To consider

Publishing joint guidance with the Nursing and Midwifery Council on the professional duty of candour

Issue

1. Revise draft explanatory guidance, developed jointly with the Nursing and Midwifery Council, for doctors, nurses and midwives about the professional duty of candour, taking account of the response to consultation. We plan to publish the final guidance at the GMC Conference on 16 March 2015.

Recommendations

2. The Strategy and Policy Board is asked to:
   a. Note progress on the development of joint GMC-NMC guidance *Openness and honesty when things go wrong: the professional duty of candour*.
   b. Note the quantitative analysis of responses to the consultation on draft guidance.
   c. Agree principles for revising the draft in light of the quantitative analysis and any concerns raised by key stakeholders.
   d. Note plans for publishing and launching the revised guidance.
Publishing joint guidance with the Nursing and Midwifery Council on the professional duty of candour

Issue

The Strategy and Policy Board previously agreed that we should develop guidance jointly with the Nursing and Midwifery Council (NMC) which expands on our existing guidance about the professional duty of candour and includes specific advice about near misses and apologies. This followed the suggestion made by the Government in *Hard Truths*, its response to the Mid-Staffordshire Public Inquiry Report, that the GMC and NMC would work with other regulators to agree consistent approaches to candour and reporting of errors.

The consultation

The draft guidance *Openness and honesty when things go wrong: the professional duty of candour* was launched for public consultation on 3 November 2014 at an event at St Thomas’s Hospital. The consultation ran from 3 November 2014 to 5 January 2015. The consultation document is at Annex A.

Consultation workshops

During the consultation period we held two engagement events. The first was a workshop at the PatientFirst conference on 26 November 2014 which was led by GMC Clinical Fellow Dr Toby Reynolds. The workshop was very well attended with around two hundred delegates – mostly doctors, nurses and other healthcare workers. It was an interactive session, with a high level of participation, and a lively discussion of the issues. There was broad agreement with the intention behind the guidance but many of the comments reflected a feeling that an unprecedented culture change would be necessary if the guidance were to be implemented successfully. Dr Reynolds’ blog about the workshop is at Annex B.

The second consultation event was a patient workshop held at the GMC on 27 November 2014. This was attended by representatives from Action Against Medical Accidents (AvMA), the Patients and Client Council in Northern Ireland (PCCNI) and the Patients’ Association. Representatives from MIND and MENCAP were also expected, together with a colleague from the NMC, but were unfortunately not able to attend on the day. The workshop was positive overall, and some interesting points were discussed, which provided an alternative perspective from the PatientFirst workshop. A note of the meeting is at Annex C.

Analysis of responses to the consultation

Because of the very tight timescale for this project, we enlisted the help of an external agency, Alpha Research, to run the on-line consultation for us. Alpha
Research closed the consultation 13 January 2015 and have analysed the results, at Annex D. The final figure for the number of responses was 544, which is very high for a piece of explanatory guidance.

**Next steps**

8 Together with the quantitative analysis, at Annex D, is information about emerging themes from the comments made by respondents, and a summary of issues raised by our key interests in response to the consultation. Based on these themes and concerns, the Board is asked to agree broad principles for redrafting the guidance as set out at the beginning of Annex D.

9 In line with the requirements of our public sector equality duty we have asked Alpha Research to highlight any issues raised by diversity-related organisations to help us understand the impact that the guidance might have on groups with protected characteristics. This will help us to undertake some follow-up engagement with these groups if necessary.

**When will the guidance be published?**

10 We had initially planned a publication date of the end of March 2015 in order to avoid the pre-election period. However, the theme of the GMC conference this year is ‘creating a culture of openness, safety and compassion’ and the guidance would clearly link well with this.

11 In light of this, we have brought the planned publication date forward and, subject to agreement with the NMC, we now aim to launch the new guidance at the GMC conference on 16 March 2015.

**What happens after publication?**

12 We are already beginning to think about how we can make sure the guidance is followed and, in particular, how the professional duty of candour set out in our guidance will fit with the statutory duty on organisations, which came into force in England towards the end of last year. We and the NMC are meeting with the Care Quality Commission on 6 February 2015 to begin discussions about implementing the guidance.

13 The Scottish Government recently, on 14 January 2015, finished consulting on *Proposals to Introduce a Statutory Duty of Candour for Health and Social Care Services*. A copy of our response to this consultation is available on request.
Supporting information

How this issue relates to the corporate strategy and business plan

This issue relates to Strategic Aim two: to help raise standards in medical education and practice.

If you have any questions about this paper please contact: Mary Agnew, Assistant Director - Education and Standards, MAgnew@gmc-uk.org, 020 7189 5325.
The consultation document for *Openness and honesty when things go wrong: the professional duty of candour*
Openness and honesty when things go wrong: the professional duty of candour

A public consultation on our draft guidance
About this consultation

We are consulting on draft guidance for doctors, nurses and midwives on their professional duty to be open and honest when things go wrong – known as the duty of candour.

Who is consulting?
The General Medical Council (GMC) and the Nursing and Midwifery Council (NMC) are independent organisations that help to protect patients and improve medical, nursing and midwifery education and practice across the UK.

- We decide which doctors, nurses and midwives are qualified to work here and we oversee their education and training.
- We set the standards that doctors, nurses and midwives need to follow, and help to make sure that they continue to meet these standards throughout their careers.
- We take action when we believe a doctor, nurse or midwife may be putting the safety of patients, or the public’s confidence in the medical, nursing or midwifery profession, at risk.

Every patient should receive a high standard of care. Our role is to help achieve that by working closely with doctors, nurses and midwives, with their employers and with patients, to make sure that the trust patients have in their doctor, nurse or midwife is fully justified.

What is the consultation about?
One of the ways we protect patients is by setting out the professional values, knowledge, skills and behaviours required of all doctors, nurses and midwives working in the UK.

The core professional standards are set out in Good medical practice\(^*\) for doctors and in The Code: Standards of conduct, performance and ethics for nurses and midwives for nurses and midwives.\(^\dagger\)
Both Good medical practice and the Code cover fundamental aspects of a doctor’s, nurse’s or midwife’s role, including working in partnership with patients and treating them with respect.

\(^*\) General Medical Council (2013) Good medical practice available at: www.gmc-uk.org/gmp (accessed 16 October 2014)

Both *Good medical practice* and the *Code* say that doctors, nurses and midwives must:

- be open and honest with patients if something goes wrong with their care
- act immediately to put matters right if that is possible
- promptly explain to patients what has gone wrong and the likely long-term and short-term effects.

This consultation is about providing more detailed guidance on these issues.

**So why is more guidance necessary?**

The Mid Staffordshire public inquiry identified the principles of openness, transparency and candour as the cornerstone of healthcare.

In his report,* Sir Robert Francis QC quoted from both *Good medical practice* and the *Code*, acknowledging that doctors and nurses are required by their regulators to be open with patients.

But he stated clearly that the current requirements for candour are not enough.

- They do not adequately cover the necessary areas: ‘individual clinical and managerial professionals, provider organisations and their collective leadership, in the NHS and the private sector, commissioners, regulators and political leaders’.
- The ways in which the requirement is currently recognised are ‘piecemeal and disjointed’.

The Department of Health (England), in response† to the recommendations in the Francis report, stated that:

‘the General Medical Council and the Nursing and Midwifery Council will be working with the other regulators to agree consistent approaches to candour and reporting of errors, including a common responsibility across doctors and nurses and other health professions to be candid with patients when mistakes occur whether serious or not’.

Eight regulators of healthcare professionals in the UK published a joint statement setting out the professional duty of candour on 13 October 2014. This statement recognises that all healthcare professionals have a common responsibility to be open and honest with patients when something goes wrong with their care.

As well as working with the other healthcare regulators on the joint statement, the GMC and NMC have been jointly developing guidance that expands on the advice given in *Good medical practice* and the *Code*.

**Why produce joint guidance?**

This is the first time we have collaborated in this way to develop common guidance for all the professionals on both of our registers.

Healthcare is usually provided by multidisciplinary teams, and we think it makes sense for doctors, nurses and midwives to be working to the same standards, particularly for a fundamental ethical principle like being open and honest when things go wrong.

---

How can I help?

We are asking doctors, nurses and midwives, and all other people interested or involved in our work, if we have got the guidance right. The consultation is open to anyone who wants to comment on the issues in the new draft guidance – this is your chance to have your say.

We would like to know whether the guidance is clear enough: we don’t want it to be difficult to put into practice because the wording is ambiguous.

We want to know if the guidance covers everything that it should: whether we’ve missed anything out, or whether we’ve included irrelevant or unhelpful information that detracts from the main message.

We also want you to tell us your ideas for how we could show how the guidance should work in practice. In the past we’ve used case studies (such as those in Good medical practice in action* and the NMC’s Raising concerns toolkit†) and other learning materials. But we’re sure there are numerous ways to show how the guidance should be interpreted in different situations.

As well as these questions, we would like to know your thoughts on two specific issues: apologising to patients or those close to them, and informing patients about near misses (when something goes wrong with patient care that could have led to harm but didn’t).

You may be aware that the GMC has been running another consultation – Reviewing how we deal with concerns about doctors‡ – that also covers the issue of doctors apologising to patients.

How do I take part?


What happens next?

We will analyse the responses to the consultation and consider how we should change the draft guidance to take account of all the comments we receive. We hope to publish the final guidance in March 2015.

However, while that consultation is on the role of apologies in our fitness to practise procedures, this consultation is about advice for professionals. Openness and honesty when things go wrong: the professional duty of candour is guidance for all doctors, nurses and midwives, advising them how to act as soon as they realise that something has gone wrong and a patient has suffered harm or distress.


‡ General Medical Council (2014) Reviewing how we deal with concerns about doctors available at: www.gmc-uk.org/concerns/25346.asp (accessed 29 October 2014)
Openness and honesty when things go wrong: the professional duty of candour

A draft for consultation
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. Healthcare professionals 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.

About this guidance

1 All healthcare professionals have a duty of candour – a professional responsibility to be honest with patients† when things go wrong. This is set out in The professional duty of candour, which prefaces this guidance and which forms part of a joint statement from eight regulators of healthcare professionals in the UK.

2 As a doctor, nurse or midwife, you must be open and honest with patients, with colleagues, and with your employers. If something goes wrong when you are providing care, you must report it whether or not it leads to actual harm.

3 This guidance builds on the joint statement from the healthcare regulators and gives more information about how to comply with the principles set out in Good medical practice and The Code: Standards of conduct, performance and ethics for nurses and midwives. Appendix 1 sets out relevant extracts from General Medical Council (GMC) and Nursing and Midwifery Council (NMC) guidance. It applies to all doctors registered with the GMC and all nurses and midwives registered with the NMC throughout the UK.

4 The guidance is divided into two parts.

a Your duty to be open and honest with patients, or those close to them, if something goes wrong, including advice on apologising (paragraphs 6–20).

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 21–30).

---


† When we refer to ‘patients’ in this guidance, we mean any people who are in your care.
Throughout the guidance we talk about your responsibilities towards patients or people in your care. We recognise that care is often provided by multidisciplinary teams and that you may be one of several healthcare professionals involved in a patient’s care. We would not expect every member of a healthcare team to talk to the patient. But you must make sure that an appropriate person – usually the lead or accountable clinician – takes responsibility for speaking to the patient or those close to them if something goes wrong.

**What to do if something goes wrong**

8 As soon as you recognise that something has gone wrong and a patient in your care has suffered physical or psychological harm or distress, you should do what you can to put matters right immediately.3, 4

9 You must then speak to the patient, unless you are sure that another, appropriate member of the healthcare team is taking on this responsibility.

10 You† should first tell the patient that something has gone wrong with their care and give them the opportunity to say they do not want to be given any more information. Most patients will want to know more about what has gone wrong. But, if the patient does not want more information, you should try to find out why. If, after discussion, the patient insists they do not want more information, 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 the patient that they can change their mind and have more information at any time.

---

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

**Do what you can before beginning treatment**

6 Patients in your care must be fully informed about all the elements of their treatment. When discussing treatment options with patients, you must discuss the risks as well as the benefits of any options.

7 You or an appropriate person* must have a clear and comprehensive conversation with the patient about risks. You should discuss risks that occur commonly, those that are serious, and those that the patient is particularly concerned about, so the patient is aware of the potential for adverse outcomes when giving consent to treatment or investigation.

---

* See paragraphs 26–27 of Consent: patients and doctors making decisions together.5
† When working in multidisciplinary teams, you must make sure that an appropriate person from the team – usually the lead or accountable clinician – is taking responsibility for talking to the patient or those close to them about what has happened. Not every member of a team will need to speak to the patient.
‡ 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.6
11 You should speak to patients as soon as possible after you realise something has gone wrong with their care, and you are able to give them some information about what has happened and the likely short-term and long-term effects. You should share all the information you have, explain if anything is still uncertain and respond honestly to any questions.7

Saying sorry

12 If someone in your care has suffered harm or distress because something has gone wrong, then you should apologise as soon as you become aware of this.8,9

13 When apologising to a patient – or those close to the patient – you should consider the following.

a You must share information in a way that the patient can understand and, whenever possible, in a place and at a time when they are best able to understand and retain it.

b You should give information that the patient may find distressing in a considerate way, and respect your patient’s right to privacy and dignity, making sure that conversations take place in appropriate settings where possible.

c Patients and those close to them are likely to find it more meaningful if you accept personal responsibility for something going wrong, rather than offer a general expression of regret about the incident.

d Patients and those close to them expect to be told three things as part of an apology:

i what happened

ii what can be done to deal with any harm caused

iii what will be done to prevent someone else being harmed.10

e You should make sure the patient knows who to contact in the healthcare team to ask any further questions or raise concerns.

f You should record the details of your apology in the patient’s clinical record.11,12 A verbal apology may need to be followed up by a written apology, depending on the patient’s wishes (or the wishes of those close to the patient), and your workplace policy.

14 If you do not feel able to apologise to the patient, or those close to them, with the required tact and sensitivity, you should:

a make sure that an appropriate member of the team takes on the responsibility to talk to the patient

b undergo training as soon as possible to develop your skills and experience in this area.
You do not have to wait until the outcome of an investigation to apologise to a patient, or someone close to them, when something has gone wrong. But you should be clear that the facts have not yet been established, tell them only what you know and believe to be true, and answer any questions honestly and as fully as you can.

Speaking to those close to the patient

15 You must show respect for, and respond sensitively to, the wishes and needs of bereaved people, 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 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.†, 18

16 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.*

17 You must use your professional judgement when considering whether to inform patients about near misses – adverse events that did not result in injury, illness, harm or damage, but had the potential to do so. Often there will be information that the patient would want or need to know about and, in these cases, you should talk to the patient about the near miss, following the guidance in paragraphs 8–15.

18 Some patients will want to be informed about near misses, and failure to be open could damage their trust in you and the healthcare team. However, in some circumstances, patients do not need to know about something that has not caused (and will not cause) them harm, and telling them may distress or confuse them unnecessarily. If you are not sure about whether to talk to a patient about a near miss, seek advice from a senior colleague.

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.

18 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.15

† 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 website16 and the PallCareNI website.17
Encouraging a learning culture by reporting errors

21 When things go wrong with patient care, the cause is usually either a flaw in an organisational system or human error. It is crucial that errors are reported at an early stage to put matters right and to learn any lessons so that future patients may be protected from harm.

22 Healthcare organisations should have a policy for reporting adverse incidents\(^\text{19}\) and you must follow your organisation’s policy. This means reporting incidents that lead to harm as well as reporting near misses: adverse incidents that did not result in injury, illness, harm or damage, but had the potential to do so.

23 A number of reporting systems and schemes exist around the UK for reporting adverse incidents and near misses.

\(a\) Adverse events and patient safety incidents in England and Wales are reported to the National Reporting and Learning System.\(^\text{20}\)

\(b\) 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.\(^\text{21}\)

\(c\) You must report adverse incidents involving medical devices to the UK-wide MHRA reporting system.\(^\text{22}\)

\(d\) Healthcare Improvement Scotland has instigated a national framework,\(^\text{23}\) which outlines consistent definitions and a standardised approach to adverse event management across National Health Service (NHS) for 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.\(^\text{24}\)

24 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 29–30 on the organisational duty of candour). If your organisation does not have such a system in place, you must speak to your manager and raise the concern in line with our guidance.\(^\text{25, 26}\)

25 You must take part in regular reviews and audits\(^\text{27, 28}\) of the standards and performance of any team you work in, taking steps to resolve any problems.
**Additional duties for doctors, nurses and midwives with management responsibilities and for senior or high profile clinicians**

26 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.

27 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.

28 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 learned from analysing adverse incidents and near misses
      - lessons are shared with the healthcare team
      - concrete action follows on from learning
      - practice is changed where needed.

**The organisational duty of candour**

29 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 is considering ways to implement the organisational duty of candour, with some writing it into law (see appendix 2).

30 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 and, if necessary, escalate your concern in line with our guidance on raising concerns.25, 26
Appendix 1: Extracts from GMC and NMC guidance that are referenced in this guidance

**From Good medical practice**\(^{139}\)

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 effects.

**From Raising and acting on concerns about patient safety**\(^{25}\)

13 Wherever possible, you should first raise your concern with your manager or an appropriate officer of the organisation you have a contract 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.

Also see the raising concerns decision making tool on the GMC website.\(^{31}\)

**From Leadership and management for all doctors**\(^{30}\)

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.

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
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.

what you and the rest of the healthcare team know about the patient’s wishes, feelings, beliefs and values.

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: Standards of conduct, performance and ethics for nurses and midwives

Preserve Safety
Nurses and midwives seek to ensure that patient and public safety is not compromised, working within the limits of your competence, exercising your professional duty of candour and raising concerns immediately whenever you encounter situations that put patients or public safety at risk.

14 Exercise candour and be transparent with all service users about all aspects of care and treatment, including when any errors have occurred.

To achieve this, you must:

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

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

14.3 document all such events formally and escalate them as appropriate to enable them to be acted on quickly.

19 Be aware of, and minimise, any potential for harm associated with your practice.

To achieve this, you must:

19.1 consider how you can take measures to minimise the likelihood of errors, near misses and the impact of harm if it occurs.

19.2 take account of current evidence, knowledge and developments in the reduction of human errors and the impact of human factors and system failures as contributory factors to errors.
Glossary

**Candour** – the ‘professional duty of candour’ is defined in the joint statement from the chief executives of statutory regulators of healthcare professionals entitled ‘Openness and honesty - the professional duty of candour’ published in October 2014 as follows:

“The Professional Duty of Candour

Every healthcare professional must be open and honest with patients when something goes wrong with their treatment or care which 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); and
- 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. Health and care professionals 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.”

**Near miss** – an unplanned event that did not result in injury, illness, harm or damage but had the potential to do so.

Appendix 2: Variations in the organisational duty of candour across the UK

**England**

The Care Quality Commission is putting in place a new requirement for healthcare providers to be open with patients and apologise when things go wrong. This duty will initially apply to NHS healthcare bodies and will later be brought in for all other registered providers. 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 ensuring that staff understand the duty and are appropriately trained.

**Northern Ireland**

The Department for Health, Social Services and Public Safety is considering whether a statutory duty of candour is required. Professor Sir Liam Donaldson, former Chief Medical Officer for England, has been appointed to carry out an expert examination of whether governance arrangements ensure a high quality of health and social care. As part of the review, which is due to report by the end of 2014, Professor Donaldson has been asked to examine the Health and Social Care (HSC) Public Health Agency’s:

- openness and transparency
- appetite for enquiry and learning
- approach to redress and making amends.

The examination will focus mainly on systems in trusts and across the HSC Public Health Agency that support identifying, reporting, investigating and learning from adverse incidents.
The examination will also consider the openness of the related processes in and across organisations, particularly with service users and their families who are most affected by individual incidents.

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 (SPSP) is a national initiative that aims to improve the safety and reliability of healthcare and reduce harm.

On 15 October 2014, the Scottish Government launched a consultation on a duty of candour for organisations providing health and social care, including health boards. The consultation, which covers disclosure, support, training and reporting, closes on 14 January 2015.

Wales

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 place a number of duties on responsible bodies. 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 has committed to making this organisational duty more explicit, in light of both the Francis report and the Robert Powell Investigation.

References


2. Nursing and Midwifery Council (draft, following consultation, as of October 2014, due for publication 2015) The Code: Standards of conduct, performance and ethics for nurses and midwives pp 7–8 and 18


4. Nursing and Midwifery Council (draft, following consultation, as of October 2014, due for publication 2015) The Code: Standards of conduct, performance and ethics for nurses and midwives p 6


8. Nursing and Midwifery Council (draft, following consultation, as of October 2014, due for publication 2015) The Code: Standards of conduct, performance and ethics for nurses and midwives p 9


11 Nursing and Midwifery Council (draft, following consultation, as of October 2014, due for publication 2015) *The Code: Standards of conduct, performance and ethics for nurses and midwives* paragraph 86

12 General Medical Council (2013) *Good medical practice* available at: www.gmc-uk.org/gmp (accessed 16 October 2014), paragraph 21c

13 Nursing and Midwifery Council (draft, following consultation, as of October 2014, due for publication 2015) *The Code: Standards of conduct, performance and ethics for nurses and midwives* paragraphs 33, 101 and 105

14 General Medical Council (2013) *Good medical practice* available at: www.gmc-uk.org/gmp (accessed 16 October 2014), paragraphs 33, 65 and 68

15 General Medical Council (2013) *Good medical practice* available at: www.gmc-uk.org/gmp (accessed 16 October 2014), paragraph 34


17 PallCareNI *Understanding Palliative and End of Life Care* available at: www.pallcareni.net (accessed 21 October 2014)

18 General Medical Council (2010) *Treatment and care towards the end of life: good practice in decision making* available at: www.gmc-uk.org/endoflife (accessed 16 October 2014), paragraph 84


27 Nursing and Midwifery Council (draft, following consultation, as of October 2014, due for publication 2015) *The Code: Standards of conduct, performance and ethics for nurses and midwives* paragraph 47


29 Nursing and Midwifery Council (draft, following consultation, as of October 2014, due for publication 2015) *The Code: Standards of conduct, performance and ethics for nurses and midwives* paragraphs 6 and 9–10


32 Nursing and Midwifery Council (draft, following consultation, as of October 2014, due for publication 2015) *The Code: Standards of conduct, performance and ethics for nurses and midwives*


Questions about the draft guidance
Our draft guidance *Openness and honesty when things go wrong: the professional duty of candour* is available on pages 4–17. Both *Good medical practice* and the *Code* say that doctors, nurses and midwives must:

- be open and honest with patients if something goes wrong with their care
- act immediately to put matters right if that is possible
- promptly explain to patients what has gone wrong and the likely long-term and short-term effects.

**Question 1: Is it helpful to have additional guidance on this issue?**

[ ] Yes  [ ] No  [ ] Not sure

Comments

**Question 2: How easy is this guidance to understand?**

[ ] Very easy  [ ] Quite easy  [ ] Quite difficult  [ ] Very difficult  [ ] Not sure

Comments
The content of the draft guidance is divided into the following sections:

- About this guidance
- Being open and honest with patients in your care, and those close to them, when things go wrong
  - Do what you can before beginning treatment
  - What to do if something goes wrong
  - Saying sorry
  - Speaking to those close to the patient
  - Being open and honest with patients about near misses
- Encouraging a learning culture by reporting errors
- Additional duties for doctors, nurses and midwives with management responsibilities and for senior or high profile clinicians
- The organisational duty of candour
- Appendix 1: Extracts from GMC and NMC guidance that are referenced in this guidance
- Appendix 2: Variations in the organisational duty of candour across the UK

**Question 3:** Do you think there is anything else that the guidance should cover?

☐ Yes  ☐ No  ☐ Not sure

Comments

**Question 4:** Is there anything you think could be removed from the guidance?

☐ Yes  ☐ No  ☐ Not sure

Comments
**Question 5:** Do you have any ideas about how we could illustrate how the guidance works in practice (e.g., case studies or decision tools)?

---

**Apologising to patients or those close to them**

In paragraphs 12–15 of the draft guidance, we give advice about how and when a doctor, nurse or midwife should apologise to patients and those close to them. Patients tell us that it can make a big difference to them if they receive a sincere, prompt, face-to-face apology, and if the healthcare professional accepts a degree of personal responsibility for the error. A generic written apology from the organisation about the incident might leave a patient or their loved ones feeling frustrated and powerless.

**Question 6:** Do you think there is anything else that doctors, nurses and midwives should consider when apologising to patients or those close to them?

[ ] Yes  [ ] No  [ ] Not sure

Comments
Reporting near misses to patients

Doctors, nurses and midwives have a duty to report adverse incidents (when something goes wrong with patient care, causing harm) as well as near misses (adverse events that did not result in injury, illness, harm or damage, but had the potential to do so). It’s important that near misses are reported so that all healthcare professionals can learn from them and prevent harm to other patients.

The professional duty of candour towards patients applies only when the patient suffers harm or distress because something has gone wrong. The duty does not currently apply to near misses: one of the questions we are asking now is whether it should.

In paragraph 19 of the draft guidance, we say that the decision whether to tell a patient about a near miss is for a doctor, nurse or midwife to make using their professional judgement, and taking into account the individual circumstances of the case:

‘You must use your professional judgement when considering whether to inform patients about near misses’.

There are some circumstances in which patients would benefit from knowing about near misses so that they can take steps to reduce the likelihood of them happening again and possibly causing them harm. But there are other circumstances where a patient would not benefit from knowing about a near miss and may find it distressing or confusing to be told about it.

Leaving the decision whether to disclose a near miss to professional judgement leaves open the possibility that some doctors, nurses and midwives will decide not to tell any patients about near misses, while others may tell patients about all near misses, even if this isn’t necessary. If a patient were to find out later about a near miss they hadn’t been told about, it could damage their trust in their doctor, nurse or midwife.

We believe that we could best illustrate how to use professional judgement when making decisions in these circumstances through learning materials (eg case studies in Good medical practice in action and the NMC’s Raising concerns toolkit) rather than including more detail in the guidance. But we’d like to know what you think.

Question 7: To what extent do you agree that patients should always be told about near misses?

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree ☐ Not sure

Comments
Question 8: Do you have any other comments or suggestions about the draft guidance?

☐ Yes  ☐ No  ☐ Not sure

Comments
We would be very grateful if you could give us some information about you to help us analyse the responses to the consultation.

Q1. Are you responding as an individual or on behalf of an organisation?
   - As an individual. Go to Q2
   - On behalf of an organisation. Go to Q13
Responding as an individual

Q2. Which of the following categories best describes you?

- Doctor
- Midwife
- Nurse educator
- Medical student
- Midwifery student
- Employer or manager (in healthcare)
- Other (please give details) ____________________________________________________________________

- Nurse
- Medical educator (teaching, delivering or administering)
- Midwife educator
- Nursing student
- Member of the public
- Other healthcare professional

DOCTORS, NURSES AND MIDWIVES ONLY

Q3. What is your current employment status: (Tick one or more)

- Registered but not practising. Go to Q6
- Permanent employment/fixed term. Go to Q4
- Self-employed. Go to Q4
- Voluntary. Go to Q4
- Agency. Go to Q4
- Other (please give details). Go to Q4 _______________________________________________________

Q4. What is your current practice setting: (tick one or more)

- NHS
- Independent/voluntary
- Other
Q5. Which of the following categories best describes your current practice? (Tick one or more areas that best describe the area you practise in)

- Direct patient care
- Management
- Education
- Policy
- Research
- Other (please give details) ________________________________

Q6. Please tick ONE box which best describes the type of organisation you work for:

- Government department or public body
- Regulatory body
- Professional organisation or trades union
- NHS employer of doctors, nurses or midwives
- Independent sector employer of, or agency for, doctors, nurses or midwives
- Education provider
- Consumer or patient organisation
- Other

Q7. Could you please tick the box below that most closely reflects your role?

- General practitioner
- Consultant
- Doctor in training
- Staff and associate grade (SAS) doctor
- Medical director
- Other hospital doctor
- Sessional or locum doctor
- Other medical manager
- Other (please give details) ________________________________

Q7a. Could you please tick the box(es) below that most closely reflect your role?

- Adult nurse
- Mental health nurse
- Learning disabilities nurse
- Children's nurse
- Health visitor
- Occupational health nurse
- Family health nurse
- Specialist community public health nurse
- Other (please give details) __________________________________________
To help make sure that our consultations reflect the views of the diverse UK population, we aim to monitor the types of responses we receive to each consultation and over a series of consultations. Although we will use this information in the analysis of the consultation response, it will not be linked to your response in the reporting process.

**ALL INDIVIDUALS**

Q8. **What is your country of residence?**

☐ England  ☐ Northern Ireland  ☐ Scotland  ☐ Wales

☐ Other – European Economic Area

☐ Other – rest of the world (please say where) ________________________________________________

Q9. **What is your age (years)?**

☐ <25  ☐ 25–34  ☐ 35–44  ☐ 45–54  ☐ 55–64  ☐ ≥65

Q10 **Are you:**

☐ female  ☐ male

Q11 **Would you describe yourself as having a disability?**

☐ Yes  ☐ No  ☐ Prefer not to say
Q12. **What is your ethnic origin?** (Please tick one) Then go to Q20

**Asian or Asian British**

- [ ] Bangladeshi
- [ ] Chinese
- [ ] Indian
- [ ] Pakistani
- [ ] Any other Asian background (please specify)  _________________________________________________

**Black or black British**

- [ ] African
- [ ] Caribbean
- [ ] Any other black background (please specify)  _________________________________________________

**Other ethnic group**

- [ ] Any other ethnic group (please specify)  ________________________________________________

**Mixed or multiple ethnic groups**

- [ ] White and Asian
- [ ] White and black African
- [ ] White and black Caribbean
- [ ] Any other mixed or multiple ethnic group (please specify)  ________________________________

**White**

- [ ] British (English, Scottish or Welsh) or Northern Irish
- [ ] Irish
- [ ] Any other white background (please specify)  ___________________________________________
Responding as an organisation

Q13. Which one of the following categories best describes your organisation?

- [ ] Body representing doctors
- [ ] Body representing nurses or midwives
- [ ] Body representing patients or the public
- [ ] Government department
- [ ] Independent healthcare provider
- [ ] NHS or HSC organisation
- [ ] Undergraduate medical, nursing or midwifery education provider
- [ ] Postgraduate medical, nursing or midwifery education provider
- [ ] Regulatory body
- [ ] Other (please give details)

Q14. In which country is your organisation based?

- [ ] UK wide
- [ ] England
- [ ] Scotland
- [ ] Northern Ireland
- [ ] Wales
- [ ] Other – European Economic Area
- [ ] Other – rest of the world (please give details)

Q15. Please give the name of your organisation

____________________________________________________________________________________________

Q16. Would you be happy for your comments in this consultation to be identified and attributed to your organisation in the reporting, or would you prefer that your response remains anonymous?

- [ ] Happy for comments to be attributed to my organisation
- [ ] Please keep my responses anonymous

All respondents

Many thanks for completing the questionnaire. If you have printed this document please scan and email to 9705nmc@alpharesearch.co.uk or post to Alpha Research Ltd, Robert House, 19 Station Road, Chinnor, Oxon OX39 4PU. Please note that the survey closes on 5 January 2015. If you would like to be informed about future consultations from the GMC and NMC please provide your email address here.

Q20. Email address: ____________________________________________________________________________
A blog by Dr Toby Reynolds about PatientFirst workshop

Heading title

1 This blog, written by GMC Clinical Fellow Dr Toby Reynolds, was published following a workshop on the professional duty of candour – and, in particular the consultation on new draft guidance Openness and honesty when things go wrong – at the PatientFirst conference on 26 November 2014.

2 The draft explanatory guidance was developed jointly with the Nursing and Midwifery Council who were unable to send a representative to attend the workshop. However, we did have input from the Care Quality Commission: Alex Baylis, Head of Acute Sector Policy talked about the CQC’s newly published Guidance for NHS bodies.

Openness is catching

Toby Reynolds reports back from an interactive session on ‘Openness and honesty: the professional duty of candour’ at the Patient First conference 2014

3 Like most doctors I am very worried by the idea of avoidable harm in medicine. Recent decades have brought unprecedented advances in treatment through research and innovation. Yet unfortunately many of our patients still suffer harm that could have been prevented. Clinical work is fraught with opportunity for error, either by individuals or systems. To do the best for our patients, we need to acknowledge that mistakes can happen, and do more to improve the way we learn from them, as individuals and as organisations. Although there are many areas in which we do this well, we still lag behind other safety-critical industries and have much work to do.

4 Much has been written about what sort of change is needed, but a good place to start is the culture, or some would say climate, in which we work. An open and honest culture allows teams to recognise and acknowledge the potential for error, learn lessons from mistakes and prevent them happening again. A closed, secretive culture motivated by fear of blame will stifle learning, both individually and across the healthcare system.
Simple as it may sound, creating an open safety culture is no easy task and will require action on many different fronts. One area in which the GMC has a contribution is by setting professional standards, specifically the draft guidance on Openness and honesty: the professional duty of candour, which has drawn on the findings of the Mid Staffordshire Inquiry and which we have developed in collaboration with the NMC.

We are currently consulting on this guidance and, as part of our consultation, last month some GMC colleagues and I ran a workshop on openness at Patient First, a national patient safety conference held at the Excel centre at London’s Docklands, which the CQC also attended.

We tried to explore some of the areas where implementing the guidance would be difficult. Setting the scene, and demonstrating how much ground there is to make up, we heard that the majority of those present (some 200 people, an even split between doctors and nurses with a few patient representatives) felt that their workplaces had some way to go in complying with the duty of candour.

We heard that one important barrier to openness, both with patients and between healthcare providers, was fear: fear of blame, even fear of litigation, but also fear of acknowledging personal fallibility. We heard too that the current working culture and attitudes have been heavily influenced by the past when secrecy and defensiveness were the norm, at least with regards to those outside the team.

Leading by example

Good leadership has a crucial role to play here: as one delegate put it “openness is catching”. An example set at the top of an organisation can both mitigate the fear of blame, and demonstrate how the good clinician is not necessarily the one who doesn't seem to make any mistakes, but the one who learns from experience and helps make sure others do too.

Fear of talking to patients about errors is commonly cited as a barrier, but we heard that patients had reacted very positively to greater openness when they were told about changes made to address problems, as well as the problems themselves. “Our patients are proud of the change that happens from incidents,” was one comment.

Feedback is important in all change, and we heard there was work to be done to reinforce the benefits of an open safety culture. “Clinicians do not see the learning from near misses and incidents, they only see their own practice and do not see the bigger picture,” was a common theme.

Resources also came up in our conversation. We heard that there is often little acknowledgement in work planning of the time required for individual professionals to report incidents and hold meetings with patients.
Multidisciplinary safety meetings, such as morbidity and mortality meetings in surgery and other specialties, often suffer from inadequate resources, as do team training initiatives to improve safety awareness and inter-professional communication.

The difficulty of broaching conversations about mistakes, near misses and adverse events was also specifically raised. We heard that this was a barrier to openness, but also that openness was a skill that could be learned. We heard of “disclosure coaches”, senior clinician mentors who advise other clinicians about how to carry out disclosure conversations with patients and their families as well as with colleagues, and how they had helped others develop openness in their practice.

These barriers will all need addressing, within the context of a healthcare system that is currently under great stress. But my overall impression from the session was that, although there is a long way to go, we can do a lot simply by being open about our own mistakes, and by communicating better the positive impact of openness in healthcare.

In the spirit of fostering this open safety culture I would be keen to hear your thoughts about what we could do as a profession in the comments below.

Toby Reynolds is a trainee in anaesthesia from North East London, currently placed at the GMC for a year through the National Medical Director’s Clinical Fellow Scheme. He is writing this blog in his personal capacity, rather than as a representative of the GMC.

18/12/2014 · by tobyreynolds2 · in Ethical guidance, Medical professionalism ·
Note of a workshop with patient representatives to discuss the consultation on draft guidance, *Openness and honesty when things go wrong: the professional duty of candour*

**Those present**

Maeve Hully  Patient & Client Council in Northern Ireland  
Katherine Murphy  The Patients’ Association  
Liz Thomas  Action against Medical Accidents  
Dr Toby Reynolds  General Medical Council  
Yael Bradbury  General Medical Council

**A summary of key points raised during discussion**

**Communication**

1. All three patient representatives agreed on the need for better communication by doctors:

   - Communication is the issue that comes up most often on the Patients’ Association patient helpline in relation to doctors. A common complaint is that doctors don’t make eye contact and, when asked a difficult question, excuse themselves and don’t return.

   - The impression given is that doctors are always thinking about litigation.

   - It was felt that nurses’ communication skills had ‘recently improved’ but that doctors still had work to do around communicating before they could be open and honest about errors with patients since it can make the patient feel even worse if it’s done badly.
2 It was agreed that it was important not to give patients misinformation, whether deliberate or not

**Definition of an error**

3 It was questioned whether it’s important to define what an error is, or whether it’s more important to focus on the fact that harm and distress had been caused.

4 It was accepted that there may often be ‘shades of grey' between whether an adverse incident was an error or a complication. Does the fact that a doctor discussed it with the patient beforehand make a difference to the way s/he talks to the patient about it?

**Assumption of openness**

5 All three attendees agreed that the default position should be that the patient should be told about things that have gone wrong with their care, even if they are not harmed by it. Circumstances will affect whether the patient is ultimately told, eg if they’ve previously expressed a preference not to know the details of their care, or if it is judged certain that it would be far more distressing to learn about a near miss than not, and there was nothing that could be gained from it. But the default must be openness. It would be uncomfortable if a group of clinicians were talking about an error that occurred to a patient without the patient knowing about it themselves.

6 Openness across all members of the healthcare team is very important.

**Anonymous reporting ‘a step backwards’**

7 It was agreed that an anonymous reporting system would feel like a step backwards. If a training need were identified there would be no way of following it up.

8 The National Reporting and Learning System (NRLS) gave some idea of the scale of the problem but would not tackle the root cause. An anonymous reporting system would likely have a similar outcome.

**There must be a link to Fitness to practise action**

9 The Patients’ Association have been working with CQC, reviewing cases that had been closed without following up concerns around communication.

10 It was recognised that the guidance has to be expressed as a positive, encouraging doctors, nurses and midwives to implement it. But it was felt that there should be a clear message behind this that Fitness to Practise action would occur if the guidance was breached.
Errors in primary care

11 It was felt that GPs made a lot of prescribing errors, which pharmacists often picked up.

Support for patients

12 Patients would need support and care after doctors or nurses had ‘discharged’ their duty of candour and the patient had been informed about what had gone wrong, that the patient must not just be left ‘adrift’.

www.gmc-uk.org