

Regulation 20: Duty of candour

Information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare

March 2015

The Care Quality Commission is the independent regulator of health and adult social care in England.

Our purpose

We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

Our role

We monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety and we publish what we find, including performance ratings to help people choose care.

Our values

- Excellence – being a high-performing organisation
- Caring – treating everyone with dignity and respect
- Integrity – doing the right thing
- Teamwork – learning from each other to be the best we can.

Contents

Foreword	4
Introduction	5
CQC's operating model	5
How our guidance and information on meeting regulations fits into our operating model	6
Overview of Regulation 20: Duty of candour	8
Aim of the regulation	8
Background	8
Our approach to the duty of candour	10
Appendix A: Regulation 20	17
Appendix B: Definitions in CQC guidance and information relating to duty of candour	20
Appendix C: Illustrative examples of incidents that trigger the thresholds for duty of candour	22

Foreword

We set out a new vision and direction for (CQC) in our strategy for 2013-2016, *Raising standards, putting people first*, and in our consultation, *A new start*, which proposed radical changes to the way we regulate health and adult social care services. We developed these changes with extensive engagement with the public, our staff, providers and key organisations.

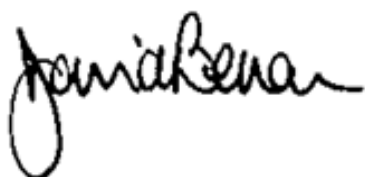
A new start set out the new overarching framework, principles and operating model that we will use. This includes the five key questions that we will ask of all services:

- Are they safe?
- Are they effective?
- Are they caring?
- Are they responsive?
- Are they well-led?

Stakeholders and the public across the care sectors welcomed our proposals, which include a more robust approach to registration; the introduction of chief inspectors; expert inspection teams; ratings to help people choose care; a focus on highlighting good practice; and a commitment to listen better to the views and experiences of people who use services. We have published handbooks for providers in each sector, which provide detailed guidance on our new approach to regulating and inspecting services.

The introduction of a statutory duty of candour is an important step towards ensuring the open, honest and transparent culture that was lacking at Mid Staffordshire NHS Foundation Trust. The failures at Winterbourne View Hospital revealed that there were no levers in the system to hold the “controlling mind” of organisations to account.

It is essential that CQC uses this new power to encourage a culture of openness and to hold providers and directors to account.



David Behan
Chief Executive
Care Quality Commission

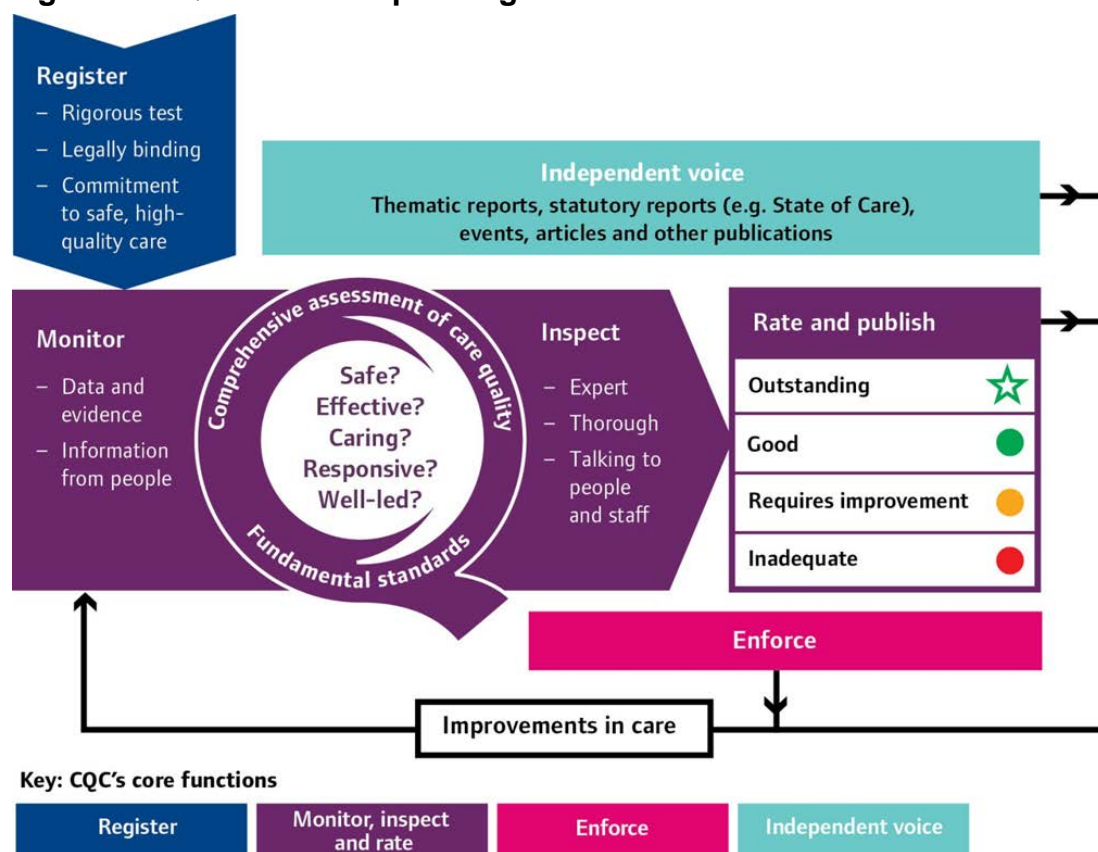
Introduction

CQC's operating model

Our provider handbooks set out the details of our new approach for each sector. They describe how we will carry out inspections, make judgements and award ratings to providers. Our approach in each sector reflects common principles that are intended to ensure that health and adult social care services provide people with safe, effective, caring, responsive and well-led care, and encourage care services to improve.

Our new operating model describes how we will register, monitor, inspect and award ratings to providers. It is illustrated by the following diagram:

Figure 1: CQC's overall operating model



Within this new approach, we must continue to ensure that providers meet Government regulations about the quality and safety of care.

How our guidance and information on meeting regulations fits into our operating model

All registered providers must demonstrate that they are meeting regulatory requirements in order to register with CQC and then continue to deliver regulated services. The law states that [our Guidance for providers on meeting the regulations](#) must be taken into account in relation to all regulatory decisions that CQC makes.

From 1 April 2015 all registered providers, must meet the new Regulation 20: Duty of candour (see [appendix A](#)). We have published our guidance for providers on how to meet the new regulations.

As this is a new regulation, in addition to our guidance for providers on meeting the regulations, we are publishing this document which contains information about the processes we will follow in light of this regulation when registering and inspecting. We will keep this information under review and update it as our approach to inspection develops. This information will help support providers in implementing this new regulation requirement, and does not constitute guidance itself. It should always be read in conjunction with our formal Guidance for providers on meeting the regulations, and it does not replace any of this existing guidance.

This information sets out how meeting the duty of candour regulation will be central to both registration and inspection.

1. Registration

As set out in our strategy, we will continue to strengthen our approach to assessing applications for registration with CQC.

In every registration assessment of a new provider we ask whether the potential provider has the capacity to deliver a service which is safe, effective, caring, responsive and well-led. New registrants must show how they will meet the requirements of the Health and Social Care Act 2008 (Regulated Activities) 2014.

From 1 April 2015, when considering new provider applications for registration, and applications from existing providers to vary registration, we will take into account the duty of candour.

Inspection

In comprehensive inspections we start by looking for good care rather than checking whether providers meet the regulations. We have developed characteristics of what good care looks like in partnership with people who use services and subject matter experts, and therefore what would constitute a rating of 'good'. We will use key lines of enquiry (KLOEs) to assess this. The characteristics of good care and the KLOEs are set out in our provider handbooks. If we find good care, we will also assess whether it meets the characteristics of an outstanding rating.

However, if we find care that does not reflect the characteristics of good, we will assess whether it requires improvement or is inadequate. We will also consider whether a regulation has been breached.

In focused inspections, we either follow up specific concerns from earlier inspections or respond to new, specific, concerning information that has come to our attention. In these circumstances, we assess whether the provider has improved so that it is no longer in breach of regulations or whether the new concern amounts to a breach of regulations. We will take our guidance for providers on meeting the regulations into account in making these judgements.

We will use our enforcement powers as outlined in our [Enforcement policy](#) both to protect patients and to hold providers and, in some cases, individuals to account.

Overview of Regulation 20: Duty of candour

Aim of the regulation

The aim of this regulation is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in relation to care and treatment.

It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology.

Providers must promote a culture that encourages candour, openness and honesty at all levels. This should be an integral part of a culture of safety that supports organisational and personal learning. There should also be a commitment to being open and transparent at board level, or its equivalent such as a governing body.

Background

The introduction of Regulation 20 is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust¹, which recommended that a statutory duty of candour be introduced for health and care providers. This is further to the contractual requirement for candour for NHS bodies in the standard contract, and professional requirements for candour in the practice of a regulated activity. In interpreting the regulation on the duty of candour we use the definitions of openness, transparency and candour used by Robert Francis in his report:

- **Openness** – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.
- **Transparency** – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.
- **Candour** – any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

1. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, chaired by Robert Francis QC, <http://www.midstaffpublicinquiry.com/sites/default/files/report/Executive%20summary.pdf>

The regulation and its implementation reflect the approach proposed by the Dalton/Williams review², including explaining notifiable safety incidents across different sectors.

The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 extend the fit and proper person requirement for directors and the duty of candour to all providers from 1 April 2015.

Regulation 20 defines what constitutes a notifiable safety incident for health service bodies and all other providers (such as primary medical and dental practices, adult social care and independent healthcare providers). Specifically paragraph 8 defines the harm thresholds that trigger the duty of candour for health service bodies. Paragraph 9 defines the thresholds for all other providers.

The definitions have been differentiated in this way to account for the different notification systems for health service bodies and all other providers. In doing so, they are intended to reduce the administrative burden caused by the introduction of this new statutory duty of candour.

The thresholds and harm definitions of moderate and severe harm for health service bodies are consistent with existing National Reporting and Learning System (NRLS) definitions, including prolonged psychological harm.

The harm thresholds set out in paragraph 9 of the regulation for all other providers are consistent with thresholds for the existing CQC notification system for reporting deaths and serious injuries. The notifiable incidents that trigger the duty of candour for all providers, including primary medical and dental practices, adult social care and independent healthcare providers are therefore consistent with existing definitions of notifiable incidents.

[Appendix B](#) provides a full description of the terms used in our guidance and information about duty of candour.

Appendix C has been developed with stakeholders to illustrate examples of notifiable safety incidents that trigger the thresholds for the duty of candour regulation.

Regulation 20 applies to providers when they are providing care and treatment to people who use services in the carrying on of a regulated activity only.

To meet the requirements of Regulation 20, a registered provider has to:

- Make sure it acts in an open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on a regulated activity.

2. Sir David Dalton and Prof. Norman Williams, Building a culture of candour: a review of the threshold for the duty of candour and of the incentives for care organisations to be candid, <https://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf>

- Tell the relevant person, in person, as soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, and provide support to them in relation to the incident, including when giving the notification.
- Provide an account of the incident which, to the best of the provider's knowledge, is true of all the facts the body knows about the incident as at the date of the notification.
- Advise the relevant person what further enquiries the provider believes are appropriate.
- Offer an apology.
- Follow up the apology by giving the same information in writing, and providing an update on the enquiries.
- Keep a written record of all communication with the relevant person.

We hope that this regulation will encourage a culture of openness and transparency within health and social care services, at all levels within organisations. In our provider guidance we also reference the NPSA Being Open Framework as key national guidance which outlines the action organisations can take to create a culture which supports staff to be open. The framework provides detailed guidance on communicating about incidents with patients, people who use services, their families and carers.

Our approach to the duty of candour

Our approach to the duty of candour is part of our new regulatory approach. This document does not attempt to describe in detail how Regulation 20: Duty of candour applies to each type of service registered with CQC, but we will be proportionate in how we apply it to different types of services. We will consider the size and type of services and the relevance of the regulation to the provided regulated activity.

Registration

Our assessment of providers upon application for registration refers to our approach to the duty of candour.

During our registration process we will test out with a provider that they understand the requirements of the regulation and ask them what systems they have in place to ensure that they will be able to meet these requirements.

The registration inspector will check that the provider has robust systems in place to meet the duty of candour regulation. This would include, but is not limited to, training for all staff on communicating with people who use services about notifiable safety incidents; incident reporting forms which support the recording of a duty of candour notification; support for staff when they notify people who use services when something has gone wrong; oversight and assurance.

If a provider applying to be registered with CQC cannot demonstrate that it will meet the requirements of this regulation from its first day of business, CQC may refuse its application for registration or impose conditions of registration.

Inspection

During the inspection process, we will assess whether the provider is delivering good quality care. Specific KLOEs under the safe and well-led questions are relevant to the duty of candour in the inspection of all providers. The KLOEs in our current handbooks are set out in the table below:

Sector handbooks	Relevant KLOE for duty of candour
<p>NHS and independent acute hospitals</p> <p>NHS and independent ambulance services</p> <p>Community health services</p>	<p>S2: Are lessons learned and improvements made when things go wrong?</p> <p>Prompt 1: Are people who use services told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result?</p> <p>W3: How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote good quality care?</p> <p>Prompt 9: Does the culture encourage candour, openness and honesty?</p>
<p>Adult social care</p> <p>Community adult social services</p> <p>Residential adult social services</p> <p>Hospice Services</p>	<p>S2: How are risks to individuals and the service managed so that people are protected and their freedom is supported and respected?'</p> <p>Prompt: Are there plans for responding to any emergencies or untoward events, and are these understood by all staff?</p> <p>W1: How does the service promote a positive culture that is person-centred, open, inclusive and empowering?</p> <p>Prompt: Is there an emphasis on support, fairness, transparency and an open culture?</p>

<p>Specialist mental health services</p>	<p>S2: Are lessons learned and improvements made when things go wrong?</p> <p>Prompt 1: Are people who use services told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result?</p> <p>W3 - How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote good quality care?</p> <p>Prompts:</p> <ul style="list-style-type: none"> 5: Do leaders encourage appreciative, supportive relationships among staff? 9: Does the culture encourage candour, openness and honesty?
<p>NHS GP practices and GP out-of hours</p>	<p>S2: Are lessons learned and improvements made when things go wrong?</p> <p>Prompt: Are people who use services told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result?</p> <p>W3: How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote good quality care?</p> <p>Prompt: Does the culture encourage candour, openness and honesty, with regular meetings and a culture of challenge and debate?</p>
<p>Primary care dental services</p>	<p>S2: How are lessons learned and improvements made when things go wrong?</p> <p>W2: How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote delivery of good quality care?</p>

Our handbooks describe what good care looks like in relation to each of the five key questions. Services that are safe ensure that when something goes wrong, people receive a sincere apology and are told about any actions taken to improve processes to prevent the same thing happening again. In services that are well-led; candour, openness, honesty, transparency and challenges to poor practice are the norm. Leadership at all levels in the organisation is central to ensuring a culture that supports this.

We will report on the duty of candour under the safety key question in our inspection reports. This will be at provider level for NHS trusts and location level for adult social care, primary medical and dental, and independent healthcare providers. We will consider whether a regulation has been breached and take our guidance for providers on meeting the regulations into account to determine whether a provider is meeting Regulation 20. An internal CQC advisory panel will support consistency in decision-making and to capture and share learning across all sectors.

Relationship between the statutory and professional duty of candour

Regulation 20 applies to organisations as opposed to individual members of staff. It requires the provider to ensure that all their staff, regardless of seniority or permanency, understand the organisation's responsibility to be open and transparent in their communication with relevant persons in relation to a notifiable safety incident. It requires the provider to understand their own role, and to put policy and processes in place to ensure they are supported to deliver it.

Providers should have policies and procedures to support a culture of openness and transparency, and ensure that staff follow them. Providers should also take action to tackle bullying, harassment and undermining, and investigate any instances where a member of staff may have obstructed another in exercising their duty of candour.

Individual members of staff who are professionally registered, are separately subject to the professional duty of candour, which is overseen by the professional regulatory bodies such as the General Medical Council (GMC), Nursing and Midwifery Council (NMC) and the General Dental Council (GDC). The provider should have a system in place to identify and deal with possible breaches of the professional duty of candour by staff who are professionally registered. This is likely to include an investigation and escalation process, which may lead to referral to their professional regulator or other relevant body.

Where staff have fulfilled their professional responsibility under duty of candour, but the provider has failed to put the processes in place to provide assurance that the statutory duty of candour has been met, we may take regulatory action for a breach of Regulation 20.

Notifications

We expect all providers to have systems in place to handle notifiable safety incidents in accordance with Regulation 20 and the other regulatory requirements in relation to such incidents.

Registered providers, and their registered managers, are required to notify CQC about certain incidents. The requirements relevant to safety incidents are set out in Regulations 16, 17 and 18 of the Care Quality Commission (Registration) Regulations 2009 – this is covered within our guidance for providers on the regulations.

To avoid duplication of reporting, the regulations allow NHS trusts to submit most notifications about ‘serious and untoward incidents’ affecting people who use their services to the National Reporting and Learning System (NRLS). GP and other primary medical services must submit all notifications directly to CQC.

Notifications for NHS bodies under Regulation 16 (certain deaths of people using the service) and 18 (serious injuries to people who use the activity) are submitted to the National Reporting and Learning System (NRLS) instead of directly to CQC. This is to avoid duplication of reporting and the regulations allow NHS trusts to submit most notifications about ‘serious and untoward incidents’ affecting people who use their services to the NRLS. For some years, NHS bodies have been encouraged to voluntarily report all moderate incidents through NRLS – and the majority do so.

Information received from staff, service users or members of the public

Information received from a member of the public or the provider’s staff relating to the statutory duty of candour will be dealt with in line with CQC’s safeguarding and whistleblowing protocols where relevant.

When we identify a breach of Regulation 20, we will assess the impact on people and decide whether or not to take regulatory action, and what action to take, in accordance with our Enforcement policy.

As the statutory duty of candour is a new regulation, we expect to learn from what we find. We will do this on a case by case basis and through regular engagement with our stakeholders.

How to contact us

Call us on: **03000 616161**

Email us at: enquiries@cqc.org.uk

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Follow us on Twitter: [@CareQualityComm](https://twitter.com/CareQualityComm)

Appendix A: Regulation 20

Regulation 20: Duty of candour

- 20.**— (1) Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.
- (2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must—
- (a) notify the relevant person that the incident has occurred in accordance with paragraph (3), and
 - (b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.
- (3) The notification to be given under paragraph (2)(a) must—
- (a) be given in person by one or more representatives of the registered person,
 - (b) provide an account, which to the best of the registered person's knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification,
 - (c) advise the relevant person what further enquiries into the incident the registered person believes are appropriate,
 - (d) include an apology, and
 - (e) be recorded in a written record which is kept securely by the registered person.
- (4) The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—
- (a) the information provided under paragraph (3)(b),
 - (b) details of any enquiries to be undertaken in accordance with paragraph (3)(c),
 - (c) the results of any further enquiries into the incident, and
 - (d) an apology.
- (5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the registered person —
- (a) paragraphs (2) to (4) are not to apply, and
 - (b) a written record is to be kept of attempts to contact or to speak to the relevant person.
- (6) The registered provider must keep a copy of all correspondence with the relevant person under paragraph (4).

(7) In this regulation—

“apology” means an expression of sorrow or regret in respect of a notifiable safety incident;

“moderate harm” means—

(a) harm that requires a moderate increase in treatment, and

(b) significant, but not permanent, harm;

“moderate increase in treatment” means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);

“notifiable safety incident” has the meaning given in paragraphs (8) and (9);

“prolonged psychological harm” means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

“prolonged pain” means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

“relevant person” means the service user or, in the following circumstances, a person lawfully acting on their behalf—

(a) on the death of the service user,

(b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or

(c) where the service user is 16 or over and lacks capacity in relation to the matter;

“severe harm” means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user’s illness or underlying condition.

(8) In relation to a health service body, “notifiable safety incident” means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—

(a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition, or

(b) severe harm, moderate harm or prolonged psychological harm to the service user.

- (9) In relation to a registered person who is not a health service body, “notifiable safety incident” means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional—
- (a) appears to have resulted in—
 - (i.) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition,
 - (ii.) an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,
 - (iii.) changes to the structure of the service user’s body,
 - (iv.) the service user experiencing prolonged pain or prolonged psychological harm, or
 - (v.) the shortening of the life expectancy of the service user; or
 - (b) requires treatment by a health care professional in order to prevent—
 - (i.) the death of the service user, or
 - (ii.) any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in subparagraph (a).

Appendix B: Definitions in CQC guidance and information relating to duty of candour

Note – all the matters set out below that are not defined within the regulation are CQC’s interpretation, for example the terms and meaning taken from Robert Francis’ report.

Act in an open and transparent way

Clear, honest and effective communication with patients, their families and carers throughout their care and treatment, including when things go wrong, in line with the definitions below.

We will use the following definitions of openness, transparency and candour used by Robert Francis in his report:

Openness

Enabling concerns and complaints to be raised freely without fear and questions asked to be answered.

Transparency

Allowing information about the truth about performance and outcomes to be shared with staff, people who use the service, the public and regulators.

Candour

Any person who uses the service harmed by the provision of a service provider is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

Apology

An ‘apology’ is an expression of sorrow or regret in respect of a notifiable safety incident; It is not an admission of guilt.

Appropriate written records

Records are complete, legible, accurate and up to date. Every effort must be made to ensure records are updated without any delays.

Cancelling treatment

Where planned treatment is not carried out as a direct result of the notifiable safety incident.

Moderate harm

'Moderate harm' means harm that requires a moderate increase in treatment, and significant, but not permanent, harm, for example a "moderate increase in treatment" means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care).

Prolonged pain

'Prolonged pain' means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

Prolonged psychological harm

'Prolonged psychological harm' means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Relevant person

This is the person who is receiving services or someone acting lawfully on their behalf in the following circumstances: on their death, or where they are under 16 and not competent to make a decision in relation to their care or treatment, or are 16 or over and lack the mental capacity in relation to the matter in accordance with the Mental Capacity Act 2005.

Severe harm

'Severe harm' means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

Written Notification

A written notification is one given or sent to the relevant person in written form containing the information provided in any initial notification made in person, details of any enquiries to be undertaken, advise of any appropriate enquiries to be undertaken by the registered person, the results of any further enquiries into the incident, and an apology (as defined above).

Appendix C: Illustrative examples of incidents that trigger the thresholds for duty of candour

These examples have been developed with stakeholders to illustrate examples of notifiable safety incidents that trigger the threshold for the duty of candour regulation. The examples presented are illustrative only and not an exhaustive list.

Where possible the examples used in this guidance are sourced or adapted from the following two documents: 'Seven steps to patient safety for primary care' (National Patient Safety Agency 2006) and 'Duty of Candour Threshold Review Group Review of Definitions' (Royal College of Surgeons 2014). Some examples, particularly those relating to mental health and prolonged psychological harm have been developed de novo by CQC through a process of engagement with external stakeholders and professional colleagues.

This document will be updated periodically to reflect learning as this is a new regulation.

Surgery	
Examples	Interpretation
A patient arrived for planned surgery but had not been given the correct advice to discontinue their Warfarin treatment. The surgery had to be postponed.	This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))
During a difficult appendectomy the patient's bowel was accidentally perforated. This was recognised the day after surgery when the patient became increasingly unwell. The patient returned to theatre where the problem was fixed and the patient made a full recovery.	This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))
Wrong site surgery: The identities of two patients on the list are mixed up and one patient undergoes the wrong operation on the incorrect site. The patient is permanently harmed as a result.	This would be an example where an incident appeared to have resulted in severe harm (regulation 20 (8)(b))
An elderly patient undergoes a coronary artery bypass operation. The patient is appropriately consented for the risks of the operation, including stroke and death. Unfortunately, the patient sustained a large stroke during the operation, and subsequently died as a result.	This would be an example where an incident resulted in death (regulation 20 (8) (a))
A patient experienced pain during an elective Caesarean section due to incomplete anaesthesia from an epidural line. The patient found this experience traumatic and subsequently had an acute episode of severe anxiety and depression which lasted more than 28 days	This would be an example where an incident appeared to have resulted in prolonged psychological harm (regulation 20 (8)(b))

Medicine	
Examples	Interpretation
A doctor causes a pneumothorax whilst placing a Central Venous Catheter (a recognised complication). The patient requires a chest drain to be inserted and a short stay on the Intensive Care Unit. The patient makes a full recovery	This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))
A patient developed a small grade 2 pressure ulcer during an admission to treat an acute cardiac problem. Although they were now fully mobile, they need district nursing visits after discharge home to check and dress the ulcer until healing was complete two weeks later	This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))
A patient incurs an extravasation injury (soft tissue burn) from an intravenous line causing irreversible scarring and bone damage.	This would be an example where an incident appeared to have resulted in severe harm (regulation 20 (8)(b))
A confused elderly patient was supposed to have 1:1 supervision on a medical ward. The patient was left unsupervised for a period of time whilst the shift change was occurring, and the patient fell out of bed, sustaining a severe head injury from which they later died.	This would be an example where an incident resulted in death (regulation 20 (8) (a))
A patient who is normally very shy sustains an extravasation injury (soft tissue burn) from an intravenous line. This causes irreversible and extensive scarring on her arm and as a result she becomes severely socially anxious for which she needs a prolonged period of therapy.	This would be an example where an incident appeared to have resulted in prolonged psychological harm (regulation 20 (8)(b))

General practice	
Examples	Interpretation
<p>A young man falls over whilst playing badminton and presents to his GP the next day with a swollen and painful foot and ankle . His GP decides not to order an x-ray and sends him home with advice to rest, ice, compress and elevate the leg. He tells the man he can weight-bear fully. Over the following week, the pain and swelling does not improve and the man re-presents at the GP surgery and sees a different doctor who sends him for an x-ray. He is found to have a fracture of the base of 5th metatarsal which should have been managed in a plaster cast and non-weight bearing. Due to this mismanagement, the patient develops a non-union over the following 6 weeks which causes him ongoing pain and eventually requires surgical intervention in hospital.</p>	<p>This would be an example of an incident leading to a service user requiring further treatment to prevent the service user experiencing prolonged pain (regulation 20 (9)(b)(ii))</p>
<p>A patient who is a heavy smoker with a persistent cough is noted to have a suspicious lesion on a chest x-ray. The GP messages the practice reception to arrange an urgent appointment with the patient, although there is no answer on the patient's home telephone as he is on holiday. The message to follow up is missed. Two months later the patient presents with shortness of breath and haemoptysis. He is admitted to hospital via MAU and is diagnosed with lung cancer. His chances of survival were believed to be significantly reduced due to the delay.</p>	<p>This would be an example of an incident leading to the shortening of the life expectancy of a service user (regulation 20 (9)(a)(v))</p>
<p>A patient is on a repeat prescription for morphine sulphate 10mg twice a day for chronic pain. The patient requests a prescription and, in error, a prescription is issued for morphine sulphate 100mg twice a day. The medication is dispensed and the patient's wife, who looks after his medicines, gives her husband 100mg tablets of morphine sulphate. He takes 2 doses over the next day and then his wife is unable to rouse him in the morning. He is admitted to hospital where he has a cardiac arrest and dies.</p>	<p>This would be an example of an incident leading to the death of a patient (regulation 20 (9)(a)(i))</p>
<p>"A patient's discharge summary from a recent inpatient episode for pneumonia described how an x-ray showed signs of a 'suspicious lung lesion' requiring a follow-up with their GP.</p>	<p>This would be an example where an incident appeared to have resulted in</p>

Examples	Interpretation
<p>The GP practice carried out further tests but failed to follow normal processes for relaying the results to the patient. The patient consequently spent several weeks in a state of extreme upset, concerned about the possibility of cancer and developed symptoms of anxiety and depression which lasted more than 28 days. Eventually he discovered his test results were normal.</p>	<p>prolonged psychological harm (regulation 20 (9)(a)(iv))</p>

Mental health	
Examples	Interpretation
<p>Prescribing error on a mental health ward resulted in a patient being given twice her normal dose of Lithium for several days. She became symptomatic for Lithium toxicity which required inpatient admission. She made a full recovery.</p>	<p>This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))</p>
<p>A distressed, aggressive patient required physical restraint whilst receiving an injection of anti-psychotic medication. During the restraint, the patient's arm was broken which required manipulation and treatment in plaster for 6 weeks. He made a full recovery from the injury.</p>	<p>This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))</p>
<p>A 9 year old boy was prescribed methylphenidate for the treatment of ADHD. At no point was an assessment made of his cardiac status nor enquiry into a family history of cardiac problems. He suffered several episodes of syncope thought to be due to extreme anxiety before collapsing with an arrhythmia, resulting in cardiac arrest and resultant permanent cognitive impairment.</p>	<p>This would be an example where an incident appeared to have resulted in severe harm (regulation 20 (8)(b))</p>
<p>A patient on a mental health unit committed suicide after lapses in risk assessment and observation.</p>	<p>This would be an example where an incident resulted in death (regulation 20 (8) (a))</p>

Mental health	
Examples	Interpretation
A 71 year old woman with apathy and memory loss is diagnosed with dementia. She is treated for several months in the memory service before she is re-evaluated and diagnosed with depression which responds to antidepressant treatment.	This would be an example of an incident leading to prolonged psychological harm (regulation 20 (8)(b))

Maternity	
Examples	Interpretation
A mother had significant post-partum haemorrhage after a difficult delivery, and there was some delay in obtaining blood for transfusion. As a result, she needed treatment in the high dependency unit for 24 hours before making a full recovery.	This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))
A pregnant woman was seen in A&E at 12 weeks gestation with abdominal pain and PV bleeding. A high vaginal swab was taken by the Gynae SHO which grew Group B Streptococcus (GBS). When the woman went in to labour 28 weeks later, the midwife attending the birth did not check the laboratory results which showed the GBS growth and so the woman was not given intra-partum antibiotic prophylaxis as per national guidelines. The child then went on to develop GBS septicaemia in the days following delivery and required treatment in the Neonatal Intensive Care unit for 5 days before making a full recovery.	This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))
An expectant mother who rang the maternity unit to report possible blood loss and reduced foetal movements was given inappropriate reassurance rather than asked to come for	This would be an example where an incident appeared to have resulted in

Maternity	
Examples	Interpretation
assessment. The baby later born with severe disabilities.	severe harm (regulation 20 (8)(b))
A woman requiring a blood transfusion for a post-partum haemorrhage received the wrong unit of blood after an error in labelling sample tubes. As a result the woman suffered a severe reaction leading to multi-organ failure and a fatal cardiac arrest.	This would be an example where an incident resulted in death (regulation 20 (8) (a))
An expectant mother with a past history of severe mental health problems was not appropriately assessed at her antenatal appointment. As a result she was not offered NICE recommended psychological therapies, prophylactic medications or specialist follow-up. After delivery she became symptomatic, and these errors led to delays to her diagnosis and treatment. This resulted in a prolonged deterioration in her mental health for more than 28 days.	This would be an example where an incident appeared to have resulted in prolonged psychological harm (regulation 20 (8)(b))

Dentistry	
Examples	Interpretation
A patient was undergoing a dental procedure in a Primary Dental Care setting requiring conscious sedation with midazolam. The patient was inappropriately given too much sedation resulting in an overdose which required admission to hospital. The patient made a full recovery.	This would be an example of an incident where a service user has required further treatment to prevent death (regulation 20 (9) (b) (i))
A patient undergoing root canal treatment sustained irreversible tissue and nerve necrosis due to severe hypochlorite extravasation occurring during the procedure.	This would be an example of an incident where a service user has suffered a change in the structure of the body (regulation 20 (9) (iii))
A patient with a severe allergy to latex went for a dental procedure. The nature of the allergy had been stated in the medical history questionnaire. The dentist did not check this history before starting the procedure and was wearing latex gloves. The patient developed an anaphylactic reaction which required hospitalisation. The patient made a full recovery	This would be an example of an incident where a service user has required further treatment to prevent death (regulation 20 (9) (b) (i))

Adult social care	
Examples	Interpretation
<p>An OT completed an assessment with a care home resident whose mobility was deteriorating. The OT advised that grab rails were needed in a person's bathroom before it was safe for them to use the bath and that in the meantime staff should assist the person to have a strip wash each morning. The manager failed to update the person's care plan or inform the care staff of this change, so staff supported the person to take a bath the following morning as usual. The person slipped when getting out of the bath and sustained a broken arm. The arm was put in a plaster cast and the person needed full assistance for all aspects of their care for 6 weeks until the cast was removed. The person made a full recovery.</p>	<p>This would be an example of an incident leading to a service user requiring further treatment to prevent the service user experiencing prolonged pain (regulation 20 (9)(b)(ii))</p>
<p>A new member of staff on induction was shadowing another care worker delivering care to a person who needed to be hoisted. Two trained members of staff were required to operate the hoist safely and the new member of staff had not yet been trained in moving and handling. The new care worker was asked to assist with the manoeuvre and did not attach one of the loops of the sling to the hoist properly. As a result, during the manoeuvre, the person slid out of the sling and onto the floor. The person sustained a broken hip requiring emergency surgery.</p>	<p>This would be an example of an incident leading to a service user experiencing changes to the structure to the body (regulation 20 (9)(b)(iii))</p>
<p>A person with a learning disability was prescribed antipsychotic medicines. They were assessed as needing full staff support in the management of their medicines. Over a period of two weeks they became increasingly anxious and distressed. When the person's medicines were checked it was discovered that their antipsychotic medicines had not been ordered the previous month and did not show on the MAR chart. This was because the correct procedure for ordering and the checking in of medicines had not been followed and the error had gone unnoticed for 18 days. This resulted in a prolonged deterioration in the person's mental health for more than 28 days.</p>	<p>This would be an example of an incident leading to prolonged psychological harm (regulation 20(9)(a)(iv))</p>