Appendix 1. Search Strategy for Literature Review

The narrative literature review was based on information derived from a number of sources.

1. Database searches

   Medline, Embase, the Cochrane Library and CINAHL computer databases were searched for articles published between 1966 and September 2013 in the English language and related to adults. The searches combined Medical Subject Headings and text terms listed in Table A1. Terms from group 1 were combined with terms from group 2.

   Table A1: Search Terms

Group 1	Group 2
error* or (medical error*) or (clinical error*) or (active error*) or (latent error*) or (system error*) or (diagnostic error*) or (latent failure*) or (active failure*) or (human error*) or (medication error*) or (drug error*) harm* or (healthcare harm*) or (healthcare-related harm*) or (iatrogenic disease*) or (adverse event*) or (adverse drug event*) or (patient-related harm*) or (patient reported harm*) or (patient safety incident*) or nosocomial or (hospital acquired) or (reported harm*) (preventable death*) or (avoidable death*) or (preventable hospital death*) or (avoidable hospital death*) or	(incident report*) or (incident reporting system*) or (voluntary report*) or (mandatory report*) (retrospective case record review*) or (case record review*) or (retrospective case note review*) or (note review*) or (record review*) or (medical record review*) (trigger*) or (trigger tool*) or (global trigger tool*) or (sentinel) or (signal) (medical audit*) or (clinical audit*) (prospective surveillance) or (sentinel surveillance) or (direct observation) (hospital standardi* mortality ratio*) or (standardi* mortality ratio*) or (standardi* hospital-level indicator*) or (HSMR) or (SHMI) or (mortality ratio) or (standardi* mortality ratio*) (patient safety indicator*) or (computer* incident code) or (discharge summary code) or (administrative code) or (adverse event code) or (complication code) or (computeri* detection) or (generic screen) (malpractice claim*) or (claim*) or (medicolegal) or neglige* or (legislation and jurisprudence)

(avoidable mortality) or (preventable mortality) or (avoidable hospital mortality) or (preventable hospital mortality)	(case control stud*) or (case control) or (matched study) (morbidity and mortality) or (morbidity and mortality meeting*) or (morbidity and mortality committee*) or morbidity and (mortality report*) or (morbidity and mortality conference*)

Relevant article titles were identified through searches and abstracts located for assessment. From the abstracts, full papers were selected for reading. Where abstracts were not included on the database, the paper was selected for review

2. Websites

Websites of the following organisations were searched: Department of Health, National Patient Safety Agency, National Confidential Enquiries, National Audit Office, NHS Institute for Innovation and Improvement, US Institute for Healthcare Improvement, US Agency for Healthcare Research and Policy and the World Health Organisation.

3. Hand searches

The key journals in the field of patient safety, BMJ Quality and Safety (formerly Quality and Safety in Healthcare) and the International Journal of Quality in Healthcare were hand searched.

4. Key Experts

Key experts in the field of patient safety were asked to recommend articles.

Appendix 2. Structured Medical Review Form

CONFIDENTIAL

PRISM MEDICAL RECORD REVIEW FORM

for Retrospective Case Record Review

Adapted from the Medical Review Form 2 by Dr Helen Hogan and Dr Graham Neale, Nov-Dec 2009. With grateful acknowledgement to Graham Neale, Maria Woloshynowych and Charles Vincent

Stage A: PATIENT INFORMATION AND BACKGROUND

A1 REVIEWER INFORMATION

Reviewer ID Number: ☐☐ Date/s of Review (dd/mm/yy): ☐☐ ☐☐ ☐☐

Total Time Taken to Complete Review: ☐☐☐☐☐☐☐☐

A2 PATIENT INFORMATION

Patient Unique Study Number: ☐☐☐☐ Patient Age at Death (years): ☐☐☐ Patient Sex (M/F): ☐

Date of admission (dd/mm/yy) ☐☐ ☐☐ ☐☐ Date of death (dd/mm/yy): ☐☐ ☐☐ ☐☐

A3 NATURE OF ILLNESS

a. Degree of urgency at the time of admission. Please circle one option.

1. Critical (requires immediate attention to stabilise airway, breathing or circulation difficulties)
2. Urgent (severe illness that requires treatment within 2 hours e.g. moderate pain, history of unconsciousness, uncontrolled minor haemorrhage, fever)
3. Semi-urgent (unwell patient admitted through A & E or outpatients who could wait over 2 hours to be treated without risk of deterioration e.g. mild pain
4. Routine (admitted for hospital-based investigations or for elective treatment)

b. From what you know about the patient's acute and chronic condition at admission please estimate their life expectancy (hours, days, months, years) assuming a normally acceptable standard of care during the hospitalisation.

_____

_____

c. If the patient had recovered from his/her presenting illness (as well as could be expected including having adequate time for recovery post discharge), and had received a normally acceptable standard of care, please describe the patient's likely health status. Please circle one option.

1. Normal, no complaints or evidence of disease
2. Able to perform normal activity; minor signs and symptoms of disease
3. Able to perform normal activity with effort; some signs and symptoms of disease
4. Cares for self, unable to perform normal activity or to do active work
5. Requires occasional assistance but is able to care for most of own needs
6. Requires considerable assistance and frequent medical care
7. Requires special care and assistance; disabled

A4 CO-MORBIDITIES

Please circle all the patient's co-morbidities:

1. No co-morbidity
2. Co-morbidity unknown
3. Cardiovascular
a)Congestive heart failure
b)Myocardial infarction
c)Peripheral vascular disease
d) Right heart failure
e) Left heart failure
f)Hypertension
g)Other serious problem (specify)
_____

4. Respiratory
a)Chronic obstructive pulmonary disease
b)Asthma
c)Other serious problem (specify)
_____

5. Gastrointestinal
a)Peptic Ulcer Disease
b)Inflammatory bowel disease
c)Mild Liver disease
d)Mod-Severe liver disease
e)Other serious problem (specify)
_____

6. Psychiatric
a)Schizophrenia
b)Affective Disorder
c)Other serious problem (specify)
_____

7. Trauma
a) Multiple trauma (eg. RTA)
8. Neurological
a)Stroke
b)Dementia
c)Epilepsy
d)Parkinson's
e)Other serious problem (specify)
_____

9. Endocrine disease
a)Diabetes: no end organ damage
b)Diabetes with organ damage
c)Other serious problem (specify)
_____

10. Renal Disease
a) Acute renal disease
b) Chronic renal disease
c) Other serious problem (specify)
_____

11. Haematological
a)Leukaemia
b)Lymphoma
c) Anaemia
d)Other serious problem (specify)
_____

12. Infection
a)AIDS
b)Chronic Infection specify (eg. Hep C, MRSA)
c) Other (specify)

13. Allergies
a) Specify
_____

14. Existing Cancer
a)Any tumour (within the last 5 years), specify
_____
b)Metastatic spread

15. Bone/ Joint Disorder
a)Severe Osteoarthritis
b)Severe Rheumatoid Arthritis
c)Osteoporosis
d) Other (specify)
_____

16. Disability
a)Wheelchair user
b)Blind
c)Deaf
d)Learning difficulty
e)Other (specify)
_____

17. Nutritional status
a)Obese
b)Cachetic
Other (specify)
18. Psychosocial
a)Smoker
b)Alcoholism
c)Drug abuse
d)Homeless
e)Other
19. Other co-morbidity. Specify
_____
_____

A5 SPECIALTY CARING FOR PATIENT

For each phase of admission, please specify which speciality was taking the lead for the patient's healthcare:

1. Early in admission (within 24 hours including A&E, MAU)) _____
2. General ward care_____
3. Care during a procedure (including surgery and anaesthesia) _____
4. End of admission assessment and discharge care _____

A6 SUMMARY OF ADMISSION

a. Was a GP Referral letter available Yes ☐ No ☐

b. If a possible diagnosis was suggested by the GP, was this pursued Yes ☐ No ☐

c. Was the GPs working diagnosis accurate Yes ☐ No ☐

Please summarise admission, procedures and events leading up to the patient's death

Stage B: PATIENT'S DEATH

a. Was the patient's death <u>caused by</u> a problem or problems in the healthcare?

Yes ☐ No ☐

b. Or did a problem or problems in healthcare <u>contribute</u> to the patient's death?

Yes ☐ No ☐

If NO to both the above questions, please go straight to Section G

Please describe the problem/s in this patient's healthcare that led to or contributed to the death Consider the following questions: Where did the event take place? Who was involved? What caused the problem/s? Consider if the problem/s arose because of staff error, an anticipated or unanticipated complication or mismanagement. What other factors contributed?

Stage C: DESCRIPTION OF THE PROBLEM/S IN THE PATIENT'S CARE THAT CONTRIBUTED TO DEATH

a. When did the patient's death occur? Please circle one option:

1. Early in admission (within 24 hours including during emergency care before full assessment, assessment in A&E department, admission ward or pre-operative assessment)
2. Care during a procedure (including surgery and anaesthesia)
3. Post-operative care or post-procedure/High dependency or ITU care
4. General ward care (after operation; or after full assessment and commencement of medical care)
5. End of admission assessment and discharge care
6. After discharge

b. Where did the problem/s in patient management that led to the death occur? Please circle as many as apply:

1. Before admission (GP, Outpatient clinic, previous admission)
2. Early in admission (includes assessment in A&E department, emergency care before full assessment, admission ward and pre-operative assessment)
3. Care during a procedure (including surgery and anaesthesia)
4. Post-operative care or post-procedure/High dependency or ITU care
5. General ward care (after operation; or after full assessment and commencement of medical care)
6. End of admission assessment and discharge care

Classification of the problem/s in care.

c. Was the death due to problems with (please circle as many as apply):

C1. Diagnosis
C2. Assessment
C3 Clinical monitoring / management (including. discharge arrangements, nursing/ancillary services)
C4. Infection control
C5. Technical problem related to operation or procedure
C6. Medication/ hydration/ electrolytes
C7. Resuscitation including CPR
C8. Other. Please specify

For each classification that you have circled above (C1 to C8) please go to the relevant section below to answer further questions.

C1. Diagnosis

Factors contributing to the diagnostic error (please circle 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) _____ __

C2. Assessment

In what respect was overall assessment inadequate? (please circle as many as apply):

1. Key information about the patient not available at presentation
2. Failure to take a full clinical history
3. Failure to examine carefully
4. Failure to take account of co-morbidity
5. Failure to gather adequate relevant information on which to base the clinical diagnosis
6. Failure to obtain appropriate assistance from colleague
7. Failure to monitor adequately
8. Failure to record
9. Failure to communicate to the rest of the team (clinical and multi-disciplinary)
10. Other (specify_____

C3 Clinical monitoring / management (including. discharge arrangements, nursing/ancillary services)

a. Was the inadequate monitoring/management related to failure to recognise:
(please circle as many as apply)

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 or safe mobilisation
7. Infection
8. Poor progress in healing (e.g. checking gut function after abdominal operation; care of wounds/ cannula sites)
9. Changes to the patient's general condition (e.g. patient develops a medical condition, e.g. CHF)
10. Other (specify) _____

b. In what respects was clinical management unsatisfactory?
Please circle as many as apply

1. Failure to take note of 'routine' observations or check if charts completed e.g. TPR charts, neurological assessment, fluid balance
2. Delay in noting lab/test results
3. Not aware of significance of lab/test results
4. Failure to act appropriately or in a timely fashion to lab/test results
5. Failure to alert Outreach team in a timely fashion in response to deteriorating observations
6. Poor note-keeping specify (eg. failure to record significant laboratory or imaging results or clear management plan)
7. Inadequate handover
8. Inadequate experience or seniority to manage patient satisfactorily
9. Lack of awareness of risks posed by a particular course of action in this patient
10. Lack of liaison with other staff
11. Inadequate 'out-of-hours' cover/working practice
12. Guideline/ protocol failure (either not available or not followed) (specify)
13. Apparent failure to recognise deterioration
14. Deterioration recognised but additional care not provided (specify, e.g. was high dependency care indicated)_____
15. Failure to recruit help specify (medical, nursing, ancillary)_____
16. Other

C4. Infection Control

a. What was the nature of the infection? Please circle as many as apply:

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) C. difficile
   c) Salmonella
   d) 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, specify_____

b.Where was the site of infection? Please circle as many as apply:

1. Surgical wound
2. Respiratory tract
3. Site of internal invasive procedure
4. Blood
5. Urinary tract
6. Skin
7. Other (specify) _____

c.What problems in care led to infection? Please circle as many as apply:

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 catheter/cannula/drain/wound
5. Other (specify)_____

C5. Technical problem related to operation or procedure

a. What was the nature of the problem (please circle as many as apply):

1 Avoidable delay in undertaking procedure

2 Inappropriate procedure - specify alternative

3 Inappropriate operator (too junior, lacking in experience)

4 Inadequate assessment/treatment/preparation before procedure (specify)

5. Anaesthetic incident
- 5.1 Intubation (specify) _____
- 5.2 Anaesthetic agent (specify) _____
- 5.3 Equipment failure (specify) _____
- 5.4 Monitoring during procedure (e.g. oxygenation, airway pressure)
- 5.5 Other (specify) _____

6 Operation/procedure
- 6.1 Difficulty in defining anatomy (specify) _____
- 6.2 Inadvertent organ damage (specify) _____
- 6.3 Bleeding specify (e.g. from slipped ligature; from vascular puncture)
- 6.4 Perforation (specify) _____
- 6.5 Anastomotic breakdown (specify) _____
- 6.6 Wound problem specify (e.g. dehiscence).
- 6.7 Siting prosthesis
- 6.8 Equipment failure specify (e.g. inappropriate use, misuse, failed)
- 6.9 Other (specify) _____

7 Inadequate monitoring during procedure (specify)

8 Infection-related
- 8.1 Wound specify (including drip-related cellulitis)
- 8.2 Internal infection, specify (e.g. abscess)
- 8.3 Failure to prevent cross infection
- 8.3 Other specify (e.g. cholangitis)

9 Other, including aspiration, inefficacious result (specify) _____

b. Where did the procedure take place? Please circle one option:

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

C6. Medication/ hydration/ electrolytes

a. What was the cause of the drug-related problem? Please circle as many as apply:

1 Common side effect
2 Uncommon side effect
3 Drug interaction
4 Allergy
5 No underlying cause (other than patient's response)
6 Incorrect preparation of drug
7 Delay in prescribing (specify) _____ _____
8 Delay in administration (after prescribing)
9 Wrong drug prescribed (specify) _____
10 Right drug but wrong dose or length of treatment
11 Right drug but wrong route (specify) _____
12 Error in administration (describe)
13 Inadequate monitoring (describe)
14 Failure to give an indicated drug
15 Other _____

b. What was the drug? Please circle:

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

C7 Resuscitation

a. What was the problem with resuscitation? Please circle:

1. Avoidable delay in initiating resuscitation
2. Inappropriate action
3. Failure to obtain appropriate tests/investigations
4. Other (specify)_____

b. Was there delay in dealing with the problem? ☐ Yes ☐ No

c. If yes, what was the reason? Please circle as many as apply:

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)_____

C8 Other problem in care not already specified

_____

_____

_____

Section D: HARM RESULTING FROM THE PROBLEM/S IN CARE

a. 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 or contributed to the patient's death? Please circle:

1. Virtually no evidence for management causation/system failure.
2. Injury entirely due to patient's pathology
3. Slight to modest evidence for management causation
4. Management causation not likely; less than 50-50 but close call
5. Management causation more likely than not, more than 50-50 but close call
6. Moderate/strong evidence for management causation
7. Virtually certain evidence for management causation

b. If so, by how many months/ years do you estimate this patient's life was shortened by the problem in care?

_____years _____months

Please comment on the factors that influenced your judgement.

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Stage E: CAUSATIVE / CONTRIBUTORY FACTORS

What factors do you feel contributed to the problem in care? Please circle as many as apply:

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 factors
1.3 Social factors
1.4 Smoker
1.5 Alcohol
1.6 Drug addiction
1.7 Co-morbidity
1.8 Other (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 staff 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)
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. Hospital/ Trust factors

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)_____

Section F: PREVENTABILITY

a. In your judgement, is there some evidence that the patient's death was preventable?

Yes ☐ No ☐

b. Rate on a 6 point scale the strength of evidence for preventability. Please circle:

1 Definitely not preventable
2 Slight evidence for preventability
3 Possibly preventable but not very likely, less than 50-50 but close call
4 Probably preventable , more than 50-50 but close call
5 Strong evidence for preventability
6 Definitely preventable

If preventable, please describe how specific improvements might have decreased the likelihood of the death occurring. Consider whether improvements could be made in each of the three areas outlined below.

c. Through improved equipment or procedures: Please specify what equipment or procedure and how improvements might be made through better design, ensuring correct use etc

_____

_____

_____

_____

d. Through improved organisation and management: Please specify how this might be achieved e.g. through improved transfer of knowledge or information, quality and availability of protocols, addressing other management issues such as staffing levels, addressing organisational cultural issues impacting on safety etc

_____

_____

_____

_____

e. Through steps to limit human error: Please specify how this may be achieved e.g. through ensuring staff who conduct a task have suitable qualifications , training or supervision, improved task planning, coordination or execution etc

_____

_____

_____

Stage G: GENERAL QUALITY ISSUES

a. Considering all that you know about this patient's admission how would you rate the overall quality of care? Please circle:

1. Excellent
2. Good
3. Adequate
4. Poor
5. Very poor

b. Do you think that the patient's death was preventable by better quality of care overall? Please circle:

1. Definitely
2. Probably
3. Uncertain
4. Probably not
5. Definitely not

c. How does the patient's care compare to the care that you might expect would be provided in a typical NHS hospital with respect to:

Initial assessment:	Satisfactory	☐	Unsatisfactory	☐
Treatment plan:	Satisfactory	☐	Unsatisfactory	☐
Ongoing monitoring:	Satisfactory	☐	Unsatisfactory	☐
Preparation for discharge:	Satisfactory	☐	Unsatisfactory	☐

Briefly describe any other quality issues related to this patient's care, not already mentioned in previous sections. This can include identification of errors, complications, mismanagement, lapses in the quality of patient care that did not result in the patient's death.

Stage H: EXPERTISE OF THE REVIEWER

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

Yes ☐ No ☐

b.If so was a second specialist opinion sought?

Yes ☐ No ☐

c.What is your question for the specialist?

_____

_____

_____

_____

d.What was the answer from the specialist?

_____

_____

_____

_____

e.Did the answer change your opinion and how?

_____

_____

_____

_____

Stage I: POST MORTEM REPORT

a. Did the medical record include a post mortem report? **Yes** ☐ **No** ☐

b. Do the findings in the post mortem report alter the conclusions indicated in the initial review?

Yes ☐ **No** ☐

Please specify how these findings have altered your conclusions. Also indicate if the findings change your recommendations in relation to prevention.

Stage J: ADEQUACY OF RECORDS FOR JUDGEMENT OF AN ADVERSE EVENT

a. Please indicate whether the following records were present in the case notes:

1.	Nursing records	Yes ☐	No ☐
2.	Pharmacy chart	Yes ☐	No ☐
3.	Fluid balance chart	Yes ☐	No ☐
4.	Observation chart	Yes ☐	No ☐
5.	Early warning system monitoring chart	Yes ☐	No ☐
6.	GP referral letter	Yes ☐	No ☐
7.	Post mortem report	Yes ☐	No ☐
8.	Evidence of communication with the GP after the patient's death	Yes ☐	No ☐

b. How adequate were the records in providing information to enable judgements of AE? Please circle:

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

Please detail below any issues related to the quality of the medical records.

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____