

Independent investigation of serious patient
safety incidents in mental health services

Good practice guidance

February 2008

Putting patient safety first

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Introduction

In June 2005, the Department of Health issued new guidance on the independent investigations of serious patient safety incidents in mental health settings. The guidance aimed to help ensure a consistent approach to investigations across the health service and to raise standards.

The guidance replaced paragraphs 33–36 in HSG (94)27, (LASSL (94)4), which previously described the conduct of independent inquiries into mental health services.¹

It is the responsibility of the strategic health authorities (SHAs) to commission an independent investigation, and there are clear criteria that determine the need for one. These criteria are:

- When a **homicide** has been committed by a person who is, or has been, under the care, that is subject to regular or enhanced care programme approach, of specialist mental health services in the six months prior to the event.
- When it is necessary to comply with the State's obligations under Article 2 of the European Convention on Human Rights. Whenever a State agent is, or may be, responsible for a **death** or where the victim sustains **life-threatening injuries**, there is an obligation on the State to carry out an effective investigation. This means that the investigation should be independent, reasonably prompt, provide a sufficient element of public scrutiny and involve the next of kin to an appropriate extent (see appendix 1).
- Where the SHA determines that a serious patient safety incident warrants an independent investigation, for example if there is concern that an event may represent **significant systemic service failure**, such as a cluster of suicides.

This document describes ways in which the process of investigation can be improved and it supports the guidance. It will be relevant to SHAs, primary care trusts (PCTs), local authorities and all mental health trusts, including foundation trusts. Foundation trusts should make arrangements with their local SHA to ensure that the SHA will commission independent investigation of serious mental health patient safety incidents on their behalf.

The three stages of the independent investigation process are described in detail:

1. **Initial service management review:** an internal trust review within 72 hours of the incident being known about in order to identify any necessary urgent action.
2. **Internal NHS mental health trust investigation:** using root cause analysis (RCA) or similar process to establish a chronology and identify underlying causes and any further action that needs to be taken. This would usually be completed within 90 days.
3. **SHA independent investigation:** commissioned and conducted independently of the providers of care.

The document also covers:

- supporting victims of serious incidents, families, carers and perpetrators;
- supporting staff;
- supporting other mental health service users;
- communication with the media.

The document has been drawn up in consultation with the Department of Health, the Healthcare Commission, SHAs, mental health trusts and the Zito Trust. Legal advice has been obtained from Capsticks and Department of Health solicitors.

Review of independent investigation reports

The National Patient Safety Agency (NPSA) has established a process in conjunction with the National Confidential Inquiry into Suicides and Homicide by People with Mental Illness (NCISH) to review the reports of independent investigations in mental health services in order to identify and communicate themes for national learning.

The investigation process

This section provides local trusts and SHAs practical advice on managing a serious incident.

Stage one – initial service management review

When any serious incident occurs, an initial internal service management review should take place within 72 hours. The aim of the review is to take any immediate clinical or managerial action necessary to ensure safety, such as ligature point removal, or make any necessary urgent changes to policies or procedures.

Action may also be required in relation to staff, other individuals or organisations. Potential evidence, such as clinical notes or medical equipment, should be secured in preparation for more detailed investigation. Early contact with carers and families is important.

To ensure a systematic approach to the initial service management review, the steps outlined below are suggested. These are provided in a checklist form in appendix 2. A record of the initial service management review should be kept by the trust.

A senior manager or clinician should be identified by the chief executive, or an executive board member of the trust, to undertake the following:

- Arrange for any immediate actions to be put in place to ensure safety.
- Obtain all relevant physical, scientific and documentary evidence, and make sure it is secure and preserved. This is described in detail in the Memorandum of Understanding between the Association of Chief Police Officers (ACPO), the Department of Health (DH) and the Health and Safety Executive (HSE).²
- Contact the police and agree who will make the initial contact with the victim's family.³
- Agree with the police who will make the initial contact with the suspected perpetrator's family.
- Identify witnesses, including staff, and other service users, to ensure they receive support.

- Identify whether the injured parties and/or perpetrator is a vulnerable adult or child and act in accordance with the protection of vulnerable adults or local safe guarding children policies.⁴
- Identify trust staff to conduct the service management review.

Following the local serious incident protocol, report to the SHA, PCT, and Mental Health Act Commission if a detained patient is involved. The incident should also be reported to the NPSA via the trust's reporting system.

An internal investigation oversight group will need to be established for the most serious incidents (see stage two).

Stage two – internal NHS mental health trust investigation

When carrying out an internal investigation trusts should take into consideration the following issues, which should be addressed in local policies:

- management of patient safety incidents;
- consent;
- confidentiality;
- data protection;
- freedom of information.

Depending on the nature of the incident, there may be other relevant policies such as vulnerable adult and safe guarding children policies and procedures that need to be taken into account.

An internal investigation oversight group should be established in the most serious incidents. This group should:

- identify senior individuals to carry out the trust's internal investigation and decide whether any other agencies or organisations need to be included;
- agree a communications plan, which will include drawing up a briefing paper for the trust board;

- agree who will be the contact person for the victims, perpetrators and families;
- oversee the internal investigation;
- liaise with the SHA so that discussions about the potential need for an independent investigation occur early;
- include the commissioning PCT in discussions;
- liaise with the police, and through the police the Crown Prosecution Service (CPS), to determine how the investigation will take place without compromising any legal process.

Reference should also be made to the DH/ACPO/HSE Memorandum of Understanding at this stage. If the Memorandum is invoked then an incident coordination group comprising senior stakeholders should meet to ensure coordination of investigations and communications. The membership of the internal investigation oversight group and the incident coordination group will have some overlap, although their functions differ.

The internal investigation should be completed as soon as possible after the event, usually within 90 days. It is important that this process takes place promptly so that any changes needed to policy or practice to enhance patient safety can be made and the independent investigation, if there is to be one, is not delayed. This process is a necessary precursor to the independent investigation. It will ensure that early action can be taken where needed, within a timescale in which it would not be feasible to have commissioned and completed an independent investigation. It is also a means of informing the scope and terms of reference for the independent investigation.

A systematic approach to investigation, such as RCA, should be used (see appendix 3 and the NPSA website⁵ for further details on RCA). The staff conducting the investigation should be of appropriate seniority and fully trained in the techniques used.

The internal investigation should follow the process described below:

1. Scope the incident, and decide how far back to investigate.
2. Decide on the terms of reference.
3. Gather information and map events, including developing a detailed chronology.
4. Analyse the available information to determine any underlying causes.

5. Recommend solutions, for example potential changes to the environment, practice, policies, procedures or staff.
6. Produce a final report outlining clear and sustainable recommendations.

It may be necessary for the trust investigation team to obtain external advice on certain issues; however, it should be unusual for individuals from outside the employment of the trust to be members of the investigation team.

Who should be involved: victims, perpetrators, their families and staff

An opportunity should be provided for the victim and their family to meet senior, appropriately experienced staff from the trust. At this meeting their involvement in the investigation process can be discussed. Subsequently, the findings of the internal investigation and the actions to be taken will need to be discussed with them. A separate opportunity should be provided for the perpetrator and their family to cover the same issues.

The investigation team will identify which staff should give evidence as part of the investigation. The trust should make staff aware of the process and what is likely to happen once it is complete (see also 'Engaging and supporting staff' on page 22).

The report

The report should be written as soon as possible and in a way that is accessible and understandable to all readers. It should:

- be simple and easy to read;
- have an executive summary, index and contents page;
- include the title of the document and state whether it is a draft or the final version;
- include the version date, reference initials, document name, computer file path and page number in the footer;
- disclose clinical information for which consent has been obtained, or if patient confidentiality has been breached, this is balanced against public interest as confirmed by legal advice;
- include the evidence of the methodology used for investigation, for example RCA;
- identify root causes and recommendations;

- ensure that conclusions are evidenced and reasoned, and that recommendations are implementable;
- include a description of how patients/victims and families have been engaged in the process;
- include a description of the support provided to patients/victims/families and staff following the incident.

Reports may be anonymised. It is not usual for internal trust reports to be put into the public domain (unlike independent investigation reports). Internal reports are usually shared within the trust and with key interested parties, such as families and the SHA. However, they should be drafted on the basis that they may become public, so issues concerning anonymity and consent are important at this stage.

Trust clinical governance processes should address how the recommendations of internal and independent reports are addressed and their implementation monitored.

If there is dissatisfaction with the outcome of the internal trust investigation, the victim, the perpetrator and their families should be made aware of the trust's Patient Advice and Liaison Service (PALS) team and the complaints procedure (See also 'Victims, perpetrators, families and carers' on page 19).

When an independent investigation should be undertaken

An initial stakeholder meeting should have already taken place soon after the incident; this should include the SHA and the commissioning PCT and it should have been decided whether an independent investigation is necessary. In some cases this will be clear, for example there should be an independent investigation if there has been a homicide by someone under recent care of mental health services (see criteria on page 5). In others, it may be the nature of a number of incidents that will determine this need, for example a cluster of suicides.

The nature and scope of the independent investigation should be determined by the quality and findings of the internal investigation and any other relevant investigations into the incident. Part of this process would be to formally review and critique the internal investigation report. Factors to take into account in this process are described in appendix 3.

Stage three – SHA independent investigation

Definition of independent investigation

An independent investigation is an investigation which is both commissioned and undertaken independently of the providers of care under investigation.

Commissioning

When a decision has been made that an independent investigation is required, the SHA is responsible for commissioning it and selecting the individuals who will undertake it.

If other agencies or partnerships will be carrying out investigations into the same event(s), for example in the case of a serious incident or death involving a child, or if local vulnerable adult procedures are invoked, then all the agencies involved should consider if it is possible to jointly commission the investigation. This will help ensure that expertise is most appropriately used, duplication of process is minimised and inter-agency lessons are learnt. In cases where joint commissioning occurs, early agreement on funding arrangements should be made.

The investigation report of the internal mental health trust investigation, and any other investigation or relevant reports from any other agencies, should be made available to the SHA. The quality of these will be taken into account by the SHA when determining the scope and process for the independent investigation. The views of families and carers should also be considered at this stage.

Starting an independent investigation

In order to ensure that independent investigations are carried out effectively there needs to be a designated individual within the SHA who has the lead responsibility for commissioning. They will be responsible for the commissioning process and ensuring that the appropriate project management support is available. There should also be an executive director who is responsible for oversight.

First steps in the commissioning process

- Listing all the agencies that have a stake in the care of those involved in the incident and ensuring that they are aware of the process and are involved in the commissioning process if appropriate.
- Identifying any legal issues that may be relevant to the independent investigation, or any court proceedings, and obtaining the appropriate legal advice.
- Obtaining fully informed, written consent from the service user(s) involved in the incident for the release of their medical records to the investigation team, and agreement that any personal details can be included in a public report.
- In the event of the service user not giving consent or lacking capacity to consent the SHA will need legal advice to agree a way forward.
- Arranging a meeting between the investigation team, trust representatives, the police and representatives from any other agencies who have agreed to participate in the investigation. Timescales, ground rules, sharing of information and terms of reference should be agreed and shared.
- Early discussion with the local coroner.
- Informing the victim, perpetrator, carers and families about the investigative process and how they can be involved. Arranging for them to meet the SHA and then the investigation team if wanted.
- Agreeing the timescale for the investigation, timings and setting a date for receipt of the final report. If the commencement of the investigation has to be delayed, the reasons must be clearly explained to the victim(s), perpetrator(s), and their carers and families.

Terms of reference

The terms of reference for the independent investigation team are to be determined by the SHA as the commissioning body and agreed with the investigation team leader. Families and carers should have the opportunity to input into the terms of reference.

Terms of reference are likely to include:

- examining the care and treatment provided, including risk assessment and risk management;
- providing a chronology of the events leading up to the incident;

- identifying care or service delivery issues, along with the factors that might have contributed to them;
- identifying underlying causes;
- making clear, implementable recommendations for the local health community.

The work of the investigation team should stay within the terms of reference unless the terms are renegotiated with the SHA.

The independent investigation team

Members of investigations teams need to be properly appointed with formal appointment letters that include a job description and indemnity cover. From the outset one member of the independent investigation team will need to be the designated lead for the investigation process.

In order to create independence and avoid any conflict of interest, no member of the independent investigation team should be in the employment of the organisation(s) or should have had any clinical involvement with the victim or the perpetrator, subject to investigation.

The skills and expertise of the independent investigation team appointed should include:

- relevant clinical, social care and managerial expertise;
- other expertise where appropriate, for example housing or probation;
- expert investigation skills, such as RCA or similar;
- excellent report writing skills;
- interviewing and communication skills; understanding of the independent investigation process;
- the treatment of witnesses (see appendix 5).

Other specific skills or experience may be required depending on the nature of the case and the findings of the internal investigation report. In appointing a team member, the SHA needs to ensure that an adequate time commitment can be given so that investigations are carried out as swiftly as possible.

Next steps

In order for the investigation to be as effective as possible, clear communication is needed from the outset. This should include the following.

- Sending a letter to all of those who will be invited to participate in the investigation with an information sheet outlining the investigation process, including covering the status of any written statements submitted to or produced as the result of interview by those participating in the investigation.
- Holding a briefing meeting for those participating in the investigation to outline the process and address their concerns.
- Holding a meeting with the victim and their family to explain the investigation process and how they will be able to participate in it.
- Holding a meeting with the perpetrator and their family to explain the investigation process.

Publication of the report

Once the independent team has completed its investigation it will present the draft report to the SHA, which will in turn share it with the trust and other organisations involved.

The trust should use the report and its recommendations to produce an action plan, to be agreed and subsequently monitored by the SHA in conjunction with the commissioning PCT(s). Adequate time should be set aside between the receipt of the final draft and publication of the report to ensure that the report is shared with interested parties. This would usually include the perpetrator and the victim and their respective families. Anyone who is or could be seen to be criticised should see an appropriate draft copy of the report (see appendix 5 – The Salmon Principles).

Careful consideration should be given to the clinical content of the report to ensure that relevant consent has been obtained and that any breach of patient confidentiality is balanced against the public interest as confirmed by legal advice. Similarly, the SHA should consider taking legal advice on the draft report to ensure that the risk of defamation is properly assessed.

It is the responsibility of the commissioners to decide whether the report will be anonymised (see comment in appendix 1).

The structure and content principles applying to independent reports should be the same as those applied to internal reports (see appendix 3 – Report writing, page 33). These principles should be clearly laid out for the members of the investigation team at their appointment.

Communications and the media

A communications plan should be developed that will cover all aspects of communication including the media, MPs, victims, perpetrators, their families, legal representatives, staff, pressure groups and other stakeholders.

SHAs and trust communications teams will need to work together to produce this plan. It is also important to work closely with the police. During the course of investigations a clear media statement needs to be ready, commenting that an investigation is underway and further detailed comment is not possible. Legal considerations should be taken into account in relation to the release of information, for example the Freedom of Information Act 2000.

Legal advice should be taken, if necessary, in relation to issues of privilege and access to communications, and draft documents produced in the course of the investigation.

SHAs and trusts should ensure that their communications teams are informed when an incident occurs and are kept informed about the progress of the investigation. A single, designated individual from the SHA and from the trust should respond to the media – these two individuals should stay in close contact and update each other on any developments. It is useful if an SHA and/or trust representative attends any court hearings to ensure that the communications strategy can be rapidly amended if necessary.

The communications plan will need to address the method of publication and distribution, for example press conference, board presentation, web or hard copy production. **SHAs should consider if the report highlights issues for wider learning outside the local health community and ensure that distribution addresses this.**

All serious incidents should be reported by the SHA to the Department of Health via the Ministerial Briefing Unit (MBU).⁶ Significant dates in relation to the incident such as court appearances and report publication should also be reported through the MBU along with sufficient update briefing for media handling and ministerial briefing.

A copy of the final report should be sent to the Head of Mental Health and People with Learning Disabilities, NPSA, so that it can be incorporated into ongoing work looking at national learning.

Support

Victims, perpetrators, families and carers

The NPSA has issued guidance to the NHS – *Being open – communicating patient safety incidents with patients and their carers*.⁷ Although this guidance is primarily aimed at communication with patients (and their families or carers) who have been harmed as a result of an error in their healthcare, the principles of honesty and openness also apply when planning discussions with victims, perpetrators, families and carers.

The basic principles (see appendix 6) underlying this communication are the:

- principle of acknowledgement;
- principle of truthfulness, timeliness and clarity of communication;
- principle of apology.

When an incident leading to serious harm or death occurs, the needs of those affected should be of primary concern to the trust, the SHA and those undertaking any investigation. Any contact should be undertaken in a respectful, dignified and compassionate manner, and in a spirit of openness. A designated, senior individual, with the appropriate skills and experience, at the trust (in the most serious incident, for example homicides, likely to be at board level) should take the lead, and agree with the family who the main family contact will be.

Victims and families want to know:

- What happened?
- Why it happened?
- How it happened?
- What can be done to stop it from happening again to anyone else?

The victim and family should be offered a meeting. The meeting should not take place at the site of the incident and staff involved in the incident should not be required to attend. The meeting should explain what support processes have been put in place and how they can be accessed.

If victims and their families do not wish to participate in a meeting with the trust then information should be put in writing. If contact is initially rejected further attempts should be made to establish contact and share information. If contact continues to be rejected the SHA should be asked to take over responsibility for victim and family liaison.

Information

Victims, families and carers need to have access to information on the investigation, and should:

- be made aware, orally and in writing, as soon as possible of the process of the investigation to be held, the rationale for the investigation and the purpose of the investigation (that is, to establish facts);
- have the opportunity to express any concerns;
- be consulted on the terms of reference for both internal and independent investigations;
- be provided with the terms of reference;
- know how they will be able to contribute to the process of investigation, for example by giving evidence;
- be given access to findings of any investigation prior to publication and receive a copy of the final report and subsequent action plan;
- be informed, with reasons, if there is a delay in starting the independent investigation or in the publication of the final report;
- be offered media advice, should the media make contact.

Advocacy

In order to ensure that victims and families are able to participate in the investigation process the following potential needs should be considered:

- need for independent advocacy – with the requisite skills to work with bereaved and traumatised individuals;
- diversity issues, for example language support, transport issues, disability;
- support and assistance in participating in the investigation process;
- provision of information;
- ongoing support after the incident;
- signposting to other organisations that might be able to provide support and information;
- support in liaison with other agencies, for example the police.

The cost of providing any of the above could be considered as part of the overall cost of an independent investigation.

Counselling

Counselling may not be an immediate need, but both short-term and longer-term potential requirements should be considered. This might include the need to signpost to organisations that can provide bereavement or post-traumatic stress counselling.

Treatment and support

It is important to make sure that appropriate treatment and support is provided where needed. Decisions about treatment and care should be taken locally on the basis of a thorough, individualised assessment of need, the evidence base, the client's wishes and resources available.

Separate meetings should be held with the victim and their family, and the perpetrator and their family, prior to publication. A copy of the report and action plan and an opportunity for feedback should be provided.

If victims and families want a further meeting this should be arranged. Victims and families should also be told how they will be kept up to date regarding the implementation of the action plan.

Families should be advised on how they can complain if they disagree with the findings of the investigation.

Engaging and supporting staff

When a serious incident occurs which leads to serious harm or death there can be significant impact on staff who were involved in or who witnessed the incident. Like victims and families, staff will want to understand what happened, why it happened and what can be done to prevent it happening again.

Staff should have the opportunity to access professional advice from their relevant professional body or union, staff counselling services and occupational health services.

Staff should also be provided with information about the stages of investigation and how they will be expected to contribute to the process. Trusts should make it clear that the investigation itself is entirely separate to any disciplinary process. If allegations are made regarding staff, reference should be made to the NPSA incident decision tree.⁸ This tool has been created to help NHS managers and senior clinicians decide whether they need to suspend (exclude) staff involved in a serious patient safety incident and to identify appropriate management action. The aim is to promote fair and consistent staff treatment within and between healthcare organisations.

At the completion of each stage of the investigation process the lessons learnt should be shared with staff involved in the incident, and more widely if it is felt appropriate.

Support provided should be ongoing and not one-off. Provision of support by someone other than the immediate line manager should be considered.

Service users

Any incident leading to serious harm or death may have an impact on and implications for other service users. If service users have witnessed the incident, appropriate support mechanisms should be put in place: it may be advisable to review risk assessments and care plans to reflect any additional needs. If appropriate, service users who witnessed the event should be asked to contribute to the investigation process. If this is the case, the outcome of the investigation and the final report should be shared with them.

Further support and advice

Further support and advice on independent investigations can be obtained from the Department of Health Investigations and Inquiries Unit.

- These supporting notes should be read in conjunction with **Department of Health guidance**.¹
- The NPSA can provide further information on **RCA**.⁵
- The **incident decision tree (IDT)**⁸ – a framework to assist NHS managers in dealing with staff involved in a serious patient safety incident.
- ***Being open – communicating patient safety incidents with patients and their carers***³ – guidance to support open and honest communication between healthcare professionals and patients and their families or carers.

Appendix 1: Human Rights Act

The Human Rights Act 1998, which incorporates the European Convention on Human Rights (ECHR) into domestic law may impact on any investigation conducted under HSG (94)27 in one of two ways. The relevant Articles of the ECHR are:

Article 2 – right to life (*NB Article 2 rights can be infringed even if the victim does not die but has sustained life-threatening injuries, and even if the case is one of self-harm*).

Article 3 – prohibition on torture, inhuman and degrading treatment and punishment.

Article 8 – the right to respect for private and family life, home and correspondence.

Article 10 – the right to freedom of expression.

The scope and format of the investigation

Article 2 imposes on States a procedural obligation to initiate an effective public investigation by an independent official body into any death or incident involving life-threatening injuries occurring in circumstances in which it appears that Article 2 has been or may have been violated and it appears that agents of the State are or may be in some way implicated.

Where an individual's Article 2 rights may well have been breached, then the State must conduct an effective investigation into that death or incident. The minimum requirements of such an investigation are:

- the authorities must act of their own motion;
- the investigation must be independent;
- the investigation must be effective in the sense that it must be conducted in a manner that does not undermine its ability to establish the relevant facts;
- the investigation must be reasonably prompt;
- there must be 'a sufficient element of public scrutiny of the investigation or its results to secure accountability in practice as well as in theory';
- the degree of public scrutiny required may well vary from case to case;
- there must be involvement of the next of kin to the extent necessary to safeguard his or her legitimate interests.

Only a minority of deaths/near deaths being investigated under this guidance will trigger a duty for the investigation to be Article 2 compliant. On the one hand, the duty does not, for example, arise in every case where someone dies in hospital. On the other hand, it will almost always arise where there is an unexpected death in custody and where there are real concerns that there were failures of care. That duty arises as a consequence of the control of and responsibility for the individual victim, so Article 2 may apply even if the patient is informal. However, every case will depend on its own facts and legal advice should be sought.

It is also important to note that any duty to carry out an Article 2 compliant investigation covers the whole span of investigations following death or incident, and not simply an investigation under this guidance in isolation. Normally, the coroner's inquest is going to be the best forum to ensure Article 2 compliance either on its own or coupled with a criminal trial and investigation carried out under this guidance. The SHA mental health independent investigation described in this document will probably not of itself have to be fully Article 2 compliant.

Again, legal advice may be needed to determine the scope of and proper procedures for any investigation that involves significant Article 2 issues.

Publication of the report

The law allows any confidential information about an individual to be published with expressed consent. This section is therefore only concerned with the situation where consent has been refused or not obtained for any other reason.

Publication of any report arising out of an investigation conducted under this guidance will engage the competing rights of an individual under Article 8 and the public under Article 10, as well as other aspects of the law on confidentiality including the Data Protection Act. Currently, the leading case on this issue is *Stone v Southeast Coast Strategic Health Authority and others* [2006] EWHC 1668 (admin), in which Michael Stone unsuccessfully challenged a decision by the commissioning agencies to publish in full a report into his care and treatment. The judge held that the agencies had properly balanced Mr Stone's right to confidentiality against the public interest in publishing the report in full, and accepted that the report only contained confidential information that was necessary to disclose in the public interest.

In his judgment, the judge weighed the considerations for and against a restriction on Article 8 rights and then weighed the considerations for and against a restriction on publication by reference to Article 10. He applied the following principles:

- neither article has precedence over the other;
- where the values under the two articles conflict, the importance of the rights being claimed in the individual case must be compared;
- the justifications for interfering with or restricting each right must be taken into account;
- the proportionality test must be applied to each.

The following factors were relevant to the judge's decision.

- The fact that a redacted report could not and would not work. It was not practicable to publish a report without disclosing details of Mr Stone's private medical information. (The following factors were relevant to the balancing exercise under Articles 8 and 10.)
- There was a concession on behalf of Mr Stone that there should be some publication to the public of the report, and that the public should be able to know what went wrong and should be able to form an intelligent understanding of the conclusions reached.
- There was a true public interest in the public knowing about the actual care and treatment supplied or not supplied, and knowing and being able to reach an informed assessment of the failures identified and the steps that may be recommended to be taken to address identified deficiencies.
- Such objectives are not met simply by releasing a full version of the report to relevant health professionals.
- Where individuals or agencies involved in Mr Stone's treatment were, or were not to be, criticised the public could legitimately expect to know the full reasons for that.
- The information was to be disclosed solely with the aim of providing an informed view of what went wrong in the case with a view to important lessons being learnt for the future, both for the assistance of other people in Mr Stone's position and for the protection and reassurance of the public.
- The information sought to be disclosed related solely to the investigation foreseeably arising out of Mr Stone's own criminal acts.
- A great deal of information relating to the background, treatment and mental health of Mr Stone was already in the public domain and at a significant level of detail. (Previous publication of private information does not mean that an individual necessarily loses their right to privacy but it is relevant to the balancing exercise and the issue of proportionality.)

- The victims (directly or indirectly) of Mr Stone's crime supported publication as did the investigation panel, Secretary of State and relevant mental health authorities.

Whilst each case must, as always, be considered on its own merits, the guidelines in the Stone case provide a useful starting point.

A further issue is anonymisation. Again, there is a balancing exercise between Article 8 and Article 10. As a general rule, the greater the degree of legitimate public interest in the outcome of the investigation, the stronger the argument that public accountability will require that professional staff be named in the report, unless there are particular factors such as police concerns about safety, as arose in the Stone case.

If an investigation is carried out as part of an Article 2 compliant process, the greater the requirement for public scrutiny of the investigation the harder it may be to justify anonymisation of any part of the report.

Appendix 2: Checklist for trust initial review and investigation

Please note that incidents should be managed on a case-by-case basis, and some tasks might need to be carried out simultaneously.

Number	Task	Lead	Timescale	Completed
1	A senior manager/clinician to be appointed by the chief executive officer or an executive board member of the trust to undertake the review.			
2	Arrange for any immediate actions to be put in place to ensure safety.			
3	Obtain all relevant physical, scientific and documentary evidence, and make sure it is secure and preserved. This is described in detail in the Memorandum of Understanding between the ACPO, the Department of Health and the HSE.			
4	Contact the police and agree who will make the initial contact with the victim's family.			
5	Similarly, with respect to the suspected perpetrator's family.			
6	Identify witnesses such as staff and service users and other involved people to ensure they receive any immediate support needed.			
7	Identify whether the victim and/or perpetrator is a vulnerable adult or child and act in accordance with the vulnerable adult or local safe guarding children procedures.			
8	Identify trust staff to conduct the service management review.			
9	Following the local serious incident protocol, report to the SHA, PCT and Mental Health Act Commission if necessary. The incident should also be reported to the NPSA via the trust's reporting system.			
10	Set up oversight group and incident coordinating group as necessary, involving key stakeholders, including the SHA (refer also to the DH/ACPO/HSE MOU).			

Appendix 3: Root cause analysis

Root cause analysis (RCA) is a technique which can be used for undertaking a systematic investigation. It looks beyond the individuals concerned and seeks to understand the underlying system features and environmental context in which the incident happened.

Retrospective and multidisciplinary in approach, RCA is designed to identify the sequence of events that led to the incident. This allows the underlying causes of the incident to emerge so that organisations can learn and put remedial action in place. A root cause is the cause or causes that if addressed will prevent or minimise the chance of a similar incident recurring in the future.

The following sections outline the relevant stages of an RCA.

Convening the investigation team

The core investigation team should ideally comprise people of appropriate seniority, objectivity and authority, and be fully trained in the RCA/investigation techniques.

Gathering information

One of the primary aims of the investigation team is to collect evidence. There is a vast array of information and data surrounding any incident and this is particularly true for mental health incidents, which typically have relevant history that often spans years. The types of information required may include the following, but this is not an exhaustive list:

- healthcare records;
- records of interviews with staff;
- relevant results and diagnostic aids;
- policies and protocols in operation at the time of the incident;
- relevant integrated care pathways where available;
- the incident report form;
- the list of key staff involved and written reports from staff.

Interviews should be held to find out what happened and how and why it happened. The interview process should be supportive and non-judgemental and be conducted in private. It is suggested that the cognitive interview approach is used for this purpose.⁵ Depending on where the incident took place, a site visit may help the team to establish whether the physical environment was a contributory factor in the incident. It can offer an insight into factors such as the line of sight between a member of staff and the service user affected by the incident or the positioning of equipment. In some circumstances a site visit may also involve a reconstruction of the incident. This is particularly useful for complex incidents when staff are unclear about who was doing what, or when the root causes have not been identified. The reconstruction should be a non-threatening event to enhance the investigation, and not to catch people out.

Mapping events

Once the basic data about the incident have been collected, a facilitator will work with staff associated with the incident to piece together the chain of events. This can be a valuable forum for developing ideas about how to adapt the system to prevent repeat incidents. Involving staff in this mapping exercise has been found to have a significant positive impact on the way a team works and engenders a sense of contributing to workable solutions. It is strongly recommended that timelines, tabular timelines and cause and effect charts are considered as the mapping tools to be used throughout the investigation. A tabular timeline is a useful way providing this information as an appendix to the report.

Identifying problems

Once information about the incident has been gathered, the problems in care and service delivery should be identified and prioritised. This enables analysis of aspects of the incident in an appropriate order.

Analysing information

The problems in care and service delivery are then analysed to determine their underlying causes (contributory factors and root causes) and the lessons that can be learnt. The investigation team should consider the circumstances that individuals faced at the time and the evidence the team had before it, and it should not be biased by either the outcome or hindsight.

Care should be taken to avoid the following:

- **Hindsight bias** is when actions that should have been taken in the time leading up to an incident seem obvious because all the facts become clear after the event. This leads to judgement and assumptions around the staff closest to the incident.
- **Outcome bias** is when the outcome of the incident influences the way it is analysed, for example when an incident leads to a death it is considered very differently from an incident that leads to no harm, even when the type of incident is exactly the same. When people are judged one way when the outcome is poor and another way when the outcome is good, accountability becomes inconsistent and unfair.

A number of tools are available and the following have been shown to work well across a number of different healthcare settings:

- brainstorming;
- change analysis;
- nominal group techniques;
- five whys techniques;
- fishbone diagrams, based on the NPSA list of contributory factors:
 - patient factors;
 - individual factors;
 - task factors;
 - communication factors;
 - team and social factors;
 - education and training factors;
 - equipment and resources factors;
 - working conditions and environmental factors;
 - organisation and strategic factors.

Recommend solutions

Retrospective Barrier Analysis is the recommended tool to assess the effectiveness of existing barriers/controls and to develop additional and/or alternative solutions.

A barrier is a defence or control measure to prevent harm to vulnerable or valuable objects (people, buildings, organisational reputation and the wider community). There are four main barriers in healthcare: physical barriers, natural barriers, human action barriers and administrative barriers. The fact that an incident has taken place means that one or more of the barriers have not been in place or have failed. The analysis offers a structured way to visualise the events related to systems failure and can be used to solve problems or evaluate existing barriers.

This stage is designed to identify:

- which barriers should have been in place to prevent the incident;
- why the barriers failed; how they could be strengthened to prevent future failure;
- which other barriers could be used to prevent the incident happening again.

In recommending solutions care should be taken to base recommendations on root causes.

Report writing

The RCA concludes with an investigation report. This needs to be written as soon as possible and in a way that is accessible and understandable to all readers. The report should:

- be simple and easy to read;
- have an executive summary, index and contents page and clear headings;
- include the title of the document and state whether it is a draft or the final version;
- include the version date, reference initials, document name, computer file path and page number in the footer;
- disclose clinical information for which consent has been obtained, or if patient confidentiality has been breached, this is balanced against public interest as confirmed by legal advice;
- include the evidence of the methodology used for investigation, for example RCA (include timelines/cause and effect charts, brainstorming/brain writing, nominal group technique, use of a contributory factor framework and fishbone diagrams, five whys and barrier analysis);

- identify root causes and recommendations;
- ensure that conclusions are evidenced and reasoned, and that recommendations are implementable;
- include a description of how patients/victims and families have been engaged in the process;
- include a description of the support provided to patients/victims/families and staff following the incident.

For further information on the RCA process, tools and templates please refer to the guidance on the NPSA website: www.npsa.nhs.uk/patientsafety/improvingpatientsafety/rootcauseanalysis/

Appendix 4: SHA checklist for independent investigation

Please note that incidents should be managed on a case-by-case basis and some tasks might need to be carried out simultaneously.

Number	Task	Lead	Timescale	Completed
1	List all the agencies that have a stake in the care of those involved in the incident and ensure they are aware of the process and are involved in the commissioning process if appropriate.			
2	Identify any legal issues that may have a relevance on the independent investigation, or any court proceedings, and obtain the appropriate advice.			
3	Obtain fully informed consent from the service user(s) involved in the incident for the release of their clinical records to the investigation team and agreement that any personal details can be included in a public report.			
4	In the event of the service user not giving consent or lacking capacity to consent, the SHA will need legal advice to agree a way forward.			
5	Arrange a meeting between the investigation team, trust representatives, the police and representatives from any other agencies who have agreed to participate in the investigation. Timescales, ground rules, sharing of information and terms of reference should be agreed and shared.			
6	Early discussion with the local coroner.			
7	Informing the victim, perpetrator, carers and families about the investigative process and how they can be involved. Arrange for them to meet the SHA and then the investigation team if wanted.			

Number	Task	Lead	Timescale	Completed
8	Agree the timescale for the investigation, timings and setting a date for receipt of the final report. If the commencement of the investigation has been delayed, the reasons must be clearly explained to the victim(s), perpetrator and their carers and family.			
9	Send a letter to all of those who will be invited to participate in the investigation with an information sheet outlining the investigation process.			
10	Hold a briefing meeting for those participating in the investigation to outline the process and address any concerns.			
11	Hold a meeting with the victim and their family to explain the investigation process and how they will be able to participate in it.			
12	Hold a meeting with the perpetrator and their family to explain the investigation process.			

Appendix 5: The Salmon Principles

The Salmon Principles, listed below, describe good practice for inquiries and investigations with respect to dealing with witnesses. They may not be applicable to every inquiry or investigation, but it is good practice to consider their relevance in each and every case. They underpin the principle that all inquiry and investigation processes should be transparent, open, inclusive, timely and proportionate.

1. Before any person becomes involved in an inquiry, the Tribunal must be satisfied that there are circumstances which affect him and which the Tribunal proposes to investigate.
2. Before any person who is involved in an inquiry is called as a witness, he should be informed of any allegations which are made against him and the substance of the evidence in support of them.
3. (a) He should be given an adequate opportunity of preparing his case and of being assisted by his legal advisers. (b) His legal expenses should normally be met out of public funds.
4. He should have the opportunity of being examined by his own solicitor or counsel and of stating his case in public at the inquiry.
5. Any material witness he wishes called at the inquiry should, if reasonably practicable, be heard.
6. He should have the opportunity of testing by cross-examination conducted by his own solicitor or counsel any evidence which may affect him.

Appendix 6: Correspondence checklists

Regular communication will be necessary between the trust, the SHA, the victim, families and other stakeholders. Communication should be tailored to the needs of the recipient(s).

The following suggest issues to be considered when writing to different stakeholders.

Initial letter to families, victims and perpetrators from the trust

The initial correspondence should consider the following areas:

- expression of condolence and regret;
- describe the process of investigation (and that other agencies may also be carrying out investigations, for example the police);
- describe the current position in the investigation process;
- describe factors that will influence the timescale of the investigation;
- describe how the family will be involved in the investigation process;
- describe how the information about the event will be assimilated and disseminated;
- provide contact information for the person who will link with the family from the trust;
- provide information on support systems/agencies for the family available from the trust and independently including the police family liaison officer.

Initial letter to the victim's family from the SHA, where family liaison is transferred from the trust

The initial correspondence to the family of the victim should consider the following areas:

- expression of condolence and regret;
- explain why the SHA is the point of liaison and not the trust;
- describe the process of investigation (and that other agencies may also be carrying out investigations, for example the police);
- describe the current position in the investigation process;
- describe factors that will influence the timescale of the investigation;
- describe how the family will be invited to be involved in the investigation process;

- describe how the information about the event will be assimilated and disseminated;
- provide contact information of the person who will link with the family from the SHA;
- provide information on the support systems/agencies available to the family, available from the trust and independently, including the police family liaison officer.

Initial letter to the perpetrator's family, where family liaison is transferred from the trust

The initial correspondence to the family of the perpetrator should consider the following areas:

- expression of condolence and regret;
- explain why the SHA is the point of liaison and not the trust;
- describe the process of investigation (and that other agencies may also be carrying out investigations, for example the police);
- describe the current position in the investigation process;
- describe factors that will influence the timescale of the investigation;
- describe how the family of the victim will be invited to be involved in the investigation process (if appropriate);
- describe how the information about the event will be assimilated and disseminated;
- provide contact information of the person who will link with the family of the perpetrator from the SHA;
- provide information on independent support systems/agencies available to the family.

Initial letter to staff from the trust

The initial correspondence to staff should consider the following areas:

- expression of condolence and regret about the incident;
- acknowledgement of the impact on staff;
- describe the process of investigation (and that other agencies may also be carrying out investigations, for example the police);
- describe the current position in the investigation process;
- describe factors that will influence the timescale of the investigation;

- describe how staff will be invited to be involved in the investigation process;
- describe how the information about the event will be assimilated and disseminated;
- provide contact information of the person who will link with the trust;
- provide information on staff support systems available within the trust and independently.

Letters inviting participation in the independent investigation

Receiving such correspondence may be very difficult for some people involved in the independent investigation. Consideration should be given to other methods of inviting participation, for example by a face-to-face request, in the presence of people who the recipient will find supportive.

Letters requesting participation in the independent investigation to families of victims and perpetrators, staff and other agencies' personnel

Correspondence inviting families, staff and other individuals to participate in the independent investigation should consider:

- acknowledging that participation may be difficult but may also be helpful to the person;
- describing the form of participation that is being requested and methods of participation available, for example one-to-one interview, with all family members together, in the presence of other supporters such as staff representatives, advocates or friends, written submissions, use of video links;
- describing the status of written statements provided to the investigation;
- offering the person an opportunity to discuss the process with a named person before making a decision to participate;
- suggesting that the person discusses participation with an advocate or supporter who is independent of the process;
- describing the implications for the investigation process of participating or not participating;
- describing what will happen to the information that is provided after the independent investigation has been completed;

- describing how poor practice issues and whistle-blowing will be dealt with;
- detailing any limits to confidentiality for all participants in the process;
- reaffirming messages contained within earlier correspondence.

Letters prior to publication of the independent investigation report

Letters to families of the victim, the perpetrator and other independent investigation participants

Consideration should be given to:

- acknowledging that the process of publication will be difficult for many involved in the independent investigation;
- describing how and where publication will occur, for example hard copy report, press statements, anticipated media involvement;
- anticipated response from the media and others with an interest in the published independent investigation report;
- stating that publication is the end of the independent investigation process;
- describing the process of how the investigation's recommendations will be enacted;
- describing how wider learning may occur, for example collation of reports for annual thematic review by the NPSA/National Confidential Inquiry
- inviting participants, particularly the family of the victim, to meet the independent investigation team or team leader, who can outline the findings of the report, recommendations, action plan;
- reiterating forms of support that will be available to participants after publication of the independent investigation report.

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List of acronyms

ACPO	Association of Chief Police Officers
CPS	Crown Prosecution Service
DH	Department of Health
ECHR	European Convention on Human Rights
HSE	Health and Safety Executive
IDT	Incident decision tree
MBU	Ministerial Briefing Unit
NCISH	National Confidential Inquiry into Suicide and Homicide by People with Mental Illness
NHS	National Health Service
NPSA	National Patient Safety Agency
PALS	Patient Advice and Liaison Service
PCT	Primary care trust
RCA	Root cause analysis
SHA	Strategic health authority

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