NHS North West

SERIOUS UNTOWARD INCIDENT REPORTING PROTOCOL

March 2008

INTRODUCTION

This protocol outlines the responsibilities of the SHA, NHS Trusts and PCTs in relation to serious untoward incidents and summarises the key information and requirements for serious untoward incident reporting and management within the Northwest of England.

The role of the SHA and Commissioning PCT is to ensure incidents are properly investigated, that action is taken to improve clinical quality and that lessons are learnt in order to minimise the risk of similar incidents occurring in the future.

Whilst Foundation Trusts have no obligation to report serious untoward incidents to the SHA, the SHA strongly encourages them to do so in order that any relevant learning may be shared with other NHS organisations across the North West, and where relevant nationally, to reduce the incidence of such events. The transition of some SUI performance management responsibility to Commissioning PCTs will require Foundation Trusts to report SUIs to the relevant Commissioning PCTs through the StEIS / UNIFY SUI reporting system. This handover process is currently underway and will be completed during 2008/09.

PCTs should make explicit in their contracts with all providers, their expectations regarding incident reporting and management, and the indicators and the process for performance management.

1 DEFINITION OF A SERIOUS UNTOWARD INCIDENT

1.1 The **principal definition** of a serious untoward incident (SUI) is any incident on an NHS site, or elsewhere, whilst in NHS-funded or NHS regulated care involving:

1. patients, relatives or visitors
2. staff
3. contractors working for the NHS, equipment, building or property

and which may or has :-

- resulted in death (this includes deaths from suspected suicide/suicide or homicide) or serious injury or was life-threatening
- contributed to a pattern of reduced standard of care
- involved a hazard to public health
- involved the absconsion of a patient detained under the Mental Health Act 1983 / 2007 and/or where a patient poses a significant risk to themselves or others (see Appendix 1)
- caused serious disruption to services

- caused significant damage to the reputation of an NHS organisation or its staff

- caused significant damage to NHS assets

- involved fraud or suspected fraud (the procedure in HSC 1999/062 and associated MOU (NHS CFS and ACPO, 2002) must also be observed in parallel)

- given rise to a significant claim for damages

- involved the suspension of a member of staff, or a student, on care/clinical, professional or managerial issues/when a 'healthcare professional alert' notice has been issued ("Healthcare Professionals Alert Notice Directions, 2006) or referral to a Professional Regulatory Body

- involvement of external investigation agencies (Police, HSE, Healthcare Commission, CSCI)

- raised severe criticism by an external body e.g. Coroner's inquest, Parliamentary and Healthcare Ombudsman, Mental Health Act Commissions

- raises concerns regarding Article 2 European Court of Human Rights (ECHR) (arguable breach of duty to protect life)

- involved significant health care associated infections e.g. outbreaks, unit / ward closures or Public Health issue, especially if they require the involvement of the Health Protection Agency

Appendix 1 provides StEIS / UNIFY Incident areas and examples

1.2 Adverse outcomes reasonably associated with routine NHS activity such as major surgical procedures, trauma interventions etc. are excluded from the above list.

1.3 Reporting managers will need to exercise a degree of judgement in deciding a threshold for reporting an incident. Organisations are advised to contact the Clinical Quality team at the SHA if in doubt.

1.4 This protocol must not interfere with existing lines of accountability nor replace the duty to inform the police and/or other organisations or agencies as required. Please refer to the joint publication "Memorandum of Understanding - Investigating Patient Safety Incidents" (2006), issued by the Department of Health, Health and Safety Executive and Association of Chief Police Officers and "Guidance for the NHS in support of the Memorandum of Understanding" (2006) for further guidance.

2 PROCEDURES THAT NHS ORGANISATIONS MUST HAVE IN PLACE

2.1 NHS organisations are responsible for identifying serious untoward incidents and taking effective action in each instance**.** It is expected that clear local

procedures are in place at each NHS organisation for identifying, reporting and investigating serious untoward incidents.

2.2 Each NHS organisation should have an authorised named person who is responsible for deciding when an incident should trigger the serious untoward incident procedure. Chief Executives must ensure that local procedures are in place so that all staff know how to identify and report a serious untoward incident as outlined in this document. Arrangements must be in place to ensure responsibilities remain clear throughout any organisational changes.

2.3 The named person should involve their communications lead in the assessment of incidents for potential media impact. The NHS Trust or PCT should prepare a press release to respond to media enquiries were media interest is anticipated. The SHA's Communications team is available for advice and will offer support in media handling for high profile incidents.

2.4 The national guidance contained in HSG (94) 27 (revised June 2005) should be followed for mental health incidents. (New guidance is imminent and will be incorporated into this protocol once released).

2.6 When a child has died or is seriously injured and non-accidental injury is suspected then all local child protection procedures **must** be followed and the Local Safeguarding Children Board **must** be informed.

3 REPORTING SERIOUS UNTOWARD INCIDENTS

3.1 NHS organisations should report any serious untoward incident to the SHA within a maximum of 72 hours or as soon as known following notification using the StEIS /UNIFY database. Care should be taken to ensure that all sections are completed and as much detail as possible is included in the initial StEIS / UNIFY report. Information should be provided in a manner, which maintains the anonymity of patients and staff involved, in line with Caldicott principles. In the event of the StEIS / UNIFY reporting system failure, contact with the SHA should be made via telephone (please see Appendix 2), and the incident entered onto StEIS / UNIFY once the system is back on line

If relevant, the following information should also be provided in the 'Further Information' field.

- number of patients affected;
- impact on patient(s)
- designation of staff involved;
- confirmation of which, if any, medical devices or equipment were involved;
- confirmation of which, if any, medicines were involved;
- the impact of the incident on staff;

- whether the patient's family has been informed and if not are there any plans to do so; if a decision not to inform the family has been taken has this been properly recorded - was the patient involved in this decision;

- if the family has been contacted - how is contact with the family being maintained; is there a named person for this purpose;

- any other information deemed relevant by the reporting organisation

3.2 Having completed the initial StEIS / UNIFY report form, the reporting organisation must then take appropriate measures to investigate the SUI. Please refer to the flowchart in Appendix 2 for details of the recommended process for incidents which meet the SHA escalation criteria and will therefore remain the responsibility of the SHA to performance manage, following the transfer of some SUI performance management responsibility to Commissioning PCTs.

3.3 Where the authorised named individual in a Trust/PCT believes that the incident has **significant** implications for the NHS in terms of clinical, managerial or media issues, and warrants the **immediate** involvement of the SHA out of hours, the SHA on-call Executive Director can be contacted when the situation requires escalation. If so, they will agree any action that needs to be taken with the relevant NHS organisation. Please refer to the flowchart in Appendix 2 for details of the recommended process.

4 INITIAL ASSESSMENT

Once the SHA has received notification of a serious untoward incident, an assessment will be carried out. As the transfer to Commissioning PCTs continues this initial assessment will be undertaken by PCTs in collaboration with the SHA. The following options will be considered:

4.1 CRITERIA FOR SUI MANAGEMENT

- the incident does not meet the StEIS / UNIFY reporting criteria and no further action is needed. Removal from StEIS / UNIFY would be requested following discussion with the reporting organisation.

- no further action is needed and the SHA confirm that the incident is closed.

- the SHA may declare a particular incident to be a major incident and involve the on-call Director of Public Health and / or Regional Director o Public Health in the incident management (for further information please see the SHA's "On-call Standard Operating Procedure for Public Health at the Regional Level" guidance).

- the commissioning PCT undertakes performance management of the incident and advises the SHA as appropriate (N.B. this process will apply once the SHA SUI performance management handover processes are completed - until this time the SHA will undertake the performance management role. If the SHA retains performance management of the incident the reporting

organisation will be requested to proceed with it's internal investigation processes and provide the SHA with an internal investigation report within 45 working days from the date the incident was reported onto the StEIS/UNIFY system).

- The incident meets the SHA escalation criteria (Appendix 3) and is managed by the SHA in collaboration with the PCT.

When SHA escalation of an incident is required the SHA will brief the Department of Health if/as appropriate and agree the level of involvement with the trust/PCT. Depending on the severity of the incident his could include:

- submission of internal investigation report in 45 working days
- agree terms of reference and investigation / review panel
- the SHA commissions an independent investigation

The SHA will liaises with the reporting organisation to confirm the appropriate level of investigation and reports required and internal investigation reports will be required within 45 working days from the date the incident was reported onto the StEIS/UNIFY system. If the organisation faces unavoidable delays in its investigation of an incident e.g. police investigation, the SHA should be notified of the reason for the delay and the anticipated delay period and a new reporting timescale will be negotiated on a case by case basis as required.

5 CRITERIA FOR ASSESSING THE 45 WORKING DAY INTERNAL INVESTIGATION REPORTS

The following criteria are used by the SHA when appraising the 45 working day Internal Investigation reports (please see Appendix 4):

- has the report examined the workings of the risk management (including incident reporting and the related incident management systems) and clinical governance arrangements at the trust/PCT; has the report assessed whether these systems are fit for purpose;

- have the authors of the report interviewed/sought information from the key workers/managers involved in the case;

- has the report adequately addressed all of the investigation terms of reference;

- is the report internally consistent, i.e. do the main conclusions follow from the body of the report;

- are the main recommendations directed at the appropriate sector of the health community - i.e. primary care, secondary care, local authority

- is there a robust action plan in place to meet the reports recommendations

Any further action will be agreed with the trust/PCT on a case by case basis as required. Once completed the incident may be recommended for closure.

6 CRITERIA FOR INCIDENT CLOSURE

Closure of incidents reported on StEIS/UNIFY may be considered after submission of the internal investigation report and action plan (if appropriate). However if there are significant recommendations closure may be delayed until these recommendations or the associated action plan has been implemented. Main criteria for the closure of an incident are:

- the report is robust and has fulfilled the terms of reference.
- an action plan has been agreed between the relevant organisations, which addresses the recommendations and has been ratified by the trust/ PCT board.
- evidence has been submitted that significant recommendations have been implemented.

APPENDIX 1

NHS NORTH WEST STRATEGIC HEALTH AUTHORITY
StEIS / UNIFY INCIDENT AREAS AND EXAMPLES

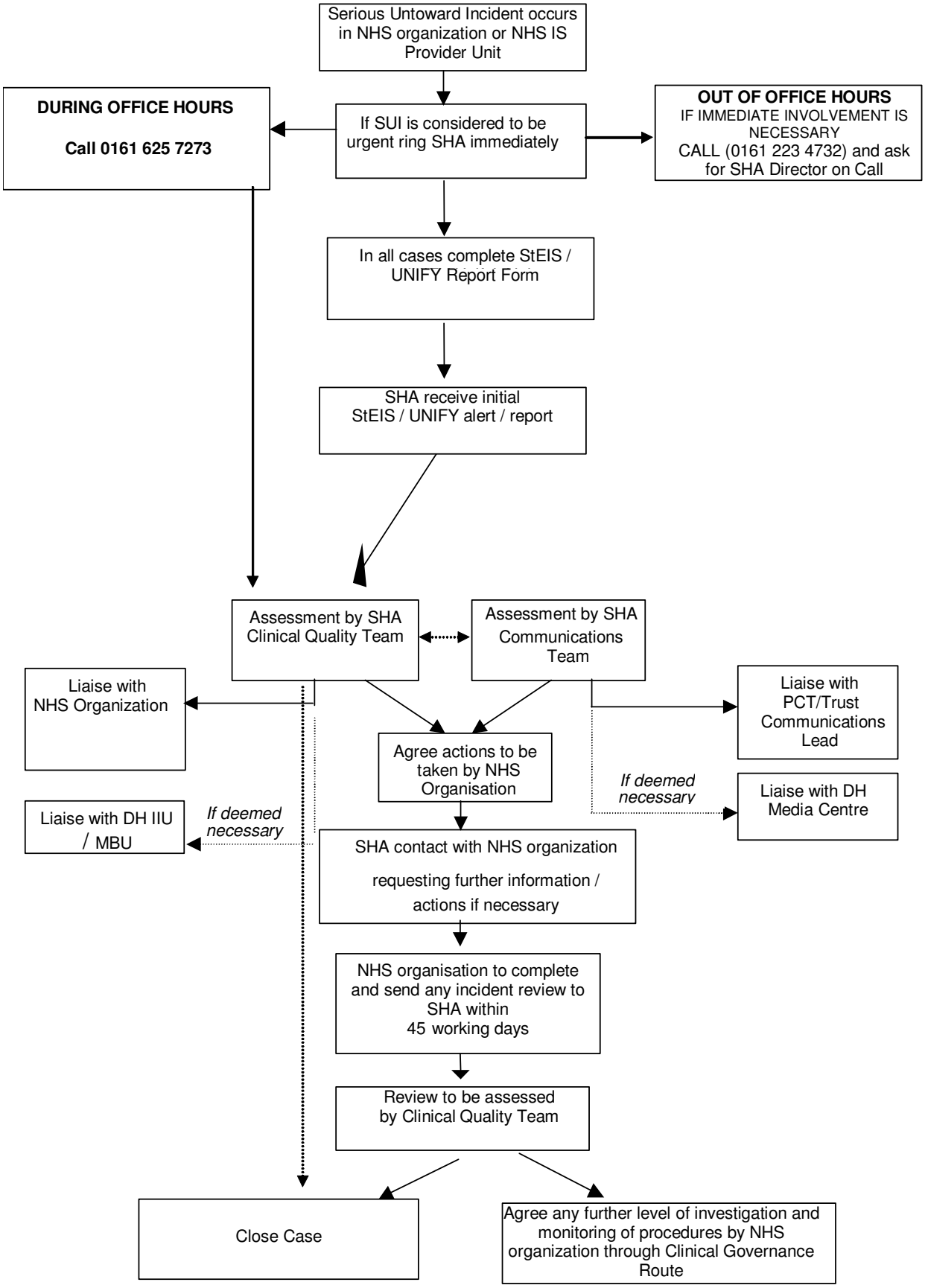
INCIDENT AREA	INCIDENT EXAMPLES
Untoward death of patients, staff, contractors working for NHS **or** **Serious risk or Injury**	**Acute and Primary Care Trusts** • Death or serious injury to a child, which results in a Part 8 serious case review under the Children Act 1989 and 2004 in which health has a major role. • Death leading to public concern and / or external inquiry involving NHS service provision (including children, vulnerable and other adults e.g. deaths in custody). • Homicide or serious injury to a member of staff (including independent contractors) or patient in the course of their duties or whilst on NHS premises. • Staff actions that may lead to the involvement of the criminal justice system. • Serious injury of a person currently in receipt of NHS care such as deliberate self-harm, accidental injury or injury inflicted by another person. • Serious injury or harm, as a result of the actions of a health care professional to a person currently in receipt of NHS care. • Serious injury to a vulnerable adult resulting in an investigation under local adult protection arrangements. • Any instance of staff or patients being poisoned / infected in the course of receiving treatment or as a direct result of NHS employment. • Inpatient admissions of Under 18 year old CAMHS clients to adult clinical units. N.B. for patients aged 16-18 years please indicate if the admission location was based on clinical / risk assessment and patient identified need (i.e. was the admission to an adult placement a deliberate clinical decision / choice) or due to lack of CAMHS beds / facilities availability.

Untoward death of patients, staff, contractors working for NHS **or** **Serious risk or Injury**	**Mental Health / Learning Disabilities Trusts** • The unexpected death of a person currently in receipt of NHS care where the death is as a result of suspected suicide, as a result of a homicide or is likely to be of public concern, e.g. of particular concern is any such death occurring on NHS premises or potentially high profile patient suicides involving bridges and railway lines. • Death resulting from violence/aggression. • Homicide or serious injury to a member of staff (including independent contractors) or patient in the course of their duties or whilst on NHS premises. • Staff actions that may lead to the involvement of the criminal justice system. • Serious injury of a person currently in receipt of NHS care such as deliberate self-harm, accidental injury or injury inflicted by another person. • Serious injury or harm of a person currently in receipt of NHS care as a result of the actions of a health care professional**.** • Serious injury to a vulnerable adult resulting in an inquiry under local adult protection arrangements. • Patients detained under the Mental Health Act 1983 / 2007 who abscond from mental health/learning disability services and who present a serious risk to themselves and/or to others. Of particular concern are those patients who abscond from medium/high secure or specialist forensic services, those who are likely to pose a risk to the public, attract media attention and/or who commit an offence whilst at large, were police are informed of the absconsion and missing persons alerts are issued. Informal admission patients who abscond but are considered to be vulnerable / high risk should also be reported. • Any instance of staff or patients being poisoned / infected in the course of receiving treatment or as a direct result of NHS employment. • Inpatient admissions of Under 18 year old CAMHS clients to adult clinical units. N.B. for patients aged 16-18 years please indicate if the admission location was based on clinical / risk assessment and patient identified need (i.e. was the admission to an adult placement a deliberate clinical decision / choice) or due to lack of CAMHS beds / facilities.

Corporate Risks	**All Trusts** • Any incident which is likely to attract media attention, is high profile or likely to be of public concern. • Serious breach of patient confidentiality, e.g. theft/loss of PC, laptop or memory stick containing patient identifiable information; inappropriate publication of sensitive data. • Removal of accreditation by an external body over major risk issues/concerns e.g. NHSLA schemes, royal colleges, university training establishments. • A pattern emerging that is causing local concern such as a high number of complaints regarding a member of staff/team, a particular service and / or hospital/unit that may warrant further investigation and action. • Serious fire or other serious damage / incident which occurs on health service premises, particularly if they result in the death or serious injury of patients or staff and / or would result in the major disruption of service provision. • Incident which results in the loss of service provision and impacts on patient or staff safety e.g. significant power failure/loss of power, equipment failure, IT / communications failure. • Any incident involving serious implications for patient or staff safety – involving potential risk as opposed to actual risk to patients or staff, which the wider health community needs alerting to.

Appendix 2

FLOW CHART FOR REPORTING SERIOUS UNTOWARD INCIDENTS



Appendix 3

NHS North West Interim Criteria For SHA Action	
Mental Health	• Inpatient suicides / attempted suicides • Homicides / attempted suicides • All absconds from Secure Accommodation, and all incidents occurring in high secure hospital services as required in line with DH guidance "Policy framework for the reporting and briefing of incidents and issues in high security hospitals (June 2007).
General	• Inpatient suicides / attempted suicides • Incidents involving police investigation or criticism from an external organisation • Clusters and trends involving multiple incidents or patients • Evidence of organisational failure • Incidents where a safety alert has been in place • Incidents where a professional alert notice is in place/requested • Incidents involving new or poorly understood areas of concern e.g. adverse outcomes from new interventional procedures/drugs, • Incidents attracting high media attention • Prison service incidents involving NHS staff • Deaths in Custody involving NHS staff • Incidents reported by Commissioning arm of PCTs
SHA priorities	• Safeguarding children - Serious Case Reviews • Maternity unit closures • High Secure Unit SUIs (as identified in MH section above) • Health Care Associated Infections (HCAI) which constitute an outbreak and/or cause ward closure / disruption to service provision • CAMHS admissions under the age of 18 into adult placement areas. All admissions of children under 16s years of age admitted to adult wards to be reported accordingly. Adolescents aged 17-18 years admitted to adult placements are requested to add clarification statement in the "further information" box on the StEIS report form identifying if the placement decision was made on clinical judgement or due to lack of specialist CAMHS placement availability.

Appendix 4

Internal Incident Investigation Report Format and Content

For SUIs which meet the SHA escalation requirement and are performance managed by the SHA, the report of the internal investigation should normally be received by the SHA within 45 working days of the incident report date on StEIS / UNIFY and should include the following: -

Title

1. Post Incident Review – Serious Untoward Incident – StEIS /UNIFY reference number

Contents Page

2. If a report is in excess of 4 pages, a contents page should be included – especially if the report contains appendices. Page and paragraph numbering is essential.

Background

3. Brief description of the matters and circumstances that have prompted the review, including the specific issues that need to be addressed within the report.

4. Care should be taken not to include here information that should be placed in the body of the report.

5. As this section is likely to set the tone of the document, particular care should be taken over use of language. In particular emotive language should be avoided.

Review Team and Terms of reference

6. The Trust should appoint a review team at the earliest opportunity. The team should be lead by a Chair of the Review Team, who ideally is experienced in incident investigation and trained in root cause analysis. The chair of the Review Team should also have sufficient authority (delegated or otherwise) within the Trust to be able to report recommendations to the Trust Board and partner organisations.

7. The other members of the review team should include appropriate clinicians, other health professionals, managers and others so that the review will be as balanced and as thorough as possible. The Trust should also consider including a lay person, patient or independent

professional on the team, to provide an objective view of the circumstances.

8. The terms of reference should closely reflect the contents of paragraphs 3-5.

9. The terms of reference should be clear and free of ambiguity to permit focussed examination of the key issues.

10. If appropriate the terms of reference should be amended in the light of a significant fact/issue emerging from the ongoing review.

11. It may be that the new fact(s)/issue(s) would need to be addressed by a separate investigation. In this case this matter should be raised in the recommendations and/or in an appendix to the report.

Process (methodology)

12. The report should clearly state the methodology and/or the process adopted to undertake the review. The report should contain information on the following:

    (a) List of documents and policies examined by the reviewer/s;

    (b) Whether patient records were examined and if so by whom; was an internal expert asked to comment on the records;

    (c) List of persons interviewed with dates and times (including the length of individual interviews). It is recommended that the questions asked of the various interviewees should be included in an appendix and cross referred by the number in this section or other relevant section of the report. It is also recommended that interview notes should also be included in the appendix; and

    (d) Any anomalies in the process e.g. key witnesses being unavailable should be mentioned here.

Facts established

11. A history of service user's treatment and care should be included.
A chronological account of what is *known* to have happened – this should 'tell the story' of the unfolding of events relating to the matters under review. The report should carefully document the following:

    (a) Whether the relevant and accurate diagnosis was/were made at the earliest available opportunity;

    (b) Whether the diagnosis was made in the most efficient and efficacious manner;

    (c) Whether the care given to the patient was effective and optimal;

(d) Whether there are any outstanding issues related to consent; and

(e) The consequence/s of any defects/shortcomings in (b) and (c).

12. The report should make specific reference/s (if appropriate) to any individual professional performance issues. If the performance of a professional is at issue, the report should make reference to any previous instances of poor performance and conduct. The report should also make reference to the steps taken by the Trust/PCT to address poor performance/conduct.

13. The report should detail (including any sanction taken by the body against the professional) any input from the professional regulatory bodies and the National Clinical Assessment Agency in the case of a professional who played a role in the current incident.

14. The above account should make explicit reference to any relevant existing policies (including clinical risk management and clinical governance policies), procedures, and protocols. The report should also allude to the extent of dissemination/staff knowledge of these policies, procedures and protocols.

15. The report should also make a reference to the extent to which the policies, procedures and protocols were adhered to in the management of the case under consideration (in relation to both the management of the care and treatment and the management of the incident).

Associated relevant factors

16. The report should include an examination of potential human error causal factors; attention should be paid to;

- Staffing levels and skill mix at the time of the incident
- Pressure to achieve targets (e.g. A&E throughput, waiting list priorities, European Working Time Directive)
- Fatigue or fitness of staff
- Communication difficulties between staff or with the patient
- Ability of staff to raise concerns (culture of organisation or team)
- Whether anyone raised a concern & if so how was it dealt with
- Whether minimum operating standards were complied with (e.g. equipment unavailable or faulty, mandatory training standards)

- Any confusion or misunderstandings about procedures or practices

- Clarity about each persons role in any procedures or practices

This list is not exhaustive.

Points causing concern about the evidence

17 This section should highlight any areas of conflict or ambiguity in the gathered evidence e.g. where people interviewed disagreed about significant matters, or where there are important gaps in the evidence.

18 The report should clearly state the criteria used to resolve conflict /inconsistencies in the evidence. The way in which the gap(s) in the evidence was/were handled should also be stated. The report should also give an indication as to how facts on which key conclusions are based were established.

Analysis/Conclusions

19. Logical and sequential connections between facts/evidence should be e.g. 'given XYZ, it would be very likely that ABC would have been the case'.

20. The report should analyse and comment on any mismatch between what is believed to have happened in practice and what should have happened (given policy/procedures/protocols and/or professional judgement of review team or expert witnesses). See also paragraph 11

21. The authors should comment on the cause/s of any such mismatch. The authors should support their views by the facts contained in the report and other evidence based on guidance and best practice.

Recommendations

The purpose of the recommendations is twofold: to minimise the impact of the present incident and to reduce the likelihood of the incident occurring again.

22. The recommendations should be precise and targeted at the appropriate level/s of the organisation and should reflect the 'improvement philosophy' behind the undertaking of the review.

23. The recommendations should address any factor that is judged to have contributed to less than satisfactory service delivery, or which may enhance already satisfactory service delivery (if latter is the case this should be made explicit). Such factors may be organisational, situational; procedural; resource related; or related to professional practice (personal style, communication, professional judgement or knowledge or personal application).

24. The recommendations made should be clearly listed in order of priority as deemed important by the review team. Please note if the Trust/PCT does not accept the recommendations, the SHA must be informed of the reasons for rejection and any proposed alternatives.

25. The recommendations should be strengthened if they can be related to examples of good and effective practice elsewhere.

26. The action points contained in the recommendations should clearly state timescales for completion.

Actions

27. Each NHS organisation that reviews an incident should ensure that;
    - The document is disseminated to relevant staff
    - All relevant new staff are inducted in the resulting process changes
    - Information is shared, where appropriate, across the health community
    - There is an understanding of how reports impact on future delivery of services and any changes made.

Lessons learned

28. The purpose of the lessons learned is twofold: to highlight changes in practice implemented since the incident and to ensure that this information is readily accessible.

Authorship/Membership

29. The report should be addressed to the relevant officer of the Trust and signed and dated by the chair of review. Full details of members on the review team should be included in the report. Membership designation should also be identified.

Appendices

30. Copies of all interview notes, documents examined, and working documents such as plans of the site of the incident should be included in the appendix. Also included should be a breakdown of the Review team, including experience/qualifications & job titles of each member. N.B. Whilst these should form part of the organisational final report, they do not need to be supplied in the SHA copy of the report unless specifically requested.

31. Statement to the effect that the incident has been or is likely (if correct) to be subject to a formal complaint or claim should be included.