How to manage statutory notifications under Regulation 17: Deaths of detained patients

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Summary

CQC has no specific statutory remit to carry out investigations into the deaths of detained patients unless the death post-dates 1 April 2015 and raises concerns that there has been a failure to provide safe care or treatment resulting in avoidable harm to the patient or a significant risk of exposure to avoidable harm. In those limited circumstances CQC can carry out a criminal investigation to ascertain whether a prosecutable breach of a relevant fundamental standard has occurred.

Such criminal investigations focus on the conduct of registered persons and are not designed to replace or replicate the broader investigatory role of HM Coroner in ascertaining in what circumstances the deceased came by his or her death.

CQC would also as part of its regulatory response to a death consider ongoing risk management by registered persons and review the information and evidence to contribute to our understanding of risk in individual provider organisations and capture learning that may inform policy and guidance.

This guidance describes how to respond when we are notified of the death of a patient detained under the Mental Health Act 1983 (MHA), or the death of a patient subject to a Community Treatment Order or Guardianship. Examples of scenarios and responses can be found in the guidance on handling specific incidents available on CQC's enforcement intranet page.

This guidance identifies how we review such notifications to decide whether further information or action is required.

The process set out in this guidance is designed to ensure accurate recording of details of deaths that are notified to us, and to describe the stage 1 decision tree initial assessment process for detained patient deaths.

It is the responsibility of the Inspection Manager to decide what action should be taken in line with CQC's Enforcement Policy and Decision Tree.

Legislative and related requirements

1. What are the legal requirements upon providers to notify us of deaths

Services are *required* to notify us when any patient dies while detained or liable to be detained under the Mental Health Act.

Registered providers are required by Regulation 17 of the *Care Quality Commission (Registration) Regulations 2009* to notify us of the death of any patient who at the time of death is either:

(i) detained under the MHA
(i.e. any patient detained under any power of the MHA, including short-term holding powers); or

(ii) liable to be detained under the MHA
(i.e. any patient who is on section 17 leave from detention in hospital, absent without leave or has been recalled to hospital whilst subject to a Community Treatment Order (CTO), whether or not that patient has yet returned to hospital).

It is the registered person's responsibility to ensure that notifications are made, and they will be committing an offence if they fail to do so. We ask providers to notify us within 3 working days of them becoming aware of the death. While this is not a legal requirement we do expect any failures to meet this to be discussed with the provider to identify the reason for delays.

2. What are the related requests and requirements upon providers to notify us of other deaths

Deaths of people subject to the MHA who are neither detained nor liable to be detained

The requirements of Regulation 17 of the 2009 Regulations do not extend to CTO patients or conditionally discharged patients, unless (in either case) they have been recalled to hospital. Nor do they extend to Guardianship patients.

However, the CQC notification form includes categories for 'CTO' and 'Guardianship' in the options for 'legal status' of patients, and we ask services to notify us when any patient dies while subject to powers under the Mental Health Act but who is neither 'detained' nor 'liable to be detained'.

Deaths of other patients receiving care or treatment by registered providers

Under Regulation 16 of the *2009 Regulations*, services are required to notify CQC of the death of any patient which *"occurs during the provision of regulated treatment or has/may have resulted from the provision of treatment (Reg 16(a.i)&(a.ii)) AND cannot be in the opinion of the registered person, be attributed to the course of the illness or medical condition that treatment was being provided for (Reg 16(b))."*

This requirement does not apply where the patient is detained or liable to be detained (because the death must be reported under the requirements of Regulation 17 as described above), nor if the death is reported to the National Reporting and Learning Service (NRLS). CQC will then be notified of the death in an aggregated format through the intelligence team.

3. What are the requirements upon CQC in relation to the deaths of detained patients?

Since April 2015, there are two specific requirements for CQC in regards to the notifications of detained patient deaths from providers;

1. CQC are responsible for receiving, collating and sharing a range of information at a national level for detained patient deaths. This means we provide reports to national programmes including the Ministerial Board on Deaths in Custody, Independent Advisory Panel on Deaths in Custody and directly to Parliament via the MHA annual report. This allows the deaths of people detained by the state in hospitals across England to be kept under review and helps to inform and drive improvements in preventing future deaths, such as informing the Equality and Human Rights Commission inquiry into the non-natural deaths of people with mental health problems in state detention
2. CQC must review deaths notified to us directly to consider whether there may have been a prosecutable breach of a fundamental standard. This may result in consideration of criminal enforcement e.g. failure to provide safe care and treatment resulting in avoidable harm or a significant risk of exposure to avoidable harm.

With all hospital based detention death notifications Inspection teams must carry out an initial assessment of the information of concern and decide what action needs to be taken. A decision support checklist has been developed to help guide staff carrying out the assessment. See Annex A

Initial assessments will allow actions to be assessed for managing any ongoing risks. This may include arranging an inspection and/or gathering

additional evidence to support criminal enforcement. In some cases no further action will be appropriate.

Criminal investigations will look at the conduct of registered person and examine whether unsafe care or treatment was provided to the deceased patient **and** whether that resulted in the death or a significant risk of exposure to avoidable harm (Regulation 12(1) and 22 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Our role does not replace or replicate the broader role of HM Coroner, responsible for identifying how the person died[1], but to hold registered persons to account, when appropriate, for failing to meet standards for safe care and treatment.

Procedural guide

4. What is the process for receipt and recording of notifications?

Providers registered under the Health and Social Care Act 2008 are expected to notify CQC about deaths of people detained or liable to be detained (and requested to notify CQC about deaths of CTO and Guardianship patients) using the form *Mental Health Act Notification – Death Notification* (http://www.cqc.org.uk/content/mental-health-notifications).

Upon receipt of a notification form, CQC National Customer Services Centre (NCSC) are responsible for ensuring that it is entered onto the Customer Relationship Management database, and informing the CQC Mental Health Act Business Support team of the notification's receipt.

The Business Support Team are responsible for inputting all information from the notification form on the MHA database. This should take place within 5 working days of receipt by the team.

Special Circumstances: Where the patient is identified as a transferred prisoner, a child or young person (under 18) or died during restraint then the MHPolicy@cqc.org.uk should be contacted immediately by NCSC or Business Support. This information will then be reviewed, with the relevant inspection manager and alerts to other national agencies may need to be made.

It will be the responsibility of the business support team *at this point* to review the notification for any significant missing data, and to contact the submitting authority where necessary to complete significant missing fields. However,

[1] Coroners and Justice Act 2009, s.5(2)

this should not delay the initial dissemination of the notification data, and the business team may be asked to obtain missing or additional data.

5. What is the process for dissemination of notification data?

Notification of the death of a detained patient are always considered significant and are the responsibility of the relevant inspector.

Under direction from their Inspection Managers the inspector will carry out an initial assessment, with input from a MHA Reviewer if required, within 10 working days of being notified of the death.

Through the MRR process the portfolio holder is responsible for making sure the following CQC staff are aware of the notification:

(i) The inspection manager responsible for the service
(ii) The Mental Health Act Reviewer responsible for the service provider reporting the death, where this is known.
(iii) The designated Intelligence Analysis team contact.

The purpose of sending the data to the relevant manager and MHA Reviewer at the same time is to ensure that any imminent inspection or monitoring activity is informed of the death notification.

Where the death reported is of a person subject to the MHA but not liable to detention at the point of death (i.e. those subject to Guardianship, or CTO patients who had not been recalled to hospital), the above notification arrangements should be adjusted as appropriate. In particular, notification of any relevant social care inspection manager will be appropriate where the person was in residential care.

Roles of CQC Officers in relation to notifications

6. What is the role of NCSC and business support teams?

The National Customer Service Centre (NCSC) Notification team and business support are responsible for ensuring that:

(i) All relevant data from both Regulation 16 and Regulation 17 notifications is uploaded into datasets enabling its reproduction and analysis for the purposes of risk-profiling and background reporting upon service providers;

(ii) The inspector is alerted when any notification under Regulation 16 of the death of an informal (or CTO, or Guardianship) patient is received.

(iii) Any further information received from the provider or coroner is immediately passed to the inspector and the system is updated to reflect the new information

(iv) To support the delivery of the national returns that CQC are required to make, including production of our MHA annual report, quarterly follow ups must be made with providers or coroners to ascertain if a final cause of death has been confirmed by the coroners, if we have not already been notified

(v) To carry out regular quality checks on the fields within the MHA database, ensuring complete data sets are available

7. What is the role of the Intelligence Analyst Team?

The Intelligence Analyst team are responsible for ensuring that

(i) All Notification data from both Regulation 16 and Regulation 17 notifications is analysed for the purposes of risk-profiling and background reporting upon service providers;

(ii) Analyses are incorporated in appropriate products and reports for internal and external use.

The purpose of sending the data to a designated Intelligence Analysis team contact is to ensure that:

(i) Data is entered and utilised to inform service provider risk profiles and background information; and

(ii) Data is linked to any other notification received under Regulation 16 (i.e. deaths of patients who are not subject to the MHA) for highlighting of any patterns or shared circumstances.

8. What is the role of the Inspection Manager and Inspector?

The Inspection Manager must ensure the inspector with the portfolio of the provider has carried out an initial assessment of any Regulation 17 notification.

The inspector / inspection manager should ask for advice from MHA Reviewers during initial assessments if they believe, or are unable to confidently assess, MHA aspects of the individuals care which could identify potential breaches of HSCA Regulations and use of HSCA enforcement powers including criminal enforcement.

9. What is the role of the MHA Reviewer?

MHA Reviewers may offer advice and input to the initial assessments carried out by inspector or inspection manager and contribute to any management review meetings.

10. Initial Assessments

Initial assessments must be completed within 10 days of the death notification. This means limited information may be available except the notification form. Although an initial decision for action must be made, there should always be an option to reopen the review if later information is shared by the provider, coroners or families that would affect the initial decision made.

Inspector in conjunction with the inspection manager should review the information about the death and assess whether this raises concerns about ongoing risk of harm to users of the service which CQC should inspect and/or whether we should gather evidence to support criminal enforcement e.g. a breach of Regulation 12(1) failure to provide safe care and treatment resulting in avoidable harm or a significant risk of exposure to avoidable harm.

Action may include;

- seeking further information from the coroner, the police or other registered persons including internal investigation reports.
- Commencing a MRM to look at potential for enforcement action or carrying out a criminal investigation.
- Undertaking MHA monitoring or regulatory inspection visits.
- Obtaining assurances and evidence from the registered provider that they have complied with their duty of candour under Regulation 20 and informed the coroner to satisfy their duties under Article 2 of the Human Rights Act.
- Taking no further action e.g. the person was on an end of life pathway, all requirements have been satisfied including referral to coroners and there are no other indicators of a failure to deliver safe care and treatment.

This list is not exhaustive, although a clear rationale for any other actions should be given by the inspector.

If the circumstances of the reported death give rise to concerns about compliance with fundamental standards and the safety of other patients, a responsive inspection or joint visit with MHA reviewers should be considered.

The notification form may provide the details necessary to inform a decision of what action may be taken, but if more details are needed the inspector should decide who would be the most appropriate person to collect this information and how to do so.

Relevant considerations include the burden upon CQC *and the service provider* of any further action requested (in some circumstances, for example, it may be less burdensome to visit a service provider to review records than to request files to be copied and provided).

In most cases, it will be appropriate to await the hospital's internal report (serious incident requiring investigation report) and post mortem report before any investigative action on the part of CQC is undertaken. Exceptions to this general principle should establish the reasons why it is not appropriate in the particular circumstances of the case.

Except where initial decisions are to request further information, the relevant Inspection Manager will be responsible for deciding whether to complete further actions or make sure the final decision and recommendations are recorded on CRM and Y drive.

11. How do we report the outcome of reviews?

The outcome of the review must always be recorded. This should be stored on the Y drive and CRM within 10 working days of death.

Where the initial assessment or further investigations concludes that no further action is necessary, a record to this effect should be made and circulated to all recipients of the notification listed above.

Where issues should be flagged for future MHA or Regulatory Review Visits, a record to this effect should be made and circulated to all recipients of the notification listed above, explaining the issue and potential concerns as clearly as possible.

Information relating to notifications under Regulations 16 and 17 will form part of the data pack provided for MH inspections and MHA provider factsheets. The CQC inspector and the MHA specialist on the team will discuss what impact this will have on the inspection approach and any associated KLoEs to be followed during the inspection.

If the outcome of a desktop review or of further investigatory action result in any recommendation or finding, this should be circulated to all recipients of the notification listed above before it is shared with service providers (or other parties, such as Coroners) in the form of a letter or investigation report. .

12. KPIs for Deaths

Provider

- Notified within three working days of them being aware of death
- Coroner informed immediately following death and details provided on the notification form

CQC

- Information input onto the system and inspector / inspection manager notified within five working days of being notified of death by provider
- Inspector to complete an initial assessment and inform other as necessary within 10 working days of being notified of the death by NCSC or Business Support

Guidance for NCSC and Business Support

- Input all information to CRM and MHA Database
- All fields must be completed; in the case of detained inpatients the provider MUST have notified us of their referral to a coroner. This should be done immediately and for all patients detained in hospital, so if the coroners details are missing you must contact the provider and ask for the details to be provided.
- Allocate to the inspector and ask them to review within 10 working days and confirm the outcome of their initial assessment, to be stored in the Y drive and on CRM.
- Special Circumstances: Where the patient is identified as a transferred prisoner, a child or young person (under 18) or died during restraint then the MHPolicy@cqc.org.uk should be contacted immediately by NCSC or Business Support. This information will then be reviewed, with the relevant inspection manager and alerts to other national agencies may need to be made.
- Review the notification for any significant missing data, and to contact the submitting authority where necessary to complete significant missing fields.

Tools for the job

- Decision tree for handling specific incident reports – **annex A**
- Decision Support Checklist for Inspectors– **annex B**
- Terms used in categorising, investigating, and reporting of deaths – **annex C**

Annex A: Decision tree for handling specific incident reports after 1st April 2015

From 1st April 2015 CQC can prosecute registered providers for failing to deliver safe care and treatment where avoidable harm has resulted to a service user or they have been exposed to a significant risk of avoidable harm. Prosecutions can arise from single specific incidents where the incident and resulting harm provides sufficient evidence of a serious breach of a prosecutable Regulation. As a result, we will now be asked more frequently by coroners, the police, SUs, their relatives and the public to explain our response to serious incidents and the action we intend to take to manage ongoing risks and hold the RP to account (criminal enforcement). It is therefore important that we maintain a record of our response to specific incidents reported. Where an MRM is held to decide our response to the incident report the MRR form should be used. In other cases a brief written record will suffice.

Stage 1 Decision Tree (initial assessment)

You should consider two questions as part of the initial assessment:

- Does the information about the specific incident raise concerns about *ongoing* risk of harm to users of the service which CQC should inspect?
- Does the information about the specific incident suggest the harm sustained was avoidable and may have resulted from a breach of a prosecutable fundamental standard e.g. breach of Regulation 12(1) failure to provide safe care and treatment? If so, should I gather evidence about the incident to support criminal enforcement?

Information received by CQC varies in quality and detail. RIDDOR reports for example often lack detail. In most cases we will need to gather further information about the incident to answer questions 1 and 2. For incidents other than deaths the RP should be contacted. Where a death is reported, the police and the coroner may be able to provide further information. You should retain records of any communications with the RP or third parties about the incident and make and retain a note of any information provided by telephone.

Response Options to Consider at Stage 1 Decision Tree (initial assessment)

- Obtain further information about the incident (from RP or others).
- Conduct a focused inspection to assess ongoing risk and/or gather evidence to support criminal enforcement. .
- Conduct a comprehensive inspection to assess ongoing risk and/or gather evidence to support criminal enforcement. .
- Take no further action.

Guidance on gathering evidence to support criminal enforcement can be found in the Inspector Enforcement Handbook. Sector enforcement inspectors and enforcement leads can also be asked to support the initial assessment and inspection planning.

Further information on the enforcement decision tree can be found at http://www.cqc.org.uk/content/enforcement-policy

Annex B: Deaths in detention – Decision support checklist for Inspectors

Inspection Manager / Region:	
Date of death notification:	
Date initial assessment completed:	
Who else was involved in the review? (name / role)	
Outcome of review and reason:	
Any further action needed? (what / who / when)	

Factors to review;

- Do you have all necessary information to make a decision about whether the death raises concerns of ongoing risk to other user of the service?
- Do you have the information you need to make a decision about whether death was avoidable or may have resulted from a breach of a fundamental standard?
- Did the provider notify us within three working days of death?
- Is it clear that the coroner has been informed (must be done for all deaths of detained patients to avoid a breach of human rights and this must be followed up with the provider if it is unclear on the notification)?
- Have you considered the age of the patient? For example, natural causes may still raise concerns if the patient is younger than we would expect and may indicate concerns regarding physical healthcare or treatment regimes
- The notification forms offer additional information about a range of factors associated with high risk or concerns specifically for detained patients – have you considered the provider responses to these against the reported cause of death? E.g. high dose antipsychotics, clozapine. Patient AWOL or on leave at time of death, self-harm in days prior to death
- Where the patient is identified as a transferred prisoner (with one month of death), under 18 or died during / clearly as the result of restraint you must immediately notify mhpolicy@cqc.org.uk
- Regulatory knowledge – is the provider on the risk register, safeguarding alerts, complaints or whistleblowing concerns, current or recent enforcement, concerns from MHA visits, patterns of deaths over the past three years?

Where used, this form should be stored in the Y drive folder with the notification form

Annex C: Terms used in categorising, investigating, and reporting of deaths

Term	Definition	Sources
Amenable	In the light of medical knowledge and technology at the time of death, all or most deaths from that cause (subject to age limits if appropriate) could be avoided through good quality healthcare	Office for National Statistics
Avoidable	Caused or contributed to by weaknesses in care/service delivery (including lapses/acts and/or omission). Those defined as preventable, amenable or both.	NHS England - Serious Incident Framework Office for National Statistics
Death within 24 hours of restraint		National Confidential Inquiry into Suicide and Homicide by People with Mental Illness
Deaths of unknown cause	Coroners are required by law to hold an inquest into these deaths. To be completed	Coroners
Other non-natural	Additional categorisation; usually accidental deaths and overdoses	Independent Advisory Panel on Deaths in Custody
Premature	Caused by diseases and illnesses that are largely avoidable, including cancer, heart disease, stroke, respiratory and liver disease. Many of the direct causes are preceded by long periods of ill-health mostly caused by lifestyle related factors.	NHS England - Five Year Forward View Public Health England - Longer Lives; Public Health Outcomes Framework Department of Health - Living Well for Longer Confidential Inquiry into the Premature Deaths of People with Learning Disabilities NICE - Tackling the causes of premature mortality (early death)
Preventable	In the light of understanding of the determinants of health at time of death, all or most deaths from that cause (subject to age limits if appropriate) could be	Office for National Statistics

	avoided by public health interventions in the broadest sense	
Restraint related	A death in which restraint was used in the previous seven days, although this may not necessarily be related to the cause of death. Restraint mentioned in the post mortem report. Restraint is a primary cause of death.	CQC Police custody Other detention settings
Sudden unexplained	Death from an unknown cause (or a cardiac cause unrelated to myocardial infarction) within 1 hour of symptom onset	National Confidential Inquiry into Suicide and Homicide by People with Mental Illness
Unexpected	Not caused by the natural course of the patient's illness or underlying medical condition when managed in accordance with best practice. This definition includes suicide and self-inflicted death.	NHS England - Serious Incident Framework Mazars - report into Southern Health
Unnatural	"Death in unexplained circumstances or from unnatural causes" are referred to a coroner for inquest. This term describes deaths before the cause has been determined. The correct description of the death as obtained from the completion of the coronial process should be used instead as soon as it becomes available.	Coroners