TITLE	**POLICY FOR THE MANAGEMENT OF ADVERSE EVENTS AND NEAR MISSES (INCLUDING SERIOUS UNTOWARD INCIDENTS)**
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AMENDMENTS RECORD

DATE	PAGE	COMMENTS	APPROVED BY
March 2007	4 & 5	Process amended to reflect new adverse event forms	
	5 & 6	New section on staff support	
	6	New section on re-grading of incidents	
	7 & 8	Duties amended to include: Divisional Management Teams, Reporter of Incident and Manager	
	11	Appendix B amended to reflect new process for dealing with adverse event forms	
	12 – 20	Appendices C -> E amended to reflect new SUI process	
	21 - 24	Appendix E: Principles of SUI investigations (new)	
	25	Appendix F: Amended guidance for statements	
	26 – 27	Appendix G: Template for Initial Mgt Report (new)	
	28 – 36	Appendix H & I: Templates for SUI report and action plan (new)	
	37 – 39	Appendices J/K/L: Flow chart and info re staff support (new)	
	40 – 41	Appendix M: Amended guidance for informing pts / relatives, to include reference to *Being Open*	
	42	Appendix N: Amended guidance for informing external agencies, to include new contact details for SHA	

	5	Addition of definition of root causes	
	6	Change to 6.7 Appendix G -> Appendix E and Appendix D -> F Amendment to para 6.8: staff access to whistleblowing policy	
	7	Addition of 6.9.The investigation	
	9	Amendment to 6.10'staff support' – internal and external	
	9	Change to 6.10.2 Appendix J, K -> K, L and Appendix L -> M	
	11	Amendment to 6.12.1 – 6.12.14:Organisational Learning	
	12 – 15	Amendments to Duties and Responsibilities	
	15 - 16	Amendments to 'Training'	
	16 - 17	Amendment to Associated Documentation: External - new number 8 and new number 10. Internal – new number 1, 3, 8 and 9	
	18	Appendix B: alteration to name of Governance & Quality Committee	
	19	Appendix C: addition of SIRG Change to order of appendices	
December 07	21	Appendix D: Guidance for informing pts / relatives	
	22 - 23	Appendix E: Initial Management report	
	24 - 32	Appendix F: SUI protocol + re-written	
	33 - 36	Appendix G: SUI reporting principles	
	37 - 38	Appendix H: Guidance for writing statements	
	39 - 46	Appendix I: Investigation report template	
	47	Appendix J: Guidance for SUI panel members	
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APPENDICES:

1. Introduction / Background

Portsmouth Hospitals NHS Trust (the Trust) recognises that in a service as large and complex as the NHS things go wrong. When they do, the Trust supports the view that the response should not be one of blame and retribution but of organisational learning with the aim of encouraging participation in the overall process and supporting staff, rather than exposing them to recrimination. Therefore, the Trust is committed to developing a just culture and to encouraging a willingness to admit mistakes without fear of punitive measures. In support of this, the Trust accepts that completion of an incident form does not constitute an admission of liability and will not result in automatic disciplinary action. There are occasions, of course, when it may be necessary to attach blame: acts of maliciousness or criminal or gross/repeated professional misconduct.

2. Status

Corporate Policy

3. Purpose

This policy details the process for the management of adverse events and near misses. It has been formulated in response to the Department of Health publications An Organisation with Memory[1], Building a Safer NHS[2], Doing less Harm[3] and the National Patient Safety Agency publications Building a memory: preventing harm, reducing risks and improving patient safety[4] and Being Open: Communicating patient safety incidents with patients and their carers[5]. The policy is also designed to ensure compliance with the requirements of Standards for Better Health[6] and National Health Service Litigation Authority (NHSLA) Risk Management Standards[7].

However, the ultimate aim is to reduce the risk of harm to patients, staff and other users of Trust premises through improving the safety and quality of services and the environment.

4. Scope/Audience

This policy applies to all staff: those of Portsmouth Hospitals NHS Trust, the MDHU (Portsmouth), Retained Services at Royal Hospital Haslar and Carillion, whilst acknowledging that for staff other than those directly employed by the Trust the appropriate line management or chain of command will be taken into account. Whilst the policy outlines how the Trust will report, manage, analyse and learn from all clinical and non-clinical adverse events and near misses, implementation does not replace the personal responsibilities of staff with regard to issues of professional accountability for governance.

5. Definitions

Adverse event: any event or circumstances arising during NHS care that could have or did lead to unintended or unexpected harm, loss or damage.

Adverse incident: an event or omission, which caused physical or psychological injury to a patient, visitor or staff member

Serious untoward incident: one where serious actual harm has resulted (commonly classified as a 'red' incident).

Near miss: a situation in which an event or omission, or a sequence of events or omissions, arising during clinical care fails to develop further, whether or not as a result of compensating action, thus preventing injury to a patient

Harm: an injury (physical or psychological), disease, suffering, disability or death. In most instances, harm can be considered to be *unexpected* if it is not related to the natural course of the patient's illness, treatment or underlying condition, or the natural course of events if harm occurs to other than a patient

Root causes: actions or omissions with two essential features:

- Practice deviated beyond safe limits; and
- The deviation had a direct or indirect effect on the eventual outcome for the patient, staff member, visitor or contractor. In cases where you cannot be sure of the impact, it is sufficient that the root cause had a potentially adverse effect.

Root cause analysis: the process by which the underlying cause(s) of adverse incidents is established

Category Near Miss:	Incident occurred but did not reach patient
Category Green Incident:	No obvious harm
Category Yellow Incident:	Minor: non-permanent harm
Category Amber Incident:	Moderate: semi-permanent harm
Category Red Incident:	Major/catastrophic
Category Redud Incident:	Major/catastrophic but involving an unexpected death

6. Process for Reporting and Investigating all Near Misses, Incidents and Serious Untoward Incidents, involving Staff, Patients and Others

6.1 Take all necessary action to ensure that the needs of the person(s) affected by the incident are attended to and thereby minimise the risk of further harm.

6.2 Complete an adverse incident form as soon as is reasonably practicable (but before going off shift) using a black ballpoint pen. Forms must be completed legibly and comprehensively, recording fact only – not opinion. All forms must be graded (see Appendix A) and include details of any 'immediate actions' taken.

6.3 Forms must not be filed in the medical records but the incident must be documented in the records, including a note of the incident number.

6.4 All incidents must be subject to an appropriate level of investigation and causal analysis (Appendix B) and, where relevant, an action plan implemented. It is accepted that not all incidents need to be investigated to the same extent or depth. Having graded each incident the level of investigation and analysis should be expanded accordingly.

6.5 Category Green/yellow

- Reporter must complete an adverse incident form
- Reporter must inform the appropriate senior member of staff/line manager
- Reporter must send top copy of form to the Risk Management Department.

- Reporter must ensure second and third copies of form are forwarded to appropriate senior member of staff
- Senior member of staff must complete details of any long-term actions necessary, on second and third copies of the form
- Senior member of staff must send second copy to the Risk Management Department: to ensure long-tem actions can be recorded
- Senior member of staff must return third copy of form to the Adverse Incident Folder - to ensure a comprehensive history of incidents and actions taken
- Senior member of staff must ensure feedback is provided to the reporter

6.6 Category Amber

- Reporter must complete an adverse incident form
- Reporter must inform the appropriate senior member of staff/line manager
- Reporter must send top copy of form to the Risk Management Department.
- Reporter must ensure second and third copies of form are forwarded to appropriate senior member of staff
- Senior member of staff must complete brief details of proposed investigation, on second and third copies of the form
- Senior member of staff must send second copy of form to the Risk Management Department – so that proposed investigation may be recorded
- Senior member of staff must return third copy of form to the Adverse Incident Folder - to ensure a comprehensive history of incidents and actions taken
- Senior member of staff must ensure feedback is provided to the reporter

6.7 Category Red – Potential Serious Untoward Incident (Appendix C)

- Witness to incident must *immediately* inform line manager and Consultant in charge
- The Line Manager must inform the Duty Manager/Divisional General Manager, relevant healthcare professionals, including the Divisional Senior Nurse
- An immediate assessment of the incident to take place, between the healthcare professionals and the Duty Manager to determine whether it is truly a serious, or potentially serious, untoward incident
- Then, if it is a serious untoward incident
    - Duty Manager must then inform Duty Executive and Risk Management Department (ext 2476/3278) and ensure statements are collected and an adverse event form is completed. These statements and the adverse event form must be forwarded to the Risk Management Department within 24 hours.
    - Consultant/Divisional Senior Nurse to discuss incident with patient/relatives, in line with the Trust's *Being Open* policy and Appendix D
- The Divisional Senior Nurse should ensure that an Initial Management Report (IMR – Appendix E) is completed and forward it to the Risk Management Department within 48 hours.

The Risk Management Department will then invoke the Serious Untoward Incident Protocol (Appendix F)

6.8 Staff are also able to raise concerns in line with the Trust's Whistleblowing Policy (Insert hyperlink). This policy enables staff to raise concerns about wrongdoing at work in a way which protects their interests, and which ensures at the same time, that instances of wrongdoing, alleged wrongdoing or apparent wrongdoing are properly investigated and dealt with. The policy is designed to:

- Provide a way for members of staff concerned about the care or safety of patients to speak out in the event of other procedures failing or being exhausted.
- Provide an effective and confidential process to enable staff to challenge practices or behaviours if they believe others are acting in an unlawful and/or unethical way
- Ensure victimisation or retribution against staff will not be tolerated
- Protect staff if they speak out appropriately

If the concern is regarding the welfare of an adult patient, staff should also refer to the Hampshire County Council *Protecting People from Abuse* guide available at http://www3.hants.gov.uk/adultprotect.htm

6.9 The Investigation

6.9.1 This section details the principles for dealing effectively and efficiently with any investigation arising from a near miss, or incident. It will:

- Provide guidance to staff on effective investigation methodology
- Encourage the appropriate use of clinical and other professional and expert advice, experience and expertise
- Utilise valuable lessons learned from near misses and incident investigations when developing risk reduction strategies, as part of the integrated governance and risk management programme of work
- Ensure compliance with near miss and incident investigation guidelines from external bodies e.g. the National Health Service Litigation Authority, Healthcare Commission

6.9.2 The objectives are to:

- Ensure that issues and events are proactively and properly investigated, root causes identified and lessons learned
- Improve practice and/or systems and policies as a result of the near miss or incident investigations
- Eliminate or minimise the risk of recurrence and demonstrate that the Trust has acted reasonably
- Improve the range and utilisation of trend analysis data to inform and support the integrated governance and risk programme and external quality assessment requirements

6.9.3 Having assessed the near miss or incident, the amount of investigation and analysis should be relative to the seriousness, complexity of the event and/or whether it resulted in actual harm and the potential for learning, such as those which are high frequency but may be of low severity. Please note all serious 'red' incidents will be investigated in line with the SUI protocol (Appendix C and F). However, whatever the requirement of the investigation into near misses and incidents, a similar step-wise process will be followed

- Initial data collection
- Analysis of the data and the event
- Recommendations and action plan
- Monitoring and Implementation

Initial Data Collection

Data can be obtained initially from a variety of sources including: policies; site inspections, interviews; incident reports; medical records; and statements

As a minimum the initial data collection should inform the following:

- Who was involved?
- What happened?
- Where exactly?
- When?

Analysis of the data

From analysis of the data the following should be determined:

- Background to the event
- Chronological narrative (i.e. precise sequence of events)
- Key care delivery problems (these relate to the direct provision of care)
- Key service delivery problems (these related to failures associated with the way a service is delivered)
- Key contributory factors (those factors which affected the performance of individuals)
- Root cause(s)
- Areas of good practice

Recommendations and action plan

The analysis following the investigation of near misses and incidents may highlight the need to amend existing practice or to introduce a new process or policy. In this instance an action plan will be formulated to ensure the appropriate implementation of those changes: this plan may involve simple short term actions or may be more complex and require considerable multidisciplinary discussion and Trust-wide consultation before implementation can be effective.

Monitoring and Implementation

The Divisional Governance Team has the responsibility to ensure that agreed actions arising out of investigations, to reduce error, are implemented across team/departments and to ensure the divisions foster an ethos of learning from error in order to minimise future risk. This will require close working with the Risk Management Department. The Divisional Governance Team must have clear processes of feedback to staff on lessons learned from adverse incident reporting and subsequent investigations.

Reports of all Serious Untoward Incident investigations are considered by the Serious Incident Review Group, which has specific responsibility for overseeing and monitoring the reporting and review of those investigations and for ensuring recommendations arising from investigations are implemented across the relevant areas of the Trust.

It is the responsibility of either the Divisional Governance Team or the Serious Incident Review Group to determine whether any of the issues raised by a near miss or incident investigation should be placed on the local or trust-wide risk register.

- An interview with a member of the education teams
- A requirement to read the relevant hospital policies and guidelines
- The writing of a piece of reflective practice describing the event
- A piece of education, often e-learning, to reinforce the messages

The trainer and trainee will agree a timetable for the completion, usually two weeks, and the trainee will be required to email the trainer with the reflective practice piece, a statement that they have read the policy and the certificate from the agreed learning

If the trainee is required to attend the review process they will be offered support from outside their department usually from a member of the education team. It is expected that those organising the review of the SUI will contact the DPME to ensure someone is available

Trainees should be encouraged to contact their educational supervisor and to discuss the issues with them.

6.10 Staff support

6.10.1 Internal Support (immediate or ongoing, if necessary)
Support may also be obtained from a colleague, a member of the Risk Management Team, a representative of your professional body or Trade Union, or the Trust solicitors.

6.10.2 External support
The Trust has adopted the well-research and practiced TRiM model: Trauma Risk intervention Management.

An adverse event may cause serious distress in those exposed to the situation. Left unresolved, some individuals may go on to develop longer term symptoms of stress and anxiety. Best practice standards have shown that intervention can prevent trauma-related problems in the future. For this reason the Trust has invested in an Adverse Incident Response (AIR) Team. The team is made up of 8 hand-picked members of Aquilis Counselling Resources for Organisations and the Trust's own Occupational Health and Safety Service, all of whom have undertaken rigorous training in diffusion and debriefing.

Generally following an adverse incident the AIR Team Coordinator will visit the ward or department to gather information about the incident and talk to staff. Having assessed the situation they will offer appropriate interventions both to diffuse the stress, and support staff involved, either directly or indirectly. (Appendices K, L)

These interventions may be:

- Practical Help: some individuals may need some immediate help to organise themselves. For example, to get home or to pick up children from school
- Information and Advice: handouts, leaflets or talk time – giving information about what to expect following what to expect following an adverse incident
- Debriefing Groups: staff are provided with an opportunity to explore, make sense of, and contain their experience in a structured and systematic way
- Debriefing 1:1: some people prefer to talk on a one-to-one basis
- Talk Groups: clusters of staff talk about their experiences
- Drop-ins: a more casual arrangement giving individuals the opportunity to ask questions, check out or tell their story.

All these interventions are voluntary and staff only attend if they wish to do so

There will be some incidents which do not involve the whole ward or department. Individuals may contact the AIR Team directly: do not underestimate the impact a seemingly small incident can have upon you.

If you are feeling overwhelmed or have any of the common signs or symptoms (Appendix M) contact the AIR Team on 02392 866402 or 7701 2402 or via the Occupational Health Department and ask for the AIR Team.

It is recognised that confidentiality is pivotal in the AIR process and that will be maintained at all times unless certain issue are disclosed. These may include

- Abuse
- Fraud
- Criminal activity
- Threat or harm to life
- Requirement of law

If issues of this nature arise, it is the responsibility of the AIR Team coordinator to report the disclosure to the appropriate senior person within the Trust.

6.10.3 Support for Medical Trainees

Trainees involved in serious untoward incident reviews will be given the appropriate support and the whole process will add to their learning

If it is identified that a trainee is involved in a serious untoward incident, the Director of Postgraduate Medical Education (DPME) or the Associate Directors will be contacted as soon as possible

If the review of the incident suggests that the doctor has had some part in the process, which requires further education, a plan will be formulated. In most cases this will involved:

- An interview with a member of the education teams
- A requirement to read the relevant hospital policies and guidelines
- The writing of a piece of reflective practice describing the event
- A piece of education, often e-learning, to reinforce the messages

The trainer and trainee will agree a timetable for the completion, usually two weeks, and the trainee will be required to email the trainer with the reflective practice piece, a statement that they have read the policy and the certificate from the agreed learning

If the trainee is required to attend the review process they will be offered support from outside their department usually from a member of the education team. It is expected that those organising the review of the SUI will contact the DPME to ensure someone is available

Trainees should be encouraged to contact their educational supervisor and to discuss the issues with them.

6.11 Re-grading of incidents

6.11.1 Near misses/green/yellow incidents

The line manager or staff in Risk Management Department, in discussion with the reporter, may re-grade any incident initially graded as a near miss, green or yellow.

6.11.2 Amber incidents

The re-grading of incidents initially graded as amber should only take place after discussion between the line manager and a member of staff from the Risk Management Department.

6.11.3 Red incidents
The relevant healthcare professional and Divisional General Manager will assess all incidents initially graded red. All incidents that have initiated the SUI process will only be downgraded following discussion at the Serious Untoward Incident Review Group.

The reporter of any incident must be informed of the changes to any initial grading.

6.12 Organisational Sharing and Learning
Portsmouth Hospitals NHS Trust recognises that there is a need to view all near misses and incidents positively as a valuable contribution to the development of better quality healthcare. The Trust is therefore committed to identifying lessons learned from near misses and incidents so that services may be improved. The organisation has a number of processes to enable this learning and sharing, and continued strengthening of those processes will be key to improving the services provided to our patients, relatives and carers. The processes include

6.12.1 Recording all incidents and actions taken onto the Trust database (Datix) by staff in the Risk Management Department. This allows the Trust to analyse incidents and identify trends in a number of ways including: by division, location, type, and severity. Data collected informs the quarterly aggregated Complaints, Litigation, Incidents and PALS (CLIP) report.

The report includes:

- Total number of reported incidents: by division
- Top 10 reported incidents: trust-wide
- Top 10 reported incidents: by division
- Total number of reported incidents: by severity
- Total number of reported incidents: by severity, by division
- Serious untoward incident summary
- Organisational learning
- Recent and future developments

6.12.2 Presentation of the CLIP report to the Governance and Quality Committee and the Trust Board and also informs reports to:

- Strategic Health Authority
- Divisional Clinical Governance Teams
- The Healthcare Commission
- Primary Care Trusts
- Other internal or external groups, on request

6.12.3 The Divisional Governance Leads cascading the CLIP report to their respective divisional teams

6.12.4 The Divisional Clinical Governance Teams feeding back on actions taken in the light of incidents, to inform future CLIP reports and further organisational learning.

6.12.5 Information being provided to and from CLIP informing the Divisional Performance Reviews and the Governance Agenda.

6.12.6 Producing reports specifically tailored to the requirements of Divisional Clinical Governance Teams, and the Health & Safety Steering Group, for dissemination as appropriate

6.12.7 The Divisional Clinical Governance Teams receive quarterly reports and feedback on actions taken in the light of incidents and near misses, to inform future CLIP reports and further organisational learning.

6.12.8 CLIP reports are posted on the Risk Management intranet website, so that they are available to all staff

6.12.9 Reporting all serious untoward incidents to the Serious Incident Review Group

6.12.10 Reporting, via the electronic reporting system, STEIS, all serious untoward incidents to the SHA for monitoring by the PCT to enable learning across the whole of the local health economy.

6.12.11 Sharing of all reports of the investigations into Serious Untoward Incidents across all divisions. It is accepted that some of the action plans and learning points will be specific to the division in which the incident took place. However, there is every likelihood that there are some learning points or recommendations that will be relevant to, and should be considered by, all staff across the Trust. (Appendix N)

6.12.12 Reporting of all patient safety incidents to the National Patient Safety Agency (NPSA) as part of the National Reporting and Learning System (NRLS). A briefing paper on each report produced by the NPSA is submitted to the Governance & Quality Committee and posted on the Trust intranet site, as an aid to both benchmarking and learning across the organisation.

6.12.13 The production of 'Bite Size Best Practice': a regular publication, which is disseminated Trust-wide and includes: information on adverse events; evidence based changes to practice; and relevant risk management articles

6.12.14 Grand Rounds: sessions held to discuss issues raised by incidents, claims, complaints or issues known to be of Trust-wide concerns

6.13 Reducing Risk

6.13.1 All risks identified from the CLIP report will be assessed in accordance with the Trust's Risk Assessment Policy and if approval obtained from the Divisional Management Team entered onto the Risk Register. In exceptional circumstances, and with the approval of the Company Secretary, a risk may be placed on the Assurance Framework. All risks, either on the Risk Register or the Assurance Framework have, in accordance with Trust policy, associated action plans. These action plans are monitored by the appropriate divisional group to ensure target dates are achieved and the risk reduced or eliminated

6.13.2 In extreme and exceptional circumstances it may be necessary to limit or suspend a service or activity whilst an investigation to determine the full extent of the risk is undertaken. Such a decision may only be taken at Executive Level.

7. Duties and Responsibilities

Trust Board

Trust Board has overall responsibility for effective risk management within the Trust and to ensure the Trust complies with its statutory obligations.

The Governance & Quality Committee
Reporting directly to the Board, the Governance & Quality Committee has overall responsibility for ensuring that, through the appropriate investigation of complaints, claims and incidents, there is continuous and measurable improvement in the quality of the services provided. The Committee receives quarterly reports on serious incidents, incidents, claims and complaints and the organisational learning that has taken place as a result of the investigations into those events, thus enabling the Trust Board to be assured that the risks associated with these activities are appropriately managed and, if necessary have been included on either the Assurance Framework or the Risk Register.

Serious Incident Review Group
The Serious Clinical Incident Review Group provides a high level forum in which to oversee and monitor the reporting and review of serious untoward incidents and will ensure recommendations arising from internal reviews and enquiries of serious untoward incidents are implemented across the Trust and progress monitored accordingly.

Chief Executive
The Chief Executive has ultimate responsibility for Corporate Governance including Risk Management but delegates this responsibility through Company Secretary and the Medical Director

Company Secretary
The Company Secretary, in conjunction with the Medical Director, has executive responsibility for delivery of the Risk Management Agenda.

Head of Governance
The Head of Governance has management responsibility for delivering the Governance Agenda. (Martin, have removed 'Risk Mgt from this sentence)

Head of Risk Management
The Head of Risk Management has responsibility for the operational and day-to-day implementation of this policy. The Head of Risk Management leads the Risk Management Team, the Complaints and Legal Services Teams.

The Risk Management Team
The Risk Management Team is responsible for supporting and advising managers and staff to ensure that this policy is implemented across the Trust. The Team is also responsible for maintaining the database of incidents and providing feedback to relevant committees, groups and staff. In addition, the Team provides a regular opportunity for liaison and discussion between Complaints, Litigation and Risk Management, to facilitate the sharing of information and aid organisational learning.

Divisional Management Teams
The Divisional Management Teams must have a sound working knowledge of this policy. The Teams have a responsibility to investigate and take action when requested, or required, on all events referred to them and to ensure actions to reduce error, arising out of near misses and incident investigations are implemented and that that implementation is monitored across appropriate departments. The Teams also have a responsibility to ensure that the divisions foster an ethos of learning from error, in order to minimise future risk. This will require close working with the Risk Management Department. The Divisional Management Team must have clear processes of feedback to staff on lessons learned from near misses and incidents subsequent investigations.

Divisional Governance Teams
The Divisional Governance Team must have a sound working knowledge of this policy, including the Serious Untoward Incident Protocol. The Teams have a responsibility to investigate and take action when requested, or required, on all events referred to them and to feedback to staff and the Risk Management Department. The Team has the responsibility to ensure agreed actions arising out of incident investigations, to reduce error, are implemented across appropriate team/departments and to ensure that the divisions foster an ethos of learning from error, in order to minimise future risk. This will require close working with the Risk Management Department. The Divisional Governance Team must have clear processes of feedback to staff on lessons learned from adverse incident reporting and subsequent investigations.

Divisional General Managers
Divisional General Managers will also assess all incidents initially graded red. In addition, they have a responsibility to ensure that all relevant serious untoward incidents are robustly investigated and, where actions are required to prevent recurrence, these are implemented

All Managers
Managers are responsible for promoting effective risk management and ensuring there are operational systems in place within their teams to fulfil the requirements of this policy. This includes ensuring staff receive feedback on reported incidents together with appropriate risk management training. Within that context, managers must ensure that their staff are released for training and fully assisted and supported throughout the handling of any incident. Where staff are experiencing particular difficulties associated with an incident, managers should consider referring the staff member or members to the Occupational Health Department, the Adverse Incident Response Team or the Director of Postgraduate Medical Education. (see section 6.10.2 and 6.10.3)

Managers must also ensure the implementation and monitoring of any changes that may be necessary following the investigation of an incident.

All Staff
All staff have a responsibility for ensuring that adverse events and near misses are reported, and for obtaining feedback on incidents reported, as part of their own accountability for governance.

All staff should be aware of what constitutes an adverse event or near miss and the process for reporting and management of such incidents.

The Reporter
The reporter must:

- Ensure the immediate safety of the patient/staff/visitor involved in the incident
- Complete an adverse incident form
- Inform the appropriate senior member of staff/line manager
- Send top copy of form to the Risk Management Department.
- Ensure second and third copies of form are forwarded to appropriate senior member of staff

For near misses/green/yellow/amber incidents, it is the Trust's expectation that the reporter will return to their line manager for feedback. This may be on a 'day-to-day' basis or form part of the annual appraisal system

The Manager

The manager must:

- Receive and investigate incidents as forwarded by the reporter and complete details of the long-term actions necessary, on second and third copies of the form
- Send second copy to the Risk Management Department: to ensure long-tem actions can be recorded
- Must return third copy of form to the Adverse Incident Folder - to ensure a comprehensive history of incidents and actions taken
- Participate in the SUI process, as required.
- Ensure feedback is provided to the reporter, on a day-to-day basis or as part of their annual appraisal
- Ensure lessons learned are shared across there area of responsibility.

8. Training

Training on the requirements of this policy is included in the Trust's Corporate Induction programme. However, all staff should be aware of the policy and the level of awareness determined within the team.

Risk Management training is provided through a variety of mediums to ensure staff receive training appropriate to their role and to reinforce the main elements of this policy. To ensure staff receive the training, the Learning and Development Team have identified the needs of staff via a Trust Training Needs Analysis (TNA), which is updated annually by Divisional Managers through the completion of an annual TNA survey. Those surveys are returned to the Learning and Development Department and processed by the Clinical Audit Department into a Divisional and Trust training demand. The Learning and Development Team then produce a Trust training plan that addresses essential training (including risk management) and which incorporates the needs and priorities of the Divisions and the Trust. Where compliance with attendance at essential training is not being achieved it is the responsibility of the Divisional Training Group to provide an action plan to the Strategic Learning and Development Committee on how this will be improved. (For further information, please see the Learning and Development Policy available on the Trust's intranet site)

The Risk Management Team will provide the relevant section of essential training to all members of staff. This training can be provided in a number of ways, including:

- Trust Induction
- Junior Doctors' Induction
- Risky Business (1 and 2)
- E-learning
- Workshops
- Updates

Details of risk management training can be found on the Trust's intranet Learning and Development site, in the Trust document *'Learning Pages'*, or by contacting the risk management department on ext 2476. It is recognised that the content of risk management training sessions will, and should, develop in the light of information and/or learning derived from the investigation of incidents and near misses.

In addition, specific training programmes are provided for Senior Managers and Trust Board and Non-Executives

Senior Managers

Risk Management training for senior managers will be provided within two months of becoming a manager. The one-day training occurs bi-monthly and includes and focuses upon: familiarisation with the Risk Management Strategy. It will include:

- Legislative background and recent changes
- The assurance framework and corporate risk register
- NHSLA and Standards for Better Health
- National Patient Safety Agency
- Adverse incident reporting and serious untoward incidents
- Complaints handling
- Claims handling
- Being Open
- Information Governance

The Recruitment Team will book any new member of staff who manages a team or a function, or whose role changes to include a management function onto the course.

Trust Board and Non-Executive Directors

Six targeted updates and workshops will be held annually and will appear on the agenda at Trust Board Away Days. The 45- minute session will include:

- Legislative background and recent changes
- The Assurance Framework and Risk Register
- NHSLA and Standards for Better Health
- National Patient Safety Agency
- Adverse incident reporting and serious untoward incidents
- Complaints handling
- Claims handling
- Being Open

9. Associated Documentation

External

1. Department of Health, June 2000. *An Organisation with a Memory*
2. Department of Health, April 2002. *Building a Safer NHS*
3. Department of Health, August 2001. *Doing Less Harm.*
4. National Patient Safety Agency, July 2005. *Building a Memory: preventing harm, reducing risks and improving patient safety*
5. National Patient Safety Agency, 2005. *Being Open: Communicating patient safety incidents with patients and their carers*
6. Department of Health, July 2004. *National Standards, Local Action, Health and Social Care Standards and Planning Framework*
7. National Health Service Litigation Authority, April 2006, *Risk Management Standards*
8. National Health Service Litigation Authority, April 2005, *Clinical Negligence Scheme for Trusts - Clinical Risk Management Standards – Maternity*
9. Medical Devices Agency, March 2002. *Safety Notice MDA SN2002(01)*
10. Hampshire County Council *Protecting People from Abuse* guide

Internal

1. Portsmouth Hospitals NHS Trust. *Risk Assessment Policy*
2. Portsmouth Hospitals NHS Trust. *Trust Policy and Protocol on Whistleblowing Policy (Human Resources Policy)*
3. Portsmouth Hospitals NHS Trust. *Health & Safety Policy*
4. Portsmouth Hospitals NHS Trust. *Being Open Policy*

5. Portsmouth Hospitals NHS Trust *Maternity Risk Management Strategy*
6. Portsmouth Hospitals NHS Trust *Maternity Policy for the Management of Adverse Events and Near Misses*
7. Portsmouth Hospitals NHS Trust *Risk Management Strategy*
8. Portsmouth Hospitals NHS Trust *Risk Management Framework*
9. Portsmouth Hospitals NHS Trust *Assurance Framework and Protocol*
10. Portsmouth Hospitals NHS Trust *Policy for the Handling of Concerns and Disciplinary Procedures Relating to the Conduct and Performance of Doctors and Dentists*
11. Strategic Health Authority *Guidance for the Serious Untoward Incident Reporting Process*

Appendix A

INCIDENT GRADING MATRIX (for grading incidents in a systematic and consistent manner)

NB: If you are unsure how to grade an incident please speak to your colleagues or contact the Risk Management Department

To establish the grade look in the table below in the four 'impact' columns for the wording that best describes the incident you are reporting. Note, if there are two or more descriptions that fit the event then use the highest scoring descriptor.

DESCRIPTOR	Impact on Individual (s)	Scope of impact in terms of number of people affected	Impact on the organisation	Financial impact / Potential for litigation
	Death • Unexpected death of pt whilst under direct care of h/care professional	Many (>50) e.g. cervical screening concerns	• National adverse publicity / severe loss of confidence in the organisation • Extended service closure	Litigation expected/certain Over £1m
	Including: • Permanent major harm • Procedures on wrong body part • Retained instruments after surgery • Radiation dose greater or less than intended • Infant abduction • Severe medication error	16 – 50	• National adverse publicity / major loss of confidence in the organisation • Service closure • Increased length of stay > 15 days	Litigation expected/certain £0.25 - £1m
Moderate	Including: • Semi-permanent harm up to one year • Serious breach of confidentiality	3 – 15	• Local adverse publicity / moderate loss of confidence in the organisation • Temporary service closure	Litigation possible but not certain High potential for complaint £50k - £0.25
Minor	Including: • Non-permanent harm (up to one month)	1 – 2	• Minimal	Litigation unlikely Possibility of complaint
None	• No obvious harm	N/A	• Minimal	Litigation remote

Appendix B

PROCESS FOR THE REPORTING AND MANAGEMENT OF AN ADVERSE INCIDENT

INCIDENT OCCURS

MEMBER OF STAFF

1. Address the immediate health needs of the person(s) involved
2. Grade incident when completing the incident form – red/amber/yellow/green/near miss (NB: incident may be re-graded following review by your Manager, the Risk Management Dept or following investigation)

[redacted]

Please see Appendix C, F and G for details of Serious Adverse Event investigation process

Issues reported / monitored via:

- Divisional Governance Teams
- Serious Incident Review Group
- Governance & Quality Committee
- Trust Board
- Divisional Performance Reviews
- Primary Care Trust

AMBER

- Complete an adverse incident form
- Inform appropriate senior member of staff
- Send top copy of form to Risk Management (if maternity incident, send to Risk Midwife)
- Ensure second and third copies of form are forwarded to senior member of staff who deals with adverse incidents
- Senior member of staff must liase with the Risk Management Department asap, to ensure appropriate type, level and ownership of investigation (i.e to be investigated by department in which incident occurred or by risk management)

Issues reported/monitored via:

- Specialty meetings
- Divisional Governance Teams (CLIP report)
- Divisional Performance Reviews
- Governance & Quality Committee
- Trust Board

YELLOW **GREEN**

- Complete an adverse incident form
- Inform appropriate senior member of staff
- Send top copy of form to Risk Management Department ((if maternity incident, send to Risk Midwife)
- Ensure second and third copies of form are forwarded to senior member of staff who deals with adverse incidents
- Senior member of staff must complete details of any long-term action
- Senior member of staff to ensure second copy of form is forwarded to Risk Management Department asap
- Senior member of staff to ensure third copy of form is returned to adverse incident folder

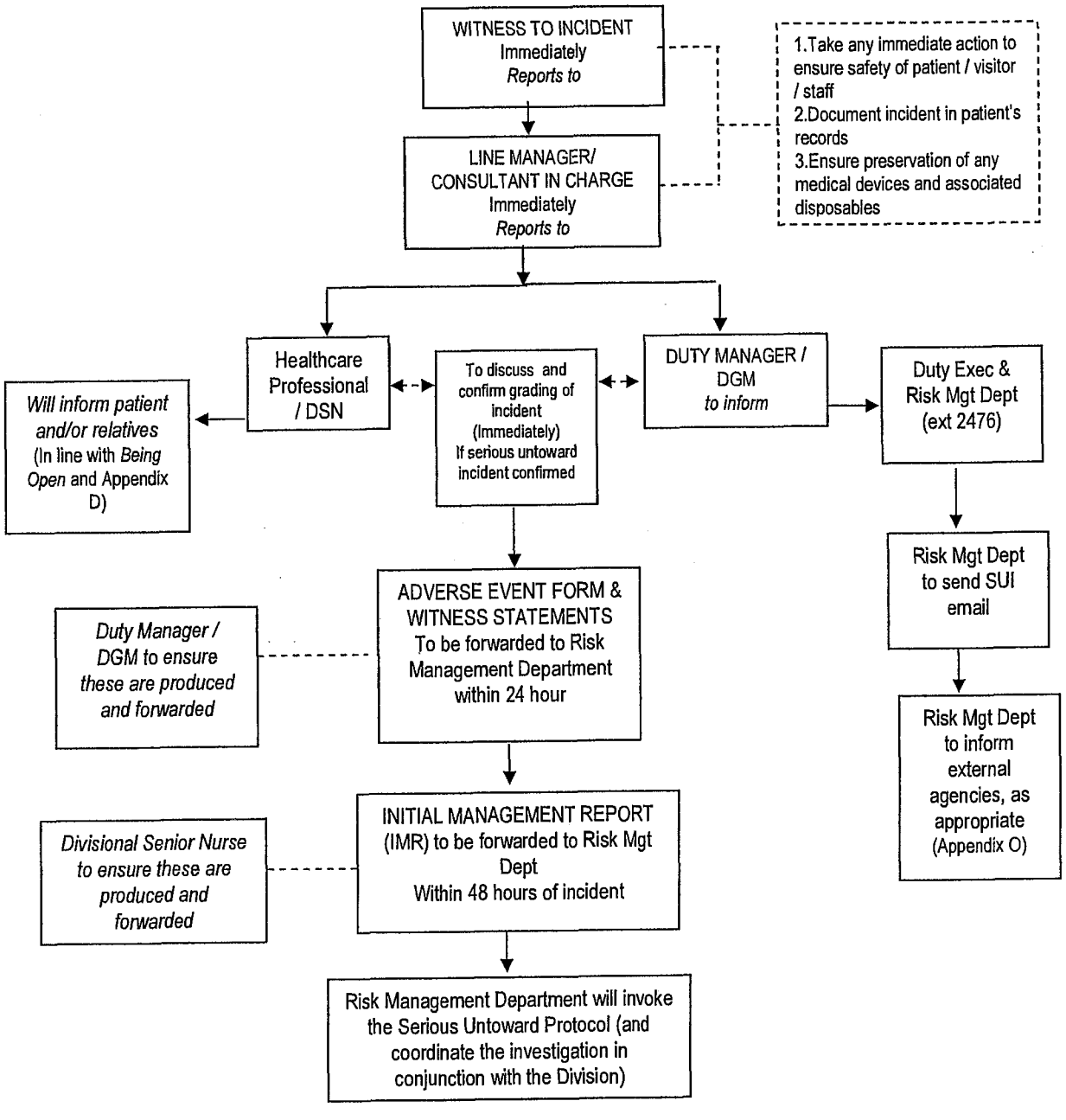
Issues reported to and monitored via:

- Divisional Clinical Governance Teams (CLIP report)
- Divisional Performance Reviews
- Governance & Quality Committee
- Trust Board

It is essential that staff receive feedback via their line management route, on reported incidents and actions taken.

Appendix C

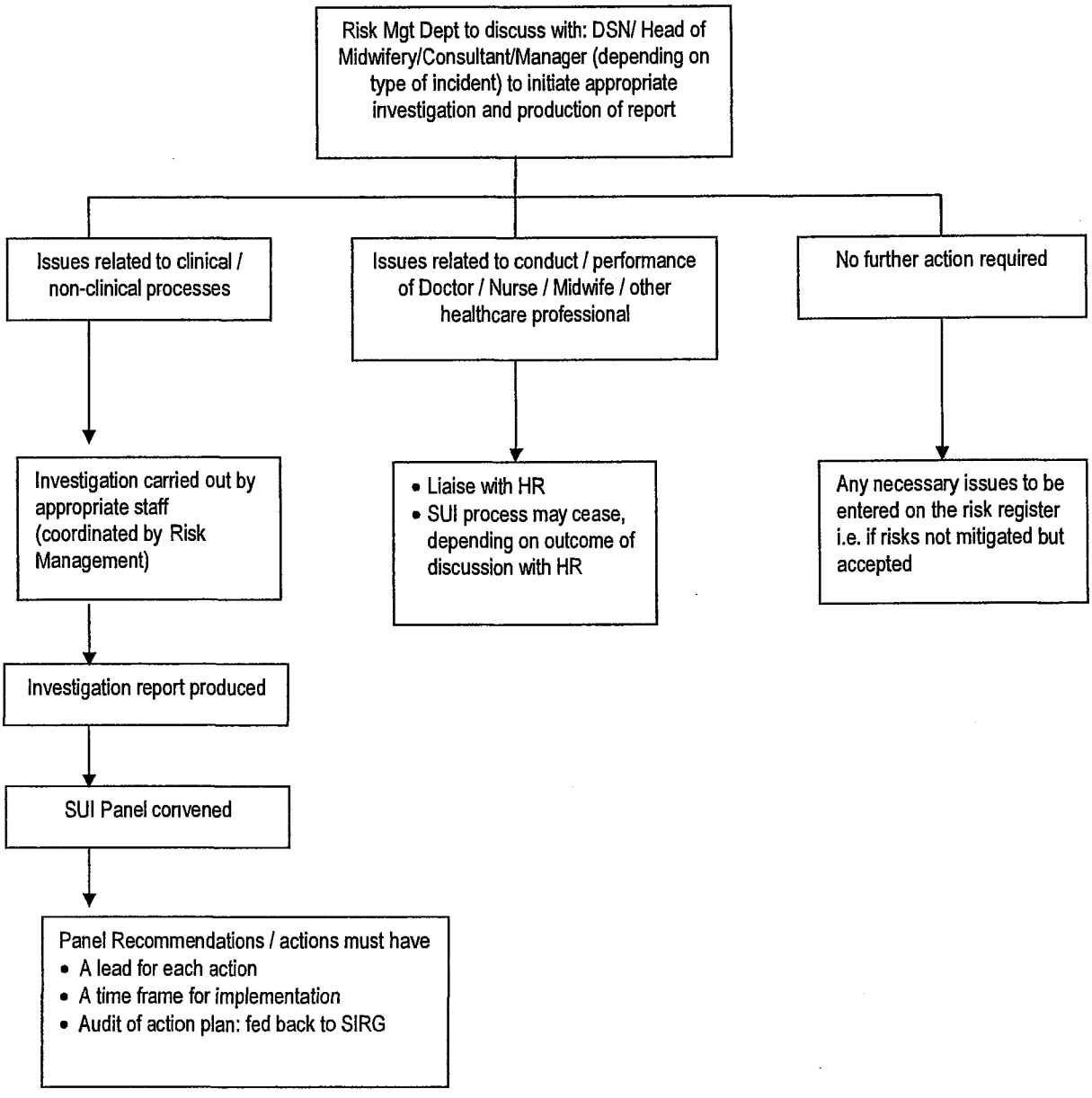
PROCESS FOR THE REPORTING AND MANAGEMENT OF SERIOUS UNTOWARD INCIDENTS



Please note:
Guidance on statement writing can be found at Appendix H
An IMR template can be found at Appendix E
Guidance on informing patients/relatives can be found in the *'Being Open Policy*

Appendix C (contd)

PROCESS FOR THE REPORTING AND MANAGEMENT OF SERIOUS UNTOWARD INCIDENTS (Contd)



Serious Untoward Incidents (SUI) will be reported to Governance & Quality Committee and reviewed bi-monthly by the Serious Incident Review Group (SIRG)

BUT

All SUIs must be discussed at Divisional Clinical Governance meetings.

Appendix D

GUIDANCE FOR INFORMING PATIENTS, RELATIVES AND STAFF

The Trust's Being Open Policy will be followed with regard to talking to patients and relatives. The advice of the Communications Manager sought before ***any*** external communication is made. Regardless, it is essential that a record of all oral communications is maintained.

Staff, patients and/or their relatives must, whenever possible, be informed ***before*** the media becomes involved. This may not be possible where an affected patient, or their relatives, choose to communicate with the media, but it is important that the Trust does not aggravate the situation by communicating with the media before attending to the affected patients, or their relatives.

Effective communication with patients begins at the start of their care: this should be no different when an incident occurs. Openness about what happened and discussing incidents promptly, fully and compassionately, using all available methods of communication, can help patients cope better with the after-effects. It is fundamental to the partnership between patients and those who provide their care and may help prevent incidents becoming formal complaints and litigation claims.

It is essential that as soon as a serious incident is identified, or there is the possibility of multiple enquiries, an appropriate person is charged with informing patients, or their relatives. Who that appropriate person should be will be dependant upon the type of incident. For example, it may be the Head of Service in which the incident arose, or the Consultant in charge of the patient's care. The important issue is that this person is identified without delay. For further information please refer to the Trust's *Being Open* Policy.

Apologies

The National Health Service Litigation Authority (NHSLA) considers it both natural and desirable for those involved in treatment which produces an adverse outcome, for whatever reason, to sympathise with the patient or the patient's relatives and to express sorrow or regret at that outcome. Such expressions of regret would not normally constitute an admission of liability, either in part of full, and it is not the policy of the NHSLA to prohibit them, nor to dispute any payment, under any scheme, solely on the grounds of such an expression of regret.

The NHSLA will assist with advice about the wording and timing of apologies and explanations. Claimants, their solicitors and their barristers frequently ask why clinicians or NHS bodies rarely apologise for adverse outcomes and why they rarely explain why, and how, adverse outcomes have occurred.

Explanations

Patients and their relatives increasingly ask for detailed explanations of what led to adverse outcomes and this is confirmed by the survey commissioned by the Department of Health: *Making Amends*. Closely linked to this desire for information is the frequently expressed view that they will feel some consolation if lessons have been learned for the future. In this area, too, the NHSLA and the National Patient Safety Agency (NPSA - through their document *'Being Open)'* are keen to encourage both clinicians and NHS bodies to supply appropriate information whether informally, formally or through mediation.

Care needs to be taken in the dissemination of explanations, so as to avoid future litigation risks but, for the avoidance of any doubt, the NHSLA will not take a point against any NHS body or any clinician seeking NHS indemnity, on the basis of a factual explanation offered in good faith before litigation is in train. The NHSLA and the NPSA considers the provision of such information to constitute good clinical practice and provided facts, as opposed to opinions, form the basis of the explanation, nothing is likely to be revealed which would not subsequently be disclosable in the event of litigation.

Formal Admissions

In keeping with the NHSLA's financial and case management responsibilities, the NHSLA will make or agree the terms of formal admissions within or before litigation.

Appendix E

INITIAL MANAGEMENT REPORT FOR SERIOUS UNTOWARD INCIDENTS (SUIs)

STRICTLY CONFIDENTIAL

1	**Patient Details**	
	Full Name	
	Address	
	DoB	
	Hospital Number	
	Consultant	
	Date of Admission	
	Date of Discharge/Death	
2	**Details of Incident**	
	Incident Form No	
	Date of Incident	
	Location	
	Name of attending Doctor (if applicable)	
	Name of attending Nurse (if applicable)	
	Brief details of incident (What happened / circumstances in which patient was found)	
3	**Key Factors/Other Information**	
	Clinical/Social	
	Environmental	
4	**Brief Account of Events leading to the Incident**	
5	**Conclusions**	

6	**Implications / Summary Recommendations**		
7	**Further investigation required?**		
		No	
		Internal investigation + external assessor	
		External inquiry	
8	**Name of person who initiated this report**		
	Designation		
	Date		

Copies of this report within 48 hours to:

Risk Management Department
Clinical Governance Lead (for information)

Appendix F

SERIOUS UNTOWARD INCIDENT (SUI) PROTOCOL

1. INTRODUCTION

This protocol describes a formal, practical process for the investigation and analysis of all serious untoward ('red') incidents: clinical and non-clinical, and details the responsibilities of staff within the process. Whilst the protocol will primarily be used for the investigation of serious adverse events, it may be applied to less serious incidents where there could be benefit in conducting a more detailed investigation.

Broadly speaking, an incident will either be investigated because of its seriousness to the individual, or for the organisation, or because of its potential for learning about the functioning of the department or organisation. What marks out a serious incident as requiring detailed investigation is the nature, scale and consequence or potential consequence. Some incidents require immediate initial investigation, whilst others can wait a few hours (e.g. until the following morning) or longer.

2. DEFINITIONS

Serious untoward incident : an event that causes major permanent injury, prolonged care or catastrophic harm or disruption to any number of persons for which the potential future risk of recurrence is possible, likely or almost certain and which, if not properly managed may result in loss of the Trust's reputation, assets or business.

A serious untoward incident may involve service users, carers, staff, visitors the general public or anyone else to whom the Trust owes a duty of care. The response to a serious untoward incident must take account of everyone involved.

Root Causes: actions or omissions with two essential features:

- Practice deviated beyond safe limits; and
- The deviation had a direct or indirect effect on the eventual outcome for the patient, staff member, visitor or contractor. In cases where you cannot be sure of the impact, it is sufficient that the root cause had a potentially adverse effect.

Root cause analysis: the process by which the underlying cause (actions or omissions) of adverse incidents is established

3. ROLES AND RESPONSIBILITIES

3.1 Staff must take all immediate, appropriate action to ensure the safety and wellbeing of the patient, staff, visitor or contractor; whoever is affected by the incident

3.2 The witness to the SUI, or potential SUI, will inform the appropriate line manager or consultant

3.3 The line manager or consultant must then inform the duty manager/divisional general manager/divisional senior nurse/other relevant healthcare professionals/head of midwifery (if relevant)

3.4 Before the incident is escalated, the Duty Manager/Divisional General Manager must discuss the incident with the relevant healthcare professional/consultant to determine if the incident is truly an SUI. If is decided that the incident is not an SUI, then it should be reported in accordance with the process for incidents other than SUIs. If it is deemed that the incident is an SUI the Duty Manager should inform the Risk Management Department on ext 2476 or by fax on 2451 and then ensure completion of an adverse event form and statements. The top copy of the adverse event form and all statements must be forwarded to the Risk Management Department within 24 hours.

3.5 As soon as is practicable Risk Management staff will inform the following, using the SUI email distribution list:

- Chief Executive
- Medical Director

- Director of Clinical Services, Nursing & Midwifery
- Head of Governance
- Non-Executive Directors who are members of the Governance Committee
- Communications Manager
- Divisional General Managers
- Divisional Clinical Governance Leads
- Divisional Clinical Director
- Divisional Senior Nurses
- Legal Services Manager
- Complaints Manager
- Risk Advisors
- Risk/Complaints Coordinators
- Head of Midwifery (if relevant)
- Other Senior Managers, as appropriate

3.6 The communications manager will immediately notify the NHS South Central communications team

- Within office hours 01865 337077
- Out of hours 08700 555 500 and quote pager number SCSHA 1

3.7 Staff in the Risk Management Department will also formally report the incident to the Strategic Health Authority, in line with guidance, and as soon as possible using the electronic reporting system (UNIFY).

3.8 The divisional senior nurse must arrange for the production of an Initial Management Report (IMR – Appendix E) and forward this to the Risk Management Department and Clinical Governance Lead within 48 hours.

3.9 The Lead Investigator (this may be a member of the Risk Management Dept or other nominated member of staff) will initiate the appropriate investigation

3.10 The Lead Investigator will instigate an initial meeting to agree the way forward:

- The investigation process to be undertaken to:
  - Gain an understanding of the aims
  - Agree the style and process of the investigation
  - Share expectations of each role and each other
  - Agree key milestones and how the various investigative strands will be brought together
- The need for any independent expert opinion established: internal or external
- The timescale for the investigation process (One month would provide sufficient time for most investigations, whilst providing an appropriate sense of urgency and allowing appropriate reporting to the NPSA and the SHA)
- Time commitment (it is likely that some dedicated and intensive periods of time will be necessary to achieve an efficient and timely investigation)

Note
If a junior doctor is involved in the investigation process the Director of Postgraduate Medical and Dental Education needs to be informed in addition to the education supervisor - to ensure that the doctor is adequately supported

If a member of NHSP is involved in the investigation process, the Governance Team at NHSP should be informed and involved in the investigation

3.11 The Lead Investigator will, in collaboration with the Risk Management Department:

- Collate all information from other team members and, if necessary, the Divisional Senior Nurses will assist in 'chasing' reports on nursing issues and the Divisional Clinical Governance Leads will assist in 'chasing' reports on medical issues
- Notify SUI panel members of the decision to hold a panel
- Notify SUI panel members of the function and conduct of the panel
- Draft and circulate the report to the Investigation Team and the SUI panel members, if different
- Arrange a date for the SUI panel
- Draft and circulate draft the Terms of Reference for the SUI panel
- Circulate medical records, as appropriate

3.12 The Lead Investigator will maintain a folder of evidence. This will include:

- Draft report
- Statements
- Medical Records
- Relevant past incidents/complaints/claims
- Related policies, procedure, guidelines – or lack of same
- Agreed Terms of Reference for the SUI panel

4. THE INVESTIGATION PROCESS

The investigation will gather the information necessary to produce a draft report, to discover the contributory factors, root causes, and to provide the minimum data set required by the NPSA. This data set will include:

- **WHAT** happened, severity of actual or potential harm, people and equipment involved
- **WHERE** did it happen: location/specialty
- **WHEN** did it happen: date and time
- **HOW** did it happen: immediate or approximate causes
- **WHY** did it happen: underlying or root causes
- **WHAT** action was taken or proposed: immediate and longer term
- **WHAT** impact did the event have: harm to the organisation/patient/others
- **WHAT** factors did or could have minimised the impact of the event

4.1 Reviewing the records: Accounts of the incident may be taken from case notes, written reports from, or interviews with, staff. The analysis may be limited if only written reports are considered, in that it may not be possible to explore the full range of conditions that allowed the event to occur. The first task, from the information immediately available, is to record the initial summary of the event and identify the most obvious problems. In some instances there may only be one, but nearly always several problems conspire to create an incident. Make an initial summary of the principal events (an outline chronology), as recorded in the available documentation, before starting any interviews. Next list the key staff involved and decide who, if anyone, should be interviewed and in what order

4.2 Framing the problem: The next task is to decide which section(s) of the process to examine. This is now always straightforward. It depends less on the conditions at the actual time of the incident and more on when and where problems first arose, which may only become apparent during the review. For instance, in a clinical situation, a haemorrhage may have been badly managed leading ultimately to the patient's death two weeks later. The chronology may summarise three weeks of care, most of which may have been of a high standard. However, the analysis should concentrate on those aspects where problems were apparent. For example, in the preparation for surgery, conduct of the surgery and postoperative monitoring, in order that the appropriate lessons are learned. Similarly, in a non-clinical situation, the chronology may summarise issues going back a considerable period of time e.g. lack of maintenance, but the analysis will concentrate on those aspects where problems were apparent e.g. failure of the lift and why

4.3 Undertaking interviews: Interviews should ideally be undertaken in private and, if at all possible, away from the immediate place of work in a relaxed setting. The purpose of the interview is simply to find out what happened and this should be explained at the outset. The style adopted should be supportive and understanding, not judgmental or

confrontational. When it becomes clear that a professional shortcoming has occurred, this should be allowed to emerge naturally from the conversation and should not be extracted by cross-examination. Most staff are genuinely disturbed when it becomes clear that something they have or have not done contributed to an incident. The staff members will normally require additional support at this point and should be allowed, through supportive discussion, to start to come to terms with what has happened (see 6.8 for further information on staff support).

The investigator and the person in charge of the unit must also decide early in the review if events have been sufficiently traumatic to warrant sending any member of staff off duty. This should not normally be considered as suspension from duty, simply a compassionate measure to enable recovery. The member of staff may also not be able to work safely and effectively in the immediate aftermath of an incident.

There are several distinct phases to the interview and it will generally be more effective to move through these phases in order. Each interview should take between 20 and 30 minutes, depending on the degree of involvement. Ideally two interviewers should be used, one leading the interview and the other taking notes and asking supplementary questions. Having two interviewers present must not be seen as overwhelming and the staff member must be informed of their right to have a friend, colleague, trade union representative or member of their professional body present during the interview.

What happened? – Establishing the chronology and outcome
First, the investigator should establish the role of the member of staff in relation to the incident as a whole and record the limits of their involvement. They should then establish the chronology of events as the staff member saw them

How did it happen? – Identifying the root causes
In the second phase, the investigator should first explain the concept of root cause analysis. They should ask the member of staff to identify the main root causes as they see them, without concerning themselves with whether or not anyone is or is not to blame for any of them. The task is to identify all important acts or omissions made by staff, or other breakdowns in the process that were (with hindsight) important points in the chain of events leading to the adverse outcome. Subsequent questions may elicit the reasons behind their actions (e.g. why did you not call for help at that stage?) and explore references to strong emotions, such as anxiety or anger, which sometimes highlight crucial points in the process.

Examples of Root Causes (this list is not exhaustive)
➢ Failure to monitor, observe or act ➢ Delay in diagnosis ➢ Incorrect risk assessment (e.g. of self-harm) ➢ Inadequate handover ➢ Failure to note faulty equipment ➢ Failure to carry out checks (preoperative/equipment) ➢ Not following an agreed policy/protocol (without justification) ➢ Incorrect policy/protocol applied ➢ Not seeking help when necessary ➢ Failure to adequately supervise a junior member of staff ➢ Treatment given to incorrect body site ➢ Wrong treatment given

Why did it happen? - Identifying the contributory factors
In the third phase, the investigator goes back and asks separately about each of the root causes of which the staff member may have information or experience. Questions should cover contributory factors at all levels of the framework:

each root cause may be associated with several factors at different levels of the framework (see below). These might include, for example, poor motivation *(Individual)*, lack of supervision *(Team)*, and an inadequate training policy *(Organisation and Management)*. Although the framework has higher level, organisational factors at the top, it may be more natural to begin by enquiring about other factors, then moving up the table.

A further distinction needs to be drawn between specific factor and general conditions in the unit. The investigator should differentiate between those contributory factors that are only relevant on that particular occasion and those which are long-standing or permanent features of the unit or, in some cases, of a member of staff. For instance, there may have been a failure of communication between doctors/nurses, managers/staff. If this is unusual, and seldom occurs, then it is a *specific contributory factor*, but not a general factor with wider implications. If, on the other hand, this problem is quite frequent then the investigator would also want to note a general contributory factor of 'poor communication', which would have clear implications for the safe and effective running of the unit.

Simply, the investigator might ask:

- Does the lack of knowledge shown on this occasion imply that this member of staff requires additional training?
- Does this particular problem, with say a guideline, mean that the whole guideline needs revising?
- Is the high workload due to a temporary and unusual set of circumstances, or is it a more general problem affecting the safety of patients, visitors or contractors?

Framework Table	
Factor types	**Influencing contributory factors**
Institutional context	Economic and regulatory context NHS Executive CNST/NHSLA
Organisational and management factors	Financial resources and constraints Organisational structure Policy standards and goals Safety culture and priorities
Work environment factors	Staffing levels and skill mix Workload and shift pattern Design, availability and maintenance of equipment Administrative and managerial support
Team factors	Oral communication Written communication Supervision and seeking help Team structure (congruence, consistency, leadership etc)
Individual (staff) factors	Knowledge and skills Competence Physical and mental health
Task factors	Task design and clarity of structure Availability and use of protocols/policies/guidelines Availability and use of test results
Patient factors	Condition (complexity and seriousness) Language and communication Personality and social factors

4.4 Closing the interview: After thanking the interviewee and telling them that they will be able to see a copy of their interview note for checking, the investigator should ask the staff member if they have any other comments to make or questions to ask

4.5 Analysis of the case: The core of the question is to ask: What happened? How did it happen? Why did it happen? What can we learn from this and what changes should we make, if any? In the analysis the same basic format is followed, this time drawing together the material from the case notes, interviews and the investigator's own observations.

The first step in the analysis is simply to produce an agreed chronology of events, identifying any important areas of disagreement between accounts or between any documentary evidence and the memories of the staff. The starting point for the chronology will generally be the point at which the events began (e.g. the patient entered the hospital or no clinical waste bags were available) though relevant events before this point (e.g. previous treatment, inappropriate instructions given) may also need to be recorded. However, it is then important to identify and focus on the most important part of the chronology.

The next stage is to identify the key root causes. These may be provided by the staff members or from the investigator's own knowledge and expertise. The investigator should look back over the list and ensure that all the root causes are specific actions or omissions on the part of the staff, rather than more general observations, which should be recorded elsewhere. It is easy to note down 'poor teamwork' as a root cause, which may be a correct description of the team but should properly be recorded elsewhere, as a contributory factor.

The next step is to attempt to specify the conditions associated with each of the root causes, using the framework as a guide and as a way of reflecting on the many factors that may affect the process. Interviews with staff will already have provided lists of both specific and general contributory factors. Where these conflict, it may be necessary to make a judgement as to the most important causes of the events.

A separate analysis should be carried out for each root cause though the depth and detail of the contributory factors identified may vary for each one. It is particularly important to distinguish specific contributory factors, which describe the reasons for the root cause on that particular occasion, from general contributory factors which the investigator judges to be more longstanding features of the individual, team or working conditions. Factors that are specific to that occasion, and which do not reflect more general problems, probably have no long term implications for the quality and safety of practice and therefore probably do not require action or changes of any kind. The final list for general contributory factors is examined and those that have implications for action are identified.

Preparation of the report

Once the interviews and analysis are completed, the Lead Investigator will prepare a final report detailing the whole incident from start to finish. If the process has been followed systematically and the interview and analysis conducted thoroughly, the report and implications of the incident should emerge from the analysis in a relatively straightforward fashion. When the composite is complete, there should be a clear view of the problem, the circumstances which led up to it, and the flaws in any process should be readily apparent. Once the report is complete, the Lead Investigator will circulate the report to all SUI panel members. The report contains sections as below:

- Terms of Reference
- Background
- Chronological narrative
- Key Care and Service Delivery Problems (these may be suggestions only at this stage)
- The contributory factors which led to the incident (these may be suggestions only at this stage – see 2.10.1)
- The root cause(s)/causal factors (these may be suggestions only at this stage – see 2.10.2)
- Areas of good practice
- Panel findings
- Recommendations and action plan with responsible lead(s) for implementation
- Sharing lessons/dissemination of report

- Monitoring arrangements
- Appendices
  - Panel membership
  - Sources of data
  - Statements: from whom
  - Interviews: with whom
  - Relevant guidance/legislation/trust policies consulted
  - Investigation process
  - Status of incident
  - Contact with the family
  - Glossary of terms

A sample blank reporting template and action plan is at Appendix H and I and the report template can be downloaded from the Trust Intranet *Trust Documents and Links and scroll down*

5.0 THE SUI PANEL

The purpose of the panel is to review a serious untoward incident so that lessons may be learned, shared and recurrence reduced. The panel is required to examine the facts, analyse the evidence presented and recommend corrective action.

It is not the remit of the panel to assess whether disciplinary action against an individual member of staff should be considered. However, if as a result of the investigation and panel review, prima facie evidence of professional misconduct is identified this will be documented and the appropriate senior manager will decide whether further action is necessary.

The panel should be held within 10 days of the draft report being produced and circulated and should consist of:

Chairman: should be somebody with the appropriate authority e.g. Executive Director or senior member of Trust staff e.g. Divisional General Manager, Head of Governance, Head of Risk Management, Complaints & Legal Services

Panel Members: may not necessarily be the same as those members who made up the investigation team. However, they should be chosen for their expertise, knowledge, seniority or relevant involvement in the investigation. It should be noted that there might be occasions when it is considered necessary for an independent clinical or administrative expert to join the panel. This independent advice may be obtained from within or outwith the Trust, dependent on the incident under investigation.

Lead Investigator: The Lead Investigator will be a member of the panel and is responsible for ensuring the panel is held in accordance with Trust Policy. This will include:

- Provision of medical records/statements/policies/other relevant documents
- Ensuring the provision of administrative support (the person undertaking this task should not be a panel member)
- Collection and destruction of all draft reports/copies of other documents, on conclusion of the panel

Conduct of Panel: The panel will be held in confidence

- Members of staff may be asked to attend for clarification of their written evidence: should this be necessary, staff should be advised of their right to be accompanied by a friend or other representative. They should also be reminded that the purpose of the interview is to establish the facts of the case and not part of any disciplinary process
- The panel may, if necessary, seek independent expert opinion
- The panel should aim to conclude its business in a timely fashion, in order that the Trust may report to the NPSA and the Strategic Health Authority within 60 days of the incident.
- The panel will agree recommendations and actions to be taken: each to be given a responsible lead and timescale for implementation

6.0 POST-PANEL ACTION

6.1 The lead investigator will:

- On behalf of the chair of the panel, contact all staff thanking them for their attendance and their contribution to the panel
- Provide all panel members with a copy of the final report, for comment/agreement

6.2 The responsible leads will ensure:

- Implementation of the action(s) for which they have been given responsibility by the SUI panel, within the recorded timescales
- The Risk Management Department is kept informed of progress against actions, to allow for accurate maintenance of the centrally held SUI summary
- Ensure that, when requested a progress report is provided to SUIRG

6.3 SUIRG will:

- Receive reports on current investigations/SUI summary
- Assist in ensuring implementation of the action plan(s), if necessary
- Identify any actions from the panels recommendations, which should be implemented on a Trust-wide basis
- Identify any issues which require the attention of the Governance & Quality Committee, Trust Board or other relevant group/committee

7. HOW WILL WE ENSURE LESSONS LEARNED ARE SHARED ACROSS THE ORGANISATION

- By presentation at SUIRG, Governance & Quality Committee and Trust Board
- By taking the SUIs to the divisional governance teams and empowering them to cascade the learning in a top down and bottom up approach
- By engaging the learning and development team
- Inclusion in Bite-Size Best Practice
- Through Grand Rounds
- Through Risk Management Training

8. COMMUNICATION

8.1 Patients and/or carers/relatives: In all cases every step must be taken to ensure that the patient and/or carer/relative are informed, in line with the Trust's *Being Open* Policy and before the media become involved. The consultant in charge should contact the patient and/or carer/relative when an incident occurs. Patients and/or carer/relative must be kept informed of the progress of the investigation. If a formal apology is to be offered this must be given as soon as possible, in writing by the Chief Executive.

8.2 Staff: The line manager of any member of staff involved in an incident is required to inform staff of the counselling and support service available through the Occupational Health Department (see 6.9 of main policy).

The Lead Investigator must keep any member of staff involved in the incident informed of the progress and advise any member of staff involved in the incident of the SUI panel's findings

The Lead Investigator (if not a risk advisor) must ensure adequate and appropriate lines of communication are maintained with the Risk Management Department

The Risk Management Department will ensure appropriate liaison between various appropriate Lead Managers, as individual SUI investigations may overlap with complaints, litigation, coroner's investigations, disciplinary procedures, managing performance, child protection of police enquiries.

8.3 Records Management: The Risk Management Department will hold all records, statements, documents and evidence, including a full copy of the final report, following completion of a panel.

8.4 Confidentiality: No details of the investigation should be released to the media without discussion with the Trust's Communication Manager and/or an Executive Director.

8.5 Multiple/Serial Incidents: In the event that the incident is such that there may be multiple enquiries, the 'hotline' arrangements will be invoked in accordance with the Trust Policy.

Appendix G

SERIOUS UNTOWARD INCIDENT INVESTIGATION PRINCIPLES

1. INTRODUCTION

The Trust has established a protocol for the investigation of serious untoward incidents (Appendix F): the following information provides the Trust with additional good practice principles to assist in the effective management of the protocol within the current Department of Health regulatory framework

2. CONTEXT

2.1 Many statutory agencies and bodies have particular requirements or recommendations on how Trusts should carry out SUI investigations. In addition many of the major inquiries into NHS incidents *(e.g. Shipman, Neale, Ayling)* have made similar recommendations

2.2. The Healthcare Commission Annual Health Check requires Trusts to demonstrate how they are meeting the Core and Developmental Standards and improving in relation to patient safety

3. MANAGING COMPLEXITY

3.1 Individual SUIs will vary in the scope of the investigation, the numbers of patients affected, the severity of the outcome, the likelihood of recurrence, the degree of public interest and the involvement of the Trust. A *one-size fits alls* approach should be avoided; timescales should be proportionate to each incident, and reflect the complexity of the investigation rather than just the severity of the outcome. However, the Trust has devised a protocol for the investigations of SUIs: the principles of which should be followed on all occasions.

3.2 Expected timescales for investigation and reporting can help manage the expectations of the staff and patient / family, clarify expectations between organisations and maintain confidence in the process.

3.3 Individual SUI investigations may overlap with complaints, litigation, coroner's investigations, disciplinary procedures, managing performance, child protection of police enquiries. The Trust protocol identifies how communication will be maintained and how potential disciplinary issues identified in the course of an SUI investigation are passed to a separate process for investigation

4. DISTRIBUTION

4.1 The process of sharing investigation findings and reports with the patient and/or family needs to comply with the principles of *Being Open*

4.2 Unless there are specific exceptions, the patient / family are likely to have a right to the full investigation report under the Data Protection Act 1998 requirements. The Trust will need to support investigators and other staff to ensure this does not inhibit them from identifying areas of concern.

4.3 Staff should, as far as possible, avoid disclosing health or personal issues in a report concerning a patient that has died, that the patient may have previously chosen not to disclose to their family

4.4. If the Trust takes a varying approach to the set protocol or takes a varying approach to how much of the investigation report is to be shared, the justification for variance needs to be clear and explicit

4.5 Our local coroner is fully aware of the Trust's SUI process and expects the report to be shared with him. Other stakeholders may also routinely, or exceptionally, request or require sight of SUI investigation reports. Therefore, the Trust will give clear and consistent guidance on to whom, how and in what circumstances, SUI investigation reports are shared.

5. PATIENT AND FAMILY SUPPORT

5.1 The Trust has reviewed their policies in the light of the NPSA Being Open guidance and local resources

5.2 Communication with patients, families and/or carers must be carried out by an appropriate person with sufficient training and experience: this will normally be the Consultant in charge of the patient's care. It is not appropriate for the lead investigator/team to also take lead responsibility for supporting the patient and the family

5.3 The Trust will make clear who is responsible for taking the lead in supporting the patient, family and / or carers

6. STAFF SUPPORT

6.1 The Trust has identified, and makes explicit in the body of this policy, the support available to staff and that all staff are able to access this support

6.2 Debriefs, if undertaken / requested, will take into account each individuals' natural coping mechanisms and timing of debriefs will respect these needs

6.3 Whilst the key purpose of an investigation is to understand and act upon the underlying cause(s), staff are informed that their statements are potentially disclosable in the event of legal action, or that they may be shared with the coroner

6.4 Staff will be informed that friend or union representative can accompany them at interview

7. RECOMMENDATIONS

7.1 SUI report recommendations should be discussed, refined and amended before their presentation in final draft

7.2 SUIRG will consider the effectiveness of the recommendations. Any consequences of, or competing priorities within the recommendations should be considered.

7.3 Whilst staff directly involved in an SUI will have the chance to correct factual inaccuracies or comment on recommendations but they will not have the right of veto. Rather than risk a situation in which the lead investigator may be pressured or influenced, any discussions surrounding controversial content or recommendations will best be supported by a third party e.g. a senior nurse or clinician

7.4 A small number of recommendations addressing root cause(s) are much more likely to be successfully implemented than a multitude of detailed actions. It is suggested that, unless there are exceptional circumstances, that five recommendations is a maximum manageable number.

7.5 Sometimes in the course of an investigation, unrelated issues can be uncovered which whilst irrelevant to the actual incident need following up and action taken. This must be done effectively but separately from the SUI action plan

7.6 The Trust will ensure that action plans do not become impossible to close by ensuring clarity. It is important to clarify that making a recommendation is not equivalent to saying the adverse outcome was avoidable.

7.7 Monitoring and sign off arrangements for action plans will be explicit and robust.

8. ACTION PLANS

8.1 Are extremely important tools in delivering system improvement following an incident

8.2 Will be developed and discussed with staff who will be required to deliver them

8.3 Will address the root cause(s) of the incident

8.4 A small number of clear and effective actions are more likely to improve safety than a long list: quality rather than quantity

8.5 Will only address those issues which the Trust has the power to address. For example, if a problem is found in another agency's procedures the action plan can only promise to inform the other agency, not ensure the procedure is actioned

8.6 Many issues identified in action plans need long term ongoing monitoring, such as ensuring certain standards in nursing documentation are maintained. In these cases, the action plan will be set out in a way that is not *'never-ending'*. For example, the action required is to ensure this audit is added to an existing audit of documentation: then normal Trust procedures will ensure the ongoing monitoring

8.7 Will be sustainable and congruent with overall clinical governance plans, as diverting resources to a particular issue at the cost of other areas is unlikely to improve overall future safety

8.8 Will not be so specific as to allow no scope for improvement or adaptation when they are applied in practice

8.9 Should not be confused with outcomes. For example, you can promise to implement robust procedures and suitable equipment for preventing pressure ulcers, but you cannot promise that a patient will never develop a pressure ulcer

8.10 Should be measurable. Not solely for ease of performance management but for practicality – if you can't measure it, you will never know it has been done.

8.11 Should not be vague aspirations such as *'improve communication'* – if this is an issue, it is necessary to specify what aspect of communication needs to be improved and exactly how that will be done

8.12 Where training is part of an action plan it should be appropriate, identify competencies to be achieved and have its impact evaluated.

9. REPORT WRITER'S AIDE-MEMOIR

9.1 The purpose of a report is to compile and summarise succinctly the information gathered, and demonstrate how this has been used to form recommendations. Details belong in appendices whilst being careful not to over-simplify a complex situation

9.2 There is no *one size fits all* – the lead investigator should maintain a consistent but not a rigid approach, and adapt style, format and length when it is appropriate to do so. However, if the report is over more than four pages long a summary will be produced

9.3 Language should be simple and clear, conforming to *plain English*, and only relevant information should be included.

9.4 The tone needs to be clear and factual without appearing cold or impersonal, and objective or neutral rather than partisan and should present the patient or staff affected as individuals although not being over personal or compromising confidentiality.

9.5 Reports should normally use the third person *e.g. refers to the patient, the doctor, the trust rather than using I / we / you*

9.6 Bullet points are appropriate for sections of the report conveying lists of facts or findings, but text is more appropriate elsewhere

9.7 Whilst a report must be factual, the lead investigator/team is required to do more than simply summarise facts, whilst not moving into speculation. Using the term *'the team believes'* or similar phrase is useful for distinguishing assumptions from fact

9.8 The report must not assume the reader understands normal processes or the normal progress of a patient's condition: these need to be clearly explained in a way lay people can understand to put the incident in context

9.9 It is easy to become blind to use of jargon and abbreviations and, for this reason, the report writer should ensure their drafts are checked

9.10 All paragraphs of a report must be numbered to aid any later referencing.

Appendix H

GUIDANCE FOR WRITING STATEMENTS

If you are unsure about whether a statement is necessary, or what should be contained within the statement, please contact the Risk Management Department BEFORE compiling your statement.

- Statements will normally only be required if the adverse event has been graded 'red' or 'amber'.
- Statements should ideally be written within 48 hours of an adverse event occurring.

What your statement should contain

- Facts only
- Who are you – name, grade, dept/ward/speciality, extension number
- Where the incident occurred
- Time of Incident
- Your involvement in the incident
- What happened
- What you knew about the patient and their condition at the time of the incident
- What you found on examination /on seeing the patient
- The situation with which you perceived you were dealing.
- What you did/did not do
    - Why/ why not?

What your statement should NOT contain

- Opinion
- Petulant comment
- A verbatim regurgitation of the entries made in the patient's case notes – statements are designed to 'flesh out' information contained therein

Please note

Statements made following an adverse incident – if litigation has not been intimated at the time the statement is written – will be disclosable if the case subsequently becomes the subject of claim. That means that the affected person's legal team will have access to the statement. For that reason, it is important that if any member of staff is unsure whether to write a statement, or the content of that statement, they should contact the Risk Management or Litigation department for advice.

Would staff also remember that, similarly, e-mails written between staff members, before legal action has been initiated, would be disclosable to the affected person's legal team should the case become the subject of a claim.

Portsmouth Hospitals NHS
NHS Trust
Risk Management Department
Education Centre
St Mary's Hospital
Milton Road
Milton
Portsmouth
PO3 6AD
02392 286000 ext 2424

INSERT DATE

PRIVATE AND CONFIDENTIAL

Dear Colleague

Thank you for agreeing to participate in the Serious Untoward Incident to be held on ..... You have been chosen for your expertise, knowledge, seniority or relevant involvement in the investigation.

The purpose of the panel, which is held in confidence, is to review the incident so that lessons may be learned, shared and any recurrence eliminated or reduced. The panel is required to examine the facts, analyse the evidence presented and recommend corrective action. It may be necessary to seek independent advice and members of staff may be asked to attend for clarification of their written evidence. However, it is not the remit of the panel to assess whether disciplinary action against an individual member of staff should be considered. If as a result of the investigation and panel review, prima facie evidence of professional misconduct is identified this will be documented and the appropriate senior manager, in conjunction with a representative from Human Resources, will decide whether further action is necessary.

Once the panel has reviewed the incident the members will agree recommendations and actions to be taken: each to be given a responsible lead and timescale for implementation. The report will then be presented to the Serious Untoward Incident Review Group, which is chaired by the Chief Executive, for monitoring of the action plan.

A copy of the draft report is attached/will follow once complete.

I hope you find this information useful but if you would like to know anything further, please do not hesitate to contact the Risk Management Department.

May I take this opportunity to thank you for taking the time to be a member of the Serious Untoward Incident Panel.

Yours faithfully

Head of Risk Management, Complaints & Legal Services

Appendix I

SERIOUS UNTOWARD INCIDENT INVESTIGATION REPORT TEMPLATE

Portsmouth Hospitals NHS
NHS Trust

CONFIDENTIAL REPORT

XX DRAFT

REPORT OF THE SERIOUS UNTOWARD INCIDENT PANEL

held on

Prepared By

Incident Number	**Division:**

CONTENTS **PAGE**

SUI EXECUTIVE SUMMARY	
Incident No:	**Date:**

Summary / background
Issues Identified
Recommendations/Actions

Note: Further information can be obtained from the Risk Management Department - please remember to quote incident number

1. Terms of Reference

The panel was held to examine the events surrounding the care and treatment provided to ..... between ..... Specifically, the following Terms of Reference were set down for the panel:

1. To establish the background and sequence of events that led to the incident.
2. To investigate the cause(s) of the incident and identify underlying failures in management and/or organisational systems
3. To investigate specific care issues
4. To identify failures or gaps in systems, policies and procedures related to this incident
5. To develop recommendations and an associated action plan, with timescales and lead persons for each action, to ensure the recommendations are implemented and lessons learned
6. To communicate any findings and recommendations across the organisation including those individuals directly affected or involved.
7. To ensure any potential disciplinary and/or performance issues are noted, for separate investigation

It is important to note that whilst acknowledging the professional responsibility and accountability of all staff and departments involved in this incident, it is **NOT** the purpose of this report to apportion blame.

2. Background

3.Chronological Narrative

4. Key Care and Service Delivery Problems	Care delivery problems relate to direct provision of care Service delivery problems relate to failures which are associated with the way a service is delivered and the decisions, procedures and systems that are part of the whole process of service delivery

5. Key Contributory Factors	Contributory factors are those which affect the performance of individuals whose actions may have an effect on the delivery of safe and effective care to patients

6. Root Cause(s)/Causal Factors	Root cause the earliest point at which action could have been taken that would have stopped the incident from happening

7. Good Practice	

8. Recommendations /Action Plan				
Recommendations	(1) Relevant staff to be informed of the outcome of the SUI investigation (2) Patient/relatives to be informed of SUI			
Rec. no.	Action required to achieve recommendation	Lead Person	Time-scale	Action Completed / Date
(1)	• Ensure all staff involved have the opportunity to view and discuss the report			
(2)	• Ensure appropriate healthcare professional has discussed SUI with patient/relatives			
(3)	•			
(4)	•			
Audit officer to confirm completion of actions:				

9. Sharing/disseminating lessons learned
This report will be shared and lessons learned by: • Discussion with staff involved in SUI • Presentation at Divisional Clinical Governance Teams, via Executive Summary • Presentation at the Serious Incident Review Group • Presentation Grand Rounds, as considered appropriate • Executive Summaries being placed on the Intranet

10. Monitoring
The action plan associated with this report will be monitored by the Divisional Clinical Governance Team and progress monitored by the Serious Incident Review Group who will report to Governance & Quality Committee on matters of non-compliance: matters of non-compliance will then be referred to responsible lead.

Appendix A: Panel Membership			
NAME	GRADE	INVOLVEMENT	CONTACT DETAILS
		Lead Investigator	
		Chair	

Appendix B: Sources of Data	
TYPE	TICK IF USED
Patient's medical records	
Staff rotas	
Interviews	
Statements	
Expert advice from independent clinician	
Post Mortem Report	
Visit to location of incident	
Complaint/claim documentation	
Photographs	
Other (please state)	

Appendix C: Statements			
NAME	GRADE	INVOLVEMENT	CONTACT DETAILS

Appendix D : Interviews			
NAME	GRADE	INVOLVEMENT	CONTACT DETAILS

Appendix E : Guidance/Legislation/Policies	
NAME	COMMENTS

Appendix F: Investigation Process	
TYPE	COMMENTS

Appendix G: Status of SUI		
ASSOCIATED ISSUES	**PLEASE TICK**	**CONTACT DETAILS**
Complaint		
Claim		
Inquest		
Media		
Other		

Appendix H: Contact with the Family		
FAMILY CONTACTED BY WHOM AND WHEN	**PLEASE TICK**	**CONTACT DETAILS**

Appendix I: GLOSSARY OF TERMS	

Appendix J

GUIDANCE FOR PANEL MEMBERS

Portsmouth Hospitals NHS
NHS Trust
Risk Management Department
Education Centre
St Mary's Hospital
Milton Road
Milton
Portsmouth
PO3 6AD
02392 286000 ext 2424

Insert Date

PRIVATE AND CONFIDENTIAL

Dear Colleague

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Once the panel has reviewed the incident, the members will agree recommendations and actions to be taken: each to be given a responsible lead and timescale for implementation. The report will then be presented to the Serious Incident Review Group, which is chaired by the Chief Executive, for monitoring of the action plan.

A copy of the draft report is attached/will follow once complete.

I hope you find this information useful but if you would like to know anything further, please do not hesitate to contact the Risk Management Department.

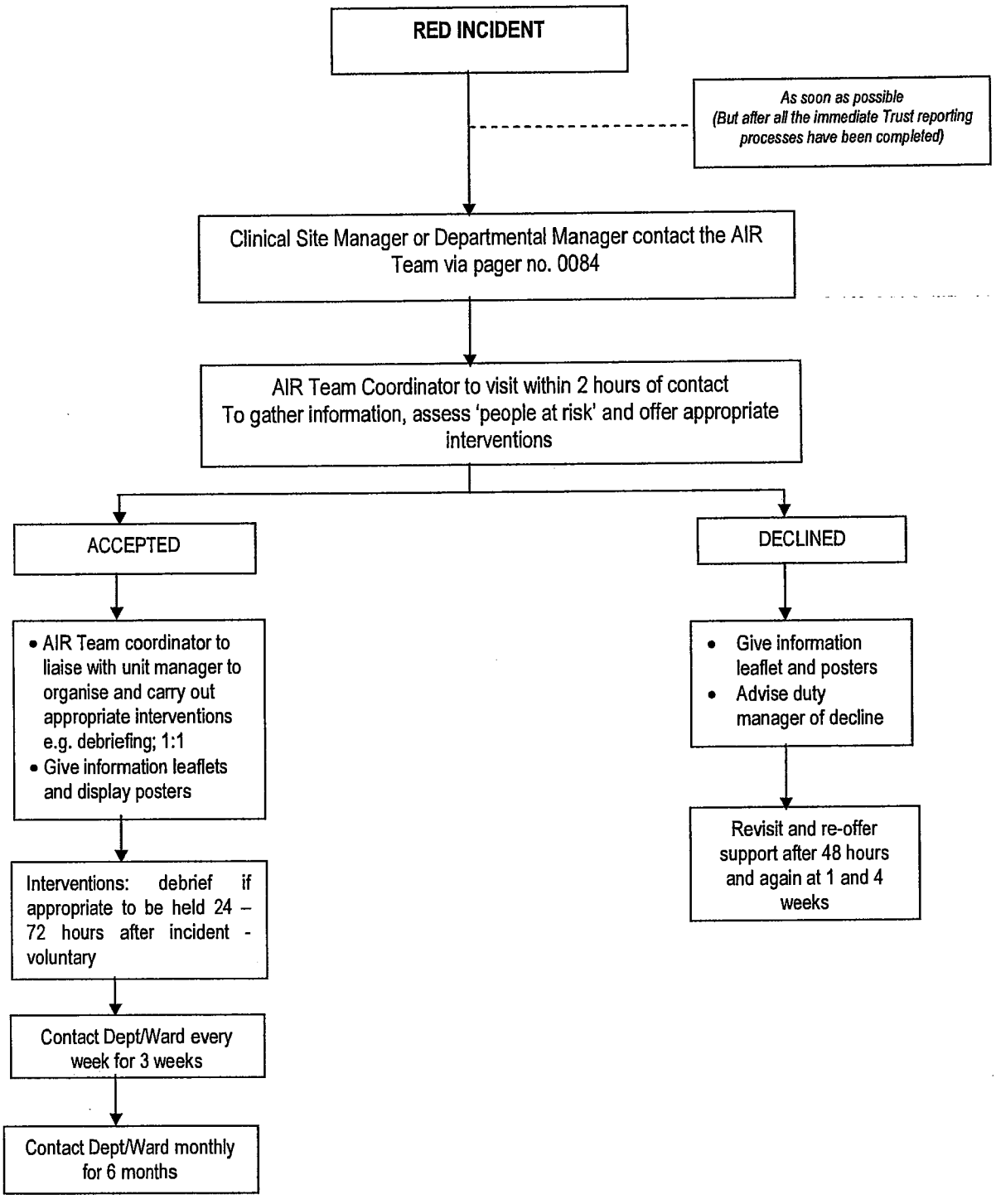
May I take this opportunity to thank you for taking the time to be a member of the Serious Untoward Incident Review Panel.

Yours faithfully

Head of Risk Management, Complaints & Legal Services

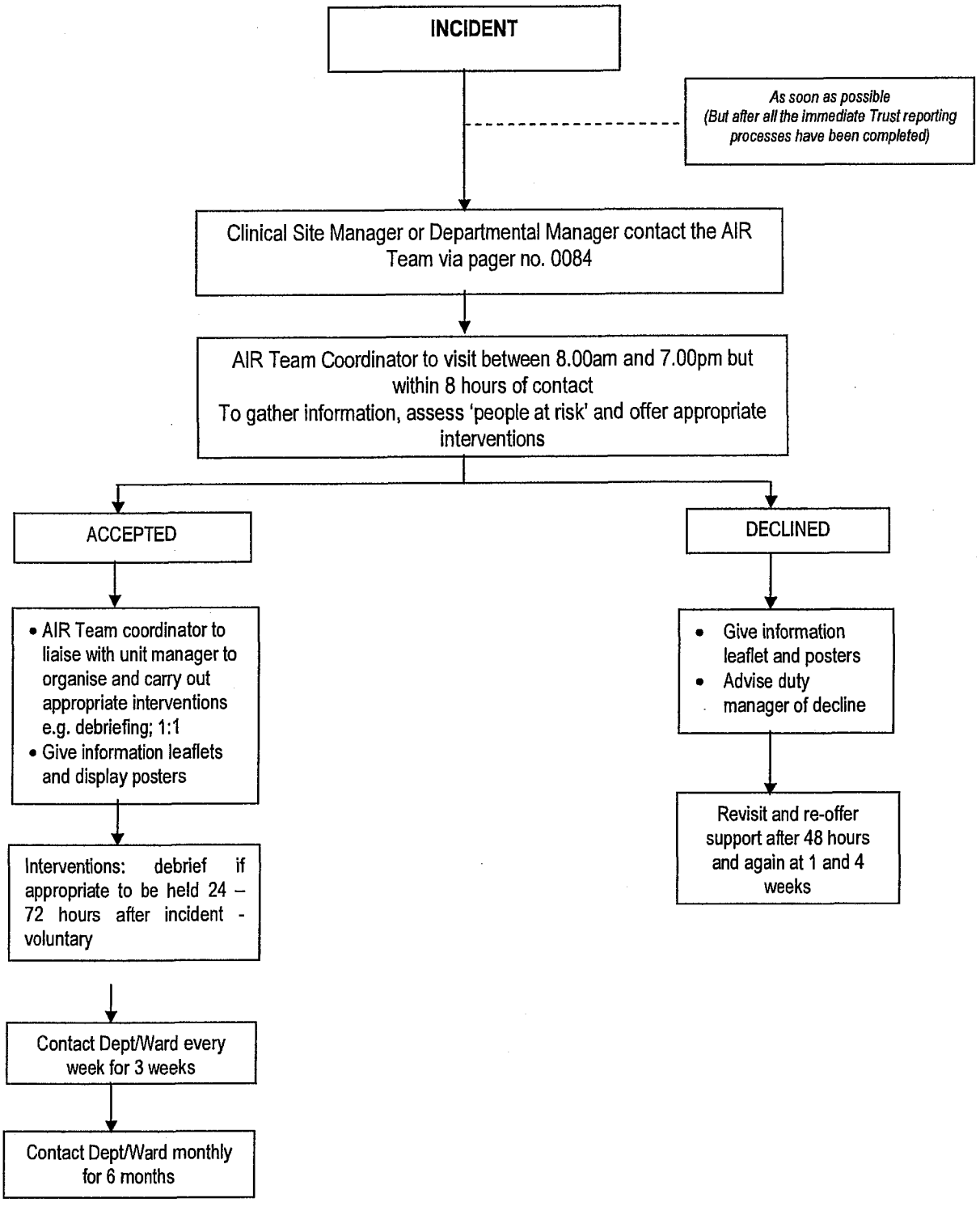
Appendix K

STAFF SUPPORT FOLLOWING SERIOUS UNTOWARD (RED) INCIDENTS



Appendix L

STAFF SUPPORT FOLLOWING OTHER ADVERSE EVENTS
(excluding those categorised red)



Appendix M

COMMON SIGNS AND SYMPTOMS FOLLOWING AN ADVERSE INCIDENT

If you are suffering any of the symptoms detailed below or would just like some independent, confidential support form the AIR Team please come along to the organised session or contact the AIR Team on 02392 866402, 7701 2402 or via the Occupational Health Department and ask for the AIR Team.

- Do you feel number or maybe feel a bit like a robot?
- Do you find yourself continually thinking about the incident?
- Do you find yourself having flashbacks?
- Are you more distracted than usual or find it hard to concentrate?
- Are you having nightmares or frightening dreams?
- Are you suddenly getting headaches or have new aches and pains in your body?
- Have you noticed changes in your behaviour, actions or responses?
- Have you recently become tearful, withdrawn, irritated, angry, impatient or intolerant?
- Can you tell something is 'just not right' with you?
- Do you just want to talk about what happened?
- Would you like some independent support?

Session
Date
Time
Venue

Appendix N

DISSEMINATION OF REPORT – LETTER TEMPLATE

Portsmouth Hospitals NHS
NHS Trust

Head of Risk Management
Complaints & Legal Services

Tel 02392 286000 ext 2424

Education Centre
St Mary's Hospital
Milton Road
Milton
Portsmouth
PO3 6AD

Insert Date

PRIVATE AND CONFIDENTIAL

Divisional Clinical Governance Leads
Portsmouth Hospitals NHS Trust

Dear Colleague

As part of the Trust's commitment to organisational learning, it has been decided that in future the reports of the investigations into Serious Untoward Incidents will be shared across all the divisions. It is accepted that some of the action plans and learning points will be specific to the division in which the incident took place. However, there is every likelihood that there are some learning points or recommendations that will be relevant to, and should be considered by, all staff across the Trust.

Once each report, its associated recommendations and action plans have been agreed, the Risk Management Department will produce an anonymous Executive Summary, to include:

- A summary of the incident
- The issues identified
- The recommendations/actions decided upon by the panel

These should then be shared at the Divisional Clinical Governance Team meetings and any other divisional meetings, as you deem appropriate.

I hope you will find this new initiative of value and that it will assist in improving patient safety across your division.

Thank you very much for your help in this matter.

Yours sincerely

Appendix O

GUIDANCE FOR NOTIFYING EXTERNAL AGENCIES

Depending on the severity and/or cause of the incident, the Trust has a responsibility to notify a number of external agencies. For category 'red' incidents, the decision to notify external agencies will case-by-case basis.

'Fast-track' reporting of serious incidents

Serious incidents will typically be regarded, in the context of the incident grading matrix outlined in Appendix B, as 'major' or 'catastrophic' adverse events. External 'fast-track' reporting will possibly include reporting to:

- **The Strategic Health Authority (SHA).** The Trust's Communications Team must report all Serious Untoward Incidents to the South Central Communications Team immediately. During office hours on: 01865 337077 and out of hours on: 08700 555 500 quoting pager no SCSHA 1. In addition staff in the Risk Management Department will also complete the on-line web-based UNIFY module as soon as possible and certainly with 48 hours of the incident. Once saved an automatic email alert will be sent to the SHA link. Once the Trust investigation is complete the Root Cause and Lessons Learned sections of UNIFY will be completed by the Risk Management Department: this must be completed as soon as possible but certainly within 60 days of the incident.
- **The National Patient Safety Agency (NPSA)** will be notified via the National Reporting and Learning System at www.npsa.nhs.uk
- **National Health Service Litigation Authority (NHSLA).** Should litigation occur as a result of an incident, the Legal Service Manager will notify the NHSLA
- **The Medicines and Healthcare products Regulatory Agency (MHRA).** This was formally two agencies: the Medical Devices Agency and the Medicines Controls Agency. All incidents relating to medical devices must be reported to the MHRA as soon as possible: on-line via the website (www.MHRA.gov.uk): by e-mail on aic@mhra.gsi.gov.uk; by mail/fax on 020 7972 8104 or by telephone on 020 7972 8080. Please note only incidents involving injury or of a serious public health concern should be reported by telephone. For reporting suspected adverse drug reactions (ADRs) staff should use the Yellow Card Scheme.
- **The Centre for Communicable Disease Control (CCDC),** via the local Consultant for Communicable Disease Control. Notifiable diseases include cholera, smallpox, typhus, measles, meningitis
- **The Health and Safety Executive.** The Health & Safety Manager will report any incidents notified under RIDDOR procedures
- **NHS Estates.** All outbreaks of fire to which the fire brigade is called must be reported within 48 hours, by the Trust's nominated fire officer. Any fire involving multiple deaths, injury or damage on a large scale should be notified immediately to NHS Estates on 0113 254 7000 or fax 0113 254 7299.
- **Serious Adverse Blood Reactions & Events (SABRE).** The UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive require that serious adverse events and serious adverse reactions related to blood and blood components are reported to the MHRA, the UK Competent Authority for blood safety. The blood transfusion team, who should always be involved in the management and investigation of any incident involving transfusion of blood products as soon as it is identified, will make reports to SABRE.
- **Radiation Protection Officer.** Any incidents involving radiation must be reported to the Trust Radiation Protection Officer (TRPO) on ext 2461. The TRPO will investigate and report to the Department of Health, as appropriate.
- **Agencies concerned with environmental and waste issues.** Reports will be made as required by the Estates Department, who should be involved in the investigation of all site issues
- **Counter-fraud Agencies.** Suspected frauds will be reported to the local counter-fraud specialist 01962 876667 or 07771 814956. The LCFS will report details in accordance with Trust policy.
- **Professional Regulatory Bodies.** Reports to professional bodies will be made by the Medical Director, Director of Clinical Services, Nursing & Midwifery or the specific professional lead for the Trust, as appropriate.

Stakeholder reporting
In addition to those agencies listed above, there are other stakeholders who require, or might require, information on specific adverse patient incidents, including:

- Patient's general practitioner
- Relevant Primary Care Trust (PCT) via the PCT risk advisor
- Coroner Code A
- Food Standards Agency **Tel:** 020 7276 8000; 020 7270 8960 (emergencies only) www.foodstandards.gov.uk
- Police **Tel:** 0845 045 4545

Others will be considered on a need to know basis.

The decision to notify the above will be reviewed by Risk Management in conjunction with the appropriate Trust Specialist and the Communications Manager, on a case-by-case basis.

Media Reporting
Consideration to the content of any press statement will need to be given; this should be under the specific auspices of the Communications Manager

If the incident involves many people, as it may do where Infectious Disease is involved, the positive use of the media as a primary means of communication with large numbers of people may be considered. In these circumstances, the prior setting up of a hot-line service, to field questions from the public, is essential. (Appendix P)

Appendix P

GUIDANCE FOR THE USE OF THE HOT LINE SERVICE

Where large numbers of enquiries from patients and relatives are anticipated, the Communications Manager (in consultation with appropriate senior staff e.g. Chief Executive, Director of Nursing, Medical Director, Divisional Manager, Head of Risk Management, Duty Director) will invoke the Hot Line Service. Depending on the pressure of calls expected there is a gradable response that can be made

The Hot Line service will be staffed by people with the appropriate skills and knowledge base; the required knowledge base will be dependant on the specialty/department involved. The numbers of staff required to man the Hot Line Service will be dependant on the anticipated number of calls that will be received. Should the number of calls exceed the anticipated volume, additional staff (with the appropriate knowledge base) will be drafted in, to ensure the Hot Line Service team is appropriately resourced.

Before invoking any Hot Line Service, the Communications Manager will ensure that:

- There is a common brief drawn up for those staff members who will be taking calls
- All staff involved are aware of when, and from whom, they should seek further advice
- All staff who man the Hot Line Service are provided with training to answering calls (Appendix P1)

Appendix P1

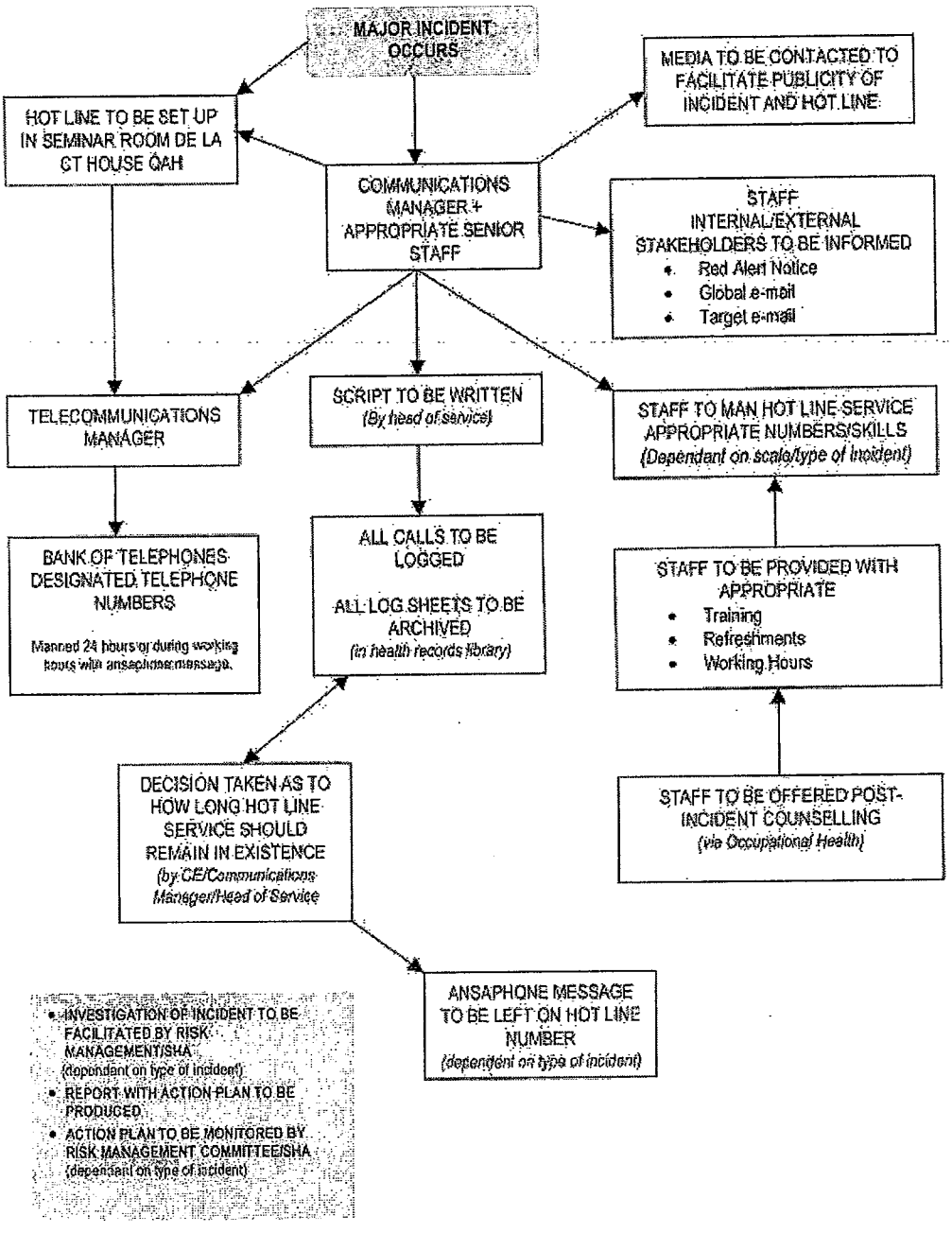
TRAINING BRIEF – HOT LINE SERVICE

The Communications Manager will ensure that all staff members who man the Hot Line Service receive the following training:

- Outline of the incident that has given rise to the Hot Line Service being invoked
- List of potential enquiries that might be made by callers to the Hot Line Service
- List of potential/suggested answers that might be given to callers to the Hot Line Service
- Advice on how to deal with distressed callers to the Hot Line Service
- Advice to be given to callers to the Hot Line Service on the availability of a call-back service. That may be used if callers appear to be very distressed or appear to have difficulty in assimilating the information provided. It may be that the call-back would be made by and alternative member of staff e.g. chaplaincy, senior member of staff from the specialty/department that gave rise to the Hot Line Service being invoked.
- Advice on the completion of log used to record the calls received by the Hot Line Service (Appendix P3)

Appendix P2

SETTING UP A HOT LINE – FLOWCHART



APPENDIX P3

CALL LOG – HOT LINE SERVICE

NAME OF STAFF MEMBER ..... TIME ON DUTY ..... TIME OFF DUTY ..... SIGNATURE .....

TIME CALL IN *(24 hr clock))*	TIME CALL COMPLETED *(24 hr clock)*	DETAILS OF CALLER *(Name, address, telephone number, relation to incident)*	ISSUES RAISED	FURTHER ACTION

Please ensure that all entries are legible and written in ink – thank you