Duty of Candour

A Guide for Practices

The duty of candour came into effect for GP practices on 1 April 2015. This is Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, which sets out fundamental standards.

It aims to ensure that providers are open and transparent with people who use services and other relevant persons 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 a written apology.

The duty of candour regulation was recommended by the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust. This is in addition to the professional requirements for candour outlined in Good Medical Practice and applies to organisations rather than individual clinicians.

It means that practices 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 or partnership level.

What does duty of candour mean for practices?

In interpreting the regulation on the duty of candour, the CQC uses the definitions Robert Francis listed 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

The new regulation defines what constitutes a notifiable safety incident. These are:

- the death of the patient, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition
- an impairment of the sensory, motor or intellectual functions of the patient, which has lasted, or is likely to last, for a continuous period of at least 28 days
- changes to the structure of the service user's body
- the service user experiencing prolonged pain or prolonged psychological harm, or
- the shortening of the life expectancy of the service user
- requirement for additional treatment to prevent one of the harms described above

Regulation 20 applies to providers when they are providing care and treatment for CQC-regulated activity only. The identification of clinical situations which meet these thresholds remains the professional judgement of the clinicians involved in the incident.

What must an organisation do to meet the requirements?

Once a notifiable safety incident has been identified a registered provider must:

- 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
- Tell the relevant person in person as soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, and support them in relation to the incident, including when giving the notification
- Provide an account of the incident which, to the best of the organisation'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 this up 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

How will the CQC regulate providers' compliance?

During the inspection process, the CQC assesses whether the provider is delivering good quality care. Specific key lines of enquiry (KLOEs) under the safe and well-led questions are relevant to assessing duty of candour in practice inspections.

During the inspection process we will test whether providers understand the requirements of the regulation and ask them what systems they have in place to ensure that they will be able to meet them.

The inspector will check there are robust systems in place. This would include:

- training for staff on communicating with patients about notifiable safety incidents
- incident reporting forms which support the recording of a duty of candour notification
- support for staff when they notify patients when something has gone wrong
- oversight and assurance

Appendix A

Examples

Scenario	Interpretation
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.	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))
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.	This would be an example of an incident leading to the death of a patient (regulation 20 (9)(a)(i)

Examples

Scenario	Interpretation
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. 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.	This would be an example where an incident appeared to have resulted in prolonged psychological harm (regulation 20 (9)(a)(iv)
A patient was prescribed an antibiotic by the practice which is known to interfere with warfarin levels went without INR monitoring for several weeks. The patient had an upper GI bleed and was admitted to hospital for 5 days for monitoring and follow-up. It was noted on admission that the INR was 7.	This would be an example where an incident appeared to have required treatment by a health care professional in order to prevent the death of the service user (regulation 20 (9)(b)(i)

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Appendix B - Regulation 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 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" 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" means the service user or, in the following circumstances, a person lawfully acting on their behalf— c. on the death of the service user, d. where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or e. 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 any other registered person, "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, 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, b. 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, c. changes to the structure of the service user's body, d. the service user experiencing prolonged pain or prolonged psychological harm, or e. the shortening of the life expectancy of the service user; or 2. 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 sub-paragraph (a)

Appendix C – Related Legislation

The Care Act 2014

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015

Health Professional Council – legal framework

Mental Capacity Act 2005

Mental Capacity Act Code of Practice

Appendix D – Relevant Guidance

Care Act 2014 (Social Care Institute for Excellence)

Care Act 2014 part 1: factsheets (Department of Health, June 2014)

Care and support statutory guidance, issued under the Care Act 2014 (Department of Health, October 2014)

Gillick competence or Fraser guidelines

Good Medical Practice 2001: Guidance on 'duty of candour' (General medical Council)

Mental Capacity Act 2005 Code of Practice

General Medical Council legal framework

Good medical practice (General Medical Council)

CQC Guide – Duty of Candour