

Regulating the duty of candour

A report by Action against Medical Accidents on
CQC inspection reports and regulation of the duty of candour

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1. Introduction

Action against Medical Accidents (AvMA) is the independent charity for patient safety and justice. For over 30 years AvMA has provided specialist independent advice and support to people who have been affected by medical accidents ('patient safety incidents') that are believed to have caused harm.

We have consistently encountered a lack of timely, open and honest explanations from some healthcare providers to patients or their families, setting out what had happened and why. AvMA, therefore, campaigned vigorously for a legal or statutory 'duty of candour', which is a duty to be open and honest with patients/families when there has been a medical accident. The family of Robbie Powell (deceased) and in particular his father Will Powell has done more than any individual to establish the need for the duty of candour at great personal sacrifice. The absence of a statutory duty of candour was first exposed in 1996 during the civil case of Robbie Powell who died as a consequence of medical negligence in 1990.

AvMA was a core participant in the Mid Staffordshire NHS Foundation Trust public inquiry. Evidence provided by AvMA helped persuade Sir Robert Francis QC to recommend a statutory duty of candour and AvMA worked hard to persuade the Government to accept the central recommendation, which it eventually did.

The duty of candour referred to in this report is the statutory duty which applies to organisations in England which are registered with the Care Quality Commission (CQC) to provide health or social care.

In November 2014 the Government amended the Health and Social Care Act 2008 to enshrine the duty of candour in law for all NHS bodies in England. The provision is contained in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20. It became one of the 'fundamental standards' recommended by Sir Robert Francis.

The CQC is responsible for monitoring compliance with the duty of candour regulations when registering providers of health and social care and as part of their ongoing monitoring and inspection process. The CQC has also published guidance to help providers understand what is expected in order to meet the standard.

The CQC has statutory powers to take regulatory action over non-compliance with the duty of candour. These include refusal or removal of registration; warnings; special measures; fines; and, in certain circumstances, criminal prosecution. In May 2015 duty of candour legislation was extended to cover primary care (GPs, dentists, pharmacists), private healthcare providers and adult social care.

AvMA remains committed to doing all that we can to ensure that the duty of candour is complied with and implemented well. We wish to ensure robust monitoring of compliance and appropriate action taken against substandard practice. We therefore decided to conduct this review of the CQC's reports on inspections of NHS bodies which took place throughout 2015. We hope our findings will inform how the CQC takes forward its monitoring and inspection of compliance with the duty of candour and help promote good practice.

We used CQC reports from 2015 to gain insight into the duty of candour's regulation and implementation during the legislation's first full calendar year. CQC reports provide a record of inspectors' approaches to assessing and enforcing compliance with the duty of candour. The reports are also our best available source regarding how well healthcare providers have carried out their new duty of candour. Relying on inspection reports, however, does mean we are limited to the second-hand interpretation and the often patchy consideration of the duty of candour by the inspectors.

It should be noted that this study only looks at reports of inspections carried out during 2015. During the course of our study we met with CQC staff with responsibility for the duty

of candour and were pleased to contribute to plans for making the approach to assessing duty of candour compliance more consistent later in 2016. We plan to carry out a similar study at the end of 2016/beginning of 2017 to see how much of a difference this has made.

About the duty of candour

Duty of candour legislation states that registered persons must act in an open and honest manner with a patient or relevant contact, be that a relative, friend or nominated individual, when a 'notifiable safety incident' has resulted in death, serious harm, moderate harm, or psychological harm lasting 28 days or longer. In accordance with the legal duty of candour, the registered provider must:

- As soon as practically possible notify the relevant person of the incident
- Offer an apology
- Provide reasonable support following the incident, including helping to find out the reasons for the accident

The notification must:

- Be given in person
- Provide an accurate and full account of the incident to the best of the registered person's understanding
- Advise the relevant person of what further enquiries into the incident the registered person believes are necessary; any results of the further enquires must be passed on to the patient or relevant contact
- Include an apology
- Be recorded in writing; a written copy must be given to the registered person

The duty of candour applies where an incident appears to have or could result in 'significant harm'. Significant harm is defined as 'moderate

harm' or worse using definitions in use in the NHS in England. This includes:

Death

Serious harm: a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage. Harm is a direct result of the mistake, rather than a natural consequence of the patient's existing illness or injury.

Moderate harm: results in an unplanned return to surgery, a transfer to another treatment area, for example, intensive care, an unplanned readmission as an inpatient or outpatient, or prolonged pain which will, or is likely to, last for a continuous period of at least 28 days.

Psychological harm: any psychological harm with which will, or is likely to, last for at least 28 days.¹

AvMA has produced a leaflet (endorsed by the CQC) which explains the duty of candour in simple terms. This can be found at the back of this report (Appendix 3) Full details of the duty of candour regulations and guidance can be found on the CQC website, using the link provided here:

www.cqc.org.uk/duty-candour

2. Methodology

We looked at reports of inspections undertaken during 2015 to see how the CQC and NHS bodies responded to the new legislation.

According to the CQC website, it was set up to 'monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety' and the CQC says 'we publish what we find, including performance ratings to help people choose care'.²

1 www.cqc.org.uk/content/regulation-20-duty-candour#full-regulation, viewed 01/04/2016

2 www.cqc.org.uk/content/what-we-do, viewed 11/03/16

CQC inspections are the major means that the CQC uses to check that registered organisations are safe and compliant with their regulations overall, and as part of this reports indicate how inspectors have reassured themselves that NHS bodies are complying with the duty of candour. The reports show what the inspectors have looked for, how much detail they have sought, and how rigorously they have expressed any need for improvement.

While the reports do give us some idea of how well the NHS bodies under scrutiny have carried out their duty of candour, we must remember that by drawing our evidence from CQC reports, we are relying on the inspectors' interpretation and reporting. It is possible that duty of candour was explored in more depth and that the registered organisation was doing much more about it than is reflected in the reports. However, as the duty of candour was such a high-profile innovation and one of the eight 'fundamental standards' agreed after the Mid Staffordshire public inquiry, we make the assumption that it would be given serious attention in the inspections carried out in 2015 and would be reflected in the reports.

Our first task was to generate a sample. By focussing our research on NHS bodies, specifically hospital trusts, we created a sample large enough to draw conclusions, but manageable enough to analyse. For ease of comparison we studied hospitals and excluded other healthcare institutions such as GP surgeries and dentists.

See Appendix 1 for the full list of CQC inspection reports on which this report is based.

Our sample consists of 90 reports, which communicate the findings of inspections that took place between 1 January and 31 December 2015 and had been published by the CQC at the time of compiling our report.

Readers will notice that the CQC often publishes reports some time after the inspection takes place. In some cases, the time between inspection and publication

reaches six months. In order to have this report in circulation by a reasonable time, we had to impose a cut-off point, meaning reports published after 10 March 2016 have been excluded.

While we may have gained more data had we waited until all reports had been published, we took the view that it is more important that we circulate our findings and recommendations now so that the CQC can respond and consolidate the inspection process sooner rather than later. In any case, our sample of 90 reports is large and broad enough to produce representative conclusions.

We collected the relevant extracts by searching the reports for the phrase 'duty of candour'. We looked for uses of the exact phrase, rather than broader references to openness and honesty, because the CQC needs to assess NHS bodies' understanding of this specific fundamental standard and legal requirement.

For example, when assessing Sherwood Forest Hospitals NHS Foundation Trust, reporters noted that, *'the policy was written in consideration of the National Patient Safety Agency guidance on being open, rather than the duty of candour regulation specifically. Consequently different terms for types of safety incidents were used interchangeably which could lead to confusion for staff following the policy. We found the policy largely met the requirements of the regulation, but there were some aspects that did not support full compliance with the duty of candour regulation.'*

For years, NHS institutions have been subject to guidance on 'being open'. More recently, NHS bodies had been subject to a 'contractual duty of candour' by virtue of their contracts with commissioners. The new statutory duty of candour, instead, imposes concrete legal requirements that the body must follow. Awareness and understanding of the relevant vocabulary is essential for effective implementation.

We began analysing the commentary by asking four simple yes/no questions:

1. Does the report refer specifically to the duty of candour?
2. Does the report criticise any aspect of the NHS body's implementation of the duty of candour?
3. Does the report make any recommendations regarding the NHS body's implementation of the duty of candour?
4. Does the report provide an example of good practice in implementing the duty of candour?

We then undertook more nuanced textual analysis. The reports do not follow a standardised approach to assessing the duty of candour, so we had to analyse each report individually, pulling out any notable observations.

We ascribed an assessment standard to each report, indicating whether the document contained 'non-existent', 'superficial', 'moderate' or 'detailed' commentary on the duty of candour. These categorisations are crude, but they do allow us to draw broad conclusions about the degree of CQC assessment. Below is a description of each of these categories:

- **Non-existent:** No mention of the phrase 'duty of candour' anywhere in the text.
- **Superficial:** A perfunctory acknowledgement that the report should cover the duty of candour. Characterised by a sentence or two, without further detail or analysis.
- **Moderate:** The report provides some detail on the NHS body's approach to the duty of candour, but omits to cover other aspects.
- **Detailed:** The report refers to a number of elements of the duty of candour and its implementation. Some relevant statistics may be provided.

Note that even where there has been a detailed assessment, this does not necessarily mean that the report adequately holds the NHS body to account for its implementation of the duty of candour. For example, a report might contain detail and criticism of implementation but fail to recommend an improvement necessary to meet the fundamental standard fully. We therefore looked in particular at whether the CQC had made any criticisms or references suggestive of a trust not being fully compliant and if so, whether any recommendations regarding the provider's compliance / implementation of the duty of candour were made.

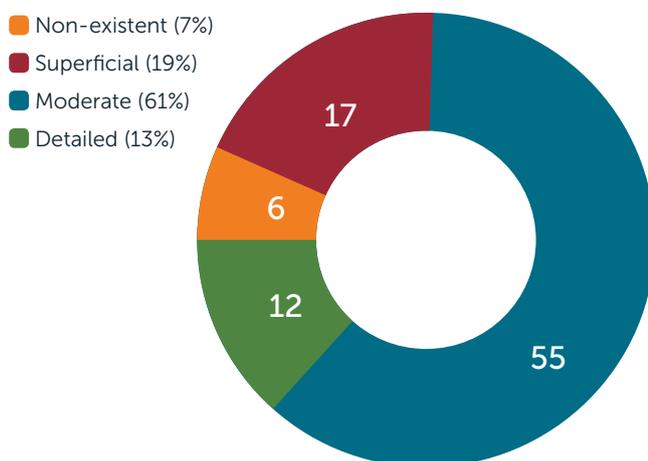
We also asked the CQC via a Freedom of Information Act request (Fol) for any further information they could provide with regard to trusts' responses to them about issues raised in their reports on duty of candour and whether any formal action had occurred specifically with regard to the duty of candour. Inspectors mainly look for evidence that systems are in place for implementing the duty of candour rather than dealing with possible individual breaches of the duty. However this should be informed by intelligence it receives about potential breaches of the duty. We therefore asked the CQC for information about intelligence it had received about potential breaches of the duty and how they had dealt with it. Our questions and the CQC's response can be found in Appendix 2.

3. Findings

Figure 1 below provides a summary of our findings in numerical terms of the standard of inspections reports with regard to the level of analysis of compliance with the duty of candour in the report. A table showing all of the NHS bodies we looked at, with links to their respective CQC reports, can be found in Appendix 1, in which column 3 indicates the level of assessment in each report.

Six (7%) of the reports do not even mention the phrase 'duty of candour' and thus are in the

Figure 1: Reporting standards



‘non-existent’ category. Certain reports may be shorter or more focused than others, but the duty of candour is a fundamental standard, so every inspection should look for relevant evidence of compliance.

Seventeen reports (19%) fall into the ‘superficial’ category, meaning that they give a perfunctory mention of the duty of candour. Superficial commentary does not demonstrate adequate reassurance that the NHS body is complying with the duty of candour and does not lay out requirements for improvement.

55 (61%) of the reports were judged to show a ‘moderate’ degree of analysis, and just 12 (13%) of the reports were judged as providing a ‘detailed’ analysis.

4. Examples of ‘superficial’ analysis

Example 1

Great Ormond Street Hospital for Children NHS Foundation Trust
www.cqc.org.uk/provider/RP4

We saw good examples of duty of candour in practice. Staff were very open when things had gone wrong, expressed full apology and offered full support to parents, children and carers. (p.2)

Here just two lines of text are dedicated to the duty of candour. The report states that the inspectors saw ‘good examples of duty of candour in practice’, but provides no supporting details and no hint of the number of cases. The report’s statement raises more questions than it answers. For example, were there times when the duty of candour was not observed? What proportion of staff were aware of and understood their duty of candour? Did Great Ormond Street have a clear policy on duty of candour? What relationship did the duty of candour implementation bear to the incident reporting process? There is no real indication of how inspectors assured themselves that the trust actually was fully complying with the letter and spirit of the duty of candour other than having seen some good examples.

Example 2

Kent and Medway NHS and Social Care Partnership Trust
www.cqc.org.uk/provider/RXY

The trust told us they have developed a policy for the implementation of ‘duty of candour’. The board had received training and ‘what it means to patients’ leaflets were available. (p.38)

Here the CQC appears to have taken the trust’s word that it has developed a duty of candour policy, rather than actually looking at the policy and assessing its efficacy. The inspectors have checked that the board has received training, but what about the staff? And, while providing leaflets for patients is a good initiative that

not many NHS bodies currently follow, the inspectors failed to mention any of the basic tenets of good duty of candour practice.

5. Examples of 'detailed' analysis

Example 1

Salford Royal NHS Foundation Trust
www.cqc.org.uk/provider/RM3

Duty of candour

- *Duty of candour (DoC) regulation requirements were reported to the Executive Assurance and Risk Committee (EARC), a Standing Committee of the Board (Chaired by the CEO) on 16 December 2014.*
- *The paper presented to EARC outlined the statutory requirement and the steps the provider needed to take following a notifiable incident in accordance with the trust 'duty of candour Procedure' presented to the committee.*
- *The procedure covered the DoC requirements associated with the trust Serious Untoward Incidents (SUI) and the Serious Incident Action Review Committee Incidents (SIARCS). It described the 'being open' procedure and the fact that the policy should be used in conjunction with the trust 'Being Open Policy'.*
- *Whilst the procedure referred to SUI and SIARAC covering the notifiable incidents including death, major harm and moderate harm (harm that requires a moderate increase in treatment, and significant, but not permanent harm), it did not refer to the requirements to ensure that DoC was applicable in cases where there had been psychological harm (which was likely to, or had lasted for more than 28 days as a result*

of an incident. It was unclear how the SUI and SIARAC incidents were mapped to all the relevant notifiable incident categories.

- *Prior to the regulation and the paper being sent to EARC, the trust had already implemented part of the process relating to DoC through the functioning of the SIARAC meeting, where the trust monitored its compliance with 'being open' with the patient. This usually resulted in a conversation with the patient and being open about the incident that had occurred.*
- *Compliance monitoring had been included within the Datix incident reporting form and a review was incorporated into the root cause analysis of the incident. Adherence to the initial process was reviewed through SIARAC minutes. We saw evidence of the completion of SIARAC review checklists during the inspection.*
- *The trust advised that they aimed to introduce 'disclosure coaches' going forwards to champion the DoC process, but this had not been implemented at the time of the inspection. (pp.12-13.)*

This report contains a specific section on the duty of candour in which inspectors note that the trust has a duty of candour policy. Given that the both Salford's Serious Incident Action Review Committee and Executive Assurance and Risk Committee assessed the policy, we know that the organisation has recognised the duty of candour's role in dealing with the aftermath of specific incidents and with ensuring that such mistakes do not happen again. The report also flags that Salford Royal plan to introduce disclosure coaches who would help staff carry out the responsibility. We have been given insight into the trust's degree of commitment and progress in terms of implementing its duty of candour.

The report also gives detail about the policy's approach to the varying level of harm covered

by candour legislation. While the trust's guidance covers incidents resulting in death, serious injury and physical injury, there is no clear approach to psychological harm. Here the CQC have been thorough in assessing the various different contexts in which the duty of candour should be applied. However, the inspectors then failed to follow up with any recommendations to rectify the issue. Due to a lack of systematic assessment, even the CQC's most detailed reports may miss parts of their duty to inspect and regulate compliance with the duty of candour.

Example 2

North Cumbria University Hospitals NHS Trust

www.cqc.org.uk/provider/RNL

Duty of candour

The trust was aware of its role and responsibilities in relation to the duty of candour requirements and had begun to embed processes that were supported by a duty of candour checklist. The Trust updated its Being Open process following the introduction of duty of candour regulation in November 2014. Monitoring arrangements indicated that in 100% of serious harm incidents; the Trust has met the duty of candour requirements. This was less so for moderate harm incidents, with the December 2014 compliance being as low as 40%. (p.5)

Duty of candour

- *The trust was aware of its role and responsibilities in relation to the duty of candour requirements and had begun to embed processes that were supported by a duty of candour checklist.*
- *The purpose of the checklist was to prompt and audit the proper application of the trust's responsibilities in this regard.*

- *The Trust updated its Being Open process following the introduction of duty of candour regulation in November 2014. Monitoring arrangements indicated that in 100% of serious harm incidents; the Trust has met the duty of candour requirements. This was less so for moderate harm incidents, with the December 2014 compliance being as low as 40%. (pp.11-12)*

This report provides a small statistical breakdown of incidents in which the trust observes the duty of candour. The inspectors looked at the trust's monitoring reports and found that staff observed the duty of candour in 100% of serious harm incidents, but in just 40% of moderate harm incidents. Including compliance statistics is both rare and helpful when formulating targeted and recommendations for improvement.

Although these two reports include detailed commentary on the duty of candour, both feature a concerning omission. Both reports criticise a trust for only fulfilling the legislation in some, but not all, cases of harm, yet fail to follow up with any recommendations for improvement. The inspectors of North Cumbria noted that compliance in moderate cases may be 'as low as 40%'. This means that in the majority of incidents, the trust is not fulfilling its obligation. The trust's 100% compliance rate in serious cases does not compensate for failing to comply in the majority of moderate cases. Indeed, 'moderate' incidents involve considerable harm and are more numerous than 'serious' cases. The CQC has overlooked its duty to regulate a fundamental standard by failing to follow up with any relevant recommendations.

Here we arrive at a number of issues. All we have to go on is the reference to 'December 2014 compliance being as low as 40%'. We have little indication of the extent to which the trust failed to fulfil the legislation. Did the trust omit to inform the patient entirely? Or, for

example, did a practitioner have a face-to-face conversation with the relevant person and then omit send a formal letter?

A significant number of NHS staff, while at AvMA training events, have voiced concerns about some of the duty of candour's formal expectations. Staff have recalled incidences when they have spoken to a patient and then felt that sending a formal letter would add little to the situation. If nobody sends a letter, the incident may go on record as an occasion when the duty of candour was not fulfilled. Inspectors need to provide more precise information about compliance rates to show how far practitioners are observing the duty of candour.

On occasion, the CQC has provided more detailed information about the extent of compliance. The inspectors of Hull and East Yorkshire NHS Foundation Trust noted that *'for example, of six incidents which related to the emergency department, only three of these had evidence indicating the date of a verbal apology given to the patient or relative. A report provided by the trust showed that between December 2014 and April 2015 the medical health group had achieved 33% against the duty of providing an apology and 40% against providing patients with feedback.'* The breakdown provided for Hull is more useful than the breakdown for North Cumbria. Compliance with the duty of candour is not absolute and we need a reporting system that reflects gradations of observation.

Secondly, we need to reconsider the use of the word 'moderate' in describing incidents that cause significant (but not permanent) harm. Most people would agree that a week-long stay in intensive care is a serious and traumatic event, even if they were to make a full recovery. Most people would, therefore, expect an explanation and an apology. Describing such events as 'moderate' belittles their impact and lulls people into the idea that it is OK not to observe the duty of candour.

Thirdly, most of the reports provide either a vague or black and white interpretation of the duty of candour. The regulations and the CQC's official guidance make clear that the duty of candour applies in cases that 'could result in' harm. This was always going to be potentially confusing for providers to interpret. It is not about referring to 'near misses', but rather to incidents which have not yet materialised in identifiable harm, but may yet do so in the future. None of the reports assess how many times the duty of candour has been applied in cases of potential harm. Such minimal discussion of potential harm is indicative of the CQC's over-simplistic approach to the duty of candour, at least in the first year of inspections.

So, even the most detailed of commentary throws up a number of issues that the CQC needs to think about before continuing with their investigations into duty of candour compliance.

6. Example of 'moderate' analysis

The majority of reports fall into the moderate category. As you would expect, the level of detail in these reports falls somewhere between that in the superficial category and that in the detailed category. While the moderate label is self-explanatory, we have provided an example below for reference.

Calderstones Partnership NHS Foundation Trust

www.cqc.org.uk/provider/RJX

Are services safe?

The majority of staff we spoke with understood the underlying principles of the duty of candour requirements and the relevance of this in their work. (p.5)

Duty of candour

The new statutory duty of candour was introduced for NHS bodies in England from 27 November 2014. The obligations associated with the duty of candour are contained in regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The key principles are that NHS trusts have a general duty to act in an open and transparent way in relation to care provided to patients. This means that an open and honest culture must exist throughout the organisation. Appropriate support and information must be provided to patients who have suffered (or could suffer) unintended harm while receiving care or treatment.

Duty of candour was built into the induction programme for new starters. All board members had received training on the duty of candour.

The trust had a strategy in place to ensure that it was meeting the regulation. The trust also had a procedure described in the core brief which was available to staff in July 2015. This noted that all staff had a responsibility for making sure incidents or complaints were acknowledged and reported as soon as they were identified and they should be managed with compassion and understanding. It also provided a link for staff to access the guidance provided by the General Medical Council and the Nursing and Midwifery Council.

The trust incident reporting system had an applicable tick box for staff to select and consider any incidents that may relate to the duty of candour. The trust was also monitoring each ward via their quality dashboard which identified any incidents where the duty of candour principles may be applicable. The trust had identified six incidents which met the criteria for duty of candour.' (p.23)

In this report, the CQC has obtained reassurance that the trust has a duty of candour policy in place; training and information are available for staff; and the trust follows a stated method to identify incidents. However, the report's definition of the duty of candour is woolly. There is no reference to the thresholds of harm, nor what 'appropriate support or information' requires. And while the report notes that the 'trust had identified six incidents', there is no attempt to discuss whether the duty of candour was actually applied adequately on each separate occasion.

Moderate reports highlight a range of issues related to the duty of candour, but omit various details necessary to reassure inspectors that a trust is fulfilling its responsibilities. Nor do moderate reports contain any specific commendable details that some other reports cover.

7. Reports indicative of poor implementation or non-compliance

We found 34 examples of where criticisms or comments suggestive of poor implementation of or non-compliance with the duty of candour were made. (Figure 2).

While reading the inspection reports we noticed that a number made criticisms of a trust's implementation of the duty of candour, but failed to follow up with a recommendation. This was the case in 20 of the 34 reports which included criticisms. For example, the report on North Cumbria University Hospitals NHS Trust noted that the trust was only complying with the duty of candour in 40% of the cases involving moderate harm, which is a fairly shocking revelation. However, this did not even result in a recommendation to improve.

The report on Sherwood Forest Hospitals NHS Foundation Trust was heavily critical of the trust's implementation of the duty of candour. It

Figure 2 – Reports including criticisms re duty of candour implementation

Without recommendations	
Barts Health NHS Trust	www.cqc.org.uk/provider/R1H
Colchester Hospital University NHS Foundation Trust	www.cqc.org.uk/provider/RDE
County Durham and Darlington NHS Foundation Trust	www.cqc.org.uk/provider/RXP
Devon Partnership NHS Trust	www.cqc.org.uk/provider/RWV
East Kent Hospitals University NHS Foundation Trust	www.cqc.org.uk/provider/RVV
East Sussex Healthcare NHS Trust	www.cqc.org.uk/provider/RXC
Great Western Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RN3
Lancashire Care NHS Foundation Trust	www.cqc.org.uk/provider/RW5
Leicestershire Partnership NHS Trust	www.cqc.org.uk/provider/RT5
North Cumbria University Hospitals NHS Trust	www.cqc.org.uk/provider/RNL
Royal Devon and Exeter NHS Foundation Trust	www.cqc.org.uk/provider/RH8
Salford Royal NHS Foundation Trust	www.cqc.org.uk/provider/RM3
Somerset Partnership NHS Foundation Trust	www.cqc.org.uk/provider/RH5
South London and Maudsley NHS Foundation Trust	www.cqc.org.uk/provider/RV5
South Tyneside NHS Foundation Trust	www.cqc.org.uk/provider/RE9
The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RDZ
West Hertfordshire Hospitals NHS Trust	www.cqc.org.uk/provider/RWG
Weston Area Health NHS Trust	www.cqc.org.uk/provider/RA3
Wirral University Teaching Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RBL
Worcestershire Acute Hospitals NHS Trust	www.cqc.org.uk/provider/RWP
With recommendations	
Barking, Havering and Redbridge University Hospitals NHS Trust	www.cqc.org.uk/provider/RF4
Buckinghamshire Healthcare NHS Trust	www.cqc.org.uk/provider/RXQ
Burton Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RJF
Central and North West London NHS Foundation Trust	www.cqc.org.uk/provider/RV3
Dorset Healthcare University NHS Foundation Trust	www.cqc.org.uk/provider/RDY
Frimley Health NHS Foundation Trust (Wexham Park Hospital)	www.cqc.org.uk/location/RDU35
Hull and East Yorkshire Hospitals NHS Trust	www.cqc.org.uk/provider/RWA
Medway NHS Foundation Trust	www.cqc.org.uk/provider/RPA
Rotherham Doncaster and South Humber NHS Foundation Trust	www.cqc.org.uk/provider/RXE
Sherwood Forest Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RK5
The Royal Orthopaedic Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RRJ
University Hospital Southampton NHS Foundation Trust	www.cqc.org.uk/provider/RHM
Walsall Healthcare NHS Trust	www.cqc.org.uk/provider/RBK
West London Mental Health NHS Trust	www.cqc.org.uk/provider/RKL

found that the trust was not complying in cases of moderate harm. Whilst the trust was rated 'inadequate' and was issued a formal warning, improving on duty of candour was not included in the list of 'must dos', but only in what it 'should do'.

If the CQC deems any oversight significant enough to comment on, we reasonably expect that inspectors should always follow up with recommendations to rectify the issue. As the body tasked with inspection **and** regulation, the CQC is not doing its full job when it notes substandard practice and fails to inform a

provider of the necessary improvements. The need to ensure proper regulation is particularly pressing here because the duty of candour is a **fundamental** standard, which an NHS body should never fail to observe.

Fourteen reports make both criticisms and recommendations regarding the duty of candour. As with other elements of their work, the CQC's recommendations were inconsistent. Inspection reports feature a list of issues that a trust **must** address in order to improve and issues that the trust **should** address in order to improve. In five of the reports, duty of candour recommendations came under the 'should' category and in nine such recommendations came under the 'must' category. The CQC appears to be inconsistent in how important it views the implementation of recommendations to improve adherence to the duty of candour.

We took a closer look at the individual recommendations, some of which were targeted and helpful and some of which were vague.

For example, the inspectors of Central and North West London NHS Foundation Trust stated that *'the trust should ensure that all staff know how to report incidents and understand the duty of candour regulation'*. These instructions are vague and give little helpful advice on where the trust specifically needs to improve. Yet, in the body of the report, the CQC stated that *'we also saw the trust was taking steps to ensure incidents, complaints and other concerns were fully investigated. Most people felt satisfied with how this is happening, but a few remained unhappy with how their individual concerns had been addressed. The Care Quality Commission will continue to look at the duty of candour as part of future inspections'*.

While the inspectors were largely pleased with the trust's implementation of the duty of candour, they offered a generalised recommendation that implied a need for overhaul, rather than pinpointing particular areas for improvement. Similarly, the

inspectors of Medway NHS Foundation Trust suggest that *'the trust should assure itself that staff understand the new duty of candour regulations'*.

On the other hand, some of the reports make targeted recommendations. For example, the inspectors of Hull and East Yorkshire Hospitals NHS Trust stated that *'the trust must ensure that all incidents are investigated in a timely manner, that lessons are learnt and that duty of candour requirements are effectively acted upon and audited'*. The inspectors have given Hull specific targets of reducing the amount of time it takes to comply with the duty of candour and conducting audits into compliance rates, as well as advising the trust that they need to embed the duty solidly into the incident learning process.

The inspectors have responded to specific issues, included the fact that *'application of the duty of candour to incidents generally and the backlog of incidents was not consistent. For example, of six incidents which related to the emergency department, only three of these had evidence indicating the date of a verbal apology given to the patient or relative. A report provided by the trust showed that between December 2014 and April 2015 the medical health group had achieved 33% against the duty of providing an apology and 40% against providing patients with feedback.'*

As with many aspects of the CQC's commentary on the duty of candour, we found that the inspectorate's approach to making recommendations was variable.

8. Follow-up where recommendations have been made

After analysing the recommendations, we wondered if any of the trusts that had been informed of a need to improve their duty of candour compliance had sent any

correspondence in response. To find this information we submitted a Freedom of Information (Fol) request. The CQC was unable to answer the question fully. Instead, the CQC provided links to three recent reports that noted breaches and stated that none of these NHS bodies had sent responses.

While the response was disappointing, we now know that the CQC does not systematically collect feedback from NHS bodies regarding their reports.

Similarly, the CQC was unable to tell us how many reports of potential breaches of the duty of candour they received in 2015. This could be for example from correspondence from patients to the CQC of feedback from the CQC's 'tell us about your care' initiative. The CQC told us that they 'do not have a central recording system for duty of candour' and claimed exemption from the Freedom of Information Act because to find out if there had been any would be too expensive. In other words, the CQC had no idea whether or not it had received reports of individual breaches of the Duty of Candour and even where its inspections had raised concerns about an NHS body's compliance it had no idea what the NHS body concerned was doing about it.

Our Fol request showed that there are holes in the CQC's knowledge, limiting the organisation's awareness of how providers respond to recommendations and national trends in patient safety. While a lack of such data collection may well be a capacity issue, it is concerning that the CQC does not hold central statistics on the implementation of a fundamental standard.

Our initial analysis shows that the CQC has monitored and regulated the duty of candour inconsistently. Our next step was to analyse with greater nuance the relevant commentary in each report. We drew three conclusions. First, both the CQC and NHS bodies are inconsistent in understanding the duty of candour's position in the incident

learning process. Second, certain trusts use innovative implementation and communication approaches and the CQC should help to share these ideas. Third, there are disparities within hospitals, and sometimes between different levels of harm or across different departments, when it comes to implementing the duty of candour.

9. Evidence of learning from incidents

The duty of candour should be seen as a part of the incident learning process. The legal requirement of honesty is designed to ensure institutions act on every incident, undertaking positive changes to avoid repetition of mistakes. We do not want to see the duty of candour become a stand-alone tick-box exercise. We want to make sure the legislation encourages every effort to learn from incidents. While the reports indicate that some trusts have embedded the duty of candour in the incident learning process, some have not. Unfortunately, many of the reports lack the detail to allow us to make a sound judgement here.

For example, the CQC's report on University Hospitals Birmingham NHS Foundation Trust provides a detailed account, showing that the trust understands the role the duty of candour plays in learning from incidents and puts the principle into action.

'We heard examples of how lessons were learnt through discussing poor care and changing practice. One incident, where a patient had suffered due to poor care had resulted in the consultant displaying a duty of candour by giving an apology to the patient and their relatives. We were told that an open, honest explanation had been given and they had described lessons learnt. This was subsequently discussed in a ward meeting and practice had changed.'

The CQC reported the following about the County Durham and Darlington NHS Foundation Trust:

'In maternity and gynaecology services at Darlington Memorial Hospital there were weekly multidisciplinary risk meetings. In maternity the meeting was run by clinical governance midwives and included good consultant input. During this meeting there was presentation and open discussion of all events reported during the week. Patient notes were fully reviewed and lessons learned were discussed. The duty of candour test was applied, ensuring that any harm identified would be escalated, including sharing of information with respective individuals.'

By contrast, the report on St Barts Health NHS Trust shows a lack of inclusion of the duty of candour in incident learning:

'We reviewed a number of Serious Incidents and there was limited assurance that the duty of candour had been upheld. One incident we reviewed occurred in December 2013 the report was completed in November 2014 and the intention to liaise with the family had not taken place in March 2015.'

And Walsall Healthcare NHS Trust, according to the CQC, lacks structured investigatory methods, meaning that the duty of candour cannot act as the first step in a rigorous incident learning process:

'Duty of candour process had improved but further training to front line staff is required. Systematic training for complaints investigation is required as the root cause analysis (RCA) process is inconsistent and lacks structure.'

In order to ensure that the duty of candour serves its purpose in encouraging trusts to learn from mistakes, the CQC must be more forceful and consistent in ensuring that trusts enshrine the duty of candour in their incident learning process.

10. Examples of active implementation / good practice

A number of the reports highlight interesting and active methods used by various trusts to implement their new duty of candour. For example, when adapting their openness policy in response to the new legislation, the Leicestershire Partnership NHS Trust (like a number of the NHS bodies we read about), had been thorough and *'undertaken an audit to understand any improvements required to meet this duty of candour. Following this a number of actions were undertaken including duty of candour considerations being incorporated into the serious investigation framework and report.'* Leicestershire's audit and subsequent actions show a thorough approach to creating and implementing duty of candour policy.

Royal Salford NHS Foundation Trust, at the time of inspection, planned to designate specialist staff to help implement the duty. Here we should note that the duty of candour does lead to many emotionally and socially difficult situations. The trust *'advised that they aimed to introduce 'disclosure coaches' going forwards to champion the duty of candour process, but this had not been implemented at the time of the inspection.'* In a similar vein, Tameside Hospital NHS Foundation Trust *'had begun 'difficult conversation' training to support staff in having open conversations with patients about harm and risk of harm.'* The fact that multiple hospitals are taking the legislation seriously enough to consider such appointments is encouraging.

On a similar note, South London and Maudsley NHS Foundation Trust and Kings College Hospital NHS Foundation Trust appointed 'candour guardians'.

A number of trusts implemented practical measures to ensure that staff were educated and working in an environment in which the duty of candour is made as easy to follow

as possible. Calderstones Partnership NHS Foundation Trust built duty of candour training into the induction programme for new starters. At University Hospitals of Morecambe Bay NHS Foundation Trust, *'the electronic system does not allow staff to move on through the programme unless all fields are completed appropriately including duty of candour.'*

Both University Hospital Southampton NHS Foundation Trust and Kent and Medway NHS and Social Care Partnership Trust recognised the importance of patient awareness of the duty of candour, deciding to produce patient information leaflets. While it is the responsibility of clinicians to disclose any mistakes, and while the obligation to request information should never lie with patients or designated contacts, hospitals would do well to make patients aware of their rights. A patient should know that they have a right to be told the truth and the confidence that the law is on their side should they feel the need to act upon any dishonesty about incidents that have caused them harm.

In fact, so few trusts have produced patient information, and as AvMA believes strongly that patients should understand the duty of candour, we have produced a patient information leaflet which is approved by the CQC. See Appendix 3 for a copy of our leaflet. Whilst the leaflet is designed for members of the public, we have received feedback from staff that this is a useful explanation of the duty of candour for them. Copies of the leaflet can be made available to health and social care organisations.

These are a selection of examples of good practice, highlighting some of the active methods NHS bodies have employed to implement the duty of candour. We have not featured every example, but rather an illuminating selection.

11. Disparities in implementation

The inspection reports confirm that there are disparities in the way hospitals implement the duty of candour. Most hospitals are consistent in complying in cases of severe harm or death, but less so in cases of moderate or psychological harm. Sometimes particular departments within trusts do not implement the Duty of Candour adequately while others do.

On a few occasions the CQC obtained statistics summarising NHS bodies' compliance rates, with breakdown between serious and moderate incidents. Such information is useful and the CQC should endeavour to include these statistics in their reports as they provide a more detailed picture of the extent of an NHS body's compliance. For example, the CQC noted that at North Cumbria University Hospital NHS Trust, *'Monitoring arrangements indicated that in 100% of serious harm incidents; the Trust has met the duty of candour requirements. This was less so for moderate harm incidents, with the December 2014 compliance being as low as 40%.'*

There was even greater non-compliance in 'moderate' cases of harm at Sherwood Forest Hospitals NHS Foundation Trust, which had not built any provisions for dealing with non-severe cases into their practice. Indeed, *'the responsibility for duty of candour was allocated at meetings where the investigation of serious incidents was planned. This meant that incidents leading to moderate harm did not have duty of candour applied as they should.'* On a similar, but less extensive note, the CQC observed that at Salford Royal NHS Foundation Trust, *'whilst the procedure referred to SUI and SIARAC covering the notifiable incidents including death, major harm and moderate harm (harm that requires a moderate increase in treatment, and significant, but not permanent harm), it did not refer to the requirements to ensure that DoC was applicable in cases where there had been psychological harm (which was*

likely to, or had lasted for more than 28 days as a result of an incident).'

Salford is also an example of how the CQC often overlooks psychological harm when discussing the duty of candour. It is often ambiguous as to whether report authors count psychological harm under the umbrella of moderate harm or have simply omitted to comment on emotional trauma. While assessing psychological harm may be more difficult than physical harm, there is no justification for ignoring significant mental health repercussions of medical accidents.

While we must not get caught up in arguing the blurred line of what constitutes a notifiable safety accident, we must remember that omitting to comply with the duty of candour in moderate incidents is a cause for serious concern. A moderate incident results in considerable upheaval and discomfort for a patient. What is more, psychological damage can last for a lifetime and can be just as debilitating as physical harm.

On the other hand, the CQC did note that the Plymouth Hospitals NHS Trust was meticulous in ensuring that any mistake causing moderate harm resulted in activation of the duty of candour: *'The patient safety team ran a regular search of the electronic system to ensure that all incidents (moderate or above) had duty of candour documentation completed.'* Though here, as with many of the reports, it is unclear whether or not psychological harm is included within the umbrella of 'moderate harm'.

A number of reports also noted that specific departments within NHS bodies did not comply adequately with the duty of candour. For example, at the Wirral University Teaching Hospital NHS Foundation Trust, *'some staff were unaware of the duty of candour legislation. We noted this to be a particular issue in the emergency department.'* And at the Lancashire Care NHS Foundation, *'the majority of staff we spoke with understood the underlying principles of the duty of candour requirements and the*

relevance of this in their work; the exception was the district nursing team staff.' After noting this discrepancy in the emergency department, the CQC failed to follow up with any recommendations. However, when the CQC noted that at the Southampton University NHS Foundation Trust *'the imaging department did not have procedures to demonstrate that the duty of candour was considered, implemented and followed for reportable incidents,'* they did follow up with a recommendation.

The evidence suggests that implementation of the duty of candour is not only inconsistent across England, it may well also be inconsistent within individual NHS bodies.

12. Conclusions and recommendations

We are disappointed and surprised that the first year of inspections following the high profile introduction of a **'fundamental'** standard like the duty of candour showed such an inconsistent and at times superficial approach. It is totally unacceptable that six inspections paid no attention at all to the duty of candour.

We appreciate the huge task that the CQC has in inspecting all registered providers and monitoring compliance with all standards. It would be unrealistic to expect inspection reports to contain a detailed analysis of implementation of / compliance with every standard. However, the large number of reports assessed as 'superficial' in this regard (19%) is also very disappointing.

In total, we found that 25% of inspections were either superficial in analysing implementation/ compliance with the duty of candour or failed to do so at all. Only 9% of reports were judged to contain a detailed analysis. We noted that all of the inspections were heavily reliant on comments from the trusts regarding their own implementation of the duty of candour. Whilst some reports mention seeing examples

of implementation, we could not find any inspection report that included independent analysis of a random selection of incidents. The approach across the inspections was inconsistent. There did not appear to be any standardised guidance on what evidence inspectors should seek.

We were concerned to find that even where inspections indicated poor implementation or non-compliance with the duty of candour, this often did not result in any recommendation to improve. We found 34 examples criticisms about duty of candour implementation. Twenty of these were not accompanied by a recommendation to improve. In the 14 reports that did contain recommendations we found that many were vague or weak. We are surprised that potential non-compliance with a fundamental standard could either be passed over with no recommendation or be met with recommendations phrased as 'should' improve as opposed to 'must' improve.

We were particularly concerned to find, as a result of our Freedom of Information request, that the CQC was unable to provide us with any information about how trusts had responded following recommendations for improvement having been made in inspection reports. It appears that no such central record is kept and that any follow up is reliant either on individual local inspectors dealing with issues, if they choose to, or is left until the next time the trust is inspected. We believe it is only reasonable to expect that the CQC should require evidence that an organisation is acting on its recommendations proactively, rather than waiting until the next inspection.

We were also concerned that the CQC told us they had no system in place for logging and following up individual reports or allegations of breaches of the duty of candour made by members of the public or other bodies. We appreciate that the CQC is not in a position to investigate every single incident or allegation of non-compliance. However, if it has no system

in place to monitor or investigate any potential breaches which are brought to its attention, the duty of candour could become no more than general guidance. The CQC invites the public to 'tell us about your care'. Intelligence gathered through this process and other reports should not only inform the inspection process but in serious cases should prompt immediate action by the CQC.

We noted that the inspection reports suggested very variable levels of awareness and understanding of and implementation of the duty of candour across NHS bodies themselves.

In spite of our concerns about the inspection process and NHS bodies' implementation of the duty of candour, we were left with the impression that the duty of candour had begun to make a positive difference within NHS bodies in England. We were pleased to see many examples of good practice and a genuine commitment on the part of so many to implement the duty of candour well. We were also impressed with the commitment and insight of members of the CQC team responsible for this standard with whom we met and who seemed to welcome the scrutiny we were applying to this issue. In the spirit of partnership and in order to maximise the potential of the duty of candour to be 'the biggest advance in patient safety and patients' rights in the history of the NHS', we make a number of recommendations below.

13. Recommendations

1. **The CQC should develop a much more robust and consistent method of assessing implementation of/compliance with the duty of candour as part of all of its inspections. At the time of this study the CQC were planning to introduce some changes and a more consistent approach to inspections and assessing compliance with the duty. It remains to be seen whether this will be the robust approach which**

the public have a right to expect. This should include at each inspection analysis of a random cross section of incidents classified as having caused moderate harm (including psychological harm) or worse. A standard line of enquiry or toolkit should be developed for inspectors to follow. It should include obtaining evidence rather than simply relying on organisations' responses. It should be more thorough. For example, if there has been training, how many and what kinds of staff and board members have been trained? It should include analysis of the organisation's own monitoring/audit of its own compliance.

2. The CQC should be more consistent and robust in identifying and recording potential non-compliance, demanding improvement and monitoring that recommendations are acted upon. Where there are indications that an organisation may not be fully complying with the duty of candour this needs to be explored in more depth and result in a strong, 'must-do' recommendation. Only where there is compliance but some room for improvement would a 'should do' recommendation be appropriate. The CQC should maintain a publicly accessible record of recommendations and steps the organisation is taking to address them. The CQC must be seen to take firmer regulatory action in serious cases of non-compliance or where recommendations have not been acted upon by a specified time.
3. The CQC should be equally on the lookout for examples of good practice in implementing the duty of candour in its inspections and should publicise these. The CQC should take a leading role in supporting a series of events for registered organisations across England on the duty of candour to raise awareness and understanding, provide examples of good practice and motivate organisations and their staff.

4. The CQC should develop updated guidance on implementation of the duty of candour. This should clarify common areas of confusion among provider organisations as identified by inspection reports and our own work. These include: clearer definition of 'moderate harm' and 'psychological harm'; clarification about the need to apply the duty of candour for incidents that still 'could' result in harm; clarification regarding harm that is a 'known complication' and how/when the duty of candour still applies; clarification that retrospective case note reviews and other ways in which an incident is discovered retrospectively are covered by the duty of candour; guidance on how to handle difficult and sensitive cases where it may not be in the patient's or their next of kin's 'best interests' to be told about an incident.
5. The CQC should develop a system for recording, assessing and, if necessary, investigating reports or allegations from members of the public or other bodies of breaches of the duty of candour by registered organisations.
6. The CQC should conduct a special or thematic review specifically of implementation/compliance with the duty of candour in a similar way that it has done for complaints and investigations.

We are grateful to staff at the CQC for their co-operation. We met with CQC colleagues during the course of this study to discuss our initial findings from this work and some of our initial recommendations, and these were received positively. We were assured that a new more robust approach was being developed for the next round of inspections during 2016. We will continue to work with the CQC to help develop monitoring regulation and promotion of the duty of candour, and plan to carry out a similar study to see if regulation of the duty of candour has improved.

Appendix 1: Trusts included in this report

Trust	Link	Rating
2gether NHS Foundation Trust	www.cqc.org.uk/provider/RTQ	Moderate
5 Boroughs Partnership NHS Foundation Trust	www.cqc.org.uk/provider/RTV	Moderate
Alder Hey Children's NHS Foundation Trust	www.cqc.org.uk/provider/RBS	Non-existent
Barking, Havering and Redbridge University Hospitals NHS Trust	www.cqc.org.uk/provider/RF4	Moderate
Barnsley Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RFF	Moderate
Barts Health NHS Trust	www.cqc.org.uk/provider/R1H	Moderate
Basildon and Thurrock University Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RDD	Non-existent
Buckinghamshire Healthcare NHS Trust	www.cqc.org.uk/provider/RXQ	Detailed
Burton Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RJF	Moderate
Calderstones Partnership NHS Foundation Trust	www.cqc.org.uk/provider/RJX	Moderate
Cambridge University Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RGT	Moderate
Cambridgeshire and Peterborough NHS Foundation Trust	www.cqc.org.uk/provider/RT1	Moderate
Central and North West London NHS Foundation Trust	www.cqc.org.uk/provider/RV3	Moderate
Chesterfield Royal Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RFS	Moderate
Colchester Hospital University NHS Foundation Trust	www.cqc.org.uk/provider/RDE	Moderate
Cornwall Partnership NHS Foundation Trust	www.cqc.org.uk/provider/RJ8	Superficial
County Durham and Darlington NHS Foundation Trust	www.cqc.org.uk/provider/RXP	Moderate
Croydon Health Services NHS Trust	www.cqc.org.uk/provider/RJ6	Superficial
Devon Partnership NHS Trust	www.cqc.org.uk/provider/RWV	Moderate
Doncaster and Bassetlaw Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RP5	Moderate
Dorset Healthcare University NHS Foundation Trust	www.cqc.org.uk/provider/RDY	Moderate
East Kent Hospitals University NHS Foundation Trust	www.cqc.org.uk/provider/RVV	Superficial
East Sussex Healthcare NHS Trust	www.cqc.org.uk/provider/RXC	Moderate
Frimley Health NHS Foundation Trust (Wexham Park Hospital)	www.cqc.org.uk/location/RDU35	Detailed
Gateshead Health NHS Foundation Trust	www.cqc.org.uk/provider/RR7	Detailed
Gloucestershire Care Services NHS Trust	www.cqc.org.uk/provider/R1J	Superficial
Gloucestershire Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RTE	Non-existent
Great Ormond Street Hospital for Children NHS Foundation Trust	www.cqc.org.uk/provider/RP4	Superficial
Great Western Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RN3	Moderate
Hampshire Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RN5	Moderate
Hertfordshire Partnership University NHS Foundation Trust	www.cqc.org.uk/provider/RWR	Moderate
Hinchingbrooke Health Care NHS Trust	www.cqc.org.uk/provider/RQQ	Moderate
Hull and East Yorkshire Hospitals NHS Trust	www.cqc.org.uk/provider/RWA	Detailed
Ipswich Hospital NHS Trust	www.cqc.org.uk/provider/RGQ	Superficial
James Paget University Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RGP	Moderate
Kent and Medway NHS and Social Care Partnership Trust	www.cqc.org.uk/provider/RXY	Superficial
King's College Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RJZ	Superficial
Lancashire Care NHS Foundation Trust	www.cqc.org.uk/provider/RW5	Moderate
Leicestershire Partnership NHS Trust	www.cqc.org.uk/provider/RT5	Moderate
Liverpool Women's NHS Foundation Trust	www.cqc.org.uk/provider/REP	Moderate
Manchester Mental Health and Social Care Trust	www.cqc.org.uk/provider/TAE	Moderate
Medway NHS Foundation Trust	www.cqc.org.uk/provider/RPA	Moderate
Mersey Care NHS Foundation Trust	www.cqc.org.uk/provider/RW4	Moderate
Mid Essex Hospital Services NHS Trust	www.cqc.org.uk/provider/RQ8	Superficial
North Cumbria University Hospitals NHS Trust	www.cqc.org.uk/provider/RNL	Detailed
North Essex Partnership University NHS Foundation Trust	www.cqc.org.uk/provider/RRD	Moderate

Trust	Link	Rating
North Tees and Hartlepool NHS Foundation Trust	www.cqc.org.uk/provider/RVW	Moderate
Northamptonshire Healthcare NHS Foundation Trust	www.cqc.org.uk/provider/RP1	Superficial
Nottingham University Hospitals NHS Trust	www.cqc.org.uk/provider/RX1	Moderate
Oxford Health NHS Foundation Trust	www.cqc.org.uk/provider/RNU	Superficial
Peterborough and Stamford Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RGN	Non-existent
Plymouth Hospitals NHS Trust	www.cqc.org.uk/provider/RK9	Moderate
Portsmouth Hospitals NHS Trust	www.cqc.org.uk/provider/RHU	Moderate
Rotherham Doncaster and South Humber NHS Foundation Trust	www.cqc.org.uk/provider/RXE	Detailed
Royal Cornwall Hospitals NHS Trust	www.cqc.org.uk/provider/REF	Superficial
Royal Devon and Exeter NHS Foundation Trust	www.cqc.org.uk/provider/RH8	Moderate
Salford Royal NHS Foundation Trust	www.cqc.org.uk/provider/RM3	Detailed
Sherwood Forest Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RK5	Detailed
Somerset Partnership NHS Foundation Trust	www.cqc.org.uk/provider/RH5	Moderate
South Essex Partnership University NHS Foundation Trust	www.cqc.org.uk/provider/RWN	Moderate
South London and Maudsley NHS Foundation Trust	www.cqc.org.uk/provider/RV5	Moderate
South Tyneside NHS Foundation Trust	www.cqc.org.uk/provider/RE9	Superficial
St Helens and Knowsley Teaching Hospitals NHS Trust	www.cqc.org.uk/provider/RBN	Moderate
Sussex Partnership NHS Foundation Trust	www.cqc.org.uk/provider/RX2	Superficial
Tameside Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RMP	Detailed
Tees, Esk and Wear Valleys NHS Foundation Trust	www.cqc.org.uk/provider/RX3	Moderate
The Hillingdon Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RAS	Non-existent
The Mid Yorkshire Hospitals NHS Trust	www.cqc.org.uk/provider/RXF	Moderate
The Princess Alexandra Hospital NHS Trust	www.cqc.org.uk/provider/RQW	Moderate
The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust	www.cqc.org.uk/provider/RCX	Moderate
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RL1	Moderate
The Rotherham NHS Foundation Trust	www.cqc.org.uk/provider/RFR	Superficial
The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RDZ	Moderate
The Royal Orthopaedic Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RRJ	Detailed
The Royal Wolverhampton NHS Trust	www.cqc.org.uk/provider/RL4	Moderate
United Lincolnshire Hospitals NHS Trust	www.cqc.org.uk/provider/RWD	Non-existent
University Hospital Southampton NHS Foundation Trust	www.cqc.org.uk/provider/RHM	Detailed
University Hospitals Birmingham NHS Foundation Trust	www.cqc.org.uk/provider/RRK	Moderate
University Hospitals Coventry and Warwickshire NHS Trust	www.cqc.org.uk/provider/RKB	Superficial
University Hospitals of Morecambe Bay NHS Foundation Trust	www.cqc.org.uk/provider/RTX	Moderate
Walsall Healthcare NHS Trust	www.cqc.org.uk/provider/RBK	Detailed
Warrington and Halton Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RWW	Superficial
West Hertfordshire Hospitals NHS Trust	www.cqc.org.uk/provider/RWG	Moderate
West London Mental Health NHS Trust	www.cqc.org.uk/provider/RKL	Moderate
Weston Area Health NHS Trust	www.cqc.org.uk/provider/RA3	Moderate
Wirral University Teaching Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RBL	Moderate
Worcestershire Acute Hospitals NHS Trust	www.cqc.org.uk/provider/RWP	Moderate
Worcestershire Health and Care NHS Trust	www.cqc.org.uk/provider/R1A	Moderate
Wye Valley NHS Trust	www.cqc.org.uk/provider/RLQ	Moderate
York Teaching Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RCB	Moderate

Appendix 2: CQC response issued under the Freedom of Information Act 2000

Our Reference: CQC IAT 1516 0935

Date of Response: 4 April 2016

Information Requested:

1. **Is it possible for you to share with us the responses you have received from providers where you have made recommendations re duty of candour (apologies if Hannah has already asked for this)**
2. **We would also like to receive information about how you have dealt with intelligence received about potential breaches of the duty of candour regulations. Specifically, could you tell us: how many reports of potential breaches of the duty of candour regulations you received in 2015**
3. **How many of these reports you investigated**
4. **How many of these reports resulted in any communication with or recommendations to or warnings made to providers?**

CQC has considered your request in accordance with the Freedom of Information Act 2000 (FOIA).

CQC has published information about the 'duty of candour' on our website:

www.cqc.org.uk/duty-candour

You may wish to refer to our guidance for providers:

www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf

The role of CQC with regards to the 'duty of candour' is to check that a provider has systems and processes in place to carry out their duty under the regulation.

We do not monitor every single incident to see whether the 'duty of candour' should have been applied, and whether it was actually was.

If an inspection found that a provider did not have systems and process in place to ensure

that they meet their duty under the regulation, then our normal enforcement procedures would apply.

Any enforcement procedures would only apply where we discover breaches in the regulation following incidents that occurred after November 2014 for NHS Trusts.

You can read further guidance about our enforcement procedures on our website:

www.cqc.org.uk/content/enforcement-policy

We will now respond to each part of your correspondence in turn.

"1. Is it possible for you to share with us the responses you have received from providers where you have made recommendations re duty of candour (apologies if Hannah has already asked for this)"

We can confirm that CQC do not make recommendations relating to registered providers compliance with the regulation.

CQC can however consider a range of enforcement powers, in line with our [enforcement policy](#). We do issue requirement and warning notices as part of our inspections.

We did find breaches at the following locations:

Wexham Park Hospital - Latest Inspection Report

www.cqc.org.uk/sites/default/files/new_reports/AAAE1979.pdf

Rotherham Doncaster and South Humber NHS Foundation Trust - Latest Inspection Report

www.cqc.org.uk/sites/default/files/new_reports/AAAE1592.pdf

London North West Healthcare NHS Trust - Report awaiting publication

www.cqc.org.uk/provider/R1K

We have conducted detailed searches of our records for these three Trusts and our colleagues in the inspection team have advised that we do not hold any correspondence specific to 'duty of candour' received in the last 12 months from those Trusts.

“2. We would also like to receive information about how you have dealt with intelligence received about potential breaches of the duty of candour regulations.

Specifically, could you tell us: how many reports of potential breaches of the duty of candour regulations you received in 2015”

As previously advised in our correspondence of 22 March we are unable to quantify the number of concerns that relate to ‘duty of candour’.

We do not have a central recording system for ‘duty of candour’. We would need to conduct a bespoke search of the notifications we have received to determine whether the information related to ‘duty of candour’.

This information is not reportable and would involve a manual check.

We therefore consider the exemption provided at section 12 of FOIA to be engaged. Please refer to our explanation of this exemption further within this response.

“3. How many of these reports you investigated”

CQC do not carry out any investigations in relation to ‘duty of candour’ but we would incorporate the information we receive into the preparation for the next inspection.

The role of CQC with regards to the ‘duty of candour’ is to check that a provider has systems and processes in place to carry out their duty under the regulation.

We do not monitor every single incident to see whether the ‘duty of candour’ should have been applied, and whether it was actually was.

If an inspection found that a provider did not have systems and process in place to ensure that they meet their duty under the regulation, then our normal enforcement procedures would apply.

“4. How many of these reports resulted in any communication with or recommendations to or warnings made to providers?”

CQC do not carry out any investigations in relation to ‘duty of candour’ but we would incorporate the information we receive into the preparation for the next inspection.

The role of CQC with regards to the ‘duty of candour’ is to check that a provider has systems and processes in place to carry out their duty under the regulation.

We do not monitor every single incident to see whether the ‘duty of candour’ should have been applied, and whether it was actually was.

If an inspection found that a provider did not have systems and process in place to ensure that they meet their duty under the regulation, then our normal enforcement procedures would apply.

Any issues CQC find with ‘duty of candour’ would be reported only in inspection reports. Therefore the inspection reports will hold the information, and this would require a bespoke intelligence exercise.

Please refer to our response to part 1 of your request for the inspection reports where we have found breaches.

Section 12 - Exemption where cost of compliance exceeds appropriate limit

FOIA requests are not the only demand on the resources of a public authority.

FOIA is not intended to place an excessive burden upon public bodies such as CQC.

Section 12 of FOIA applies where the cost to CQC of complying with any individual request would exceed £450. In such cases, CQC is allowed to refuse to comply with the request for information.

Section 12 states:

“(1) Section 1(1) does not oblige a public authority to comply with a request for information if the authority estimates that the cost of complying with the request would exceed the appropriate limit.”

As a public authority we wish to be transparent and open about our work, but we have a

statutory responsibility to use our resources effectively.

Section 2(3) of schedule 1 of the Health and Social Care Act 2008 states that *"It is the duty of the Commission to carry out its functions effectively, efficiently and economically."*

A public authority, such as CQC, is not obliged to comply with a request for information if the authority estimates that the cost of complying with the request would exceed the appropriate limit.

In calculating whether this appropriate limit is exceeded, regulation 4(4) of the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 requires that the time taken in responding to requests (locating, retrieving and extracting the information) must be calculated at a rate of £25 per person per hour.

We estimate it will take longer than 18 hours and cost more than £450 (as defined under regulation 3(3) of the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004) to perform an interrogation of all of the records held to gather the requested information and formulate a response to part 2 your request.

CQC does not consider conducting such a search of our records to be an effective and efficient use of our limited resources.

In accordance with section 12 of FOIA, CQC chooses not to conduct such an exercise because of the high cost involved.

This response acts as a refusal notice in accordance with FOIA.

Use of this exemption does not require a public interest test.

In making the decision we have referred to guidance published on the Information Commissioner's Office (ICO) website:

<https://ico.org.uk/for-organisations/guide-to-freedom-of-information>

CQC Complaints and Internal Review procedure:

If you are not satisfied with our handling of your request, then you may request an internal review.

Please clearly indicate that you wish for a review to be conducted and state the reason(s) for requesting the review. To request a review please contact:

Information Rights
Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

E-mail: information.access@cqc.org.uk

Please be aware that the review process will focus upon our handling of your request and whether CQC have complied with the requirements of the Freedom of Information Act 2000. The internal review process should not be used to raise concerns about the provision of care or the internal processes of other CQC functions.

If you are unhappy with other aspects of the CQC's actions, or of the actions of registered providers, please see our website for information on how to raise a concern or complaint:

www.cqc.org.uk/content/contact-us

Further rights of appeal exist to the Information Commissioner's Office under section 50 of the Freedom of Information Act 2000 once the internal review process has been exhausted.

The contact details are:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
SK9 5AF

Telephone: 01625 545 745

Website: www.ico.org.uk

Appendix 3: AvMA duty of candour leaflet



The charity for
patient safety
and justice

The duty of candour

The legal duty to be open and honest
when things go wrong

What it means for patients and their families



Leaflet endorsed by  Care Quality Commission

The duty of candour

What it means for patients and their families

THE DUTY OF CANDOUR is a statutory (legal) duty to be open and honest with patients (or 'service users'), or their families, when something goes wrong that appears to have caused or could lead to significant harm in the future. It applies to all health and social care organisations registered with the regulator, the Care Quality Commission (CQC) in England.

This leaflet explains what to expect if such an incident occurs and what to do if you think your healthcare provider has not complied with the duty of candour.

What kind of incidents are covered by the duty of candour?

The regulations for registration with the CQC place an over-arching responsibility on health and social care organisations to be open and transparent.

The regulations define a 'notifiable safety incident' as 'an unintended or unexpected incident... that could result in, or appears to have resulted in the death of a service user... or severe or moderate harm or prolonged psychological harm to the service user'.

In other words, the organisation must tell you about any incident where the care or treatment may have gone wrong and appears to have caused significant harm, or has the potential to result in significant harm in the future.

What can you expect when you are told about an incident?

You should be informed about what happened as fully as possible and in a sensitive way, in person. This should happen as soon as reasonably practical after the incident is known about and should include an apology. This should also be followed up with a written account and apology.

You should be informed about what will happen next, for example what safety measures will be taken or what enquiries or investigation will be carried out.

You should be told about where you can get support, such as counselling if appropriate, or independent advice (for example from Action against Medical Accidents – see back page for contact details).

You should be kept informed about any investigation and its outcome.

What about older incidents?

The duty of candour regulations came into force in November 2014 for NHS bodies and April 2015 for all other organisations.

If the incident occurred before the regulations came into force, the CQC may not be able to take formal regulatory action or prosecute over a breach of the duty. However, they will take account of how organisations follow the spirit of the duty currently.

Learn more about the duty of candour and many other subjects at www.avma.org.uk/help-advice

The regulations *do* apply if the incident occurred after the regulations came in, but it is only realised later (for example, through a complaint investigation) that it met the definition of a 'notifiable safety incident'.

What if the organisation has not complied with the duty of candour?

If any organisation registered with the CQC fails to comply with the duty of candour, they could face regulatory action from the CQC and, in the most serious or persistent cases, even criminal prosecution.

If you think the organisation is in breach of the duty of candour, it is usually best to raise it with them first. This can either be with the health professional with whom you have most contact, or by making a formal complaint.

You can contact us at Action against Medical Accidents (AvMA – see back page for contact details). We will explain the procedures to you and offer specialist independent advice.

If you want us to, we can put you in contact with the CQC to let them know that there has been a breach of the duty of candour. You can also contact the CQC directly (see back page for contact details).

The CQC is not able to investigate every breach of the duty of candour. It is unlikely to take formal regulatory action or prosecute unless the breach is serious or widespread. However, the CQC will use feedback it receives to inform its monitoring and inspection of registered providers.

What you need to know

THE DUTY COVERS any incident that appears to have caused, or has the potential to cause, significant harm*

ORGANISATIONS DON'T LEGALLY have to tell you about incidents that cause a 'low level of harm' (e.g. minor or short-term harm) or 'near misses' but it is good practice to be open and to learn from all incidents

THERE DOES NOT NEED to be certainty that an incident has caused significant harm – only that it appears that it has or may do so in the future*

INCIDENTS WILL BE COVERED if the 'reasonable opinion of a healthcare professional' would be that they did or could have caused significant harm*

THE EMPHASIS SHOULD BE on being open with you if there is any doubt

AvMA CAN HELP YOU to understand your rights and advise you on what to do next. See our contact details on the back page to get in touch

**There is no current requirement for GPs, dentists, private healthcare and adult social care services to inform you about incidents which 'could' result in significant harm but haven't yet done so. There is, however, still an overarching duty for them to be open and honest.*

Learn more about the duty of candour and many other subjects at www.avma.org.uk/help-advice

Contact details

Care Quality Commission (CQC)

The CQC is the independent regulator of health and adult social care organisations in England and is responsible for monitoring compliance with standards such as the duty of candour.

The CQC has legal powers to take action against organisations who do not comply.

Tel: 03000 61 61 61

www.cqc.org.uk

You can find the full regulations themselves and the CQC guidance for organisations on how to comply at:

www.cqc.org.uk/duty-candour

Action against Medical Accidents (AvMA)

AvMA is the charity for patient safety and justice. We provide free specialist advice and support to people when things go wrong in healthcare, and we are the charity which led the campaign to bring about the duty of candour.

Helpline: 0845 123 2352

(10am – 5pm Monday-Friday)

Before contacting the helpline, please visit the help and advice section of our website for self-help information and leaflets.

www.avma.org.uk/help-advice

Action against Medical Accidents (AvMA)

For advice and information

Visit our website for a wide range of advice, information and support, including:

- making a complaint
- inquest support
- taking legal action

www.avma.org.uk/help-advice

Or call our helpline (10am-3.30pm Mon-Fri)
0845 123 2352

Action against Medical Accidents (AvMA) is a registered charity in England and Wales (number 299123) and in Scotland (number SCO39683)

www.avma.org.uk

 www.facebook.com/AvMAuk  [@AvMAuk](https://twitter.com/AvMAuk)

Action against Medical Accidents

Freedman House,
Christopher Wren Yard
117 High Street
Croydon CR0 1QG

020 8688 9555 (office)

Please use the helpline number (left) for help or advice regarding a medical accident

avma
action against medical accidents

Action against Medical Accidents

Freedman House
Christopher Wren Yard
117 High Street
Croydon CR0 1QG

020 8688 9555

www.avma.org.uk

 www.facebook.com/AvMAuk

 [@AvMAuk](https://twitter.com/AvMAuk)

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avma
action *against* medical accidents