ORIGINAL ARTICLE

Case record review of adverse events: a new approach

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Objectives: To redesign the existing clinical review form (RF2) used in previous retrospective case record review studies in order to clarify the review process and provide a more powerful analysis of adverse events; and then to ask clinicians to pilot and evaluate the new modular review form (MRF2). The review form is divided into five sections, each with a defined purpose, providing a modular structure.
Design: Design and testing of the MRF2 on a sample of medical and nursing records, and evaluation of the reviewers' responses regarding the new review form.
Setting: Hospital based teams from eight countries.
Results: The modular review form was reported to be comprehensive, well structured, and clear. Most of the reviewers agreed with the positive statements regarding the review form. Overall, the modular structure was thought to be helpful. Several modifications have been made to the final version to take account of criticisms and suggestions.
Conclusions: The full potential of case record review has yet to be explored. The benefits of this review form include a modular format which enables reviewers or project leaders to select the focus of their review based on resources and the purpose of the review, and to identify contributory factors which indicate areas for improvement and prevention. The training of reviewers is of vital importance for record review. Record review remains one of the primary methods for assessing the incidence of adverse events and the new format is suitable for both prospective and retrospective review.

The use of case record review to identify adverse events has been important in the drive to improve patient safety.[1 2] The Harvard Medical Practice study[3] carried out in New York in the mid 1980s provided powerful evidence of the scale of harm to patients in hospital. These initial findings were substantiated in further studies in the United States,[4] in Australia,[5] the UK,[6] Denmark,[7] and New Zealand,[8] and there are ongoing studies in other countries.

The basic methodology was developed in the early 1970s for the Californian Insurance Feasibility Study.[9] Retrospective case record review studies are carried out in two stages. First, using Review Form 1 (RF1), medical records are screened according to 18 predefined criteria (for example, unexpected death, hospital acquired infection/sepsis, unplanned return to the operating theatre) to identify records of patients more likely to have suffered an adverse event. Records meeting one or more of the screening criteria are forwarded for clinical review using Review Form 2 (RF2). In this second stage trained clinicians examine each case record in detail to determine whether or not an adverse event has occurred and to extract information about the nature and causes of adverse events. Each research group[4–8] made minor modifications to the RF2, adding or subtracting specific questions, but the basic format used in the Harvard study[3] was maintained.

The methodology of case record review has considerable strengths. It has provided a more complete indication of the incidence of adverse events or critical incidents than reporting systems, even when they are backed by additional monitoring by a dedicated risk manager.[10] Familiarity and other biases are reduced when external independent assessors are used to conduct the review. The review forms provide a standardised method of recording and data collection which is robust when used on a random sample of case records. The epidemiological data obtained are potentially useful for comparative studies, although any comparisons need to take account of variations in methodology, particularly with the definition and inclusion criteria.

Readers are invited to respond to the three questions listed at the end of the accompanying commentary by Ross Wilson on page 402 by using the rapid response function http://qhc.bmjjournals.com/cgi/eletter-submit/12/6/402.

Case record review is, however, wholly dependent on the accuracy, completeness and legibility of patient records. Some information, such as the effects of the adverse event on the patient, is not generally recorded and often the adverse event itself is not explicitly stated in the record and may not be recognised until the patient is readmitted. Low to moderate inter-rater reliability has been reported.[5 11] Finally, retrospective case record review can be time consuming and expensive. Despite these limitations, however, case record review has yielded important epidemiological data that have had a major effect on governmental policies and action by healthcare providers.[2]

RATIONALE FOR A REVISED REVIEW FORM

Earlier studies[3–5] focused on the incidence and type of adverse events with some attempt to identify causes and methods of prevention.[12] The original review form uses a mixture of taxonomies which are not always clearly distinguished. Reviewers in our study found that the structure of the review form meant that results did not always reflect the underlying clinical reality. For instance, with a standard RF2 a postoperative infection is classified as an operative event (because it occurred within 30 days of surgery) and non-technical (because it was not directly related to the operation itself). In a subsequent examination of the data we analysed in detail the narratives provided by the reviewers.[13] This enabled us to define when in the process of care the adverse event occurred and the nature of the underlying problem

(box 1, C1–C5). As a result, a postoperative chest infection would be classified as a ward based event and the problem as one related perhaps to drug administration (oversedation), to failure to monitor (such as over a weekend), or to failure to provide physiotherapy.

Adverse events frequently involve a chain of events and a series of care management or care delivery problems leading up to the incident itself.[14] In previous versions of the form multiple problems were sometimes identified, but were not prioritised and were not sufficiently distinguished in the final analyses. However, we found that there is usually one critical period in which the primary problem occurred. We therefore introduced the concept of a ''principal problem'', being the most important problem in the delivery of care. This enabled a precise identification of a particular period in the process of care, now incorporated in the review process, and a defined principal problem which greatly clarified the review process. To provide additional clarity we divided the review form into five sections each with a defined purpose, providing a modular structure to both the form and the review process.

A final important change has been a much stronger emphasis on the broader organisational, environmental, and other factors that contribute to adverse events. While earlier versions paid some attention to these factors, the approach was not sufficiently systematic. The present approach is based on a previously devised framework[15] and method of individual case analysis.[16] Identifying contributory factors is best done from observation and interview, although this is quite labour and resource intensive. We believe that expert reviewers or those familiar with the working environment can often comment on some of the major contributory factors. This is particularly important as the identification of such factors offers a route to devising methods of prevention.

Thus, we have attempted to address three areas in which the earlier review forms have limitations:

- We have divided hospital stay into distinct periods of care and then identified the clinical aspects associated with each period—to address the former mixed categories of the type of adverse event.
- We have introduced the term ''principal problem'' to help clarify the review process in order to identify the healthcare management or treatment, or delay or lack of treatment, that led to the adverse event.
- We have provided a comprehensive list of contributory factors to include organisational, environmental, and other contextual factors that influence the provision of health care.

THE MODULAR REVIEW FORM (MRF2)

The MRF2 comprises five stages or modules:

(A) Patient information and background to the adverse event
(B) Disability caused by the adverse event
(C) Period of hospitalisation during which the adverse event occurred
(D) Principal problems in the process of care
(E) Causative/contributory factors and preventability of the adverse event

Once an adverse event has been identified following the first stage review (RF1), reviewers are required to complete stages A and B in full. When completing stage A they are required to identify one or more of five periods of care during which adverse event(s) occurred (C1–C5). Next they complete the relevant part(s) of stage C. In so doing, they are required to identify the nature of the underlying cause(s) of the adverse event ranging from errors in diagnosis to mismanagement at the time of discharge. This leads to the completion of one or more of subsections D1–D7. Finally, stage E provides the opportunity for identifying contributory factors and potential preventability. Details of each stage are shown in box 1 and fig 1. The modular structure allows reviewers to select which stages to complete, depending on the focus of the review. The MRF2 is available on the *QSHC* website (http://www.qshc.com/supplemental).

The objectives of this study were to pilot and evaluate the new review form (MRF2) using an evaluation questionnaire.

Box 1 Structure of the modular review form (MRF2)

(A) Patient information and background to adverse event (AE)
- Patient data
- Primary illness; prognosis
- Co-morbidity; specialty
- Main features of AE
- Identification of principal problem
  → identify period(s) of care (C1–C5)
- Adequacy of records

(B) The injury and its effects
- Disability (including death) caused by AE
- Effect of AE on hospital resources (e.g. additional bed days)
- Additional treatment as a result of AE

(C) Period of hospitalisation during which AE occurred (as identified in stage A)
- C1: Care on admission ward including preoperative care →
- C2: During procedure including surgery, anaesthesia →
- C3: Immediate postoperative and ITU/HDC care →
- C4: General ward care →
- C5: Care/assessment during discharge
  → principal problem (D1–D7)

(D) Principal problems in the process of care (as identified in relevant subsection(s) in C)
- D1: Diagnostic/assessment error
- D2: In relation to patient's overall condition
- D3: Medical management/monitoring including nursing care
- D4: In relation to infection
- D5: Procedure (including anaesthesia/surgery)
- D6: In relation to drug/IV fluid/blood transfusion
- D7: In relation to a resuscitation procedure

(E) Causative/contributory factors and preventability of AE
- Causative factors: patient characteristics, task factors, individual factors, team factors, work environment, organisational/management factors
- Preventability of AE
- Expertise of reviewer

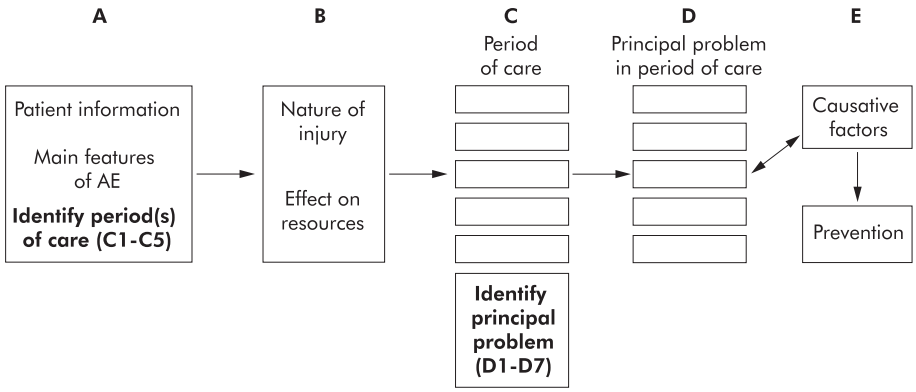

Figure 1 Flow chart of the Modular Review Form 2 (MRF2).

PILOTING AND PRELIMINARY EVALUATION OF THE MRF2

After publication of our case record review study,[6] a considerable number of clinicians and researchers contacted us to ask for copies of the review forms with a view to conducting studies in their own hospitals. All those who had previously requested the materials were contacted and invited to take part in piloting the MRF2. Of 36 individuals contacted, 20 agreed to take part.

Procedure

Twelve teams (from the UK (2), Italy (2), France, Spain, Australia (2), New Zealand, Japan and USA (2)) took part in piloting the MRF2. Team members had a range of clinical expertise and specialist interests including epidemiology, paediatrics, nursing, infectious diseases, pharmacy, endocrinology, anaesthetics, nephrology, and emergency medicine. Eight teams sent 44 completed forms and the remaining four provided summaries of 20 adverse events. The number of reviewers per team ranged from 1 to 3 and the number of review forms completed per reviewer ranged from 1 to 6.

Participants were asked to identify 5–10 known adverse events and to review each one using the MRF2. The reviewers were warned that it takes time to understand the review process and, in particular, to interpret definitions correctly. The instruction document provided definitions of important concepts, an outline of the review process, and a list of conditions which reviewers have had difficulty with in previous review studies such as hospital acquired infection, pressure sores, and falls. Reviewers were given the opportunity to contact the research team with queries related to the review process.

After using the new forms, participants were asked to rate them on an evaluation questionnaire consisting of ratings of the statements shown in table 1 together with questions on the strengths and weaknesses of each stage of the review form and the form overall. In addition to this we posed some specific questions on issues of concern. For example: ''Did you find the concept of the 'principal problem' in the process of care clear and meaningful? If not, do you have any alternative suggestions?'' and ''Did you find it possible to rate the contributory factors in a case when working from records alone?'' Participants were required to either return fully completed review forms or to provide a summary of the adverse events they had reviewed on the evaluation questionnaire.

RESULTS

In most cases the MRF2 was completed adequately and, in some cases, the level of detail was exceptional. Most of the reviewers (7–10 teams) agreed with the 12 positively worded statements regarding the MRF2 (table 1). Only one reviewer gave consistent negative feedback (disagreeing with nine statements). Several useful comments were received on how the review form could be improved and, where possible, the final version has been modified accordingly. A summary of comments is included in box 2.

Three teams directly reported difficulty with the term ''principal problem''. Of these, one was uncertain whether the question referred to the ''principal problem for admission or with patient'', with two others finding that the principal problem was not sufficiently distinguished from the adverse event itself. The remaining teams reported that, on the whole, they found the term useful.

Five teams found ''*…it possible to rate the contributory factors in a case when working from records alone*'' whereas four teams did not. Of the three remaining teams, one lead reviewer left this question blank, another had ''intimate knowledge of the adverse event'', and the third thought it was necessary to include someone from the department in the review team. Almost all said it was ''*…easier to rate contributory factors if you were familiar with the department in which the adverse event occurred*''. Comments on the guidance notes, where given, were generally positive but additions and clarifications were requested, particularly for definitions of terms. One team also suggested moving more definitions into the review form itself. As a result of the study we have modified the MRF2 to take account of criticisms and suggestions (table 2).

DISCUSSION

The review form was generally thought to be comprehensive, well structured, and clear. The new format scored particularly well on its comprehensive nature and its division into modules, although some difficulties with terminology and definitions remained. A few teams reported difficulty with the term ''principal problem'', although most found the term useful after some additional clarification had been provided. The definition of an adverse event needs particular emphasis, both on the review form and during the review process. We have since added further explanatory statements and have provided illustrative examples—such as was it a diagnostic error, technical mishap, or failure to monitor?

Identifying contributory factors is difficult but reviewers with detailed knowledge of the type of adverse event or local circumstances can provide useful indications on contributory factors which will form the basis of improvement and prevention strategies. Completion of this and other sections draws on the expertise and experience of the reviewer and, in that sense, their judgement is required. This can be addressed with training and reliability checks.

Table 1 Responses to questionnaire statements

Statement	Mean	Median	Scores* 1	2	3	4	5
The review form is comprehensive	3.92	4	0	0	2	9	1
The review form is well structured	3.58	4	1	1	2	6	2
The review terminology is clear	3.42	4	0	4	0	7	1
The modular structure is useful	3.92	4	0	1	2	6	3
The amount of explanation and instruction on the form itself is about right	3.42	4	0	3	2	6	1
The accompanying separate instructions are helpful	3.67	4	0	1	3	7	1
The range of options for each section is sufficient	3.97	4	0	3	0	7	2
The review form records sufficient patient information	3.83	4	0	2	1	6	3
The review form records sufficient detail about problems in process of care	3.67	4	0	3	1	5	3
The review form records sufficient detail about the impact of AE	3.75	4	0	3	0	6	3
The review form records sufficient detail about the causes of AE	3.58	4	0	4	0	5	3
The information on the review form has the potential to lead to meaningful clinical improvements	3.58	4	0	2	2	7	1

AE = adverse event.
*The MRF2 was rated on a 5 point scale: 1 = strongly disagree; 2 = disagree; 3 = no opinion; 4 = agree; 5 = strongly agree.

Box 2 Comments from reviewers

General comments

Strengths of the review form

- Layout comprehensive and easy to follow.
- Comprehensive but lengthy—relatively easy to complete.
- The modular structure is definitely helpful in identifying the particular period of care in which problems arose.
- Clear separation of different components allows detailed review.
- Good basis; good mix of open ended questions and categorisation of events.
- Useful for clinicians for risk management.
- Strong emphasis on identifying systemic factors and contributory causes.
- Easy to complete.
- Problems can be identified with greater precision by probing with follow up questions.
- Specific and potential to obtain a lot of information.

Limitations of the review form

- Layout initially appears confusing.
- Too complex—too specific and too exhaustive–need specialist experience to complete and/or considerable dedication to unearth circumstances surrounding an adverse event.
- Not enough information for epidemiological analysis but too complicated for clinical use.
- Not suitable for root cause analysis.
- Some questions are too subjective—will get different answers from different reviewers.
- Too time consuming.
- Sometimes impossible to answer questions—need more ''don't know'' or ''data not available'' options.
- Repetition in some areas.

Devising a review form that is capable of encompassing almost all aspects of hospital care inevitably results in a long document. We have, where possible, tried to reduce the level of detail in the interest of making the whole process more manageable. We purposely kept the guidance notes short and inserted definitions within the review form itself, as some reviewers in our previous study[6] found it irksome to consult the manual while completing the form. While the complete form may still look daunting, reviewing a single record only involves completing a relatively small number of specific subsections. The process could be made more efficient with an electronic version of the form. Reviewers may have to adapt the forms to their particular country and circumstances, and perhaps add additional guidance notes appropriate to the local setting. However, results from this pilot study suggest that the underlying structure should prove robust. Reviewers with a particular interest in a certain type of adverse event may wish to include much more detailed questions on some aspects of care.

Our experience of studying adverse events and piloting these forms indicates that training of reviewers remains of vital importance. Clinical ability and acumen, although essential, do not guarantee that the review process will be either understood or adhered to. Preparation by review of trial cases followed by discussion is essential. Without training in identifying the key issues quickly and efficiently, the process can become unduly time consuming. In our experience[6 13] most disagreements usually revolve around definitions and terminology rather than differences of opinion on clinical matters.

We acknowledge that the present study is only a preliminary test of the modified review form and that it needs to be compared with previous versions and tried out in larger studies in a variety of settings. As no formal comparison with the old form has been made, we are unable to comment on whether the MRF2 is an improvement on previous versions. Furthermore, we were unable to control for variation in the specific instructions and information that was given to the reviewers by team leaders or the variability of specialties and experience of each review team. However, it is worth acknowledging the practical setting in which these forms may be used. We consider that the positive nature of the present findings suggests that the modified form should be considered for use in future case record reviews.

In our view the full potential of case record review has yet to be explored. Most adverse event reviews conducted so far have been labour intensive, large scale studies. However, we believe that there is considerable potential for small scale studies which may be either local clinical review or formal research. Case record review could be especially valuable for routine review at the local level, particularly when specific types of cases are targeted and with a full exploration of causes and methods of prevention. The modular structure of the present form allows those with limited resources to cut

Table 2 Specific comments from reviewers to MRF2

Stage	Suggestions/difficulties	Authors' comments
A	Need to elucidate meaning of principal problem Add to co-morbidity list Include time of event	This has been clarified by re-structuring the stage and giving examples The co-morbidity list has been modified Space to record the time of the event is included
B	Answers to the following will be subjective: • Additional bed days caused by AE • Degree of disability • Emotional trauma	Agree—but approximate data are useful
C	May be difficult to determine: • Person responsible at that period of care • Date and time of event	Agree—but may be able to determine whether or not there was lack of input from experienced staff
D	May be difficult to determine: • How management contributed to the AE and respects in which it was unsatisfactory • Quality of hand over • Person responsible at the time of AE and whether or not it was appropriate • Whether there were avoidable delays or inappropriate procedures • The cause of drug related injury	Agree—but experienced reviewers will be able to make ''intelligent estimates''
E	Impossible to relate the relative importance of contributory factors Difficult to determine reasons for failure to prevent AE Specialist reviewers would be needed	It is important that reviewers are adequately trained and that they are aware of their own limitations As the form is modular, stage E may be omitted. Specialists should be consulted on specific points

Key messages

- For 25 years a basic form has been used for recording the results of case record review to identify adverse events in hospital practice.
- The method has provided epidemiological data but has been of limited value in defining targets for improvement in care
- We present a revised form which has a modular structure. Key components define (1) the period of care during which action or inaction led to the adverse event and (2) the type of clinical action or inaction.
- A further module offers the opportunity of recording factors that may have contributed to the adverse event.
- This revised form received mostly favourable comments when assessed by researchers in 12 other units.
- The method needs to be tested in practice; it may be of particular value in institutions that wish to identify areas of improvement based on contributing factors.
- As with previous versions of the form, training in completing the form is essential.

down the review process to its essentials and adapt it to their particular purpose. There is also considerable scope for using record review prospectively in combination with staff interviews. Record review, whether retrospective or prospective, remains one of the primary methods for assessing the incidence of adverse events.[10 11]

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The Modular Review Form 2 (MRF2) is available on the *QSHC* website at www.qshc.com/supplemental.

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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

Date of Review: ☐☐☐☐☐☐ (d d m m y y)

Reviewer ID Number: ☐☐☐

Time Commenced Review: ☐☐☐☐

Case Number: ☐☐☐☐

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)
- ☐ 2 Urgent (emergency)
- ☐ 3 Semi-urgent
- ☐ 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-intenstinal
- ☐ 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
- ☐ Cachetic
- ☐ 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

SURGERY

☐ 3 Anaesthesiology
☐ 4 Cardiac Surgery
☐ 5 Colon/Rectal Surgery
☐ 6 General Surgery
☐ 7 Gynaecology
☐ 8 Neurosurgery
☐ 9 Obstetrics
☐ 10 Orthopaedic Surgery
☐ 11 Paediatric Surgery
☐ 12 Plastic Surgery
☐ 13 Thoracic Surgery
☐ 14 Vascular Surgery
☐ 15 Urological Surgery
☐ 16 ENT Surgery
☐ 17 Eye Surgery
☐ 18 Other (specify) _____

MEDICINE

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

OTHER

☐ 44 Dentistry/Oral Surgery
☐ 45 Dietary
☐ 46 Hospital Physical Plant
☐ 47 Midwifery
☐ 48 Nursing
☐ 49 Osteopathy
☐ 50 Pharmacy
☐ 51 Physical or Occupational Therapy
☐ 52 Podiatry
☐ 53 Support Services (e.g. transportation)
☐ 54 Other (specify)_____

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 ☐ **Yes** ☐ **No**
2 Prolonged/subsequent stay or treatment ☐ **Yes** ☐ **No**
3 Death ☐ **Yes** ☐ **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

☐ 1 health care management
☐ 2 health care management interacting with disease process
☐ 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%)
- ☐ 2 rarely (1-9%)
- ☐ 3 occasionally (10-24%)
- ☐ 4 frequently (> 25%)

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

_____

_____

_____

A7 (cont.)

Identify any other problems (major lapses in care) related to <u>this</u> AE and when these occurred in relation to the principal problem

1. _____

2. _____

3. _____

Specify the period(s) during which the principal problem in care occurred. Tick as many as apply to the principal problem. This will identify which sub-section in Stage C you will need to complete.

- ☐ **C1**. Care on admission to a ward (includes pre-operative assessment and assessment in A&E department and emergency care before full assessment)
- ☐ **C2**. Care during a procedure (including surgery and anaesthesia)
- ☐ **C3**. Post-operative care or post-procedure/High dependency or ITU care
- ☐ **C4**. General ward care (after operation; or after full assessment and commencement of medical care)
- ☐ **C5**. End of admission assessment and discharge care

Was there an error in handling the AE? ☐ **Yes** ☐ **No** ☐ **Not clear**

If so, give details _____

_____

_____

A8 ADEQUACY OF RECORDS FOR JUDGEMENT OF AE

How adequate were the records in providing information to enable judgements of AE?

- ☐ 1 Medical records were adequate to make a reasonable judgement
- ☐ 2 Some deficiencies in the records (specify) _____
- ☐ 3 Major deficiencies (specify) _____
- ☐ 4 Severe deficiencies, impossible to make judgements about AE (specify) _____

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) _____ _____

Total number of extra days attributable to the AE _____

* Intensive Care Unit / Coronary Care Unit /

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 (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)	→ D2
☐ 3	Management/monitoring incl. Nursing/Ancillary care (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)	→ D3
☐ 4	Infection-related	→ D4
☐ 5	Technical problem related to a procedure (including inappropriate/unnecessary procedures, e.g. urinary catheterisation)	→ D5
☐ 6	Failure to give correct medication/maintain correct hydration / electrolytes / blood (including failure to provide prophylactic medication e.g. anti-coagulants/antibiotics)	→ D6
☐ 7	Resuscitation	→ D7
☐ 8	Other (e.g. falls; specify) _____	

_____

Were there any other problems during this period/section of care not 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?

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

- ☐ 1 Emergency
- ☐ 2 Semi-emergency
- ☐ 3 Elective
- ☐ 4 Not clear

Who undertook the procedure or anaesthesia?

- ☐ 1. Consultant or fully trained operator *with* assistant
- ☐ 2. Consultant or fully trained operator *without* assistant
- ☐ 3. Supervised trainee
- ☐ 4. Unsupervised trainee
- ☐ 5. Other (specify) _____
- ☐ 6. Not clear

What was the nature of the principal problem underlying the AE

- ☐ 1 Diagnosis → D1
- ☐ 2 Overall assessment (incl. Pre-op assessment) → D2
- ☐ 3 Management/monitoring (incl. Nursing/Ancillary care) → D3
- ☐ 4 Infection-related related to a procedure → D4
- ☐ 5 Technical problem related to a procedure → D5
  (e.g. Intubation; Equipment failure; Monitoring during procedure)
- ☐ 6 Drugs/ Fluids (incl. anaesthetic agent) / 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 _____

_____

_____

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, CO_2, 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 vasular 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?

- ☐ 1 Intravenous
- ☐ 2 Intra-muscular
- ☐ 3 Subcutaneous
- ☐ 4 orally
- ☐ 5 sublingual
- ☐ 6 intrathecal
- ☐ 7 topical
- ☐ 8 rectal
- ☐ 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?

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

_____

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 <u>each</u> of the following factors according to its importance, as you see it, in the occurrence of this particular adverse event.

Unlikely to be relevant	Possibly relevant	Somewhat important	Very important
U	1	2	3

	U	1 2 3
1. Patient characteristics		
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)	☐	☐ ☐ ☐
1.2 Personality or social factors	☐	☐ ☐ ☐
1.3 Was co-morbidity an important contributory factor?	☐	☐ ☐ ☐
1.4 Other patient characteristics (specify) _____	☐	☐ ☐ ☐
2. Task factors		
2.1 New, untested or difficult task or procedure	☐	☐ ☐ ☐
2.2 Evidence of lack of guidelines/protocols or their use	☐	☐ ☐ ☐
2.3 Test results unavailable, difficult to interpret or inaccurate	☐	☐ ☐ ☐
2.4 Poor task design/structure	☐	☐ ☐ ☐
2.5 Other task factors (specify) _____	☐	☐ ☐ ☐
3. Individual factors		
3.1 Staff working outside their expertise	☐	☐ ☐ ☐
3.2 Lack of knowledge of individuals	☐	☐ ☐ ☐
3.3 Lack of skill of individuals	☐	☐ ☐ ☐
3.4 Attitude/motivation problem	☐	☐ ☐ ☐
3.5 Long shift/under pressure	☐	☐ ☐ ☐
3.6 Other individual staff factors (specify) _____	☐	☐ ☐ ☐
4. Team factors		
4.1 Poor teamwork	☐	☐ ☐ ☐
4.2 Inadequate supervision	☐	☐ ☐ ☐
4.3 Poor verbal communication	☐	☐ ☐ ☐
4.4 Inadequate handover	☐	☐ ☐ ☐
4.5 Poor written communication (e.g. defects in notes)	☐	☐ ☐ ☐
4.6 Other team factors (specify) _____	☐	☐ ☐ ☐
5. Work environment		
5.1 Defective or unavailable equipment	☐	☐ ☐ ☐
5.2 Problems with provision or scheduling of services (e.g. theatre list, lab tests, x-rays)	☐	☐ ☐ ☐
5.3 Inadequate functioning of hospital support services (e.g. pharmacy, blood bank or housekeeping)	☐	☐ ☐ ☐

	U	1	2	3
5.4 Inadequate staffing at the time of the AE	☐	☐	☐	☐
5.5 Out of hours (time of day/day of week) factors	☐	☐	☐	☐
5.6 Other work environmental factors (specify) _____	☐	☐	☐	☐

6. Organisational/Management factors

	U	1	2	3
6.1 Lack of essential resources (e.g. ITU beds)	☐	☐	☐	☐
6.2 Poor co-ordination of overall services	☐	☐	☐	☐
6.3 Inadequate senior leadership	☐	☐	☐	☐
6.4 Other organisational/management factors (specify)_____	☐	☐	☐	☐

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 _____

_____

_____

_____

A9 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: ☐☐☐