

NPCC Homicide Working Group

An SIO's Guide to Investigating Unexpected Death and Serious Harm in Healthcare Settings – Revised 2015 (v10.6)

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This document has been developed on behalf of the NPCC by the Homicide Working Group and has been approved for publication by the NPCC Crime Business Area.

The NPCC Homicide Working Group promotes the use of discretion and good judgement by police professionals.

The material in this document is not intended to be prescriptive and those using it should tailor it to the needs of their investigation. It is NOT PROTECTIVELY MARKED under the Government Protective Marking Scheme and it is disclosable under the Freedom of Information Act 2000.

1. Overview

In February 2006 the Association of Chief Police Officers (ACPO) signed a memorandum of understanding (MOU) with the Department of Health and the Health & Safety Executive entitled Investigating patient safety incidents involving unexpected death or serious untoward harm. In November 2006 the Department of Health published practical advice for the NHS about what to do when faced with a patient safety incident that may require investigation by the police and/or Health & Safety Executive. . The MOU has now been withdrawn although it is acknowledged that much of the content is still relevant for conducting investigating in Healthcare settings and has been included within this guide.

In 2012 an SIO guide was published on POLKA to provide strategic advice to police officers managing investigations into serious harm and death in healthcare settings. It supplements the advice contained in the Murder Investigation Manual 2006 and focus on those factors in police investigations in healthcare that experience has shown are important.

The 2012 guide has now been updated to include further detail to support investigations in residential care and nursing homes. It also provides some information in relation to Adult safeguarding procedures which will form part of any investigation concerning an adult at risk (vulnerable adult). In keeping with the original MOU the text of this guidance refers in the main to the National Health Service. However, many of the principles are applicable to incidents in other settings, including in the independent healthcare sector and nursing and residential care homes.

This document should be read in conjunction with the associated guidelines for the NHS (the NHS 'Serious Incident Framework' www.england.nhs.uk/ourwork/patientsafety/serious-incident/ senior investigating officers should also consult the joint Police and HSE Work Related Death Protocol 2011 and the associated practical guide, which are shown in the supplementary material.

The 2012 Liaison Agreement between the Health & Safety Executive (HSE) and the Care Quality Commission (CQC) has now been reviewed and has been published as a Memorandum of Understanding (MOU) between CQC, HSE and local authorities in England. This MOU applies to both health and adult social care in England. It comes into effect on 1 April 2015, to reflect the new enforcement powers granted to the Care Quality Commission (CQC) by the Regulated Activities Regulations 2014. www.mou-cqc/hse/local-authorities-in-england.pdf

A Memorandum of Understanding between The CPS, ACPO, The Chief Coroner and The Coroner's Society of England and Wales was published in 2013 and provides useful guidance for the SIO on the relationship and working practices agreed between these partner organisations.

In April 2015 the Care Act 2014 is due to be enacted. This will place a statutory duty on Local Authorities to form Adult safeguarding Boards with partners and a requirement for joint agency investigations where appropriate (Bringing such investigations in line with the safeguarding of children).

2. Source of referrals and potential handling

Referrals about care and treatment in healthcare come to the police service from a variety of sources. They include:

NHS

NHS referrals to the police are likely to come from providers of healthcare though they may be received from clinical commissioning groups (commissioners of the majority of secondary healthcare hospitals) and the NHS England regional teams who commission primary healthcare (GPs, pharmacists, ophthalmology services) and specialised health care such as Prison and Military (highly specialised services for more rare conditions)

The NHS should refer cases to the police only when any or all of the following circumstances apply:

- evidence or suspicion that the actions leading to harm (including acts of omission) were reckless, grossly negligent or wilfully neglectful
- evidence or suspicion that harm/adverse consequences were intended

Investigating officers should find out from the person making the referral that the matter has been discussed with the chief executive or an executive director of the NHS organisation concerned. They should also ensure that the incident meets the above criteria. If not, the reason for referral should be clarified.

Coroners

Coroners are independent judicial officers with statutory responsibility for investigating the causes and circumstances of any death reported to them which may be violent, unnatural or of unknown cause, or where the cause of death arose in state detention – s1 Coroners and Justice Act 2009

State detention may also include persons who die and at the time are deprived of their liberty under the Mental Capacity Act 2005 and are therefore subject of a Deprivation of Liberty Order. [Chief Coroners Guidance No. 16 Deprivation of Liberty Safeguards \(DoLS\)](#)

There will be occasions when a death from seemingly natural causes will need to be reported to the Coroner – see *R v Inner North London Coroner exp Touche* [2001] EWCA Civ 383

A Coroner's authority to inquire into a death flows from the report of a body being within the Coroner's area and not where the death occurred.

Coroners provide a local service and their areas vary according to the size and nature of the area and population. Coroners are required to establish whether an investigation is needed when a death is reported to them. The Coroner's investigation establishes the identity of the deceased and how, when and where the deceased came by his/her death.

The Coroner may write to the appropriate authorities identifying matters that may prevent future deaths and provide public reassurance through the investigation process which may or may not include an Inquest. The Inquest determination, finding and conclusions cannot apportion civil liability generally or criminal liability on the part of a named individual.

The powers of the Coroner in relation to investigations and to deaths are set out in schedule 5 of the Coroners and Justice Act 2009.

Schedule 1 Part 1 of the 2009 Act states that:-

(1) A senior coroner must suspend an investigation under this Part of this Act into a person's death in the following cases.

(2) The first case is where a prosecuting authority requests the coroner to suspend the investigation on the ground that a person may be charged with—

- (a) a homicide offence involving the death of the deceased, or
- (b) an offence (other than a service offence) that is alleged to be a related offence.

The Coroner's primary function in relation to a death is to establish the identity of the deceased, when, where and how death occurred (by what means and in what circumstances) and whether it is necessary to make any recommendations to prevent similar occurrences. Some Coroners have dedicated investigative staff to help them. Others rely on the police to act as investigators.

Coroners make two sorts of referral to the police:

For an investigation under the Coroner's Act where the Coroner expects a police officer to investigate the death and prepare a file for the inquest by obtaining witness statements and other evidence. In these circumstances the police officer is acting as a Coroners' officer.

For a criminal investigation where the Coroner is concerned that the circumstances of the death may involve criminal liability.

At the outset of an investigation under the Coroner's Act, the investigating officer should agree with the Coroner the scope and nature of the investigation being requested. Where possible the investigating officer should meet the Coroner to discuss the nature of the concerns and the sort of investigation needed. It is good practice for the investigating officer to confirm in writing to the Coroner the scope and nature of the investigation to be undertaken.

Investigating officers should be clear with the NHS and other organisations when they are acting on behalf of the Coroner to establish the cause of death rather than investigating a crime. This avoids confusion about their role. If the matter becomes a criminal investigation, the investigating officer should make it clear to the NHS organisation and others that the status of the investigation and their role in it has changed.

This guide refers specifically to the involvement of Coroners in healthcare related deaths.

Relatives and their representatives

Relatives or their representatives may complain to the police about the care and treatment received by their kin when they believe something unlawful has happened. This is an increasingly common source of referral to the police.

Often relatives' concerns result from the unexpected death of a family member, a breakdown in the relationship between them and the healthcare provider or a lack of understanding about the care and treatment.

When relatives complain, officers should be clear with them about the likely police response. They should be encouraged to use the NHS complaints process or await the outcome if they have a response to a formal complaint pending. They should not be led to believe at the initial meeting that the police will automatically start a criminal investigation.

[Learn more about the NHS complaints system](#)

Other Statutory Bodies

Other agencies may refer a matter to the police. Some examples of this include local authority referral following the death of a baby in an NHS hospital if the child is on the child protection register or a local authority adult safeguarding alert concerning the mistreatment of an adult at risk in a private care home setting which triggers a multi-agency safeguarding investigation. In such circumstances investigating officers need to follow this and safeguarding children and protection of adults at risk guidance.

[Learn more about protecting children and adults at risk](#)

Concerned informants ('Whistle Blower')

[The Public Interest Disclosure Act 1998](#) was introduced to protect employees who are worried about apparent wrongdoing in the work place and want to 'blow the whistle'. The Act applies to all NHS employees and employees within local authority and privately operated care home environments. The Act also caters for all self-employed NHS professionals e.g. family doctors. For the purposes of the Act, the employer of self-employed professionals is the relevant clinical commissioning group or NHS England regional teams.

A concerned informant must make their disclosure in good faith in order to qualify for protection and the wrongdoing must involve:

- a crime
- the breach of legal obligation (regulatory, administrative or common law)
- miscarriage of justice
- danger to health and safety and/or patient safety
- damage to the environment
- attempts to cover up such malpractice.

Investigating officers should treat each referral on its merits and pay particular attention to circumstances where it is alleged that evidence is being destroyed or the concerns are about corporate failure. Allegations about NHS trusts – acute, mental health or community trusts or clinical commissioning groups or NHS England – should be discussed with the chief executive or an executive director of the relevant NHS England regional team. Allegations about primary care practitioners including family doctors, dentists, pharmacists and opticians should be discussed with the appropriate region of NHS England.

Allegations about mistreatment in Care Homes must be assessed by the local authority Adult Safeguarding Team in consultation with the Care Quality Commission and if appropriate Police Safeguarding Teams who will determine the level and nature of the investigation.

The SIO will need to consider the ongoing status of such a witness and whether their continued engagement with the Police may require them to be treated as a 'tasked witness'.

Inspectorates and regulators

Inspectorates and regulators may make referrals to the police service. Likely sources are the Care Quality Commission, Healthcare Inspectorate Wales, the Medicines and Healthcare products Regulatory Agency, Local Authorities, the Trust Development Authority, Monitor and the Health and Safety Executive. Professional regulatory bodies such as the General Medical Council or the Nursing & Midwifery Council may also make referrals where they have concerns about the behaviour and actions of individual practitioners.

In these cases the investigating officer may want to arrange a briefing meeting with the organisation concerned and, if it seems appropriate, invite a prosecutor from the CPS to attend. Representatives from partner organisations who also have an investigative / regulatory responsibility should be involved in cases concerning the actions of healthcare organisations.

In England this will include representatives from the Care Quality Commission and / or HSE and in Wales may include representatives from HSE and / or Healthcare Inspectorate Wales (HIW)¹ / Care and Social Services Inspectorate Wales (CSSIW)²

Investigating officers should note that there are national agreements between regulators to help in liaison and effective communication. For example the Care Quality Commission and Health & Safety Executive have developed appropriate working arrangements where they have similar interests in health and social care. www.hse.gov.uk/healthservices/arrangements.htm

Where concerns are raised about failings in clinical practice that may have led to patient death advice on the appropriate response, including whether any failing would be considered a matter for the police or is better dealt with via the NHS' processes for learning from patient safety incidents (which seek to avoid inappropriate blame of staff or institutions) can be obtained from the Patient Safety Domain of NHS England and NHS Wales.

¹ Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of all health care in Wales. HIW reviews and inspects NHS and independent healthcare organisations in Wales to provide independent assurance that services are safe and of good quality.

² Regulator for social care and social services in Wales, from child minders and nurseries to homes for older people

3. **Establishing the need to investigate**

Once a referral has been received from any source the investigating officer should make a mature and objective assessment of the allegations and evidence. The decision about the next steps should be based on the balance of the evidence and supporting information. If necessary, an investigation should be conducted under the terms of the Murder Investigation Manual. Senior investigating officers need to act promptly in cases where the preservation and integrity of evidence is thought to be at risk.

Calling an incident co-ordination group

The investigating officer should always consider calling an incident coordination group in response to a complaint, referral from a Coroner or in response to other concerns.

The meeting of the incident co-ordination group should be called as soon as practicable after the referral and in any case **the group should meet within five working days of the referral.**

The request for such a meeting should be made to the chief executive of the healthcare organisation concerned. Responsibility for organising the initial meeting of the incident co-ordination group rests with the NHS.

In the event of early and clear allegations in respect of corporate failings regarding a death in a healthcare setting, the investigating officer must take this into account and consider with whom they make the initial request for a meeting, and membership of the incident coordinating group in consultation with other relevant stakeholders.

The police representation at the incident co-ordination group should normally be an accredited SIO at the level of inspector or above.

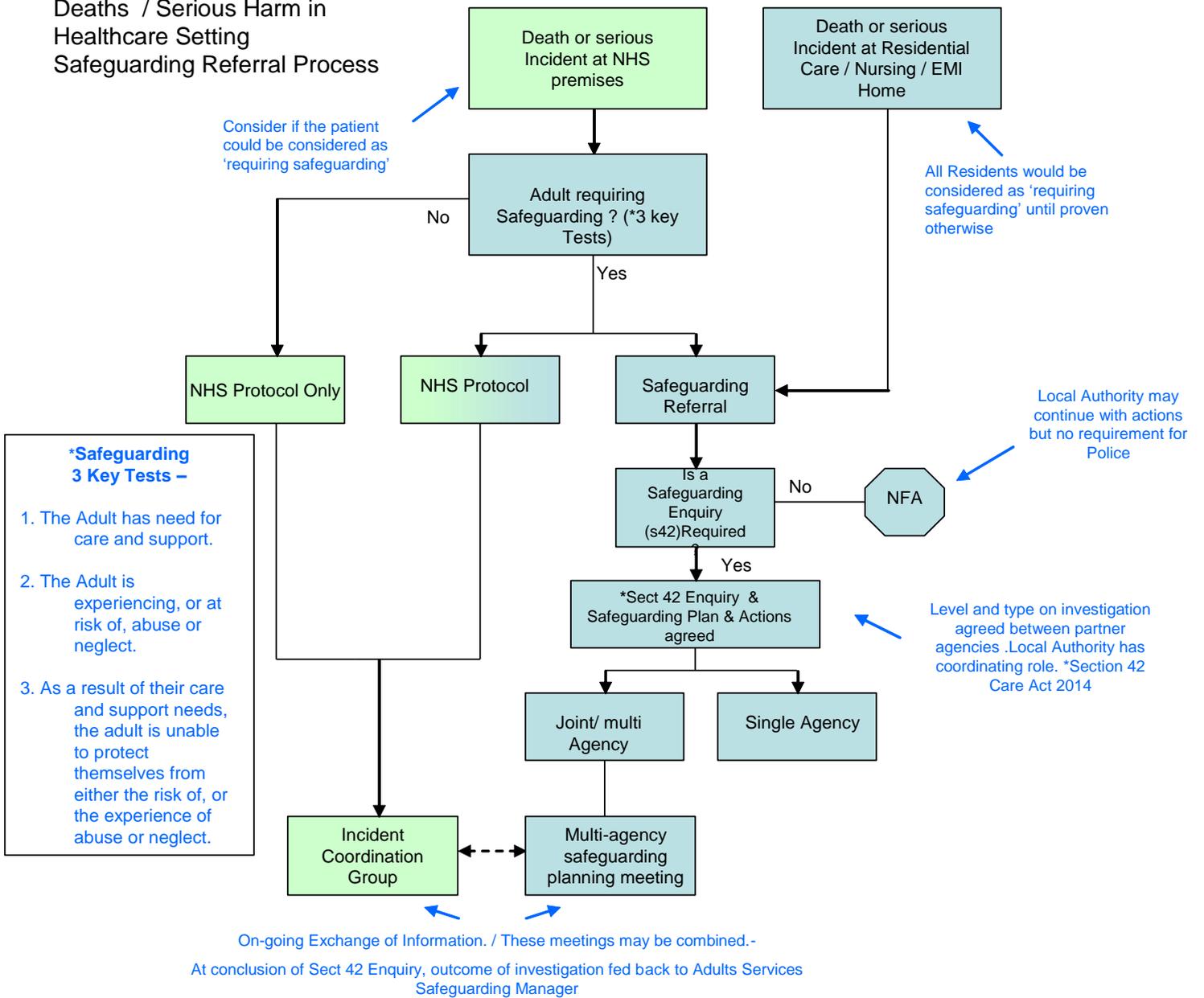
Safeguarding Considerations

Safeguarding is a recognised multi-agency process for protecting children and adults at risk of harm or potential risk of harm or abuse. Their investigative responsibilities are set out in the [Safeguarding adults: Roles and Responsibilities in Health and Care Services](#) document. Children are afforded protection in law by the Children Act 1989 and 2004. Some adults need the additional protection of safeguarding procedures that put a duty on professionals to share information and work together. The purpose of safeguarding is the coordination of activity to protect an individual at risk or to protect other adults who may be at risk from the same circumstances.

In the event of safeguarding referrals, which for the purpose of this guidance, may come from various sources including local hospital, local authority or privately provided residential care home, there should be an early strategy meeting between key statutory agencies, this process is managed and coordinated by the local authority adult safeguarding team. This is now a legal obligation under the provisions of the 2014 Care Act (section 42). www.legislation.gov.uk/ukpga/2014/23/section/42/enacted The composition of a multi-agency coordinating group may vary dependent upon the scale and nature of the referral. Members could include, CQC, HSE, HIW, police, local authority and health representatives (commissioners and /or Providers).

Following the strategy meeting it may be decided that the matter need not be dealt with under safeguarding protocols, in which case the safeguarding process, as far as the Police are concerned, would be completed. In any case if the matter relates to an incident in an NHS setting the SIO may wish to consider calling an Incident Coordination Group (see above). If a decision is made that the matter under referral should be dealt with under safeguarding the Incident Co-ordinating Group and the multi-agency strategy meeting could run in parallel to ensure information is shared between the two

Deaths / Serious Harm in Healthcare Setting
Safeguarding Referral Process



4. Key considerations when investigating in healthcare

The investigating officer's task at the outset is to decide whether the incident is an expected outcome of an individual's illness, the result of care and treatment that was necessary and proper, results from an error or mistake, or demonstrates wilful harm, neglect or recklessness of an individual or demonstrates the liability of an organisation.

Organisational liability is an important consideration in light of the Corporate Manslaughter and Corporate Homicide Act 2007 and the offences of Ill Treatment and Wilful Neglect under Section 20 of the Criminal Justice and Courts Act 2015.

The following considerations will help the investigating officer assess an incident in a structured way:

- Is the incident the expected outcome of the individual's illness?
- Is the incident the result of care and treatment that was necessary and proper?
- Does the incident appear to be an unintentional error/mistake?
- Does the incident suggest an intention to kill or commit grievous bodily harm?
- Does the incident suggest that an individual(s) is liable? If so, does the incident suggest manslaughter, an unlawful act or gross negligence? If gross negligence is suspected then the Adomako filter test needs to be applied (see Section 6 Potential Offences for more details)
- Is there evidence of ill treatment or wilful neglect under the provisions of the Mental Capacity Act 2005 or under Sections 19 and 20 of the Criminal Justice and Courts Act 2015 ?
- Does the incident suggest that the organisation is liable? If so, then as a minimum the following conditions must be met: did the failings occur before or after the commencement of the [CMCHA 2007](#); does the organisation come under the jurisdiction of the Act; is there a relevant duty of care; is the organisation covered by an exemption; is there evidence of senior management failure and is that failure a gross breach of the duty of care; did that gross breach lead to the death.

Investigating officers must have enough evidence and information available to reach an objective judgement in the first 3 circumstances detailed above. This may include the opinion of a pathologist, expert adviser and CPS lawyer. They should also have had access to healthcare documentation including any investigation report carried by the healthcare provider. In cases of death they should report their conclusions to the Coroner and, where appropriate, offer them to families and relatives.

Most errors and mistakes in healthcare are entirely unintentional and are investigated by the NHS under their own procedures which emphasise the importance of learning and improvement, not seeking to apportion blame. Where appropriate, the investigating officer can ask to be kept informed of the outcome of any such investigation through the incident coordination group. Information provided by the NHS may help the investigating officer make an objective decision as to whether to commission an investigation.

Cases concerning possible homicide, grievous bodily harm or investigations into large scale ill-treatment or neglect should be investigated in accordance with the provisions of the Murder Investigation Manual.

The police will lead investigations if a serious criminal offence (other than under health and safety law) is suspected. However, it is important that the knowledge and expertise of the regulatory enforcing authorities such as the Health & Safety Executive, the Care Quality Commission and Healthcare Inspectorate Wales are properly harnessed in any corporate manslaughter investigation.

Other considerations

Responsibility of the NHS to investigate

NHS bodies have a responsibility to ensure the safety and well being of patients and staff and to investigate when things go wrong. This responsibility rests with every NHS chief executive and with the board of their organisation and is a critical component of corporate and clinical governance. NHS organisations must conform to national and local policies and procedures in discharging this responsibility.

Responsibility of the Local Authority to investigate.

The Care Act 2014 requires that every local authority must make enquiries or ensures others do so if it believes an adult is, or is at risk of, abuse or neglect. This broad responsibility also applies to all healthcare settings including Hospitals and residential care homes regardless of whether they are operated by the local authority.

In order to protect adults with care and support needs experiencing or at risk of abuse or neglect the local authority must cooperate with each of its relevant partners and they in turn must cooperate with the local authority. Relevant partners could include Police, NHS England, NHS trust and Foundation trusts, CQC, Clinical Commissioning Groups and the Health & Safety Executive.

Responsibility of the Care Quality Commission to investigate.

The Care Quality Commission (CQC) is the independent regulator of health and adult social care in England. It checks that care in hospitals, dental practices, GP practices, ambulances, care homes, people's own homes and elsewhere meets government standards of quality and safety

CQC has powers to undertake investigations under Section 48 of the Health and Social Care Act 2008 into the provision of NHS and adult social care. It is up to the CQC to determine when such action is appropriate.

CQC's powers to investigate do not extend to the provision of wholly private healthcare. An investigation differs from an inspection to monitor compliance in that it normally necessitates a much wider and deeper look at a range of concerns, potentially across all locations within a single provider or a major location, such as an NHS hospital, or even a local care economy.

CQC will consider using their investigatory powers where there has been a serious failing in care or exercise of functions by providers of NHS funded care, providers of adult social care and health authorities in England, which has affected (or may affect):

- people's basic safety;
- the effectiveness of a service; or
- the responsiveness of a service to people's needs.

The Care Quality Commission (CQC) can bring prosecutions against registered providers of health and adult social care services in England for breaches of a number of the fundamental standards of care that providers are required to meet For example, where a registered service provider in England fails to provide care and treatment in a safe way, this is a prosecutable offence where it causes avoidable harm, or presents a significant risk of avoidable harm, to a service user

Responsibility of Healthcare Inspectorate Wales to investigate

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of all health care in Wales. HIW's core role is to review and inspect NHS and independent healthcare organisations in Wales to provide independent assurance for patients, the public, the Welsh Government and healthcare providers, that services are safe and good quality. Services are reviewed against a range of published standards, policies, guidance and regulations.

As part of this work HIW will seek to identify and support improvements in services and the actions required to achieve this. If necessary, HIW will undertake special reviews and investigations where there appears to be systematic failures in delivering healthcare services, to ensure that rapid improvement and learning takes place. In addition, HIW is the regulator of independent healthcare providers in Wales and is responsible for ensuring that all registerable providers of Independent Healthcare comply with the requirements set out in the Care Standards Act 2000 and associated regulations and standards. Compliance with these statutory provisions and adherence to standards helps ensure services provided to patients meet essential safety and quality standards and regulations. Where service providers fail to meet their legal obligations consideration will be given to taking appropriate enforcement action, which can include Civil, or criminal action

HIW's primary focus is on:

- Making a contribution to improving the safety and quality of healthcare services in Wales
- Improving citizens' experience of healthcare in Wales whether as a patient, service user, carer, relative or employee
- Strengthening the voice of patients and the public in the way health services are reviewed
- Ensuring that timely, useful, accessible and relevant information about the safety and quality of healthcare in Wales is made available to all.

Primacy

The police hold primacy in a serious criminal investigation. Issues of patient confidentiality in terms of key witness evidence may need to be resolved between agencies in the wider interest of public safety. The incident coordination group (NHS) or multi agency safeguarding strategy meeting (Local Authority) should resolve and agree levels of investigation to be conducted by interested stakeholders. The investigating officer will be able to address potential issues of compromise of integrity of evidence through this group.

Preserving evidence and safeguarding the scene

In the immediate aftermath of a patient safety incident steps must be taken by the investigating officer to ensure evidence is secure and preserved. This is particularly true of busy NHS clinical areas that are in constant use by patients and staff and when people are following routine NHS operational practice e.g. sterilising equipment after a procedure or operation.

The availability of physical, scientific and documentary evidence may be critical to understanding what has happened and to the conduct of a satisfactory investigation by any agency. Destruction of evidence may also delay the introduction of safety measures. It may also lead to a more protracted and complex investigation than necessary.

It is especially important where a criminal offence is suspected that evidence is retained, since failure to do so may undermine legal proceedings.

Some healthcare incidents come to light sometime after the event(s). In these cases, the evidence may be less easy to identify and find. However, the approach outlined below should also be followed.

The following practical steps should be taken to preserve and safeguard evidence – including long after the event. The steps are divided into three distinct phases: assessment, protection and communication.

Assessing the nature of evidence

The 2006 MOU placed an obligation on the NHS to ensure that any relevant physical, scientific and documentary evidence is secured and preserved. This rests with the person responsible for risk management.

The investigating officer, in conjunction with senior leads from the relevant partner agencies concerned, should take responsibility for assessing what evidence is to hand. This must be done with an eye to how it might help any future investigation. For example, evidence in healthcare settings (which includes hospitals, dental surgeries and residential care homes) may include:

- records e.g. notes, letters, drug charts, print-outs from monitors and anaesthetic machines taken at the time (NB such print-outs may be automatically erased after 24 hours)
- equipment e.g. instruments, syringes and devices
- incineration bins
- clothing, including that of patient and staff
- packaging e.g. from drugs and equipment
- the scene more generally e.g. a treatment room
- personal possessions
- body of a patient
- samples e.g. blood, tissue
- photographs of the scene, with time and date (photographs of equipment should include serial numbers)
- CCTV
- Staff communication devices (pagers, etc.)

Such an assessment must be made even when the original incident(s) took place long ago. For example, archived medical records may need to be traced, recovered and stored or batch numbers of drugs traced.

The Care Quality Commission, as the independent regulator of health and adult social care in England, has investigative powers that may assist this activity in such an investigation. For example they may hold information gathered through inspection, contacts with the registered provider or through statutory notifications. Statutory notifications are events such as deaths or serious injury to a person using services that the registered provider is required, by law to submit to the CQC.

Protecting evidence

Once evidence has been identified, all efforts must be taken to protect it. Such steps may include placing a clinical area temporarily out of bounds to staff and patients however this restriction should continue for no longer than necessary. Support staff e.g. cleaners and engineers must also be notified. An identified person must take responsibility for holding and safeguarding any such evidence. This might include packaging the evidence carefully or preserving it in a fridge. Receipts should be provided and a record kept when any evidence – including equipment – is removed from any healthcare premises.

Communicating

A senior member of NHS staff – usually the person responsible for risk management – is responsible for briefing the investigating officer about what evidence is available, where it is, who has had access to it and what efforts have been made to protect it.

Specialist advice about medicines (for human use) and medical devices

The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health and has responsibility for the regulation of medicines (for human use) and medical devices in the UK. The MHRA also acts as the law enforcement authority under statutory legislative provisions. Its main aim is the protection and promotion of public health and this is delivered by ensuring that medicines, and medical devices meet appropriate standards of quality, and are acceptably safe. The MHRA is able to provide investigating officers with expert advice and help.

Medical Device Alerts, Drug Alerts and other safety information, together with contact points, are available to download from the Agency's website:

www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

When to contact Medical Healthcare products Regulatory Agency

If there is suspicion that a medicine or medical device has been involved in an unexpected death, informing the MHRA at the earliest possible stage will be advantageous; expert advice and guidance can be provided to the investigation team and MHRA may be able to take direct action to protect public health.

Where there is suspicion that a medicine or device is faulty, falsified or counterfeit, the Agency has powers to conduct a criminal investigation and prosecute offenders...

An MHRA investigation may also reveal that a medicine or device failed to meet its specification, thus ruling out one possible cause of the incident. Where a device does not fully meet its performance claim, the likely effect on the incident can be assessed

The MHRA has databases with reports of device incidents and defective medicines. While the detail of the investigation often cannot be divulged - except against a court order - generalised data may be available and helpful. For example, a summary of similar previous incidents may help to put the police investigation into context. The Health and Safety Executive maintain a list of failures in equipment, process, procedures and substances used in the workplace.
www.hse.gov.uk/safetybulletins/

Medical devices

Medical devices are used for diagnosis, prevention, monitoring, treatment or alleviation of a disease; alleviating or compensating for a disability, for investigation, replacement or modification of the anatomy or of a physiological process and for controlling conception. For example, they include: infusion pumps, wheelchairs, anaesthetic machines, MRI scanners and bandages.

In general, a medical device cannot be marketed in Europe without carrying a CE marking. A CE marking is applied by the manufacturer and means that the device meets the relevant regulatory requirements and, when used as intended, works properly and is acceptably safe. For all but the very lowest risk devices, such as un-medicated bandages, this must be verified by an independent certification body, called a Notified Body, before the CE marking can be affixed. The MHRA is responsible for appointing UK Notified Bodies and regularly audits them to ensure that they perform to high standards.

Medical devices are not necessarily risk free, but in order to place a medical device on the market, the manufacturer must be able to demonstrate that risks have been reduced as far as possible and that any residual risk is acceptable when weighed against the benefit to the patient. MHRA needs to assess this during any investigation concerning unexpected death involving a medical device.

MHRA's Devices Division employs product specialists with in-depth knowledge about a wide range of devices and medical technologies whose main role within the Agency is to investigate adverse incident reports received from healthcare professionals and the healthcare industry. The Division also has a Compliance Unit whose role is to investigate and resolve any non-compliance of the Medical Devices Regulations 2002 (as amended) for medical devices as they are first placed on the market and who act as the enforcement authority for these Regulations, in conjunction with the MHRA's Enforcement Group .

Medicines

The manufacture, supply and distribution of medicines is tightly controlled within the European Union. Pharmaceutical manufacturers and distributors operating in the UK are subject to a system of licensing and inspection, which ensures that licensed medicinal products conform to European standards of quality, safety and efficacy, and that those medicines are manufactured, stored and distributed in compliance with the European Union's agreed standards of good distribution practice.

There is a statutory requirement to enforce medicines regulations and the MHRA's Enforcement Group is tasked to carry out investigations on behalf of the Secretary of State for Health. Investigation officers in the group draw on powers (entry, inspect and seizure) conferred by the legislation to undertake investigations into suspected illegal activity and bring prosecutions through the criminal courts. MHRA investigators are predominantly from an investigative background and have been trained to Police standards.

Any illegal activities involving medicines and their availability, manufacture, import, sale, supply and administration: from sale and supply of unlicensed products to manufacture and distribution of licensed products. Cases also can involve administration of medicines by doctors, dentists, other health service professionals, hospital and pharmacy services.

Sanctions available range from seeking basic compliance and revoking licenses through to criminal conviction leading to a maximum of two years imprisonment and/or an unlimited fine on prosecution.

The Group liaises closely with police forces and regulatory bodies.

Falsified Medicines and Devices and illegal trading.

Medicines and medical devices are increasingly subject to illegal trading; both through the authorised supply chains but predominantly through the illicit supply chain (Internet websites).

The supply of falsified and counterfeit and unregistered medicines and medical devices is a growing problem worldwide and one which the MHRA takes very seriously. The MHRA has a falsified medical products strategy, which is available in full on the MHRA website.

Fees

There would generally be no charge for MHRA advice to the police service related to investigation activities. Exceptionally however charges might be necessary, for example, where separate costs may be incurred for external specialist testing etc

Sharing information including confidential patient information (NHS)

The NHS, police, CQC, HSE and HIW, have a duty to uphold the health and safety of patients and the public as well as responsibilities for investigation and enforcement. In discharging this duty, the four organisations will share all appropriate information where necessary to ensure patient safety. Such sharing should take account of the health and safety of patients and the public and the legal responsibilities and duties of the three organisations, in particular the limits on what information the organisations may disclose during criminal investigations.

The four organisations must also share information to discharge their specific responsibilities.

NHS

- to ensure the safety of patients and wider NHS systems and processes
- to continue to manage health services in a timely and effective manner and ensure the delivery of services to patients.
- To investigate adverse incidents in order to learn and prevent recurrence

Police/HSE

- to investigate a potential offence
- to conduct investigations in a way that helps maintain patient safety as a priority
- to conduct investigations in a timely and effective manner.

CQC

- to protect and promote the health, safety and welfare of people who use health and social care services
- to encourage improvements in health and social care.
- to work in partnership with other regulators and agencies.
- to play our role in the systems that aim to protect people who are at risk

Subject to legal requirements and safety concerns, there are a number of factors to bear in mind when making judgments about sharing information.

These include:

- the nature and degree of risk associated with the incident itself and the circumstances and individuals involved
- the purpose for which any shared information is to be used and by whom
- whether consent for disclosure is necessary and, if so, whether it can be obtained

- current law and guidance e.g. the statutory requirement to provide information to the HSE and the obligations put upon different professionals by their individual codes of conduct
- confidentiality agreements with those with whom information is shared
- the justification for any necessary breach of patient confidentiality.

Sharing information is an important matter for the incident coordination group (NHS) or multi agency safeguarding strategy meeting (Local Authority) to consider. Where necessary, legal or other specialist advice e.g. from professional, regulatory or indemnifying bodies – including that of the CPS should be sought.

It may sometimes be necessary for the police to interview staff employed in healthcare settings. To enable proper early assessment of the evidence, all staff should be encouraged to give witness accounts as soon as possible. The preferred position if appropriate should be to interview staff as witnesses rather than suspects unless there is clear evidence of criminality. Where necessary, healthcare staff should be given access to legal or staff association representation.

For the NHS, any decision to share or withhold information should be in line with the Department of Health's Confidentiality Code of Practice (November 2003) [Code of Practice PDF](#). The code is a guide to required practice for those who work in or under contract to NHS organisations concerning confidentiality and patients' consent in relation to their health records. It is a source of guidance for NHS managers and staff and should be to hand at any meeting of the incident coordination group.

- pages 1 to 10 of the code provide a summary of the key confidentiality issues
- pages 33 and 34 provide specific guidance about common law and disclosure in the public interest or to protect the public. Also included are examples of disclosure to protect the public including in the circumstances of serious crime, risk of harm and national security
- paragraphs 30 and 31 (page 34) have direct relevance to the sort of issues an incident coordination group may be considering. They say:

'Under common law, staff are permitted to disclose personal information in order to prevent and support the detection, investigation and punishment of serious crime and/or to prevent abuse or serious harm to others where they judge, on a case by case basis, that the public good that would be achieved by the disclosure outweighs both the obligation of confidentiality to the individual patient concerned and the broader public interest in the provision of a confidential service.

Whoever authorises disclosure must make a record of any such circumstances, so that there is clear evidence of the reasoning used and the circumstances prevailing. Disclosures in the public interest should also be proportionate and be limited to relevant details. It may be necessary to justify such disclosures to the courts or to regulatory bodies. A clear record of the decision-making process and the advice sought is in the interest of both staff and the organisations they work within.'

Each NHS organisation has a Caldicott Guardian. A Caldicott Guardian is a senior person responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing. The guardian plays a key role in ensuring that the NHS, councils with social services responsibilities and partner organisations satisfy the highest practicable standards for handling patient identifiable information this role is supported by the guidance (Caldicott 2: "To Share or Not to Share? The Information Governance Review" 2013), which included an additional principle - The duty to share information can be as important as the duty to protect patient confidentiality.

Investigating officers can seek the advice of the Caldicott Guardian if guidance is needed about the disclosure of patient identifiable information. The Investigating Officer should inform the Incident Coordination group that this has been done, or of their intention to do so.

Investigating officers should also consider adding a disclaimer to written statements saying that the contents of the statement will be shared with other organizations e.g. the trust or a professional regulator when the police have completed their investigation. This will reduce the need for staff to be interviewed more than once and speed the investigative work of other organisations.

Sharing information including confidential patient information (Care Act 2014)

Safeguarding Adult Boards (SAB) must arrange a Safeguarding Adult Review (SAR) when an adult in its area dies as a result of abuse or neglect, whether known or suspected, and there is concern that partner agencies could have worked more effectively to protect the adult. SABs must also arrange a SAR if the same circumstances apply where an adult is still alive but has experienced serious neglect or abuse.

In order to carry out its functions SABs will need access to information that a wide number of partners may hold. Some of these partners will be statutory, such as the NHS and the police. Others will not be, such as private health and care providers

An SAB may request a person to supply information to it or to another person. The person who receives the request must provide the information provided if: the request is made in order to enable or assist the SAB to do its job; the request is made of a person who is likely to have relevant information and then either—the information requested relates to the person to whom the request is made and their functions or activities the information requested has already been passed on to another person subject to this requirement.

Agencies should draw up a common agreement relating to confidentiality and setting out the principles governing the sharing of information based on the best interests of the adult at risk of abuse or neglect.

The Caldicott principals apply to disclosures made under adult safeguarding.

Dealing with public safety and minimising risk

Investigating officers should bear in mind at all times the operational implications to the NHS/healthcare provider of policing decisions e.g. closing an operating theatre so that it can be treated as a crime scene.

Similarly investigating officers should discuss with the healthcare employer whether the actions of a professional need to be reported to their regulator e.g. General Medical Council or Nursing and Midwifery Council so that the regulator can consider applying interim orders to prevent them from practising.

At all times a balance needs to be struck between public and patient safety and operational policing imperatives.

Supporting patients and relatives

The family of a victim is involved in the investigation from the start, regardless of how a referral is made. The investigating officer's first contact is therefore of great importance. The family may not be aware of concerns about the death, particularly if the referral has been made by another party. The involvement of the police may suggest to people that a crime has been committed. This can create a poor impression of the healthcare provider when this may not be justified.

A full explanation of why the police or investigative body has become involved and how these organisations work (e.g. on behalf of the Coroner), is central to establishing a good working relationship. The purpose of an investigation, its aims and expectations are important matters that must be explained to families and friends at the start. This avoids the likelihood of their developing

unrealistic concerns and expectations. The investigating officer may consider deploying a Family Liaison Officer to be the point of contact between the police investigation and the family.

Handling communications

Investigations involving healthcare providers and professionals sometimes attract high levels of media interest and concern. The investigating officer needs to manage this aspect of the investigation carefully. This should be done in association with the relevant healthcare provider so as to minimise inappropriate and unnecessary alarm in the community, while ensuring that factual and appropriate information is provided to the media and the public. Media releases should consider community reassurance messages.

There are two main elements of managing communications:

- a media strategy
- an internal communications strategy which includes families, relatives and healthcare staff.

These strategies are of equal importance. In managing communications, the investigating officer must exploit the media and internal communications because both offer investigative opportunities.

Effective communications can result in:

- crucial evidence being established
- new witnesses being discovered
- important information coming to light
- people being eliminated from the investigation
- Suspects being identified.

The media strategy should be negotiated in association with interested parties through the incident coordination group (NHS) or multi agency safeguarding strategy meeting (Local Authority). The message must be consistent and one agency identified as having the lead for media enquiries.

The media strategy should also address how further complaints from or involving other police forces or healthcare providers are to be dealt with.

The investigating officer may also wish to consider commissioning a community impact assessment to better understand and manage any community concerns or tensions.

5. Potential offences

Many potential offences may be uncovered during an investigation of untoward harm or death in a healthcare environment. A number of these offences may not be offences that the police normally deal with. In particular, there is potential for a number of breaches of the Health & Safety at Work Act to have been committed. It is important therefore that at an early stage consultation and advice is sought from the CPS and full liaison with the CQC and / or HSE is entered into (see Work Related Death – Protocol for Liaison and Investigators Guide). The CPS has special casework lawyers whose early advice and guidance as to the law will be invaluable.

Early and full consultation with the CQC and / or HSE will help establish and agree primacy. The HSE will be able to offer advice about systems of working and with matters of clinical governance.

The more obvious offences for an investigation of this nature are as follows. The definitions are provided with particular reference to medical issues.

Murder

Murder is defined at Common Law as:

Where a person of sound mind and discretion unlawfully kills any reasonable creature in being and under the Queen's peace, with intent to kill or cause grievous bodily harm.

Murder is the unlawful killing of a person with the intention to kill or cause grievous bodily harm. Nothing less will suffice. Foresight that a consequence is almost certain to result is not the same as intention, though it may be evidence of it.

There is some legal authority for the proposition that, where the sole, bona fide intention of a doctor is the relief of pain through the administration of drugs, in the knowledge that those drugs, as an unwanted side effect, also inevitably hasten the patient's death, then that is not murder.

Involuntary manslaughter

Involuntary manslaughter is an unlawful killing without an intention to kill or cause grievous bodily harm i.e. an unintentional killing. Apart from the intent (mens rea) the elements of the offence are the same as for murder. There are two types of involuntary manslaughter, which are manslaughter

- Caused by the defendant's gross negligence
- Caused by his unlawful act

Unlawful act' manslaughter requires that:

- a) The killing must be the result of the accused's unlawful act, though not his unlawful omission. It must be unlawful in that it constitutes a crime. A lawful act does not become unlawful simply because it is performed negligently. The act must be a substantial (more than minimal) cause of death but not necessarily the only operative cause (see causation).
- b) The unlawful act must be one, such as an assault, which all sober and reasonable people would inevitably realise must subject the victim to, at least, the risk of some harm resulting there from, albeit not serious harm.
- c) It is immaterial whether the accused knew that the act was unlawful and dangerous, and whether he intended harm; the mental state or intention required is that appropriate to the unlawful act in question.
- d) Harm' means physical harm.

Gross negligence manslaughter

Manslaughter by gross negligence is an offence contrary to Common Law. There has been difficulty in the past concerning identifying the elements which make the killing unlawful but the law has been clarified by the decision of the House of Lords in the case of R v Adomako (1994). It requires the satisfaction of a four-stage test.

This offence is committed **when a person who owes a duty of care to another, breaches that duty of care and this leads to the death of the other person and the conduct of the person who owes duty of care is considered to be so bad as to be criminal.**

The four-stage test (**the Adomako test**) for gross negligence manslaughter is.

- the existence of a duty of care to the deceased

- a breach of that duty of care
- causing the death of the victim
- whether that breach of duty should be characterised as gross negligence and therefore a crime.

The Corporate Manslaughter Act abolished this common law offence for corporations and others covered by the Act.

The Standard and the Breach

The ordinary law of negligence applies but a higher degree of negligence is necessary to render a person guilty of manslaughter than to establish civil liability against him. Those with a duty of care must act as the reasonable man would do in their position. If they fail to do so, they will have breached their duty of care. The test is objective. In a medical context, the standard of the duty of care owed is that of the ordinary skilled man exercising and professing to have that special skill but it must be remembered that there may be more than one proper standard so that a doctor will not be negligent if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that art. Mere failure to adhere to 'best practice' will not amount to gross negligence.

The Adomako Case

The defendant was the anaesthetist during an eye operation on a patient. In the course of the operation the tube from the ventilator supplying oxygen to the patient became disconnected. The patient suffered a cardiac arrest some nine minutes after the disconnection but the anaesthetist failed to notice the disconnection until after resuscitation procedures had commenced, despite an alarm sounding to indicate that the patient's blood pressure had dropped.

The defendant was found guilty of gross negligence manslaughter; the Court of Appeal upheld the conviction and the House of Lords approved the four-stage test for gross negligence manslaughter outlined above.

It is a question for the jury to decide whether, having regard to the risk of death involved, that the defendant's conduct was so bad, in all circumstances, as to amount to a criminal act or omission. Recklessness (which is a subjective matter) could form an element of the prosecution case in order to help prove the gross negligence, but see the Attorney General's reference (2 of 1999) which states that proving the reckless or intentional state of mind of the offender is not a pre-requisite for a conviction of manslaughter by gross negligence.

A person may become liable for manslaughter by gross negligence of a positive duty arising from the nature of their occupation – such as a doctor, nurse and carer.

The prosecution **must** prove that the injuries inflicted by the offender's actions were a significant cause of the victim's death. It does not have to prove that the death was **not** due to some other intervening event, such as medical negligence during the victim's treatment.

It is possible to convict a person of manslaughter by gross negligence on the evidence of that person's actions alone without evidence of mens rea (state of mind) i.e. it is an objective test. A jury is obliged, when considering this offence, to look at all the circumstances before reaching a verdict, so an individual's state of mind must be taken into account where relevant.

The standard and the breach are judged on the ordinary law of negligence. Those with a duty of care must act as the reasonable person would do in their position. The test is objective. It does not matter that the defendant did not appreciate the risk, provided that such a risk would have been

obvious to a reasonable person in the defendant's position. The risk in question is a risk of death, not of serious injury.

Corporate manslaughter

The Corporate Manslaughter and Corporate Homicide Act 2007 mainly came into force on 6 April 2008 across the UK.

The Act sets out a new offence for convicting an organisation where a gross failure in the way activities were managed or organised results in a person's death. This applies to a wide range of organisations across the public and private sectors – including the NHS and the independent healthcare sector.

In England and Wales and Northern Ireland, the new offence is called corporate manslaughter. It is called corporate homicide in Scotland.

An organisation will be guilty of the new offence if the way in which its activities are managed or organised causes a death and amounts to a gross breach of a duty of care to the deceased.

Juries will consider how the fatal activity was managed or organised throughout the organisation, including any systems and processes for managing safety and how these were operated in practice.

A substantial part of the failure within the organisation must have been at a senior level. Senior level means the people who make significant decisions about the organisation or substantial parts of it. This includes both centralised, headquarters functions as well as those in operational management roles.

In England and Wales and Northern Ireland, the consent of the relevant director of public prosecutions is needed before a case of corporate manslaughter can be taken to court.

When dealing with corporate manslaughter the CPS consider that the following points need to be proved:

- the defendant is a qualifying **organisation**
- the organisation **causes** a person's death
- there was a **relevant duty of care** owed by the organisation to the deceased
- there was a **gross breach** of that duty and
- a substantial element of that breach was in the way those activities were managed or organised **by senior management** and the defendant must not fall within one of the **exemptions** for prosecution under the Act.

Causation

Demonstrating causation is a critical first step in an investigation in healthcare. Early expert and legal advice helps the investigating officer determine whether there is a case to be investigated.

When prosecuting for an offence of homicide, there are a number of elements the Crown must prove. One of these is the element of causation.

In simple terms, the prosecution must prove that the death was 'caused' (wholly or in part) by the defendant. This appears to be straightforward but some judges have recognised the inherent difficulties:

'Where the law requires proof of the relationship between an act and its consequences as an element of responsibility, a simple and sufficient explanation of the basis of such relationship has proved notoriously elusive.' - R v Cheshire [1991] 3 All ER 670.

Recent experience has shown that causation is hard to prove in certain types of cases - typically, but not exclusively, those involving medical negligence.

The classic statement on causation in manslaughter was provided by the present Lord Chief Justice in R v

HM Coroner for Inner London, ex parte Douglas-Williams (1998) 1 All ER 344:

"...that the unlawful act caused death in the sense that it more than minimally, negligibly or trivially contributed to the death.

"In relation to both types of manslaughter it is an essential ingredient that the unlawful or negligent act must have caused the death at least in the manner described. If there is a situation where, on examination of the evidence, it cannot be said that the death in question was/was not caused by an act which was unlawful or negligent as I have described, then a critical link in the chain of causation is not established. That being so, a verdict of unlawful killing would not be appropriate and should not be left to the jury."

It can be seen from this that the prosecution must be able to link the act at least to an operative cause of death. It is not sufficient to say that it may have been a cause of death.

Mental Capacity Act 2005

Section 44 of the Mental Capacity Act 2005 creates certain offences in connection with the ill-treatment or wilful neglect of a person who lacks capacity.

The offence is triable either way and carries a maximum penalty on indictment of 5 years imprisonment and/or a fine.

A person lacks mental capacity if, at the material time, he/she is unable to make a decision for him/herself because of an impairment of, or a disturbance in the functioning of, the mind or brain: section 2(1) It is immaterial if the impairment or disturbance is permanent or temporary: section 2(2).

A lack of capacity cannot be established merely by reference to a person's age or appearance, or by a condition, or an aspect of behaviour, which might lead others to make unjustified assumptions about capacity: section 2(3).

The question of whether a person lacks capacity within the meaning of the Act is to be decided on the balance of probabilities: section 2(4). Accordingly, there must be evidence to support the fact that the person lacked mental capacity at the time the offence was committed against him/her.

Even if the victim has capacity, it will still be an offence if the person who has the care of him/her reasonably believed he/she lacked capacity and ill-treated or neglected him/her. Reasonable belief means that, in all the circumstances, a reasonable person would believe that the victim lacked capacity.

The Act applies to everyone who looks after or cares for someone who lacks mental capacity. This includes both those who have the day-to-day care of that person as well as those who only have very short term care, whether they are family carers, professional carers or other carers.

The Act does not define 'ill-treatment' and 'wilful neglect'; therefore, these concepts should be given their ordinary meaning. For assistance on what constitutes 'wilful neglect', reference should be made to Archbold 2015 paragraphs 17-47/48 and 19-375/391 which deal with 'wilful neglect' and 'ill treatment' of children.

A person who has genuinely failed to appreciate that, for example, the other person needed medical care, through for example personal inadequacy, is not guilty of the offence of wilful ill-treatment/neglect: see Archbold 2015 17-48.

Offences of ill-treatment and wilful neglect are continuing offences: R. v. Hayles [1969] 1 Q.B. 364, 53 Cr.App.R. 36, CA.

Under the Code for Crown Prosecutors, if the evidential test is met in wilful neglect or ill-treatment cases, the public interest will nearly always demand that a prosecution occurs, due to the position of trust that the suspect held in relation to the victim, as well as the extreme vulnerability of the victim.

Criminal Justice and Courts Act 2015 - III Treatment and Wilful Neglect

The offences are set out in sections 20 to 25 of the Criminal Justice and Courts Act 2015. They apply to individuals and organisations paid to provide or to arrange for the provision of formal health and adult social care services in both the public and private sectors, including where care is self-funded. The offences also apply to all formal healthcare provision for children in both the NHS and private sector, other than in specific excluded children's settings and services which are already subject to existing legislative and regulatory safeguards;

The section 20 offence applies to individuals. A care worker who ill-treats or wilfully neglects a person he has care of, commits an either way offence punishable with 5 years' imprisonment on indictment, or imprisonment for a term not exceeding 12 months on summary conviction. A fine can be imposed in addition or in the alternative.

"Care worker" means an individual who, as paid work, provides health care (other than excluded health care) for an adult or child, or social care for an adult. It includes an individual who, as paid work, supervises or manages individuals providing such care or is a director or similar officer of an organisation which provides such care.

"Paid work" refers to payment other than reasonable expense, payment for being a foster parent, for a benefit under social security legislation or a payment made under arrangements under section 2 of the Employment and Training Act 1973 (arrangements to assist people to select, train for, obtain and retain employment).

The meanings of "Health care" and "Social care" are set out in sections 20(5) and 20(6). Health care includes all forms of health care provided for individuals, including health care relating to physical health or mental health and health care provided for or in connection with the protection or

improvement of public health, and procedures that are similar to forms of medical or surgical care but are not provided in connection with a medical condition,

“Social care” includes all forms of personal care and other practical assistance provided for individuals who are in need of such care or assistance by reason of age, illness, disability, pregnancy, childbirth, dependence on alcohol or drugs or any other similar circumstances.

The offence is punishable with imprisonment for a term not exceeding 5 years or a fine (or both) on indictment or up to 12 months or a fine (or both) on summary conviction.

The section 21 offence applies to organisations. A care provider commits an offence if a care worker the care provider is responsible for, ill-treats or wilfully neglects an individual being cared for, provided the care provider’s activities are managed or organised in a way which amounts to a gross breach of a relevant duty of care owed by the care provider to the individual who is ill-treated or neglected, and, in the absence of the breach, the ill-treatment or wilful neglect would not have occurred or would have been less likely to occur.

Section 21(2) defines a ‘care provider’ as a body corporate or unincorporated association which provides or arranges for the provision of health care (other than excluded health care) or adult social care, or an individual who provides such care and employs or otherwise makes arrangements with individuals to assist in providing that care.

The intention is to ensure that the definition covers not just provider organisations such as hospitals (whether NHS or privately run) and companies, but also partnerships such as GP practices, and sole traders such as single-handed GP practices.

Subsection (6) clarifies the meaning of a “gross” breach of a duty of care by a care provider, as being where the care provider’s conduct falls far below what could reasonably be expected in the circumstances.

Subsection (7) provides that where the provision or making of arrangements for the provision, of health or social care is incidental to the carrying out of other activities, it is to be disregarded for the purposes of the care provider offence. For example, a prison that makes arrangements for one of its prison officers to accompany a prisoner, who has suddenly fallen ill, to hospital would not be treated as a care provider, because the arrangements made are merely incidental to the organisation’s primary custodial activities.

The overall approach to this offence is modelled, insofar as is practicable, on that of the offence of corporate manslaughter/homicide established in the Corporate Manslaughter and Corporate Homicide Act 2007 (“CMCHA 2007”). It focuses on the way an organisation managed or organised its activities, and on the duty of care that the organisation owed towards the victim.

The offence is punishable with a fine on indictment or summary conviction. In addition the court may make a remedial order and/or a publicity order.

Health and Safety offences

The main legislation enforced by the Health and Safety Executive (HSE) is The Health & Safety at Work Act 1974.

The principal relevant offences are:

Section 3

General duties of employers and self-employed to persons other than their employees

- 1) It shall be the duty of every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health or safety.
- 2) It shall be the duty of every self-employed person to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that he and other persons (not being his employees) who may be affected thereby are not thereby exposed to risks to their health or safety.
- 3) In such cases as may be prescribed, it shall be the duty of every employer and every self-employed person, in the prescribed circumstances and in the prescribed manner, to give to persons (not being his employees) who may be affected by the way in which he conducts his undertaking the prescribed information about such aspects of the way in which he conducts his undertaking as might affect their health or safety.

Section 7

General duties of employees at work.

- 1) It shall be the duty of every employee while at work to take reasonable care for the health and safety of himself and of other persons who may be affected by his acts or omissions at work; and
- 2) as regards any duty or requirement imposed on his employer or any other person by or under any of the relevant statutory provisions, to co-operate with him so far as is necessary to enable that duty or requirement to be performed or complied with

Section 8

Duty not to interfere with or misuse things provided pursuant to certain provisions.

- 1) No person shall intentionally or recklessly interfere with or misuse anything provided in the interests of health, safety or welfare in pursuance of any of the relevant statutory provisions.

Section 36

Offences due to fault of other person

- 1) Where the commission by any person of an offence under any of the relevant statutory provisions is due to the act or default of some other person, that other person shall be guilty of the offence, and a person may be charged with and convicted of the offence by virtue of this subsection whether or not proceedings are taken against the first-mentioned person.
- 2) Where there would be or have been the commission of an offence under section 33 by the Crown but for the circumstance that that section does not bind the Crown, and that fact is due to the act or default of a person other than the Crown, that person shall be guilty of the offence which, but for that circumstance, the Crown would be committing or would have committed, and may be charged with and convicted of that offence accordingly.

Section 37

Offences by bodies corporate

- 1) Where an offence under any of the relevant statutory provisions committed by a body corporate is proved to have been committed with the consent or connivance of, or to have been attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate or a person who was purporting to act in any such

capacity, he as well as the body corporate shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

- 2) Where the affairs of a body corporate are managed by its members, the preceding subsection shall apply in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

Section 38

Restrictions on institution of proceedings in England and Wales

Proceedings for an offence under any of the relevant statutory provisions shall not, in England and Wales, be instituted except by an inspector or the Environment Agency or by or with the consent of the Director of Public Prosecutions.

The control of substances hazardous to health regulations

Although the Health and Safety at Work etc Act 1974 applies to all risks associated with health and safety there are also specific regulations that may also apply. For example in the case of Health Acquired Infections such as MRSA or C Difficile the relevant legislation will be The Control of Substances Hazardous to Health Regulations 2002 – (COSHH).

Further information on specific regulations can be found at www.hse.gov.uk/legislation.

Regulation 7 states that - (1) Every employer shall ensure that the exposure of his employees to substances hazardous to health is either prevented or, where this is not reasonably practicable, adequately controlled.

Regulation 3 extends the duty to other persons - (1) Where a duty is placed by these Regulations on an employer in respect of his employees, he shall, so far as is reasonably practicable, be under a like duty in respect of any other person, whether at work or not, who may be affected by the work carried out by the employer.

6. Attendance at and management of an incident coordination group

Purpose of the incident coordination group

The purpose of the incident coordination group is to provide strategic oversight of a patient safety incident involving the NHS and the police, CQC, HIW and /or HSE. It is a forum for communicating, exchanging information and coordinating multiple investigations.

It allows all three organisations to set out their needs so that actions can be agreed that do not prejudice the work of each organisation e.g. legal proceedings, or the phasing, extent and timing of further NHS investigations. It should be the means by which the investigating officer engages the NHS and other organisations in a potential investigation in healthcare.

The incident coordination group has no role in directing the investigations of the police, CQC and/or the HSE and should not replace any gold group³ instigated to manage any critical issues arising as a result of the incident or investigation.

Those who attend on behalf of these organisations should be sufficiently senior to take decisions concerning the management of the incident. They must also have relevant skills, experience and training to deal with any immediate concerns.

Police representation should normally be an accredited senior investigating officer at the level of inspector or above. HSE representation is normally at main-grade inspector level. NHS representation will normally be at executive director level. CQC representation will normally be at Head of Inspection level. HIW representation will normally be at the Head of Investigation level.

In instances of suspicious death, the incident coordination group may ask the Coroner if he or she wishes to send a representative to the meeting, in addition to the police. In instances of the unexpected death of a child where an investigation under child protection procedures might be appropriate, the incident coordination group may want to ask children's social services if they want to send a representative.

It is expected that the NHS chair the first meeting of the group unless circumstances preclude it.

³ Guidance on the management of the Gold process can be found in the ACPO Advice on Critical Incident Management document which provides clarity to the concept and terminology of critical incidents and consistency to their management

Matters to discuss at the Incident co-ordination group

What should be discussed	What to consider
Nature of the incident(s)	<ul style="list-style-type: none"> • What has happened, when and how? • Who is involved
Reasons for meeting, including an explanation from the organisation responsible for calling the meeting	<ul style="list-style-type: none"> • Why has the meeting been called? Are other parties involved e.g. relatives, the Coroner
NHS actions to date, including the outcome of any internal or external investigation or root cause analysis	<ul style="list-style-type: none"> • What has the NHS done to date? • Are written reports available?
Public safety concerns	<ul style="list-style-type: none"> • Does this matter raise such concerns? • If so, what are they?
Safety of NHS systems and the need for continuity of patient care.	<ul style="list-style-type: none"> • Is there a need for remedial action and / or further investigation by the NHS? • Does the matter need to be reported to another body e.g. MHRA?
The extent of further, immediate NHS investigations and how these may need to be constrained in subject matter or format by the needs and requirements of the Police and /or CQC/HSE	<ul style="list-style-type: none"> • Is patient safety at risk? • If so, what has to be done to minimise this risk?
Role and responsibilities of the Police and / or CQC/HSE and next steps to be taken (except where this would jeopardise any investigation or subsequent legal proceedings)	<ul style="list-style-type: none"> • Each organisation should describe what it needs to do next and how it will fit – or conflict – with what others propose to do
Other statutory responsibilities	<ul style="list-style-type: none"> • Do the organisations have other statutory responsibilities they should consider e.g. are there any safeguarding considerations in respect of a child or a vulnerable adult?
Need to inform professional regulatory bodies e.g. General Medical Council, General Dental Council, Nursing and Midwifery Council	<ul style="list-style-type: none"> • Does this individual(s) need to be referred? • Who should do this? • At what stage should this referral be made?
Securing and preserving evidence	<ul style="list-style-type: none"> • Has this been done and by whom? • What has been preserved and where located?
Sharing information	<ul style="list-style-type: none"> • What information is available • When is the information required • What may be shared – Is Consent required? • Consult with Caldicott Guardian
Needs of and support to patients, relatives and NHS Staff	<ul style="list-style-type: none"> • How are these to be met and by whom?
Information to other interested parties e.g. the Coroner	<ul style="list-style-type: none"> • Who else needs to know? • What can they be told?

Handling communications/media	<ul style="list-style-type: none"> • Is the incident likely to attract the attention of the media? • What will be said in response? • Who will say it and in what circumstances? • Has a joint media strategy been agreed?
Future handling and co-ordination, including the appointment of a liaison officer from each organisation	<ul style="list-style-type: none"> • Who from each organisation is to act as single point of contact and lead (SPOC)?
Freedom of information / Disclosure	<ul style="list-style-type: none"> • Agree protocol for material ownership, retention and return

Note: It is a fundamental responsibility of the police service to preserve life. In this regard, investigating officers must have a primary regard for public and patient safety when investigating incidents in healthcare.

Similarly, healthcare providers in their capacity as the employer of healthcare professionals should take responsibility for reporting professional staff to regulators.

In the event of early and clear allegations in respect of corporate failings regarding a death in a healthcare setting, the investigating officer must take this into account and consider the membership of the incident coordinating group in consultation with other relevant stakeholders.

6a. A summary of Safeguarding Procedures

Under the Care Act 2015 a number of the previously used safeguarding references have changed. The previous references are detailed in brackets below -

Safeguarding Concern (Alert) – Reporting of concerns of actual or suspected abuse or neglect. Any immediate protection needs are identified and addressed ⁴

Decision – Is this an Adult at requiring safeguarding? Once duty is triggered the decision will be what action should be taken and by whom.

Safeguarding Planning Meeting (Strategy meeting) – Formulating a multi-agency plan for assessing risk and undertaking the investigation into the adult protection concerns managed by the local authority

Section 42 Enquiry ⁵. (Investigation) – Coordinating the collection of information/evidence about the abuse or neglect that has or may occur. This may include evidence required for a criminal investigation but also may include other investigative processes such as a disciplinary investigation

Safeguarding Plan (Protection Plan) – Coordinating a multi-agency response to the abuse in order to reduce or eradicate the risk of further abuse taking place.

Safeguarding Meeting (Case Conference) – A multi-agency meeting following a safeguarding investigation which may involve the service user, to agree a protection plan.

Closing safeguarding meeting / case conference – To review and finalise the investigation.

Safeguarding Adults Review (SAR) - A Serious Case Review should be considered by the Safeguarding Adults Board (SAB) when one or more of the following applies -

- SABs must arrange an SAR when an adult in its area dies as a result of abuse or neglect, whether known or suspected, and there is concern that partner agencies could have worked more effectively to protect the adult.
- SABs must also arrange a SAR if an adult in its area has not died, but the SAB knows or suspects that the adult has experienced serious abuse or neglect. In context of SARs something can be considered serious abuse or neglect where, for example the individual would have been likely to have died but for an intervention, or has suffered permanent harm or has reduced capacity or quality of life (whether because physical or psychological effects) as a result of the abuse or neglect.

The purpose of the review is to establish the following -

- Whether there are lessons to be learned from the circumstances of the case about the way in which local professionals and agencies work together to safeguard adults at risk.
- What those lessons are, how they will be acted upon and what is expected to change as a result.
- To improve inter-agency working and better safeguarding of adults at risk including the review of procedures where there may have been failures

⁴ Adult safeguarding means protecting a person's right to live in safety, free from abuse and neglect. The Care Act requires that each local authority must make enquiries, or ensure others do so, if it believes an adult is, or is at risk of, abuse or neglect. An enquiry should establish whether any action needs to be taken to stop prevent abuse or neglect, and if so, by whom;

⁵ The objectives of an enquiry into abuse or neglect are to: establish facts; ascertain the individual's views and wishes and seek consent; assess the needs of the adult for protection, support and redress; and make decisions as to what follow-up action should be taken with regard to the person responsible, or the organisation, for the abuse or neglect.

7. Early contact with the Crown Prosecution Service

Purpose of early contact

Crown prosecutors are responsible for deciding in all investigations involving serious criminal allegations, whether a person should be charged and, if so, with what. Crown prosecutors make these decisions in accordance with the evidential and public interest tests set out in the Code for Crown Prosecutors and with the director of public prosecution's guidance on charging.

The Special Crime Division (SCD) of the CPS ultimately deals with serious, sensitive and complex casework, which must be undertaken at CPS Central Casework Divisions rather than in the Areas. This includes cases of alleged gross negligence manslaughter against members of the health care profession where the death has resulted from a failure of medical expertise, for example the administration of the wrong amount of a drug, but not deaths resulting from a lack of care, for example, dropping a patient from a hoist. SCD only deals with cases where death results. Serious injury as a result of failure of medical expertise and death as a result of failure of care should be referred to Complex Casework Units.

Any allegation with a corporate element must be dealt with by SCD, unless the corporation is a partnership, when the CCU will deal. If any NHS trust or a healthcare- providing company is being investigated under the CMCHA 2007 then the investigating officer should contact SCD for initial advice.

Early advice from Crown Prosecutors

Prosecutors readily offer appropriate advice if they feel it contributes to the effectiveness of an investigation and prosecution.

An investigating officer may consult the CPS at any stage of an investigation. In serious cases in healthcare, investigating officers are encouraged to seek CPS advice as soon as an investigation changes from a purely intelligence-gathering operation into one intended to lead to a criminal investigation and potential prosecution. Early advice from the CPS can ensure from the start that cases are brought in a timely manner. The early involvement of prosecutors can bring other benefits, including:

- the CPS can advise which is the correct office to contact
- the prosecutor can identify, and where possible, rectify evidential or legal deficiencies and bring to an early conclusion cases that cannot be strengthened by further investigation
- the CPS can make an early assessment of the level of lawyer expertise and resources needed to deal effectively with a case
- the prosecutor can be identified at an early stage to ensure continuity of approach
- the CPS can highlight public interest considerations that may affect any eventual prosecution
- the CPS can guide the investigating officer on general lines of inquiry
- the prosecutor may also be able to recommend a particular expert
- the prosecutor can advise on the nature and scope of expert evidence to be sought including specific questions to ask of the expert
- case-management issues can be taken into account when planning the investigation

8. Use of expert advisers – for assessment/filter and for the purpose of giving evidence

What is an expert adviser?

An expert adviser is any person who can help an investigation because their specialist knowledge and/or experience allows them to give an opinion on a particular matter, or provide a specialist service directly related to their expertise. An expert adviser is independent of the police and is usually called upon to advise on a specific problem. They will be able to assist the investigating officer to understand whether the situation in question is unusual or beyond what would normally be expected in a medical environment.

An expert adviser is not necessarily an expert witness. An expert, as defined by the CPS, is 'a person whose evidence is intended to be tendered before a court and who has relevant skill or knowledge achieved through research, experience or professional application within a specific field sufficient to entitle them to give evidence of their opinion and upon which the court may require independent and impartial assistance'. The difference between an expert and other witnesses is that experts are the only witnesses allowed to give 'opinion evidence'. An expert adviser's status may change to that of an expert witness as the investigation progresses.

What makes a suitable expert adviser will depend on the context of a particular case. An expert adviser's expertise and qualifications are useful to an investigation only if they are relevant to the issue in that investigation. Expertise can be demonstrated through formal, recognised qualifications or through experience. The type of expertise that is appropriate depends on the nature of the problem.

Choosing experts

The Specialist Operations Centre of the National Crime Agency (NCA) provides information, advice and support to those involved in the investigation of major crime, covert issues and techniques, and uniform policing. It maintains a database containing the details of expert advisers. This facility is available 24 hours a day, seven days a week contact – 0845 0005463

The operations centre does not accredit expert advisers on its database. It is the investigating officer's responsibility to ensure that an expert adviser has the necessary and relevant expertise to aid their investigation.

In the first instance the investigating officer should contact the above number to identify expert advisers who appear to have the appropriate expertise. An investigating officer who does not want to use any of the expert advisers identified by the SOC, may find an expert adviser through other means:

- In force Forensic Manager / Advisor
- personal recommendations from other investigators and CPS prosecutors
- academic institutions
- royal colleges (medical and nursing)
- healthcare solicitors

Please refer to ACPO (2006) Practice Advice on the Management of Expert Advisers for more details about this matter, including the responsibilities of the investigating officer.

Whatever the view of the experts, their statements of evidence/reports should be constructed with the following principles in mind:

- 1) What treatment should have been offered in each case? Experts should cover in their report the basic conditions of a particular disease and how the symptoms present themselves. They can then go on to describe how the condition would normally be treated in their own experience, with reference to recognised protocols of the day.
- 2) Experts commissioned to provide evidence should construct their evidence as simply as possible to enhance understanding. A glossary of terms for complex medical terminology is good practice. Experts must be professionally correct, because opinions are likely to be challenged by defence experts. Reports should be set out in a way that allows the police/counsel etc. to dissect the report and ask for further work or clarification.
- 3) Experts should have an understanding of the terms criminal gross negligence, unlawful act in the context of homicide and gross breach of a duty of care. Experts should also be able to refer to the key consideration in determining whether there has been a breach of a duty of care, namely whether the act or omission in question was “reasonable” in all the circumstances. Language used to describe negligence should be consistent, and if appropriate able to demonstrate both why one act is more negligent than another and the level of negligence.
- 4) When reading the statements of the experts the prosecutor seeks to apply the criminal standard of proof, namely, the evidence to prove any element of the offence must be sufficient to satisfy the jury so that they are sure, or satisfied beyond reasonable doubt. Experts should bear this in mind when expressing opinions or findings so that the level of certainty they can give is clear. Is it for example, only to the level of more likely than not (i.e. on the balance of probabilities), or to the higher level, of being sure so that other reasonable possibilities can be excluded?
- 5) Experts must give consideration to explaining the use of statistical information in reports and what the statistics are seeking to establish.
- 6) Any documentation referred to in text must be included.
- 7) Analysis of supplementary paperwork such as prescription charts/fluid charts/observation charts must be undertaken. Paperwork differs from ward to ward, let alone from hospital to hospital. Experts should be advised by the commissioning investigating officer that if they are commenting on procedures that have been carried out and are critical of conduct then the criticism needs to be set against the context of relevant guidance, and is supported by evidence of what the expert witness would have done under the same circumstances.
- 8) Expert must be supplied with copies of relevant hospital protocols I procedures.
- 9) As with the operational expert adviser and expert witnesses (assessment/filter); the employment of the evidential expert should be the subject of agreed terms of reference underpinned by a contract.
- 10) CPS prosecutors will usually assist investigating officers, on request, with drafting specific questions or terms of reference for an expert.

9. Conducting interviews – witness and suspect

Investigating serious harm and unexpected deaths in a healthcare setting can be challenging for an investigating officer, particularly in the first 48 hours. It is often unclear whether a criminal offence has been committed. The benefits therefore of establishing and obtaining early witness and suspect accounts from healthcare professionals connected to an investigation cannot be overstated. These include:

- outlining the incident
- identifying lines of enquiry
- understanding the scope of the investigation
- obtaining first accounts
- establishing the likelihood of more detailed interviews
- demonstrating an open-minded approach to the enquiry
- recognising categories of significant, vulnerable or intimidated witnesses
- providing an early update to the CPS or other agencies (as appropriate).

Investigating officers should set out in policy what they seek to achieve from interviewing healthcare staff and witnesses and whether or not persons at that stage are considered to be suspects. If persons are identified as suspects it is vital to record specifically what these people are suspected of and why.

In the absence of any clear indication of criminality it is possible for the investigating officer and investigative team to pursue the inquiry through witness interviews to establish in a balanced and proportionate manner what has happened.

Healthcare professionals are highly trained and experienced in their chosen fields, often with a high degree of academic attainment. They nonetheless share similar concerns to everybody else when they are asked to provide statements and/or be interviewed by police officers. A brief explanation to the effect that obtaining a statement necessitates an officer interviewing a person can assist an enquiry and lessen witness tensions.

The memorandum of understanding written in conjunction with the NHS encourages staff to provide early voluntary witness statements. Investigating officers should encourage this stance and seek to establish good lines of communication to facilitate the process.

Any barriers to obtaining relevant information need to be removed. Witnesses should not normally be cautioned until the investigating officer has decided that there are grounds to suspect them of an offence. The principle aim in the early stages of an investigation should be to identify and record what has happened. As stated earlier, in most cases no criminal offence is likely to have taken place.

Considerations for the investigating officer

- legal requirement for the witness interview e.g. to assist the Coroner
- is the person being interviewed a witness or suspect
- explaining the difference between a witness interview to obtain a statement and an interview under caution
- establishing and communicating at an early stage the context and content of the statement
- explaining to healthcare professionals about the need for interview i.e. obtaining best evidence and information, establishing sequence of events in respect of the patient care etc.
- location of interview/statement. Healthcare professionals may want to be interviewed at the place of work during working hours. Their availability particularly that of doctors, may be severely restricted. This may cause logistical problems for both the SIO and healthcare establishment
- realistic length of interview. Most police officers and healthcare professionals underestimate the time needed to obtain a detailed account of events
- provision of legal advice. Some doctors may postpone providing a statement until they have contacted their professional body. This may mean arranging the interview through a representative of their defence union - common practice in some areas. In some cases it can help to establish good lines of communication. Nurses asked to provide a statement often follow the same procedures
- consider deploying a tactical interview manager (TIM) to coordinate witness and suspect interview strategies.

Tactical interview manager (tier 5 trained officers)

Tactical interview managers (TIM) are officers who are trained to tier five of the national investigative interviewing strategy. These officers are trained to assist investigating officers with formulating and applying ethical strategies in relation to the interviewing of witnesses and suspects.

This will include identifying and providing advice on dealing with significant, vulnerable and intimidated witnesses.

An interview manager can provide a considerable amount of support and assistance to the investigating officer and investigation team if they are consulted at an early stage of a healthcare investigation.

Their training covers a number of aspects including.

- Formulating ethical interview strategies
- Liaison with specialists
- Identifying the most appropriate method for recording an interview
- Coordinating interviews

- Debriefing interviewers
- Independently analysing information obtained
- Quality assuring the interview process
- Pre- interview disclosure strategies.

These facets can be particularly useful in healthcare settings as most of the logistical problems that beset large enquiries revolve around the management of witnesses.

Obtaining witness statements from healthcare professionals can be a lengthy process due to the competing demands of their patients. It is important therefore that investigating officers are able to maximize the limited time they are allocated.

An interview manager can provide a structured approach for officers ensuring that the relevant material is obtained.

Suspect interviews

In some cases the identity of an offender is clear and the investigation of an alleged criminal offence straightforward. An interview manager can however, provide structured advice to the investigating officer on the best way to interview witnesses and suspects.

This guidance is designed to help in cases where identifying the offence and offender is unclear. These investigations arise from unexpected or unexplained causes of death. Invariably, they centre on an allegation of negligence of one or more healthcare professionals.

As has already been stated, it is advisable in the early stages of these types of enquiries that “first account” statements are obtained as expeditiously as possible from all persons involved.

When potential criminal culpability is identified, investigating officers are likely to have a statement from the suspect and copies of the relevant medical records and/or exhibits as appropriate.

If the investigation has been protracted, the investigating officer will have had chance to consult the CPS. Having applied the “Adomako” filter the investigator should be clear about which area of potential criminality they are investigating.

The investigating officer then has to consider whether an arrest is necessary and/or proportionate. Can the desired result be obtained by interviewing the person under caution?

Senior investigating officers can consider the option of inviting a person to attend a police station with relevant legal support to be formally interviewed under caution. Three potential outcomes of this practice can be expected.

- 1) A legal adviser advises a client to make no comment and relies on their earlier statement.
- 2) The suspect or his legal adviser will read out a statement and then decline to comment further.
- 3) The interview takes a long time as the person explains in detail their account and understanding of complex medical matters. These interviews are often subject to regular

client/solicitor consultation periods as they consider the implications of records/exhibits set against the individual question.

The investigating officer may, however, believe that **“the arrest is necessary for the prompt and effective investigation of the offence”**. In either case an interview manager should provide advice to the investigating officer about the most effective way to secure the best evidence.

A medical expert in the appropriate field can provide help identify suitable topic areas for questioning which can be incorporated into an interview strategy.

Investigating a medical case increases an officer’s understanding of medical issues but he or she is unlikely to develop enough expertise to be able to interpret fully the answers to technical questions. This is one reason for engaging the help of an expert adviser.

Investigating officers may consider using an expert to help prepare questions and monitor a “live” interview to try to address technical points more efficiently. The interviewer must guard against the interview being conducted through a third party or becoming a debate around different interpretations of medical practice.

People under arrest, under caution or providing a statement voluntarily must be encouraged to describe actions, conduct or procedure in terms a lay person can understand. If this procedure is adopted throughout there is less chance of misinterpretation. Witnesses and suspects who take more time to think through their answers can better demonstrate their understanding. It also allows the expert, senior investigating officer and CPS lawyer to make informed decisions about culpability, further work or satisfactory resolution of an investigation.

Other relevant guidance

- ACPO (2005) Practice Advice on Core Investigative Doctrine. College of Policing (CoP) Wyboston.
- ACPO (2006) Murder Investigation Manual. CoP, Wyboston.
- ACPO (2006) Practice Advice on the Management of Expert Advisers. CoP, Wyboston.
- ACPO (2008) Family Liaison Officer Guidance. CoP, Wyboston
- ACPO (2009) Freedom of Information Manual of Guidance. www.npcc.police.uk
- Attorney General (2005) Attorney General's Guidelines on Disclosure of Information in Criminal Proceeding. www.gov.uk/attorney-general-s-guidelines-on-disclosure
- CPS (undated) Joint Operational Instructions for the Disclosure of Unused Material. www.cps.gov.uk
- CPS / ACPO / Chief Coroner / The Coroners' Society of England and Wales, Memorandum of Understanding (June 2013) www.cps.gov.uk/publications/docs/mou_cps_acpo_chief_coroner_june_2013.pdf
- Department of Health, ACPO, HSE (2006) Memorandum of Understanding - Investigating patient safety incidents involving unexpected death or serious untoward harm: a protocol for liaison and effective communications between the National Health Service, Association of Chief Police Officers and Health & Safety Executive. (Now Archived) [Link to webarchive.nationalarchives.gov.uk](http://webarchive.nationalarchives.gov.uk)
- Department of Health (2010) Guidance for access to health record requests. www.dh.gov.uk
- General Medical Council (2006) Good medical practice. www.gmc-uk.org
- General Medical Council, Nursing & Midwifery Council, ACPO and CPS (2006) Information-sharing protocol. www.gmc-uk.org
- Health and Safety Executive (2011) Work-related deaths: A protocol for liaison. www.hse.gov.uk/pubns/wrdp1.pdf
- Home Office (2007) Achieving best evidence in criminal proceedings: Guidance on interviewing victims and witnesses, and using special measures. www.cps.gov.uk/publications/docs/best_evidence_in_criminal_proceedings.pdf
- HSE / CQC / Local Authority MOU (2015) www.cqc/hse/la-mou-pdf
- NHS (2006) Guidelines for the NHS (in support of the Memorandum of Understanding) - Investigating patient safety incidents involving unexpected death or serious untoward harm: a protocol for liaison and effective communications between the National Health Service, Association of Chief Police Officers and the Health & Safety Executive – now achieved
- NHS Litigation Authority (undated) Clinical negligence reporting guidelines (5th edition). www.nhsla.com
- Nursing and Midwifery Council (2008) The Code: Standards of conduct, performance and ethics for nurses and midwives. www.nmc-uk.org

- Protocol for exhumation 2003 – National Crime and Operations Faculty polka.pnn.police.uk/
- British National Formulary (use of medicines) / British National Formulary for children / Palliative Care Formulary The British National Formulary provides UK healthcare professionals with authoritative and practical on line information on the selection and clinical use of medicines www.bnf.org
- Palliative drugs (as above) – palliativedrugs.com provides independent information for health professionals about drugs used in palliative and hospice care www.palliativedrugs.com

Organisations that can provide help to SIOs

<p>Care Quality Commission</p> <p><i>The Care Quality Commission is the independent watchdog for health and adult social care in England. It promotes continuous improvement in the services provided by the NHS, independent healthcare and adult social care organisations.</i></p>	<p>Telephone: 03000 616161</p> <p>www.cqc.org.uk</p>
<p>Care and Social Services Inspectorate Wales</p> <p>Responsible for inspecting social care and social services to make sure that they are safe for the people who use them.</p>	<p>Telephone 03007900126</p> <p>http://cssiw.org.uk</p>
<p>Coroner</p> <p><i>Coroners are independent judicial officers. They inquire into deaths reported to them which appear to be violent, unnatural or of sudden and unknown cause.</i></p>	<p>www.coronersociety.org.uk</p>
<p>Council for Healthcare Regulatory Excellence</p> <p><i>The Council for Healthcare Regulatory Excellence is the health professions' watchdog. Their primary purpose is to promote the health, safety and wellbeing of patients and the public.</i></p>	<p>Telephone: 020 7389 8030</p> <p>www.chre.org.uk</p>
<p>Department of Health</p> <p><i>The Department of Health has responsibility for standards of health care in the country, including the NHS. It sets the strategic framework for adult social care and influence local authority spend on social care. It also set the direction on promoting and protecting the public's health, taking the lead on issues like environmental hazards to health, infectious diseases, health promotion and education, the safety of medicines, and ethical issues</i></p>	<p>Telephone: 020 7210 4850</p> <p>www.dh.gov.uk</p>
<p>General Chiropractic Council</p> <p><i>The General Chiropractic Council is established by Parliament to regulate, develop and promote the chiropractic profession.</i></p>	<p>Telephone: 020 7713 5155</p> <p>www.gcc-uk.org</p>
<p>General Dental Council</p> <p><i>The General Dental Council is the organisation which regulates dental professionals in the United Kingdom. All dentists, dental hygienists, dental therapists, clinical dental technicians and orthodontic therapists must be registered with the organisation to work in the UK</i></p>	<p>Telephone: 020 7887 3800</p> <p>www.gdc-uk.org</p>
<p>General Medical Council</p> <p><i>The General Medical Council aims to deliver and protect the highest standards of medical ethics, education and practice, in the interest of patients, public and the profession. It works with doctors throughout their careers helping to register to practice, issuing guidance on standards, monitoring professional development and adjudicating fairly on complaints.</i></p>	<p>Telephone: 0845 357 8001</p> <p>www.gmc-uk.org</p>
<p>General Optical Council</p> <p><i>The General Optical Council's purpose is to protect the public by promoting high standards of education and conduct amongst opticians.</i></p>	<p>Telephone: 020 7580 3898</p> <p>www.optical.org</p>

<p>General Osteopathic Council</p> <p><i>The General Osteopathic Council is one of the 13 UK health and social care regulators. The regulators are set up to protect the public so that whenever you see a health or social care professional, you can be sure they meet the required standards</i></p>	<p>Telephone: 020 7357 6655</p> <p>www.osteopathy.org.uk</p>
<p>Health and Safety Executive</p> <p><i>The Health and Safety Executive's role is to protect people against risks to health or safety arising out of work activities. It conducts and sponsors research; promotes training; provides an information and advisory service; and submits proposals for new or revised regulations and approved codes of practice</i></p>	<p>Telephone: 0845 345 0055</p> <p>www.hse.gov.uk</p>
<p>Health and Care Professions Council</p> <p><i>The Health and Care Professions Council is a statutory regulator that works to protect the health and well-being of people using the services of the health professionals registered with them. It currently registers over 180,000 professionals from 13 professions</i></p>	<p>Telephone: 020 7582 0866</p> <p>www.hpc-uk.org</p>
<p>Healthcare Inspectorate Wales</p> <p>HIW inspect NHS and independent healthcare organisations in Wales against a range of standards, policies, guidance and regulations</p>	<p>Telephone 0300 0628163</p> <p>www.hiw.org.uk/home</p>
<p>Medicines and Healthcare products Regulatory Agency</p> <p><i>From 1 April 2003, the Medicines and Healthcare products Regulatory Agency (MHRA) replaced the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA). The MHRA is an Executive Agency of the Department of Health with trading fund status.</i></p>	<p>Telephone: 020 7084 2000</p> <p>www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency</p>
<p>Monitor</p> <p><i>Monitor regulates NHS foundation trusts, making sure they are well managed and financially strong so that they can deliver excellent healthcare for patients</i></p>	<p>Telephone: 020 7340 2400</p> <p>www.monitor-nhsft.gov.uk</p>
<p>NHS Business Services Authority - Counter Fraud and Security Management Service (CFSMS)</p> <p><i>The Counter Fraud and Security Management Service has responsibility for all policy and operational matters relating to the prevention, detection and investigation of fraud and corruption and the management of security in the National Health Service.</i></p>	<p>Telephone: 020 7895 4500</p> <p>www.cfsms.nhs.uk</p>
<p>NHS Litigation Authority</p> <p><i>The NHSLA is a Special Health Authority (part of the NHS), responsible for handling negligence claims made against NHS bodies in England. In addition to dealing with claims when they arise, it has an active risk-management programme to help raise standards of care in the NHS and hence reduce the number of incidents leading to claims. It also monitors human rights case-law on behalf of the NHS through its Human Rights Act Information Service.</i></p>	<p>Telephone: 020 7430 8700</p> <p>www.nhsla.com</p>
<p>National Clinical Assessment Service</p> <p><i>The NCAS provides a service to support the NHS deal with doctors and dentists whose performance gives cause for concern. It aims to provide advice about the local handling of cases, and where necessary carry out clinical performance assessments to clarify areas of concern and make recommendations on how difficulties may be resolved.</i></p>	<p>Telephone: 020 79728170</p> <p>www.ncas.nhs.uk/</p>

<p>National Crime Agency Specialist Operations Centre</p> <p><i>The Specialist Operations Centre (SOC) provides front line policing with information, advice and support in relation to surveillance law, major crime and vulnerable and intimidated witnesses. Made up of four teams, the SOC comprises a mixture of NCA and police officers and provides a single point of contact for police forces and law enforcement agencies.</i></p>	<p>Telephone 0845 0005463</p> <p>soc@nca.pnn.police.uk</p>
<p>Nursing and Midwifery Council</p> <p><i>The core function of the Nursing and Midwifery Council is to establish standards of education, training, conduct and performance for nursing and midwifery and to ensure those standards are maintained, thereby safeguarding the health and wellbeing of the public</i></p>	<p>Telephone: 020 7637 7181</p> <p>www.nmc-uk.org</p>
<p>Patient Safety Domain - NHS England</p> <p><i>The Patient Safety Domain of NHS England took on some of the functions of the National Patient Safety Agency when the NPSA was abolished in 2012. These include the responsibility to collect information on patient safety incidents in the NHS and to use that information to provide advice and guidance to the NHS on mitigating risks to patient safety. The Patient Safety Domain can provide advice on the nature of risks to patient safety and the relevant actions that NHS organisations are expected to take to mitigate those risks</i></p>	<p>http://www.england.nhs.uk/ourwork/patientsafety/</p>
<p>Public Health England</p> <p>Public Health England was established on 1 April 2013 to bring together public health specialists from more than 70 organisations into a single public health service. The agency plays a critical role in protecting people from infectious diseases and in preventing harm when hazards involving chemicals, poisons or radiation occur.</p>	<p>Telephone: 020 7654 8000</p> <p>www.PublicHealthEngland.org.uk</p>
<p>Royal Pharmaceutical Society of Great Britain</p> <p><i>The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation. The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.</i></p>	<p>Telephone: 020 7735 9141</p> <p>www.rpharms.com</p>
<p>SHOT (Serious Hazards of Transfusion)</p> <p><i>The Serious Hazards of Transfusion (SHOT) Scheme collects data on serious hazards of transfusion of blood components. Through the participating bodies, the information obtained contributes to: improving the safety of the transfusion process; informing policy within the Transfusion Services; improving standards of hospital transfusion practice; aiding production of clinical guidelines for the use of blood components.</i></p>	<p>Telephone: 0161 251 4208</p> <p>www.shotuk.org</p>

Glossary of terms

Adverse event: any unexpected or untoward event that has a short or long term detrimental effect on patients, visitors, staff and the organisation. This includes incidents related to clinical and non clinical working practices

Adverse incident: any incident which adversely affects, or has the potential to affect, the health and safety of employees, patients, users or other persons

Caldicott Guardian: a senior and identified person within the healthcare establishment responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing. The Guardian plays a key role in ensuring that the NHS, Councils with Social Service responsibilities and partner organisations satisfy the highest practicable standards for handling patient identifiable information

Clinical governance: a framework through which NHS organizations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

Continuing care: A long periods of treatment for patients whose recovery will be limited.

Gross negligence: This is a concept which arises in the common law offence of manslaughter - see "gross negligence manslaughter" below

Gross negligence manslaughter: This offence is committed when a person who owes a duty of care to another, breaches that duty of care and this leads to the death of the other person and the conduct of the person who owes duty of care is considered to be so bad as to be criminal.

Healthcare associated infections: are infections that are acquired in hospitals or as a result of healthcare interventions. There are a number of factors that can increase the risk of acquiring an infection, but high standards of infection control practice minimise the risk of occurrence.

Healthcare setting: any place where a person is under the care of a health professional. It includes but is not restricted to; hospitals (NHS & private), GP surgeries, dental surgeries, residential care homes and hospices.

Involuntary manslaughter: This offence is committed a) where death results from an unlawful act which any reasonable person would recognise as likely to expose another to serious risk of injury, and b) where death is caused by a reckless or grossly negligent act or omission (See Halsbury's Laws of England, Fourth Edition, Volume 11(1), paragraph. 426 and the 2005 Cumulative Supplement Part 1). Clarification of these terms is given below.

Killing with subjective recklessness as to death or serious bodily harm: A person is subjectively reckless as to a risk of death or serious bodily harm if he himself foresees that risk as a highly probable consequence of his conduct, he takes that risk and in all the circumstances it is unreasonable for him to do so.

Manslaughter: Like murder, the offence of manslaughter involves a killing of a person. The difference between murder and manslaughter is the mental element necessary to support the charge. Manslaughter may be classified as voluntary or involuntary.

NHS patient: for the purposes of the MOU protocol and these guidelines an NHS patient is defined as – 'a person receiving care or treatment under the NHS Act 1977' – in practical terms this generally means NHS-funded patients on NHS premises, and includes NHS patients being cared for in non-NHS premises or where patients/people other than NHS patients are on NHS premises, the expectation is that the spirit of the MOU will apply.

Palliative care: A term applied to the treatment of incurable disease in which the aim is to mitigate the sufferings of the patient not to affect a cure.

Patient safety: the process by which an organisation makes patient care safer. This should involve: risk assessment; the identification and management of patient-related risks; the reporting and analysis of incidents; and the capacity to learn from and follow-up on incidents and implement solutions to minimise the risk of them recurring.

Patient safety incident: any unintended or unexpected incident which could have or did lead to harm for one or more patients *receiving NHS funded healthcare*. *This is also referred to as an adverse event/incident or clinical error, and includes near misses.*

Serious adverse events: or serious adverse reaction is defined by the regulatory agencies as one that suggests a significant hazard or side effect and results in any of the following six outcomes. A serious adverse event/reaction occurs during investigation of a medicinal product (plus its comparators), device, or treatment.

Suspected unexpected serious adverse reactions: are generally held to be events resulting in any of the following six outcomes, with the nature or severity being inconsistent with the applicable product information:

- Death
- A life threatening adverse experience that places the subject, in the view of the investigator, at immediate risk of death from the adverse event
- Requires or prolongs inpatient hospitalisation
- Results in persistent or significant disability/incapacity. *This criterion applies if the "disability" caused by the reported adverse event results in a substantial disruption of a person's ability to conduct normal life functions*
- A congenital anomaly/birth defect
- Important medical events that may not result in death, be life threatening, or require hospitalisation may be considered a serious adverse experience when, based upon appropriate medical judgement, they may jeopardise the subject and may require medical or surgical intervention to prevent one of these outcomes.

Recklessness: In broad terms, "recklessness" in a criminal law context is where a person takes an unjustified risk.

Voluntary manslaughter: This offence is committed where a person has, as in murder, an intention to kill or an intention to cause grievous bodily harm, but kills under provocation, suffering from diminished responsibility by reason of abnormality of mind or in pursuance of a suicide pact.

Information about local children safeguarding boards and local arrangements for the protection of vulnerable adults

Local safeguarding children boards: statutory guidance to local safeguarding children boards

The core objectives of the LSCB are set out in section 14(1) of the Children Act 2004 as follows:

- to coordinate what is done by each person or body represented on the Board for the purposes of safeguarding and promoting the welfare of children in the area of the authority
- to ensure the effectiveness of what is done by each such person or body for that purpose.

The scope of LSCBs' role includes safeguarding and promoting the welfare of children in three broad areas of activity.

First, activity that affects all children and aims to identify and prevent maltreatment, or impairment of health or development, and ensure children are growing up in circumstances consistent with safe and effective care. For example:

- mechanisms to identify abuse and neglect wherever they may occur
- work to increase understanding of safeguarding children issues in the professional and wider community, promoting the message that safeguarding is everybody's responsibility
- work to ensure that organisations working or in contact with children operate recruitment and human resources practices that take account of the need to safeguard and promote the welfare of children
- monitoring the effectiveness of organisations' implementation of their duties under section 11 of the Children Act 2004
- ensuring that children know who they can contact when they have concerns about their own or others' safety and welfare
- ensuring that adults (including those who are harming children) know who they can contact if they have a concern about a child or young person.

The second area of activity is proactive work that aims to target particular groups. For example:

- developing/evaluating thresholds and procedures for work with children and families where a child has been identified as 'in need' under the Children Act 1989, but where the child is not suffering, or at risk of suffering, significant harm
- work to safeguard and promote the welfare of groups of children who are potentially more vulnerable than the general population – e.g. children living away from home, children who have run away from home, children in custody, or disabled children.

The third area is responsive work to protect children who are suffering, or at risk of suffering, harm, including:

- children abused and neglected within families, including those:
 - harmed in the context of domestic violence
 - as a consequence of the impact of substance misuse
- children abused outside families by adults known to them
- children abused and neglected by professional carers, within institutional settings, or anywhere else where children are cared for away from home children abused by strangers
- children abused by other young people
- young perpetrators of abuse
- children abused through prostitution.

Where particular children are the subject of interventions, then that safeguarding work should aim to help them to achieve all five outcomes, to have optimum life chances. It is within the remit of LSCBs to check the extent to which this has been achieved as part of their monitoring and evaluation work. Protection of vulnerable adults

Non-statutory voluntary guidance

A multi-agency management committee. To achieve effective inter-agency working, agencies may consider that there are merits in establishing a multi-agency management committee (adult protection), which is a standing committee of lead officers. Such a body should have a clearly defined remit and lines of accountability, and it should identify agreed objectives and priorities for its work. Such committees should determine policy, co-ordinate activity between agencies, facilitate joint training, and monitor and review progress.

Experience in other areas of practice has shown that such committees are often most effective where agency boundaries are coterminous.

Further actions in such a framework will be to:

- **identify role, responsibility, authority and accountability** with regard to the action each agency and professional group should take to ensure the protection of vulnerable adults
- **establish mechanisms** for developing policies and strategies for protecting vulnerable adults which should be formulated, not only in collaboration and consultation with all relevant agencies but also take account of the views of service users, families and carer representatives
- **develop procedures** for identifying circumstances giving grounds for concern and directing referrals to a central point
- **formulate guidance** about the arrangements for managing adult protection, and dealing with complaints, grievances and professional and administrative malpractice
- **implement equal opportunity policies and anti-discriminatory training** with regard to issues of race, ethnicity, religion, gender, sexuality, age, disadvantage and disability

- **balance the requirements of confidentiality** with the consideration that, to protect vulnerable adults, it may be necessary to share information on a 'need-to-know basis' bearing in mind the provisions of the Public Interest Disclosure Act 1998)
- **identify** mechanisms for monitoring and reviewing the implementation and impact of policy.

Making a complaint about NHS services

A complaint can be made about any function provided by the NHS. The process for doing this is contained in the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009. All NHS organisations must comply with them.

The current framework for handling complaints was reduced from a three-tier process to a two tier process comprising:

- Local resolution;
- Parliamentary and Health Service Ombudsman.

A complaint may be made by anyone who is affected or likely to be affected by the incident. In certain circumstances a complaint may be made by a person acting as a representative of the complainant.

The first step will normally be to raise the matter (in writing or by speaking to them) with the practitioner, e.g. the nurse or doctor concerned, or with the commissioner of the service (usually the Clinical Commissioning Group) but not to both. A complaints manager should be allocated to deal the case. The complainant should be offered the option of discussing with the complaints manager how they wish to have the complaint handled, the response time for the complaint to be investigated and reported on. If they decline this the complaints manager should write to the complainant and advise them how long the complaint should take. Normally this should be no longer than 6 months from the date of the complaint unless they are written to by the complaints manager advising them of the delay and the reason why.

This process is known as “local resolution” and most complaints are resolved at the local stage. However, there is a time limit of 12 months in which the complaint must be made. This starts from the date of the incident being complained about or when it came to the complainant’s attention.

If a complainant needs assistance in making a complaint, officers from the Patient Advice and Liaison Service (PALS) are available in all hospitals. They offer confidential advice, support and information on health-related matters to patients, their families and their carers.

Additionally assistance can also be provided by the Independent NHS Complaints Advocacy Service. This supports people who wish to make a complaint about their NHS care or treatment. Contact details for your local NHS Advocacy Service can be obtained from the complaints manager, PALS, or by calling your Local Authority.

If a complaint remains unhappy with the outcome at a local level, you can refer the matter to the Parliamentary and Health Service Ombudsman who is independent of the NHS and government.

Getting independent help

Independent help, advice or support when making a complaint, is available to the complainant, free, via the Independent Complaints Advocacy Service (ICAS). They will arrange an interpreter for the complainant if needed.

Contact details

Independent Complaints Advocacy Service (ICAS)

Email: pohwericas@pohwericas.net

Website: www.pohwer.net

ICAS has offices throughout the country:

North East, telephone: 08120 3732

North West, telephone: 0845 120 3735

Yorkshire, telephone: 0845 120 3734

East Midlands, telephone: 0845 650 0088

East of England, telephone: 0845 456 1084

London (south east), telephone: 0845 337 3061

London (south west), telephone: 0845 337 3063

London (north central), telephone: 0845 120 3784

London (north west), telephone: 0845 337 3065

London (north east), telephone: 0845 337 3059

Essex, telephone: 0845 456 1083

West Midlands (Birmingham), telephone: 0845 120 3748

West Midlands (Stafford), telephone: 0845 337 3054

West Midlands (Worcester), telephone: 0845 337 3056

South East, telephone: 0845 600 8616

South West, telephone: 0845 120 3782

Other regions, telephone: 0845 456 1082

Other useful contact details for people making a complaint

Health and Safety Executive

An independent regulator that acts in the public interest to reduce work related death, injury and ill health across Great Britain's workplaces.

Telephone 0845 345 0055 www.hse.gov.uk

Action Against Medical Accidents (AVMA)

An independent charity which promotes better patient safety and justice for people who have been affected by a medical accident

Telephone: 0845 123 23 52 www.avma.org.uk

General Dental Council

Protects the public by regulating dental professionals in the UK

Telephone: 0207 887 3800 www.gdc-uk.org

General Medical Council

Has a number of roles, including dealing with doctors whose fitness to practice is under question

Telephone: 0845 357 3456 www.gmc-uk.org

General Optical Council

Statutory body that regulates the optical professions (dispensing opticians and optometrists)

Telephone: 0207 5803898

www.optical.org

Care Quality Commission

Regulates fundamental standards in the provision of NHS, independent health and adult social care and promotes improvement in the quality of services. Telephone: 03000 616161

www.cqc.org.uk

Health and Care Professions Council

Regulates arts therapists, biomedical scientists, chiropodists/podiatrists, clinical scientists, dieticians, occupational therapists, orthoptists, paramedics, physiotherapists, prosthetists & orthoptists, radiographers, speech and language therapists.

Telephone: 0207 582 0866 www.hpc-uk.org

Health Service Ombudsman

Undertakes independent investigations into complaints about the National Health Service

Telephone: 0845 015 4033 www.ombudsman.org.uk **Information Commissioner**

Promotes good information handling practice and enforces data protection and freedom of information legislation

Telephone: 0845 563 6060 www.ico.gov.uk

Nursing and Midwifery Council

Set up by Parliament to ensure nurses, midwives and health visitors provide high standards of care to their patients and clients

Telephone: 0207 637 7181 www.nmc-uk.org

Prisons and Probation Ombudsman

Investigates complaints from prisoners and those subject to probation supervision

Telephone: 0845 010 7938 www.ppo.gov.uk

The Law Society

Helps people find a suitable solicitor in their area, if they decide to take legal action

Telephone: 0870 606 2555 www.lawsociety.org.uk

Royal Pharmaceutical Society

The regulatory and professional body for pharmacists in England, Scotland and Wales. Its primary objective is to lead, regulate and develop the pharmacy profession

Telephone: 0207 735 9141 www.rpsgb.org.uk

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