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Duty of Candour

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Guidance for all EQS staff and EQS partner organisations



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The professional duty of candour

Every healthcare professional must be open and honest with patients when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress. This means that healthcare professionals must:

- tell the patient (or, where appropriate, the patient's advocate, carer or family) when something has gone wrong.
- apologise to the patient (or, where appropriate, the patient's advocate, carer or family).
- offer an appropriate remedy or support to put matters right (if possible).
- explain fully to the patient (or, where appropriate, the patient's advocate, carer or family) the short and long term effects of what has happened. Healthcare professionals must also be open and honest with their colleagues, employers and relevant organisations, and take part in reviews and investigations when requested. They must also be open and honest with their regulators, raising concerns where appropriate. They must support and encourage each other to be open and honest, and not stop someone from raising concerns.

In more detail...

1. All healthcare professionals have a duty of candour – a professional responsibility to be honest with patients when things go wrong. This is described in The professional duty of candour, which introduces this guidance and forms part of a joint statement from eight regulators of healthcare professionals in the UK. When we refer to 'patients' in this guidance, we also mean people who are in your care.
2. As a doctor, nurse, physiologist or midwife, you must be open and honest with patients, colleagues and your employers.
3. This guidance complements the joint statement from the healthcare regulators and gives more information about how to follow the principles set out in Good medical practice and The Code: Professional standards of practice and behaviour for nurses and midwives. Appendix 1 sets out relevant extracts from General Medical Council (GMC) and Nursing and Midwifery Council (NMC) guidance. This guidance



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applies to all doctors registered with the GMC and all nurses and midwives registered with the NMC across the UK. It is also relevant to all physiologists.

4. This guidance is divided into two parts.
 - (a) Your duty to be open and honest with patients in your care, or those close to them, if something goes wrong. This includes advice on apologising.
 - (b) Your duty to be open and honest with your organisation, and to encourage a learning culture by reporting adverse incidents that lead to harm, as well as near misses (paragraphs 22–33).
5. This guidance is for individuals. We recognise that care is normally provided by multidisciplinary teams, and we don't expect every team member to take responsibility for reporting adverse incidents and speaking to patients if things go wrong. However, we do expect you to make sure that someone in the team has taken on responsibility for each of these tasks, and we expect you to support them as needed.

Being open and honest with patients in your care, and those close to them, when things go wrong

Discuss risks before beginning treatment or providing care

6. Patients must be fully informed about their care. When discussing care options with patients, you must discuss the risks as well as the benefits of the options.
7. You or an appropriate person must give the patient clear, accurate information about the risks of the proposed treatment or care, and the risks of any reasonable alternative options, and check that the patient understands. You should discuss risks that occur often, those that are serious even if very unlikely, and those that the patient is likely to think are important (see Supreme Court judgement).

In what circumstances do I need to apologise to the patient?

8. This guidance is not intended for circumstances where a patient's condition gets worse due to the natural progression of their illness. It applies when something goes wrong with a patient's care, and they suffer harm or distress as a result. This guidance also applies in situations where a patient may yet suffer harm or distress as a result of something going wrong with their care.



9. When you realise that something has gone wrong, and after doing what you can to put matters right, you or someone from the healthcare team must speak to the patient.* The most appropriate team member will usually be the lead or accountable clinician. If this is not you, then you must follow the guidance in paragraph 5.
*(*If the patient has died, or is unlikely to regain consciousness or capacity, 'patient' in paragraphs 9–16 should be read as 'those close to the patient').*

When should I speak to the patient or those close to them, and what do I need to say?

10. You should speak to the patient as soon as possible after you realise something has gone wrong with their care. When you speak to them, there should be someone available to support them (for example a friend, relative or professional colleague). You do not have to wait until the outcome of an investigation to speak to the patient, but you should be clear about what has and has not yet been established.
11. You should share all you know and believe to be true about what went wrong and why, and what the consequences are likely to be. You should explain if anything is still uncertain and you must respond honestly to any questions. You should apologise to the patient (see paragraphs 13–19).

What if people don't want to know the details?

12. Patients will normally want to know more about what has gone wrong. But you should give them the option not to be given every detail. If the patient does not want more information, you should try to find out why. If after discussion, they don't change their mind, you should respect their wishes as far as possible,* having explained the potential consequences. You must record the fact that the patient does not want this information and make it clear to them that they can change their mind and have more information at any time.
*(*If the patient needs to give their consent to a proposed investigation or treatment, then you need to give them enough information to make an informed decision.)*

Saying sorry

13. Patients expect to be told three things as part of an apology:
(a) what happened.
(b) what can be done to deal with any harm caused.
(c) what will be done to prevent someone else being harmed.
14. Apologising to a patient does not mean that you are admitting legal liability†for what has happened. This is set out in legislation in parts of the UK and the NHS Litigation Authority also advises that saying sorry is the right thing to do. In addition,



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a fitness to practise panel may view an apology as evidence of insight.
(† ‘Legal liability’ here refers to a clinical negligence claim. The NHS Litigation Authority ‘will never withhold cover for a claim because an apology or explanation has been given’)

15. When apologising to patients and explaining what has happened, we do not expect you to take personal responsibility for something going wrong that was not your fault (such as system errors or a colleague’s mistake). But the patient has the right to receive an apology from the most appropriate team member (see paragraph 9), regardless of who or what may be responsible for what has happened.
16. We do not want to encourage a formulaic approach to apologising since an apology has value only if it is genuine. However, when apologising to a patient, you should consider each of the following points.
 - (a) You must give patients the information they want or need to know in a way that they can understand.
 - (b) You should speak to patients in a place and at a time when they are best able to understand and retain information.
 - (c) You should give information that the patient may find distressing in a considerate way, respecting their right to privacy and dignity.
 - (d) Patients are likely to find it more meaningful if you offer a personalised apology – for example ‘I am sorry...’ – rather than a general expression of regret about the incident on the organisation’s behalf. This doesn’t mean that we expect you to take personal responsibility for system failures or other people’s mistakes (see paragraph 15).
 - (e) You should make sure the patient knows who to contact in the healthcare team to ask any further questions or raise concerns. You should also give patients information about independent advocacy, counselling or other support services‡ that can give them practical advice and emotional support
(‡ For example, you could direct them to Action against Medical Accidents (AvMA) or to their local Healthwatch group in England, Patient and Client Council in Northern Ireland, the Patient Advice and Support Service in Scotland or the Community Health Council in Wales. See [Patients’ help on the GMC website](#) or [When to make a referral on the NMC website](#) for further information).
 - (f) You should record the details of your apology in the patient’s clinical record. A verbal apology may need to be followed up by a written apology, depending on the patient’s wishes and on your workplace policy.



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Speaking to those close to the patient

17. If something has gone wrong that causes a patient's death or such severe harm that the patient is unlikely to regain consciousness or capacity, you must be open and honest with those close to the patient. Take time to convey the information in a compassionate way, giving them the opportunity to ask questions at the time and afterwards.†
(† If a patient has previously asked you not to share personal information about their condition or treatment with those close to them, you should respect their wishes. While doing so, you must do your best to be considerate, sensitive and responsive to those close to the patient, giving them as much information as you can).
18. You must show respect for, and respond sensitively to, the wishes and needs of bereaved people. You must take into account what you know of the patient's wishes about what should happen after their death, including their views about sharing information. You should be prepared to offer support and assistance to bereaved people – for example by explaining where they can get information about, and help with, administrative and practical tasks following a death; or by involving other members of the team, such as chaplaincy or bereavement care staff.‡
(‡ For information about patient and carer support and advocacy services, counselling and chaplaincy services, and clinical ethics support networks, see the advice and resources listed on the National End of Life Care Programme website and the PallCareNI website).
19. You should make sure, as far as possible, that those close to the patient have been offered appropriate support, and that they have a specific point of contact in case they have concerns or questions at a later date.

Being open and honest with patients about near misses

20. 'near miss' is an adverse incident that had the potential to result in harm but did not do so.§ You must use your professional judgement when considering whether to tell patients about near misses. Sometimes there will be information that the patient needs to know or would want to know, and telling the patient about the near miss may even help their recovery. In these cases, you should talk to the patient about the near miss, following the guidance in paragraphs 10–16.
(§ This does not include adverse incidents that may result in harm but have not yet done so – the patient must be told about these events and they must be reported in line with this guidance).
21. Sometimes failing to be open with a patient about a near miss could damage their



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trust and confidence in you and the healthcare team. However, in some circumstances, patients may not need to know about an adverse incident that has not caused (and will not cause) them harm, and to speak to them about it may distress or confuse them unnecessarily. If you are not sure whether to talk to a patient about a near miss, seek advice from your healthcare team or a senior colleague.

Encouraging a learning culture by reporting errors

22. When something goes wrong with patient care, it is crucial that it is reported at an early stage so that lessons can be learnt quickly and patients can be protected from harm in the future.
23. Healthcare organisations should have a policy for reporting adverse incidents and near misses, and you must follow your organisation's policy.
24. A number of reporting systems and schemes exist around the UK for reporting adverse incidents and near misses.
 - (a) Adverse and patient safety incidents in England and Wales are reported to the [National Reporting and Learning System](#).
 - (b) You must report suspected adverse drug reactions to the [UK-wide Yellow Card Scheme](#) run by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Commission on Human Medicines.
 - (c) You must report adverse incidents involving medical devices to the UK-wide MHRA reporting system.
 - (d) Healthcare Improvement Scotland has a [national framework](#), which outlines consistent definitions and a standardised approach to adverse incident management across the NHS in Scotland.
 - (e) The procedure for the management and follow-up of serious adverse incidents in Northern Ireland is set out on the [Department of Health, Social Services and Public Safety's website](#).
 - (f) In England, general practitioners and other primary medical services must submit all notifications directly to the [Care Quality Commission \(CQC\)](#).
25. In addition to contributing to these systems, you should comply with any system for reporting adverse incidents that put patient safety at risk within your organisation (see paragraphs 32–33 on the organisational duty of candour). If your organisation does not have such a system in place, you should speak to your manager and – if necessary – raise a concern in line with our guidance.



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26. Your organisation should support you to report adverse incidents and near misses routinely. If you do not feel supported to report, and in particular if you are discouraged or prevented from reporting, you should raise a concern in line with our guidance.
27. You must not try to prevent colleagues or former colleagues from raising concerns about patient safety.† If you are in a management role, you must make sure that individuals who raise concerns are protected from unfair criticism or action, including any detriment or dismissal.
(† A fitness to practise panel is likely to consider a more serious sanction if there is evidence of a failure to raise a concern, or of an attempt to cover up).
28. You must take part in regular reviews and audits of the standards and performance of any team you work in, taking steps to resolve any problems. You should also discuss adverse incidents and near misses at your appraisal. Additional duties for doctors, nurses and midwives with management responsibilities and for senior or high- profile clinicians.
29. Senior clinicians have a responsibility to set an example and encourage openness and honesty in reporting adverse incidents and near misses. Clinical leaders should actively foster a culture of learning and improvement.
30. If you have a management role or responsibility, you must make sure that systems are in place to give early warning of any failure, or potential failure, in the clinical performance of individuals or teams. These should include systems for conducting audits and considering patient feedback. You must make sure that any concerns about the performance of an individual or team are investigated and, if appropriate, addressed quickly and effectively.
31. If you are managing or leading a team, you should make sure that systems, including auditing and benchmarking, are in place to monitor, review and improve the quality of the team's work.
 - (a) You must work with others to collect and share information on patient experience and outcomes.
 - (b) You should make sure that teams you manage are appropriately trained in patient safety and supported to openly report adverse incidents.
 - (c) You should make sure that systems or processes are in place so that:
 - lessons are learnt from analysing adverse incidents and near misses.
 - lessons are shared with the healthcare team.



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- concrete action follows on from learning.
- practice is changed where needed.

The organisational duty of candour

32. All healthcare organisations have a duty to support their staff to report adverse incidents, and to support staff to be open and honest with patients if something goes wrong with their care. Each of the four UK governments has considered ways to implement the organisational duty of candour, with some writing it into law (see appendix 2).
33. If systems are not in place in your organisation to support staff to report adverse incidents, you should speak to your manager or a senior colleague. If necessary, you should escalate your concern in line with our guidance on raising concerns.



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Appendix 1: Extracts from GMC and NMC guidance that are referenced in this guidance

From Good medical practice

23. To help keep patients safe you must:

- (a) contribute to confidential inquiries
- (b) contribute to adverse event recognition
- (c) report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another person, at risk
- (d) report suspected adverse drug reactions
- (e) respond to requests from organisations monitoring public health.

When providing information for these purposes you should still respect patients' confidentiality.

24. You must promote and encourage a culture that allows all staff to raise concerns openly and safely.

55. You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should:

- (a) put matters right (if that is possible)
- (b) offer an apology
- (c) explain fully and promptly what has happened and the likely short-term and long-term effect

From Raising and acting on concerns about patient safety

13. Wherever possible, you should first raise your concern with your manager or an appropriate officer of the organisation you have a contract "*Openness and honesty when things go wrong: the professional duty of candour*" with or which employs you – such as the consultant in charge of the team, the clinical or medical director or a practice partner. If your concern is about a partner, it may be appropriate to raise it outside the practice – for example, with the medical director or clinical governance lead responsible for your organisation. If you are a doctor in training, it may be appropriate to raise your concerns with a named person in the deanery – for example, the postgraduate dean or director of postgraduate general practice education.



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Doctors with extra responsibilities

- 21.** If you are responsible for clinical governance or have wider management responsibilities in your organisation, you have a duty to help people report their concerns and to enable people to act on concerns that are raised with them.
- 22.** If you have a management role or responsibility, you must make sure that:
- (a) there are systems and policies in place to allow concerns to be raised and for incidents, concerns and complaints to be investigated promptly and fully.
 - (b) you do not try to prevent employees or former employees raising concerns about patient safety – for example, you must not propose or condone contracts or agreements that seek to restrict or remove the contractor’s freedom to disclose information relevant to their concerns.
 - (c) clinical staff understand their duty to be open and honest about incidents or complaints with both patients and managers.
 - (d) all other staff are encouraged to raise concerns they may have about the safety of patients, including any risks that may be posed by colleagues or teams.
 - (e) staff who raise a concern are protected from unfair criticism or action, including any detriment or dismissal.

Also see the [raising concerns decision making tool on the GMC website](#).

From Leadership and management for all doctors

- 24.** Early identification of problems or issues with the performance of individuals, teams or services is essential to help protect patients.

All doctors

- 25.** You must take part in regular reviews and audits of the standards and performance of any team you work in, taking steps to resolve any problems.
- 26.** You should be familiar with, and use, the clinical governance and risk management structures and processes within the organisations you work for or to which you are contracted. You must also follow the procedure where you work for reporting adverse incidents and near misses. This is because routinely identifying adverse incidents or near misses at an early stage, can allow issues to be tackled, problems to be put right and lessons to be learnt.
- 27.** You must follow the guidance in Good medical practice and Raising and acting on concerns about patient safety when you have reason to believe that systems, policies, procedures or colleagues are, or may be, placing patients at risk of harm.



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Doctors with extra responsibilities

28. If you have a management role or responsibility, you must make sure that systems are in place to give early warning of any failure, or potential failure, in the clinical performance of individuals or teams. These should include systems for conducting audits and considering patient feedback. You must make sure that any such failure is dealt with quickly and effectively.

29. If you are managing or leading a team, you should make sure that systems, including auditing and benchmarking, are in place to monitor, review and improve the quality of the team's work. You must work with others to collect and share information on patient experience and outcomes. You must make sure that teams you manage are appropriately supported and developed and are clear about their objectives.

From Consent: patients and doctors making decisions together

75. In making decisions about the treatment and care of patients who lack capacity, you must:

- (a) make the care of your patient your first concern.
- (b) treat patients as individuals and respect their dignity.
- (c) support and encourage patients to be involved, as far as they want to and are able, in decisions about their treatment and care.
- (d) treat patients with respect and not discriminate against them.

76. You must also consider:

- (a) whether the patient's lack of capacity is temporary or permanent
- (b) which options for treatment would provide overall clinical benefit for the patient
- (c) which option, including the option not to treat, would be least restrictive of the patient's future choices
- (d) any evidence of the patient's previously expressed preferences, such as an advance statement or decision.
- (e) the views of anyone the patient asks you to consult, or who has legal authority to make a decision on their behalf, or has been appointed to represent them.
- (f) the views of people close to the patient on the patient's preferences, feelings, beliefs and values, and whether they consider the proposed treatment to be in the patient's best interests.
- (g) what you and the rest of the healthcare team know about the patient's wishes, feelings, beliefs and values.



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From Treatment and care towards the end of life: good practice in decision making

84. Death and bereavement affect different people in different ways, and an individual's response will be influenced by factors such as their beliefs, culture, religion and values. You must show respect for and respond sensitively to the wishes and needs of the bereaved, taking into account what you know of the patient's wishes about what should happen after their death, including their views about sharing information. You should be prepared to offer support and assistance to the bereaved, for example, by explaining where they can get information about, and help with, the administrative practicalities following a death; or by involving other members of the team, such as nursing, chaplaincy or bereavement care staff

From The Code: Professional standards of practice and behaviour for nurses and midwives

Preserve safety

You make sure that patient and public safety is protected. You work within the limits of your competence, exercising your professional 'duty of candour' and raising concerns immediately whenever you come across situations that put patients or public safety at risk. You take necessary action to deal with any concerns where appropriate.

14. Be open and candid with all service users about all aspects of care and treatment, including when any mistakes or harm have taken place.

To achieve this, you must:

14.1. act immediately to put right the situation if someone has suffered actual harm for any reason or an incident has happened which had the potential for harm.

14.2. explain fully and promptly what has happened, including the likely effects, and apologise to the person affected and, where appropriate, their advocate, family or carers, and

14.3. document all these events formally and take further action (escalate) if appropriate so they can be dealt with quickly.

16. Act without delay if you believe that there is a risk to patient safety or public protection.

To achieve this, you must:



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16.1. raise and, if necessary, escalate any concerns you may have about patient or public safety, or the level of care people are receiving in your workplace or any other healthcare setting and use the channels available to you in line with our guidance and your local working practices.

16.2. raise your concerns immediately if you are being asked to practise beyond your role, experience and training.

16.3. tell someone in authority at the first reasonable opportunity if you experience problems that may prevent you working within the Code or other national standards, taking prompt action to tackle the causes of concern if you can.

16.4. acknowledge and act on all concerns raised to you, investigating, escalating or dealing with those concerns where it is appropriate for you to do so.

16.5. not obstruct, intimidate, victimise or in any way hinder a colleague, member of staff, person you care for or member of the public who wants to raise a concern, and

16.6. protect anyone you have management responsibility for from any harm, detriment, victimisation or unwarranted treatment after a concern is raised.



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Appendix 2: The statutory duty of candour for care organisations across the UK

England

The CQC has put in place a requirement for healthcare providers to be open with patients and apologise when things go wrong. This duty applies to all registered providers of both NHS and independent healthcare bodies, as well as providers of social care from 1 April 2015. The organisational duty of candour does not apply to individuals, but organisations providing healthcare will be expected to implement the new duty throughout their organisation by making sure that staff understand the duty and are appropriately trained.

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 intends to make sure that providers are open and transparent in relation to care and treatment with people who use their services. It also sets out some specific requirements that providers must follow when things go wrong with care or treatment, including informing people about the incident, providing reasonable support, giving truthful information and apologising when things go wrong. The CQC can prosecute for a breach of parts 20(2)a and 20(3) of this regulation. Openness and honesty when things go wrong: the professional duty of candour

Northern Ireland

In January 2015, former Northern Ireland Health Minister Jim Wells MLA announced plans to introduce a statutory duty of candour for Northern Ireland. This announcement followed the publication of the [Donaldson Report](#), which examined the governance arrangements for making sure health and social care is of a high quality in Northern Ireland.

The annual report of the chief medical officer for Northern Ireland 2014, published in May 2015, restated the commitment to introduce a statutory duty of candour in Northern Ireland.

'In response to the Donaldson review the Minister announced plans to introduce a statutory duty of candour for Northern Ireland. That duty came to prominence in England as a result of conclusions from the Francis report – a public inquiry into the Mid Staffordshire NHS Foundation Trust. Openness and transparency are crucial elements of patient safety. When things go wrong, patients, service users and the public have a right to expect that they will be communicated with in an honest and respectful manner and that



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every effort will be made to correct errors or omissions and to learn from them to prevent a recurrence.

‘The Health and Social Care service in Northern Ireland already operates under statutory duties of both quality and involvement. Meaningful engagement with patients and clients, carers and the public will improve the quality and safety of services. It is not the intention of the duty of candour to promote a culture of fear, blame and defensiveness in reporting concerns about safety and mistakes when they happen.’

Scotland

The [Healthcare Quality Strategy for NHS Scotland](#) is aiming to achieve an NHS culture in which care is consistently person-centred, clinically effective and safe for every person, all the time.

The [Scottish Patient Safety Programme](#) is a national initiative that aims to improve the safety and reliability of healthcare and reduce harm.

Following public consultation between October 2014 and January 2015, the Scottish Government published the [Health \(Tobacco, Nicotine etc. and Care\) \(Scotland\) Bill on 5 June 2015](#). The purpose of the duty of candour provisions of the Bill are to support the implementation of consistent responses across health and social care providers when there has been an unexpected event or incident that has resulted in death or harm, that is not related to the course of the condition for which the person is receiving care.

The duty of candour procedure (which will be set out in regulations to be made using powers in the Bill) will emphasise learning, change and improvement – three important elements that will make a significant and positive contribution to quality and safety in health and social care settings.

The new duty of candour on organisations will create a legal requirement for health and social care organisations to inform people (or their families/carers acting on their behalf) when they have been harmed (physically or psychologically) as a result of the care or treatment they have received.

There will be a requirement for organisational emphasis on staff support and training to ensure effective implementation of the organisational duty.



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Wales

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 place a number of duties on responsible bodies providing NHS care. This includes a duty to be open when harm may have occurred:

‘where a concern is notified by a member of the staff of the responsible body, the responsible body must, where its initial investigation determines that there has been moderate or severe harm or death, advise the patient to whom the concern relates, or his or her representative, of the notification of the concern and involve the patient, or his or her representative, in the investigation of the concern’.

The [Welsh Government’s Health and Care Standards Framework](#), includes a standard called ‘listening and learning from feedback’. In meeting this standard, the framework advises that ‘health services are open and honest with people when something goes wrong with their care and treatment’. The standards provide a framework for how services are organised, managed and delivered on a day-to-day basis.

The Minister for Health and Social Services has confirmed that findings from the recent independent reviews of complaints handling by [NHS Wales](#) and of [Healthcare Inspectorate Wales](#) will inform an NHS Wales Quality Bill Green Paper by the end of 2015, which is likely to include further consideration of a duty of candour.