
 3 Expected to survive >3 month
A4 CO-MORBIDITIES
 Please tick all of the following co-morbidities that apply to this patient *or*
 No co-morbidities
 Not known
Cardio-vascular

-
- Coronary artery disease
-
-
- Peripheral vascular disease
-
-
- Cardiac insufficiency or dysrhythmia
-
-
- Hypertension

Respiratory

-
- Asthma
-
-
- COPD (chronic obstructive pulmonary disease)
-
-
- Other serious lung problem (e.g.
- severe tuberculous scarring, pneumonectomy*
-) (specify) _____

Gastro-intestinal

-
- Chronic or recurrent dyspepsia
-
-
- Inflammatory bowel disease Crohn's / colitis
-
-
- Chronic liver disorder

Endocrine

-
- Diabetes
-
-
- Endocrine disorder (e.g.
- thyroid, adrenal*
-) (specify) _____

Neurological

-
- Epilepsy
-
-
- Stroke
-
-
- Parkinson's
-
-
- Dementia
-
-
- Other serious neurological disorders (e.g.
- MS, MND*
-) (specify) _____

Renal

-
- Chronic renal disease

Haematological

-
- Anaemia
-
-
- Leukaemia
-
-
- Lymphoma
-
-
- Other (specify) _____

Existing cancer

-
- Specify _____

Bone/joint disorders

-
- Osteoporosis
-
-
- Severe rheumatoid arthritis
-
-
- Severe osteoarthritis

Disability

-
- Wheel chair bound
-
-
- Blind
-
-
- Deaf
-
-
- Learning difficulty
-
-
- Other (specify) _____

Psychiatric

-
- Schizophrenia
-
-
- Affective disorder
-
-
- Other (specify) _____

Psychosocial

-
- Alcoholism
-
-
- Drug abuse
-
-
- Smoker
-
-
- Homeless
-
-
- Other (specify) _____

Infection

-
- AIDS
-
-
- Chronic infection (e.g.
- Hep C, MRSA*
-) (specify) _____

Trauma

-
- Multiple Traumas (e.g.
- RTA*
-)

Nutritional status

-
- Obese
-
-
- Cachectic
-
-
- Other (specify) _____

Other co-morbidity

-
- Specify _____

Allergies

-
- Specify _____

A5 SPECIALTY CARING FOR PATIENT

Indicate with a tick (✓) under which specialty the patient was admitted.

Indicate with a cross (✗) which specialty was responsible for the patient when the AE occurred.

GENERAL 0 uncertain 1 Accident & Emergency (A&E) 2 General Intensive Care

S U R G E R Y	<input type="checkbox"/> 3 Anaesthesiology	<input type="checkbox"/> 9 Obstetrics	<input type="checkbox"/> 15 Urological Surgery
	<input type="checkbox"/> 4 Cardiac Surgery	<input type="checkbox"/> 10 Orthopaedic Surgery	<input type="checkbox"/> 16 ENT Surgery
	<input type="checkbox"/> 5 Colon/Rectal Surgery	<input type="checkbox"/> 11 Paediatric Surgery	<input type="checkbox"/> 17 Eye Surgery
	<input type="checkbox"/> 6 General Surgery	<input type="checkbox"/> 12 Plastic Surgery	<input type="checkbox"/> 18 Other (specify) _____
	<input type="checkbox"/> 7 Gynaecology	<input type="checkbox"/> 13 Thoracic Surgery	_____
	<input type="checkbox"/> 8 Neurosurgery	<input type="checkbox"/> 14 Vascular Surgery	_____

M E D I C I N E	<input type="checkbox"/> 19 Cardiology (incl. CCU)	<input type="checkbox"/> 28 Internal Medicine (not otherwise classified)	<input type="checkbox"/> 36 Physical Medicine
	<input type="checkbox"/> 20 Dermatology	<input type="checkbox"/> 29 Medical Oncology	<input type="checkbox"/> 37 Psychiatry
	<input type="checkbox"/> 21 Endocrinology	<input type="checkbox"/> 30 Medical Ophthalmology	<input type="checkbox"/> 38 Pulmonary Disease
	<input type="checkbox"/> 22 Family Practice	<input type="checkbox"/> 31 Neonatology	<input type="checkbox"/> 39 Radiation Therapy
	<input type="checkbox"/> 23 Gastroenterology	<input type="checkbox"/> 32 Nephrology	<input type="checkbox"/> 40 Radiology
	<input type="checkbox"/> 24 Geriatrics (care of the elderly)	<input type="checkbox"/> 33 Neurology	<input type="checkbox"/> 41 Rehabilitation Unit
	<input type="checkbox"/> 25 Haematology	<input type="checkbox"/> 34 Pathology	<input type="checkbox"/> 42 Rheumatology
	<input type="checkbox"/> 26 Immunology and Allergy	<input type="checkbox"/> 35 Paediatrics	<input type="checkbox"/> 43 Other (specify) _____
	<input type="checkbox"/> 27 Infectious Disease		_____

O T H E R	<input type="checkbox"/> 44 Dentistry/Oral Surgery	<input type="checkbox"/> 48 Nursing	<input type="checkbox"/> 52 Podiatry
	<input type="checkbox"/> 45 Dietary	<input type="checkbox"/> 49 Osteopathy	<input type="checkbox"/> 53 Support Services (e.g. transportation)
	<input type="checkbox"/> 46 Hospital Physical Plant	<input type="checkbox"/> 50 Pharmacy	<input type="checkbox"/> 54 Other (specify) _____
	<input type="checkbox"/> 47 Midwifery	<input type="checkbox"/> 51 Physical or Occupational Therapy	_____

A6 IDENTIFYING MAIN FEATURES OF THE ADVERSE EVENT

An adverse event has to fulfil all **three** criteria:

- a) an **unintended injury or complication**,
- b) **temporary or permanent disability and/or increased length of stay or death**
- c) **caused by health care management**

a) INJURY or COMPLICATION Was there a patient injury or complication? Yes No

b) DISABILITY / EXTENDED STAY Did the injury or complication result in disability at the time of discharge and/or a prolonged hospital stay (or re-admission or out-patient treatment) or death?

- | | | |
|--|------------------------------|-----------------------------|
| 1 Disability at discharge | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2 Prolonged/subsequent stay or treatment | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3 Death | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

c) CAUSE OF INJURY OR COMPLICATION

This question relates to circumstances that led to the injury such as a procedure or treatment that caused the injury or whether there was some omission in management or ordinary standard of care. One way to help understand this question is to consider whether the injury or complication would have occurred if the procedure had not been carried out. For example where a patient suffered a wound infection following surgery there is strong evidence that healthcare management is responsible (the wound infection would not have occurred without the surgery). Where the patient may have been predisposed to wound infections then the confidence score for will be reduced.

Was the patient's injury/complication caused by

- | |
|--|
| <input type="checkbox"/> 1 health care management |
| <input type="checkbox"/> 2 health care management interacting with disease process |
| <input type="checkbox"/> 3 solely by disease process |

A6 (cont.)

After consideration of the clinical details of the patient's management, *irrespective of preventability*, what **level of confidence do you have that the HEALTH CARE MANAGEMENT caused the injury?**

- 1 Virtually no evidence for management causation/system failure.
Injury entirely due to patient's pathology (no AE: then STOP)
- 2 Slight to modest evidence for management causation
- 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

If more than one AE is identified, please see instructions in the manual

A7 ADVERSE EVENT SUMMARY

Date of adverse event

--	--	--	--	--	--

d d m m y y

Describe AE in context of overall illness

Give details of the pre-admission assessment / waiting period relevant to AE _____

Give details of contributory events leading up to the AE _____

Give details of any key action/inaction that played a significant part in the causation of the AE _____

Give details of the injury or complication caused by the AE _____

Give any other details relevant to the AE (e.g. time of event if known) _____

With this clinical scenario indicate, if possible, how often this sort of injury or complication may occur?

- 1 very rarely (<1%) 3 occasionally (10-24%)
- 2 rarely (1-9%) 4 frequently (> 25%)

Describe the principal problem in the patient's care that led to the AE (e.g. was it a diagnostic error, technical mishap, failure to monitor, etc.) _____

Stage B: THE INJURY AND ITS EFFECTS

B1 DISABILITY CAUSED BY ADVERSE EVENT

Describe the impact of the adverse event on the patient (e.g. increased pain and suffering for x days; delayed recovery from primary illness; patient not given adequate care and support; contributed to or caused death)

Please use your judgement to assess the degree of disability (tick the relevant number)
Physical impairment

- 0 No physical impairment or disability (still an AE if hospital stay was prolonged)
- 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 (specify what was the contribution of AE to the death)
 - 8.1 Death unrelated to AE
 - 8.2 Minimal contribution from AE
 - 8.3 Moderate contribution from AE
 - 8.4 Death entirely due to AE
- 9 Cannot reasonably judge

Emotional trauma

- 0 No emotional trauma
- 1 Minimal emotional trauma and/or recovery in one month
- 2 Moderate trauma, recovery in one to six months
- 3 Moderate trauma, recovery in six months to a year
- 4 Severe trauma effects lasting longer than a year
- 5 Cannot reasonably judge

B2 THE EFFECT OF THE ADVERSE EVENT ON HOSPITAL RESOURCES

Was a portion of, or the entire hospitalisation, due to the AE (including transfer to another hospital where known)

- 1 No increase in hospital days
- 2 Portion of hospital stay
- 3 Re-admission (entire subsequent hospital stay)

Estimate how many additional days, or partial days, were spent in hospital because of the AE?

_____ days (*)

Estimate the total number of days attributable to the AE.

Indicate which specialty and number of days, or partial days, per specialty attributable to the AE.

Medical specialty (specify) _____ No. of extra bed days per specialty _____
Surgical specialty (specify) _____
ICU/CCU/HDU* (specify) _____
Other (specify) _____

* Intensive Care Unit / Coronary Care Unit /
High Dependency Unit

Total number of extra days attributable to the AE _____

This should match the previous question above (*)

B3 ADDITIONAL TREATMENT AS A RESULT OF THE AE

What additional *procedures* (medical or surgical procedures, including any unnecessary investigations) were performed as a result of the AE?

What additional *medications* (including intravenous fluids and blood transfusion) were administered as a result of the AE?

What additional *treatment* (e.g. physiotherapy, counselling) was given as a result of the AE?

Stage C: PERIOD OF HOSPITALISATION DURING WHICH ADVERSE EVENT OCCURRED

Complete: Section(s) relevant to the adverse event (see A7) AND Section C6

C1 ADVERSE EVENT RELATED TO CARE ON ADMISSION WARD (Including PRE-OP ASSESSMENT)

When did the principal problem occur?

- 1. in A&E (accident & emergency department) before admission to the ward
- 2. during the initial ward assessment (up to first working diagnosis and initial treatment)
- 3. during the pre-operative assessment

Who was responsible for the initial care?

in A&E

- 1. Casualty officer unsupervised
- 2. Casualty officer supervised
- 3. A&E registrar
- 4. A&E consultant
- 5. Other (specify) _____

On the ward

- 1. Ward doctor (house officer) apparently unsupervised
- 2. Ward doctor supervised
- 3. SHO (senior house officer)
- 4. Registrar
- 5. Consultant
- 6. Other (Specify, e.g. anaesthetist for pre-op assessment) _____

For patients requiring surgery, who was responsible for the pre-op assessment?

- 1. As for initial assessment on the ward
- 2. Anaesthetist
- 3. Assistant anaesthetist
- 4. Other (specify) _____

What was the nature of the principal problem in this phase of care (indicate as many as apply)

In A & E or On Ward

- 1 Failure to diagnose primary condition correctly → D1
- 2 Overall assessment → D2
(e.g. Failure to perform a satisfactory assessment of patient's overall condition including appropriate tests; No evidence of focussed assessment such as of cardio-respiratory system)
- 3 Management/monitoring incl. Nursing/Ancillary care → D3
(e.g. Failure to act upon results of tests or findings; Failure to set up adequate monitoring; Failure to provide prophylactic care (e.g. physiotherapy); Failure to provide high-dependency/ ITU care)
- 4 Infection-related → D4
- 5 Technical problem related to a procedure → D5
(including inappropriate/unnecessary procedures, e.g. urinary catheterisation)
- 6 Failure to give correct medication/maintain correct hydration / electrolytes / blood → D6
(including failure to provide prophylactic medication e.g. anti-coagulants/antibiotics)
- 7 Resuscitation → D7
- 8 Other (e.g. falls; specify) _____

Were there any other problems during this period/section of care not covered by the above?

Yes No

If so, specify _____

C2 PROCEDURE RELATED PRINCIPAL PROBLEM (including surgical operations, anaesthesia, manipulation of fractures, invasive medical/endoscopic/radiological procedures)

To which procedure was the AE related?

- | | |
|--|--|
| <input type="checkbox"/> 1 Administration of anaesthetic
(specify type; e.g. inhalation, local, epidural) | <input type="checkbox"/> 9 Gaining IV access |
| <input type="checkbox"/> 2 Surgical operation | <input type="checkbox"/> 10 Setting up CVP line |
| <input type="checkbox"/> 3 Manipulation of fracture | <input type="checkbox"/> 11 Catheterising bladder |
| <input type="checkbox"/> 4 Endoscopic procedure | <input type="checkbox"/> 12 Draining fluid from body cavity |
| <input type="checkbox"/> 5 Needle biopsy | <input type="checkbox"/> 13 Thoracic drain for pneumothorax |
| <input type="checkbox"/> 6 Vascular catheterisation | <input type="checkbox"/> 14 Lumbar puncture |
| <input type="checkbox"/> 7 Interventional radiology | <input type="checkbox"/> 15 Administering drugs other than orally |
| <input type="checkbox"/> 8 Other specialist procedure (specify) | <input type="checkbox"/> 16 Siting a naso-gastric (or naso-enteric) tube |
| | <input type="checkbox"/> 17 Other ward-based procedure (specify) |

When was the procedure (or the administration of anaesthesia) carried out?

Date _____ Time of start _____

Time of finish _____

Specify patient's medical condition that required the procedure if different from the primary diagnosis indicated in A3

Was the procedure

- | | |
|---|--------------------------------------|
| <input type="checkbox"/> 1 Emergency | <input type="checkbox"/> 3 Elective |
| <input type="checkbox"/> 2 Semi-emergency | <input type="checkbox"/> 4 Not clear |

Who undertook the procedure or anaesthesia?

- | | |
|---|--|
| <input type="checkbox"/> 1. Consultant or fully trained operator <i>with</i> assistant | |
| <input type="checkbox"/> 2. Consultant or fully trained operator <i>without</i> assistant | |
| <input type="checkbox"/> 3. Supervised trainee | |
| <input type="checkbox"/> 4. Unsupervised trainee | |
| <input type="checkbox"/> 5. Other (specify) _____ | |
| <input type="checkbox"/> 6. Not clear | |

What was the nature of the principal problem underlying the AE

- | | |
|--|------|
| <input type="checkbox"/> 1 Diagnosis | → D1 |
| <input type="checkbox"/> 2 Overall assessment (incl. Pre-op assessment) | → D2 |
| <input type="checkbox"/> 3 Management/monitoring (incl. Nursing/Ancillary care) | → D3 |
| <input type="checkbox"/> 4 Infection-related related to a procedure | → D4 |
| <input type="checkbox"/> 5 Technical problem related to a procedure
(e.g. Intubation; Equipment failure; Monitoring during procedure) | → D5 |
| <input type="checkbox"/> 6 Drugs/ Fluids (incl. anaesthetic agent) / Blood | → D6 |
| <input type="checkbox"/> 7 Resuscitation | → D7 |
| <input type="checkbox"/> 8 Other (specify) _____ | |

Were there any other problems during this period/section of care not covered by the above?

Yes No

If so, specify _____

C3 PRINCIPAL PROBLEM DURING IMMEDIATE POST-PROCEDURAL CARE, HIGH DEPENDENCY CARE or ITU CARE

When did the principal problem occur?

- 1. during the immediate post-procedural care (i.e. whilst in the recovery area)
- 2. during high dependency care
- 3. during care in the intensive care unit

Who was responsible for post-procedural, HDU or ITU care?

- 1 Doctor who carried out procedure
- 2 HDU or ITU Team
- 3 Assistant (specify) _____
- 4 Specific doctor (specify) _____
- 5 Anaesthetist
- 6 Ward doctor
- 7 Other (specify) _____
- 8 Not clear

What is the nature of the principal problem?

- 1 Diagnosis → D1
- 2 Overall assessment → D2
- 3 Management/monitoring (incl. Nursing/Ancillary care) → D3
(e.g. Failure to monitor adequately; Failure to treat appropriately;
Failure to ensure condition stable before handover)
- 4 Infection-related → D4
- 5 Technical problem related to a procedure → D5
- 6 Drugs (including anaesthetic agent) / Fluids / Blood → D6
- 7 Resuscitation → D7
- 8 Other (specify) _____

Were there any other problems during this period/section of care not covered by the above?

Yes No

If so, specify _____

C4 PRINCIPAL PROBLEM RELATED TO WARD CARE (Including errors in clinical management)

If the principal problem was in ward care, was it due to (Tick all that apply)

- 1 a failure in medical care (i.e. care by ward doctors)
- 2 a failure in nursing care
- 3 a failure in care from professions allied to medicine:
 - 3.1 Physiotherapy
 - 3.2 Dietician/nutritionist
 - 3.3 Pharmacist
 - 3.4 Chiropody
 - 3.5 Social worker
 - 3.6 Other (specify) _____

Describe the principal problem: _____

Who was responsible for the episode of ward care related to the principal problem?

- 1 Ward doctor (house officer or SHO status) who 'knew' the patient
- 2 Ward doctor *unlikely* to 'know' patient
- 3 Ward doctors under guidance of specialist registrar
- 4 Trained specialists (specialist registrar/consultant)
- 5 Senior nurse
- 6 Junior nurse
- 7 Agency nurse
- 8 Other allied professional (specify) _____
- 9 Other (specify) _____
- 10 Cannot determine from record

What was the nature of the principal problem? (tick the appropriate number(s))

- 1 Diagnosis → D1
- 2 Overall assessment → D2
- 3 Medical management/monitoring (incl. Nursing/Ancillary care) → D3
- 4 Infection-related → D4
- 5 Technical problem related to a procedure → D5
- 6 Drugs/ Fluids / Blood → D6
- 7 Resuscitation after collapse → D7
- 8 Other (specify) _____

Were there any other problems during this period/section of care not covered by the above?

Yes No

If so, specify _____

C5 FAILURE TO ASSESS ADEQUATELY AT THE TIME OF DISCHARGE

Which doctor was directly responsible for assessing the patient before discharge?

- 1. House-officer
- 2. Registrar
- 3. Consultant
- 4. Other (specify) _____

What is the nature of the principal problem?

- 1 Diagnosis → D1
- 2 Overall assessment → D2
- 3 Medical Management/monitoring/ Nursing care → D3
(e.g. Clinical condition not under good control; Patient not well enough to be discharged, e.g. mobilised; Failure to teach patient about their condition; Failure to communicate adequately with services in community care, including GP)
- 4 Infection-related → D4
- 5 Technical problem related to a procedure → D5
- 6 Drug problem/ Fluids (e.g. Medications not appropriate) / Blood → D6
- 7 Resuscitation → D7
- 8 Other (specify) _____

Were there any other problems during this period/section of care not covered by the above?

Yes No

If so, specify _____

C6 NATURE OF THE PRINCIPAL PROBLEM

From your responses to all sections completed above indicate which section(s) in D are to be completed

- D1
- D2
- D3
- D4
- D5
- D6
- D7

Stage D: PRINCIPAL PROBLEMS IN THE PROCESS OF CARE

Go to the relevant sections in Stage D as identified in Stage C (C6)

D1 ADVERSE EVENT RELATED TO DIAGNOSTIC OR ASSESSMENT ERROR

Was the adverse event the result of diagnostic error? Yes No

If yes, give details _____

Was the adverse event the result of a delay in diagnosis? Yes No

If yes, what was the length of delay? _____

Was the person responsible for the diagnostic assessment (at which there was unacceptable error or delay) of appropriate seniority or experience? Yes No

If no, explain _____

Factors contributing to the diagnostic error (tick as many as apply).

- 1 Failure to take an adequate history and/or to perform a satisfactory physical examination.
- 2 Failure **or delay** to employ indicated test.
- 3 Test was incorrectly performed
- 4 Test was incorrectly reported
- 5 Failure **or delay** to receive report
- 6 Failure **or delay** to act upon results of tests or findings.
- 7 Failure to draw sensible/reasonable conclusions or make a differential diagnosis
- 8 Failure **or delay** to get expert opinion from:
 - 8.1 more senior member of team
 - 8.2 specialist clinical team
 - 8.3 non-clinical specialist (e.g. radiologist) (specify) _____
- 9 Expert opinion incorrect
- 10 Other (specify) _____

Did other factors contribute to AE?

- 1 Led to inappropriate or inadequate treatment
- 2 Risk:benefit ratio of treatment was not assessed/appreciated
- 3 Patient's degree of vulnerability was not recognised
- 4 Other (specify) _____

Were there any other problems related to diagnostic assessment? Yes No

If yes, give details _____

D2 ADVERSE EVENT FROM FAILURE TO APPRECIATE PATIENT'S OVERALL CONDITION

Was the person responsible for the care of this patient of appropriate seniority or experience?

Yes No

If no, explain (e.g. lack of appropriate supervision) _____

In what respect was overall assessment inadequate?

- 1 Failure to take a full clinical history
- 2 Failure to examine carefully
- 3 Failure to take account of co-morbidity
- 4 Failure to monitor adequately
- 5 Failure to record
- 6 Failure to communicate to the rest of the team (clinical and multi-disciplinary)
- 7 Other (specify) _____

How did this contribute to AE?

- 1 Patient's degree of vulnerability was not recognised
- 2 Risk:benefit ratio of treatment was not assessed/appreciated
- 3 Led to inappropriate or inadequate treatment
- 4 Other (specify) _____

Were there any other problems related to assessment or management of the patient's overall condition?

Yes No

If yes, give details _____

D3 AE ARISING FROM A FAILURE IN CLINICAL MONITORING / MANAGEMENT
(incl. DISCHARGE ARRANGEMENTS, NURSING/ANCILLARY SERVICES)

Indicate if the patient was:

- 1 Post operative (including post-delivery, postmanipulation of fracture)
- 2 Undergoing medical (non-surgical) treatment
- 3 Undergoing rehabilitation
- 4 Other (specify) _____

Was the adverse event the result of problems in the monitoring / observation of this patient?

Yes No

If yes, give details _____

Was the adverse event the result of failure in overall management (acting on observations) of the patient?

Yes No

If yes, what was the problem in management? _____

Was the AE the result of failure to ensure condition stable before handover to other areas?

Yes No

If yes, give details _____

Was the person responsible for the care of this patient of appropriate seniority or experience?

Yes No

If no, explain _____

Was the inadequate monitoring/management related to failure to recognise:

- 1 Abnormal vital signs (including neurological status)
- 2 Problems with fluids/electrolytes including renal function
- 3 Side-effects of medication
- 4 Cardio-pulmonary dysfunction
- 5 Damage to skin and pressure areas
- 6 Adequate mobilisation
- 7 Infection
- 8 Poor progress in healing (e.g. checking gut function after abdominal operation; care of wounds/canular sites)
- 9 Changes to the patient's general condition (e.g. patient develops a medical condition, e.g. CHF)
- 10 Other (specify) _____

Continue overleaf

D3. (Cont.)

In what respects was clinical management unsatisfactory?

- 1 Failure to take note of 'routine' observations e.g. TPR charts, neurological assessment, fluid balance (check if charts completed)
- 2 Delay in noting lab/test results
- 3 Not aware of significance of lab/test results
- 4 Failure to act appropriately on lab/test results
- 5 Poor note-keeping
- 6 Inadequate handover
- 7 Lack of liaison with other staff
- 8 Inadequate 'out-of-hours' cover/working practice
- 9 Guideline/ protocol failure (either not available or not followed)
(specify) _____
- 10 Apparent failure to recognise deterioration
- 11 Deterioration recognised but additional care not provided (specify, e.g. was high dependency care indicated) _____
- 12 Failure to recruit help
 - 12.1 Medical
 - 12.2 Nursing
 - 12.3 Ancillary (specify) _____
- 13 Other (specify) _____

Was there a failure in discharge procedure?

Yes No

If yes, indicate which of the following apply to this patient regarding and give details

- 1 Failure to educate the patient including use of protocols (e.g. for asthma, diabetes, post MI)

- 2 Failure to show evidence that discharge status was appropriate to home conditions (e.g. careplan)

- 3 Failure to liaise adequately with community carers (e.g. GP, district nurse, social worker)

- 4 Other (specify)

What other factors interacted with failure in monitoring/management, handover or discharge to cause to the AE?

- 1 Condition not treated or not treated adequately
- 2 Patient's degree of vulnerability was not recognised
- 3 Risk:benefit ratio of treatment was not assessed/appreciated
- 4 Other (specify) _____

Were there any other problems related to monitoring/management including handover and discharge?

Yes No

If yes, give details _____

D4 ADVERSE EVENT IN RELATION TO FAILURE TO PREVENT/CONTROL/MANAGE INFECTION

What was the site of infection/infection related to?

- 1 Surgical wound
- 2 Internal invasive procedure
- 3 Urinary tract
- 4 Respiratory tract
- 5 Blood
- 6 Other (specify) _____

What was the nature of the infection?

- 1. Contaminated wound
- 2. Side-effect of drugs (specify type):
 - a. Antibiotic-induced C. difficile
 - b. yeast infection
 - c. Immuno-suppressive drugs
 - d. Other (specify) _____
- 3. Cross-infection (specify type):
 - a. MRSA (describe) _____
 - b. Salmonella
 - c. Other (specify) _____
- 4. Foreign body (specify type):
 - a. Urinary catheter
 - b. Venflon or intravenous catheter
 - c. Swab
 - d. Drainage tube
 - e. Shunt
 - f. Other (specify) _____
- 5. Stasis (specify type):
 - a. Respiratory depression
 - b. Urinary retention
 - c. Other (specify) _____
- 6. Other type of infection (specify) _____

Was the person responsible for the prevention/control/management of infection of appropriate seniority or experience?

Yes No

If no, explain _____

What were the errors in managing the AE due to infection? Give details.

- 1 Failure to drain pus or remove necrotic material _____
- 2 Failure to give appropriate antibiotics (including overuse) _____
- 3 Failure to give appropriate physiotherapy (e.g. chest) _____
- 4 Failure to maintain care of catheters/canulas/drains/wounds _____
- 5 Other (specify) _____

How did this contribute to AE?

- 1 Failure to minimise risk in a vulnerable patient
- 2 Risk:benefit ratio of treatment was not assessed/appreciated
- 3 Led to inappropriate treatment
- 4 Other (specify) _____

Continued overleaf

D4. (Cont.)

Were there any other problems related to the management of infection?

Yes **No**

If yes, give details _____

D5 ADVERSE EVENTS DIRECTLY RELATED TO A PROBLEM WITH AN OPERATION OR PROCEDURE

Was the procedure

- 1 ward-based
- 2 in operating theatre suite
- 3 elsewhere (e.g. radiology; specify) _____

Do you consider the procedure was performed by a person of appropriate seniority?

Yes No

If no, give reasons _____

Choose one of the following that best describes the nature of the adverse event (give details where possible)

1 Avoidable delay in undertaking procedure _____

2 Inappropriate procedure – specify alternative _____

3 Inadequate assessment/treatment/preparation before procedure (specify) _____

4 Anaesthetic incident

4.1 Intubation (specify) _____

4.2 Anaesthetic agent _____

4.3 Equipment failure _____

4.4 Monitoring during procedure (e.g. oxygenation, CO₂, airway pressure) _____

4.5 Other (specify) _____

5 Operation/procedure accident

5.1 Difficulty in defining anatomy (specify) _____

5.2 Inadvertent organ damage (specify) _____

5.3 Bleeding (specify, e.g. from slipped ligature; from vascular puncture) _____

5.4 Perforation. (specify nature) _____

5.5 Anastomotic breakdown (specify contributory factors) _____

5.6 Wound problem (e.g. dehiscence). (specify) _____

5.7 Siting prosthesis _____

5.8 Equipment failure (e.g. inappropriate use, misuse, failed; specify) _____

5.9 Other (specify) _____

6 Inadequate monitoring during procedure (specify) _____

7 Infection-related

7.1 Wound (including trip-related cellulitis) _____

7.2 Internal infection (e.g. abscess, specify) _____

7.3 Other (e.g. cholangitis, specify) _____

8 Other, including inefficacious result (specify) _____

Continue overleaf

D5. (Cont.)

Did other factors contribute to the procedure-related AE?

Yes **No**

If yes, specify

- 1 Patient's degree of vulnerability was not recognised
- 2 Risk:benefit ratio of treatment was not assessed/appreciated
- 3 Led to inappropriate or inadequate treatment
- 4 Other (specify) _____

Were there any other problems related to the management of a procedure?

Yes **No**

If yes, give details _____

How long was any *extended* operation time as a result of the AE? _____ minutes

How long was any *additional* operation time as a result of the AE? _____ minutes

D6 ADVERSE EVENT RELATED TO PRESCRIBING, ADMINISTRATION OR MONITORING OF DRUGS OR FLUIDS (including BLOOD)

How was the drug / fluid administered?

- | | | |
|---|--|--|
| <input type="checkbox"/> 1 Intravenous | <input type="checkbox"/> 4 orally | <input type="checkbox"/> 7 topical |
| <input type="checkbox"/> 2 Intra-muscular | <input type="checkbox"/> 5 sublingual | <input type="checkbox"/> 8 rectal |
| <input type="checkbox"/> 3 Subcutaneous | <input type="checkbox"/> 6 intrathecal | <input type="checkbox"/> 9 Other (specify) _____ |

Was there an error in the prescription/preparation of drugs/iv fluids/blood? Yes No

If so, specify _____

Was there an error or accident in administering drugs/iv fluids/blood?
(e.g. too high dose, incorrect site, haematoma)

Yes No

If so, specify _____

Was there a failure to monitor drug action/toxicity/fluid balance?

Yes No

If so, specify _____

What was the drug?

- | | | |
|---|--|--|
| <input type="checkbox"/> 1 antibiotic | <input type="checkbox"/> 7 sedative or hypnotic | <input type="checkbox"/> 13 potassium |
| <input type="checkbox"/> 2 antineoplastic | <input type="checkbox"/> 8 peptic ulcer medication | <input type="checkbox"/> 14 NSAID |
| <input type="checkbox"/> 3 anti-seizure | <input type="checkbox"/> 9 antihypertension | <input type="checkbox"/> 15 Narcotic (e.g. morphine/pethidine) |
| <input type="checkbox"/> 4 anti-diabetes | <input type="checkbox"/> 10 antidepressant | <input type="checkbox"/> 16 Diuretics |
| <input type="checkbox"/> 5 cardiovascular | <input type="checkbox"/> 11 antipsychotic | <input type="checkbox"/> 17 Other (specify) _____ |
| <input type="checkbox"/> 6 antiasthmatic | <input type="checkbox"/> 12 anticoagulant | _____ |

Name of drug: _____

Describe the drug's adverse effect: _____

What was the nature of the drug-related injury?

- 1 Drug less effective than expected (e.g. as result of delayed treatment; dose too little)
- 2 Side-effect of drug
- 3 Effect of high dose for this patient in this circumstance
- 4 Idiosyncratic (allergic) re-action
- 5 Drug-drug interaction
- 6 Other (specify) _____

Was the person responsible for managing the drug regimen for this patient of appropriate seniority or experience?

Yes No

If no, explain _____

Would a doctor using reasonable medical judgement prescribe the drug, even with knowledge beforehand that this adverse effect could occur?

Yes No

Continue overleaf

D6. (cont.)

What was the cause of the drug-related injury?

- 1 No underlying cause (other than patient's response)
- 2 Delay in prescribing (specify) _____
- 3 Delay in administering (after prescribing) _____
- 4 Wrong drug prescribed (specify) _____
- 5 Right drug but wrong dose or length of treatment _____
- 6 Right drug but wrong route (specify) _____
- 7 Error in administration (describe) _____
- 8 Inadequate monitoring (describe) _____
- 9 Other (specify) _____

Did other factors contribute to the drug-related AE?

- 1 Patient's degree of vulnerability was not recognised
- 2 Risk:benefit ratio of treatment was not assessed/appreciated
- 3 Led to inappropriate treatment
- 4 Other (specify) _____

Were there any other problems related to the management of fluids or blood?

Yes No

If so, specify _____

D7 ADVERSE EVENT ARISING FROM A RESUSCITATION PROCEDURE

What was the condition which led to the need for resuscitation?

- 1 Cardiac arrest (cause) _____
- 2 Respiratory failure/arrest (cause) _____
- 3 Coma (specify) _____
- 4 Fits
- 5 Bleeding (specify) _____
- 6 Multiple trauma
- 7 Metabolic disorder (e.g. hypoglycaemia) (specify) _____
- 8 Overwhelming infection (specify) _____
- 9 Other (specify) _____

Was the person responsible for the care of this patient during resuscitation of appropriate seniority or experience?

Yes No

If no, explain _____

Was there delay in dealing with the problem?

Yes No

If yes, what was the reason?

- 1 Staff not available
- 2 Staff not competent
- 3 Equipment not available
- 4 Lack of suitable or needed drugs
- 5 Lack of control (management)
- 6 Other (specify) _____

Was there confusion regarding correct action to take?

- 1 Inappropriate action
- 2 Failure to obtain appropriate tests/investigations
- 3 Other (specify) _____

How did this contribute to AE?

- 1 Patient's degree of vulnerability was not recognised
- 2 Risk:benefit ratio of treatment was not assessed/appreciated
- 3 Led to inappropriate treatment
- 4 Other (specify) _____

Were there any other problems related to the management of the patient during resuscitation?

Yes No

If yes, give details _____

Stage E: CAUSATIVE / CONTRIBUTORY FACTORS and PREVENTABILITY OF AE

E1 CAUSATIVE FACTORS

*The occurrence of an adverse event, and the actions or omissions of those involved, may be influenced by many contributory factors. Many of these could only be assessed satisfactorily by interviewing the staff involved in the care of the patient. Please indicate, where possible, likely causative factors. Mark unlikely factors with **U**, possible factors with **1, 2 or 3**.*

Please rate each of the following factors according to its importance, as you see it, in the occurrence of this particular adverse event.

	Unlikely to be relevant U	Possibly relevant 1	Somewhat important 2	Very important 3
	U	1	2	3
1. Patient characteristics	U	1	2	3
1.1 Patient was not able to understand/communicate with clinical/nursing team (e.g. deaf, stroke, language difficulties in absence of interpreter or cultural differences)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.2 Personality or social factors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.3 Was co-morbidity an important contributory factor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.4 Other patient characteristics (specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Task factors	U	1	2	3
2.1 New, untested or difficult task or procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Evidence of lack of guidelines/protocols or their use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.3 Test results unavailable, difficult to interpret or inaccurate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4 Poor task design/structure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.5 Other task factors (specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Individual factors	U	1	2	3
3.1 Staff working outside their expertise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Lack of knowledge of individuals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.3 Lack of skill of individuals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.4 Attitude/motivation problem	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.5 Long shift/under pressure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.6 Other individual staff factors (specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Team factors	U	1	2	3
4.1 Poor teamwork	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Inadequate supervision	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.3 Poor verbal communication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.4 Inadequate handover	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.5 Poor written communication (e.g. defects in notes)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.6 Other team factors (specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Work environment	U	1	2	3
5.1 Defective or unavailable equipment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Problems with provision or scheduling of services (e.g. theatre list, lab tests, x-rays)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.3 Inadequate functioning of hospital support services (e.g. pharmacy, blood bank or housekeeping)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.4 Inadequate staffing at the time of the AE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.5 Out of hours (time of day/day of week) factors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.6 Other work environmental factors (specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Organisational/Management factors	U	1	2	3
6.1 Lack of essential resources (e.g. ITU beds)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2 Poor co-ordination of overall services	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.3 Inadequate senior leadership	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.4 Other organisational/management factors (specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

E2 Give details on the 3 MOST IMPORTANT contributory factors to this AE

1. _____

2. _____

3. _____

E3 ASSESS THE PREVENTABILITY OF THE ADVERSE EVENT

In your judgement, is there some evidence that the AE was preventable? Yes No

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

If you ticked 2 - 6, answer the following questions:

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

Can you identify any reason(s) for the failure to prevent this AE _____

E4 EXPERTISE OF REVIEWER

Was the reviewer's judgements limited or hampered by lack of subspecialty knowledge?

Yes No

Mark **Yes** if you think a specialist's review is necessary and indicate which specialty or discipline (e.g. pharmacy) listing as many as necessary:

Describe the judgement which is limited or hampered by lack of subspecialty knowledge and the clinical question you would pose to a specialist _____

Describe the resolution of the question(s) posed following consultation with a specialist _____

Specialist's ID number: