Implementing the contractual requirements relating to the Duty of Candour

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NHS STANDARD CONTRACT 2013-2014 TECHNICAL CONTRACT GUIDANCE

Annex 4

Implementing the contractual requirements relating to the Duty of Candour

1. Of primary concern is ensuring that patients/their families are told about patient safety incidents that affect them, receive appropriate apologies, are kept informed of investigations and are supported to deal with the consequences.

2. The contractual duty of candour applies to patient safety incidents that occur during care provided under the NHS Standard Contract and that result in moderate harm, severe harm or death (using NPSA definitions (1)) that are reported to local risk

management systems. It will not apply to low/no harm incidents to avoid excessive burdens but these incidents should still be reported to the patient if appropriate.

3. There should be an appropriate investigation to establish the facts of the incident. This should be consistent with published guidance2 and the procedures set out in SC35.

4. The contractual requirements are as follows;

I. The patient or their family/carer must be informed that a suspected or actual patient safety incident has occurred within at most 10 working days of the incident being reported to local systems, and sooner where possible. Incidents may be identified well after they take place but the clock starts ticking when the incident is reported to local risk management systems.

11. The initial notification must be verbal (face to face where possible) unless the patient cannot be contacted in person or declines notification. Providers must take into account any circumstances that will affect the ease of communication with the patient (language barriers, communication difficulties, relevant disability).The verbal notification must be accompanied by an offer of a written notification. The notification must be recorded for audit purposes.

III. It may initially be unclear whether a patient safety incident has occurred, or what degree of harm was caused. This is not a reason to avoid disclosure. Patients or their carers/families must be told if there is a suspected patient safety incident

that might involve moderate or severe harm or death within 10 working days of the incident being reported. They should be given all the facts that are known at the time, and be kept updated throughout the process of investigation.

IV.. An apology must be provided - a sincere expression of sorrow or regret for the harm caused must be provided verbally and in writing. This does not require fault to have been demonstrated. *Being Open3* provides more detail on how to apologise. Expressing regret for harm caused is not the same as admitting liability and the risk of litigation should not prevent an apology.

V. A step-by-step explanation of what happened, in plain English, based on the facts, must be offered as soon as is practicable. This may constitute an initial view, pending an investigation, but patients and families must be kept informed ofprogress.

1 Definitions for levels of harm are contained in *Seven Steps to Patient Safety,* available at http://www.nrls.npsa. nhs. uk/resources/collections/seven-steps-to-patientsafety/? entryid45=59787

2 Root Cause Analysis report writing and templates, available at http://www. nrls. npsa. nhs. uklresources/all-settings-specialties/?entryid45=5984 7&p=3

3 *Being Open,* available at http://www.nrls.npsa.nhs.uklresourcesI?EntryId45=83726

VI. Full written documentation of any meetings must be maintained, according to the principles in the *Being Open* guidance. If the patient or their family/carer explicitly decline any offers of meetings, this must be clearly

recorded and open
to audit.

VII. Information that emerges during an investigation or subsequent to the initial explanation must be offered to patients and their carers/families as soon as is practical. It is helpful to establish regular updates with affected individuals. Any incident investigation reports must be shared **within 10 working days of being signed off as complete and the incident closed** by the relevant authority(Board, Medical Director, commissioner etc.). This includes action plans and the details of investigations and means the actual written reports and, if necessary, plain English explanations of their contents.

VIII. Providers should inform the patient's commissioner (and lead commissioner if appropriate) when they are communicating with a patient and their family/carers about an incident. To reduce the burden of reporting this could take the form of regular reports on the number of incidents concerned as part of the 6-monthly contract review process or other contractual discussions. Providers must be able to provide copies of the documentation and information given to the patient and their family/carer to their commissioner if necessary, to demonstrate compliance with contractual requirements, ensuring data protection and Caldicott principles are observed.

5. There may be circumstances where a patient safety incident is not reported to local risk management systems, but commissioners become aware that it has occurred through other means. These incidents (if

resulting in moderate or severe harm or death) are also subject to the contractual duty of candour and, in addition, may represent further failures in reporting. Incidents that have not been reported are, by their nature, harder to detect and verify. In the first instance, they should be raised with the relevant provider. Where a relevant patient safety incident is found to have occurred and not been reported to either the patient or local systems in breach of existing requirements, this should be treated extremely seriously. Commissioners should consider referral to CQC for breach of registration requirements in the case of serious incidents and deaths.

Identification of a breach

6. A breach is a failure to comply with the steps in the Contract clauses as expanded above. Commissioners should establish and advertise to local clinicians, HealthWatch groups and providers the existence of a contact point within the commissioner for raising potential breaches of the contractual requirement. This may be part of the commissioner's existing complaints handling team or the commissioning function with responsibility for quality of care or patient experience. This should also be the point of referral from providers' complaints handling processes.

7. Providers should notify their commissioners when a complaint they receive includes reference to a failure to disclose a patient safety incident to. Providers should not establish separate complaints processes for failures of disclosure.

8. Clinicians, local Healthwatch organisations and anyone else with concerns about a failure to disclose a patient safety incident to a patient/their family can choose to raise the concern with the relevant provider or commissioner. The provider must notify the commissioner of any concerns/complaints reported to it.

9. Concerns from clinicians, local Healthwatch organisations, the public or via the provider's complaints process, about failures of disclosure, should prompt the commissioner to investigate to determine if the circumstances represent a breach of the above requirements. This will involve determining if a patient safety incident involving the patient concerned is recorded on the local risk management system and whether there are records of any disclosure.

10. Where an incident is alleged to have occurred, but has not been reported to local risk management systems, it will be difficult to confirm whether it has happened. Where it is thought that an incident occurred but has not been reported, commissioners should undertake a review of the case notes and any further investigations required to establish the facts. Commissioners will need to balance the importance of enforcing the contractual duty with other burdens placed on them when deciding how vigorously to investigate an allegation. While they may not pursue an allegation for which there is little evidence, repeated allegations from different sources should prompt greater scrutiny.

11. There are likely to be circumstances where allegations about a lack of openness relate to an organisation's overall perceived behaviour. The contractual duty of candour is not designed to deal with general perceptions about how transparent an organisation is. The contractual duty of candour relates to specific reportable patient safety incidents and their disclosure to the patient or their family. If there is no evidence a patient safety incident has occurred involving moderate harm or worse, to a patient, the contractual duty of candour is not relevant.

12. An explanation of the commissioner's investigation of the potential breach, their findings, details of any action taken, or an explanation for why no action is being taken, should be provided to the source of the notification.

Consequences of a breach of the requirement

13. There are a range of actions available to commissioners where a provider breaches the requirement. These are set out in SC35:

• requiring a direct written apology and explanation for the breach to the individual(s) affected from the provider's chief executive:

• publication of the fact of a breach prominently on the provider's website;

• notification to CQC by the commissioner.

14. Where there is a breach of the national quality requirement to notify patients/ carers of a suspected or actual patient safety incident that resulted in moderate or

severe harm or death, then commissioners must apply the nationally set consequence i.e. recovery of the cost of the episode of care or £10000 if the cost of the episode of care is unknown.

15. It is likely that circumstances will arise which are not covered by this guidance. Where a situation does not fall within the circumstances described above, commissioners should also refer to the *'Being Open'* guidance for more detailed -guidance on what providers should be doing. Concerns raised about a provider may not be covered by the specific details of the contractual requirement, but failure to follow the principles in *Being Open* may indicate wider failures in the provision of care, which are subject to other contractual requirements around quality or safety, or indeed regulatory requirements set by COC.

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