GOV.UK

Department of Health & Social Care

Guidance

Investigating healthcare incidents where suspected criminal activity may have contributed to death or serious life-changing harm (accessible version)

Published 17 December 2024

Applies to England

Contents

occurred as a result of an incident where there is suspected criminal activity in the course of healthcare delivery. See annex B for a definition of terms used in this document. This document will:

- assist those responsible for carrying out any safety, regulatory or criminal investigation
- provide clarity for all involved on their responsibilities and liabilities
- help to ensure that such investigations are handled correctly

As a result, the document should help to protect the public and facilitate both justice and learning.

2.2 The document has been developed in consultation with the signatories named in section 1, together with the Department of Health and Social Care (DHSC), and is based on an earlier protocol first published in 2006 (https://webarchive.nationalarchives.gov.uk/20080728191742/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4129918).

2.3 Professor Sir Norman Williams' review (https://www.gov.uk/government/publications/williams-review-into-gross-negligence-manslaughter-in-healthcare) into 'gross negligence manslaughter (GNM)' in healthcare settings, published in June 2018, recommended that a new MoU be agreed between relevant bodies to replace the 2006 protocol. It recommended that, as a minimum, the MoU should:

- establish a common understanding of the respective roles and responsibilities of the organisations involved
- support effective liaison and communications
- cover what is expected of 'expert witnesses', in particular that they should consider the 'wider system' as a whole in which the actions of an individual took place; this includes examining aspects of the organisation's culture, work patterns and leadership as well as a consideration of job workload, procedures and the working environment

2.4. This document will be disseminated by signatories to promote a greater understanding of legal issues among healthcare professionals and of healthcare issues among non-healthcare signatories. It has been drafted with a view to supporting the development of a 'just culture' in healthcare, which recognises the need to consider the wider context and circumstances in which any incident involving a breach of a duty of care occurs. This includes considering the wider systems in place at the time of the incident, to support a fair and consistent evaluation of the actions of individuals.

3. Aims and purpose

3.1 This MoU sets out how healthcare organisations, regulatory bodies, investigatory bodies and prosecutorial bodies in England will work together in cases where there is suspected criminal activity on the part of an individual in relation to the provision of clinical care or care decision-making. It covers any such incidents occurring in the course of healthcare delivery where suspected criminal activity on the part of an individual is believed to have 'led to or significantly contributed to' the death or serious life-changing harm (whether of a physical or psychological nature) of a patient or service user.

3.2 An outcome from the use of this MoU is to help support the development of a 'just culture' in healthcare which recognises the impact of wider systems on the provision of clinical care or care decision-making, as set out in recommendation 3.5 of the Williams' review into GNM in healthcare.

3.3 The signatory organisations are independent from each other and have different legal remits and obligations for safety, regulatory and criminal investigations, and patient safety learning responses. Those which have a remit for such investigations and learning responses should, wherever possible (that is, insofar as their legal and investigatory policies allow), co-ordinate activities and share information where it is appropriate, lawful and reasonable to do so. Information should not be shared where doing so conflicts with statutory obligations; the duty to comply with statutory obligations must take precedence.

3.4 This MoU aims to:

- facilitate efficient and effective co-ordination of appropriate approaches, patient safety learning responses and investigations, while taking steps to avoid prejudicing regulatory or criminal investigations or criminal proceedings
- ensure relevant information and 'confidential information' is quickly, lawfully and efficiently shared between the relevant signatories where necessary to progress learning responses, investigations and proceedings
- ensure evidence is quickly identified, secured and handled in accordance with best practice
- allow steps to be taken quickly to manage ongoing risk and as far as possible protect the public and service users

4. When the MoU applies

4.1. The MoU applies when more than one of the signatories needs to investigate, in parallel, any incident where there is a reasonable suspicion that a criminal offence has or may have been committed by an individual

'providing healthcare services' in a health or care setting that leads to or significantly contributes to the death or serious life-changing harm of a patient or service user.

The MoU therefore only covers the most serious cases: acts of deliberate harm or circumstances where the acts or omissions of a member of healthcare staff amount to a breach of duty of care which results in death or life-changing harm, and are so reprehensible and fall so far below the standards to be expected (taking into account relevant qualifications, experience and responsibilities) that it amounts to a crime.

4.2 The MoU has been signed by NHS England on behalf of the wider NHS in England. It should therefore be used when incidents as described in paragraph 4.1 occur in the delivery of NHS-funded healthcare and in the delivery of privately funded or local authority-funded healthcare that occurs on NHS premises. While no organisation is appropriately placed to sign this MoU on behalf of private healthcare organisations, DHSC has consulted with the Independent Healthcare Providers Network (IHPN)[footnote 1] on its drafting and it is expected that the principles contained within it should also apply when incidents requiring investigation as described in paragraph 4.1 occur in the delivery of privately funded healthcare outside of NHS premises or as part of NHS service provision.

4.3 The MoU applies to such incidents occurring in England only.

4.4 The processes outlined in this MoU should be put in place as soon as is practical to ensure that:

- all parties to the response are properly co-ordinated
- evidence is properly secured
- investigations and patient safety learning responses take place effectively and efficiently
- affected patients or service users, families, carers and loved ones are kept well informed and supported, and are also provided with the opportunity to be actively involved throughout the investigative process

4.5 It may not be immediately clear following the incident that a criminal offence may have been committed. The types of incident that may prompt an NHS organisation to involve the police are those that display one or more of the following characteristics:

- reasonable suspicion that the actions leading to harm were intended to cause harm
- reasonable suspicion of 'gross negligence' and/or 'recklessness'

Where a local concern, review or investigation identifies reasonable suspicion of a criminal offence, the procedures set out in the MoU should be instigated. The police should consult the CPS where they consider it

An act or omission will be taken to 'lead to or significantly contribute to' death or serious life-changing harm if, in this context, it is related directly to the death or serious life-changing harm and the death or serious life-changing harm is not related to the natural course of the service user's illness or underlying condition.

Provider

'Provider' (in template agreement wording within 'Annex E: information sharing and data handling' and 'Annex F: confidentiality agreement') means any party to this agreement which discloses or makes available directly or indirectly 'confidential information' to one or more parties to this agreement.

Providing healthcare services

'Providing healthcare services' in this context means individual clinical care or individual care decision-making. Note that relevant acts of omission are included within the remit of this MoU.

Reasonable suspicion

A person is taken to have a clear and 'reasonable suspicion' in this context if they have clear, objective, specific facts, observations or evidence that justify that suspicion. The grounds for suspicion are taken to be objective if a reasonable person given the same information would form the same suspicion.

Recipient

'Recipient' (in template agreement wording within 'Annex E: information sharing and data handling' and 'Annex F: confidentiality agreement') means any party to this agreement which receives or obtains directly or indirectly 'confidential information' from another party to this agreement.

Recklessness

'Recklessness' is unjustified risk taking. Someone acts recklessly with respect to:

- a circumstance when they are aware of a risk that it exists or will exist
- a result when they are aware of a risk that it will occur; and

it is in the circumstances known to them unreasonable to take the risk. Failure to consider a risk - however obvious it might be - does not give rise to recklessness; but closing one's mind to a risk requires first realising that there is one and this is equivalent to awareness.

> Definition taken from LexisNexis practical guidance and legal research - legal glossary: recklessness (http://www.LexisNexis.co.uk/legal/glossary/recklessness), accessed on 12 August 2024.

Serious life-changing harm

'Serious life-changing harm' includes any serious injury that leads to a lessening of bodily, sensory, motor, physiologic, cognitive or emotional function that changes an individual's life permanently, leading to long-term medical problems, or reduced life-expectancy. (This is similar to 'catastrophic injury'. See also 'severe harm' as defined in the RAR 2014.)

The wider system

The 'wider system' is defined as the work system in which events of interest took place. Taking a systems-based approach means considering the event in the context of the wider system:

- identifying the different components of the socio-technical work system and how they interact
- looking beyond the immediate events, to organisational or management decisions, policy and regulations that influenced the events of interest

Consideration of the 'wider system' shifts the focus from looking at an incident in isolation to understanding the complex inter-connected