

Regulating the
duty of candour

Requires improvement

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

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1. Introduction

The duty of candour is a fundamental standard that was introduced as law in November 2014 following the Mid-Staffordshire NHS Foundation Trust public inquiry. Action against Medical Accidents (AvMA), an independent charity, led the campaign for a statutory or legal 'duty of candour'. AvMA remains committed to ensuring the duty of candour is complied with and is properly regulated.

The [Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2014: Regulation 20](#) (regulation 20) enshrines the duty of candour in England. The Care Quality Commission (CQC) monitors compliance and has published guidance to ensure providers are aware of duty of candour requirements. One of the key methods of monitoring whether providers are safe and compliant are the CQC inspections. These inspection reports allow us to understand what convinces a CQC inspector that the provider is compliant with regulations.

In 2016, AvMA published a report (www.avma.org.uk/Regulating-the-duty-of-candour.pdf) that assessed the CQC's regulation of the duty of candour in NHS trusts in the legislation's first full calendar year. This new report allows us to compare the CQC's assessment of compliance with the duty of candour in 2015 to that of 2017.

The 2016 report created an assessment standard and analysed each individual inspection report. We have adopted this for ease of comparison. It has allowed us to assess if there has been improvement in the CQC inspections. This report will also look into action taken under the duty of candour regulations in regard to NHS trusts, primary care and private care providers, and how reports of alleged non-compliance received from the public are dealt with.

2. The duty of candour requirements

The duty of candour ensures registered persons act in an open and transparent manner with patients, their carers, families or relevant contact after a notifiable incident occurs. The definition of a notifiable incident includes those which result in death, serious or moderate harm, or psychological harm that lasts at least 28 days. Legislation holds that when the duty of candour is triggered then the registered person must:

1. Notify the relevant person of the incident as soon as practically possible
2. Offer an apology
3. Provide the relevant person with support after the incident and include them in the incident investigation.

A written notification must:

1. Be given in person
2. Provide an accurate and comprehensive account of the incident
3. Advise the relevant person of further enquiries that can be taken regarding the incident. Results from further investigation that may take place must be shared with the relevant person.
4. Include an apology.

The duty of candour is triggered when an incident appears to have or could cause significant harm. Using the NHS England definitions, significant harm is defined as moderate harm or worse. This includes:

- **Death**
- **Serious harm:** a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions. This includes the 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 re-admission as an inpatient or outpatient, or prolonged pain which will, or is likely to, last for a continuous period for at least 28 days.
- **Psychological harm:** any psychological harm that will, or is likely to, last for 28 days or more.

The CQC has full details of the duty of candour on their website (www.cqc.org.uk/duty-candour), including guidance and regulations.

3. Methodology

We analysed CQC reports of inspections carried out in 2017 as one way of assessing how well the CQC is regulating the duty of candour. We have followed a similar method to the 2016 report in order to allow a comparative assessment of how the CQC inspection reports deal with the duty of candour.

To some extent the reports allow us to assess how well the duty of candour is being applied in NHS trusts, however; there are limitations. We are relying on the inspectors' interpretation of findings and reporting. The duty of candour may have been further assessed outside the remit of the reports. Furthermore the NHS bodies may be doing more than the reports describe.

In order to generate a sample we focused on NHS bodies, specifically hospital trusts. The sample contains 59 reports, which hold the findings of inspections carried out between 1 January and 31 December 2017. Due to the time between inspection and publication, we imposed a cut-off point. This ensured we could publish our report within a reasonable time. We excluded reports published after 1 March 2018. Although the cut-off limited our data, we felt our sample was large enough to produce

representative conclusions. However it is a smaller sample than the 90 reports that were assessed for the 2016 report.

[Appendix 1](#) has the full list of CQC inspection reports that are the subject of this report.

We obtained relevant extracts by searching for the phrase 'duty of candour'. This allowed us to focus on how the CQC have assessed the NHS bodies' understanding and implementation of the duty of candour. Furthermore this mirrors the strict search used in the 2016 report allowing for a comparative assessment.

In order to accurately compare the 2015 and 2017 inspection reports, we have used the same method to assess the findings. This allows for an accurate representation of improvement or lack thereof. In light of this, we broadly assessed the findings by asking:

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?

Assessment standard

We individually assessed each report and extracted important observations. We then applied the assessment standard, created for the 2016 report, to each report. The categories used are:

- **Non-existent:** No mention of the phrase 'duty of candour' in the report
- **Superficial:** A cursory acknowledgement of the duty of candour, usually a sentence or two without further detail or analysis.

- **Moderate:** The report provides a degree of detail on the NHS body’s approach to the duty of candour but fails to cover other aspects.
- **Detailed:** The report refers to number of elements of the duty of candour and its implementation. Often there is inclusion of relevant statistics.

In a number of reports themselves, the duty of candour was superficially assessed or wasn’t included in the report but was included in the evidence appendix. We have used both the final report and the evidence appendix to determine the assessment standard of the duty of candour (*for example, a report that includes only a superficial assessment in the main report but has a detailed assessment in the evidence appendix would be assessed as ‘detailed’*).

It is important to highlight that even when a detailed assessment of the duty of candour has been completed, it doesn’t mean the report has sufficiently called the NHS body to account for its implementation of the duty of candour. The CQC inspector may have reported a detailed assessment and criticism of implementation but omitted recommendations that would see regulation 20 fully met. Therefore we have also assessed whether recommendations to improve compliance with the duty of candour were made and have been included in the report.

Freedom of Information request

We also made a Freedom of Information request to the CQC ([appendix 2](#)) in order to establish:

- What regulatory action, if any, has been taken with providers since the introduction of the duty of candour, and
- How many reports/allegations of non-compliance had been received from members of the public.

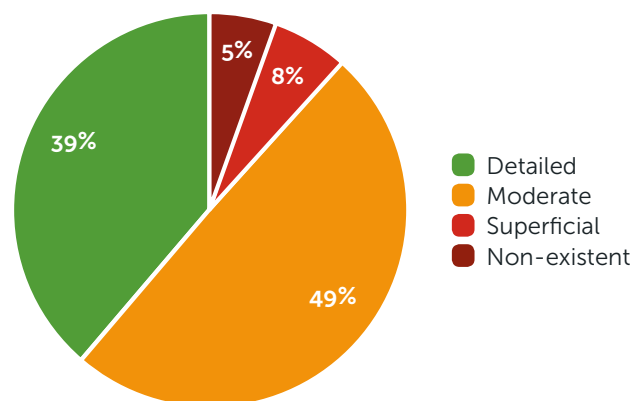
Further discussions were held with staff at the CQC to elicit further information not provided in the response to the Freedom of Information request.

We would like to express our gratitude for the help and co-operation of staff at the CQC.

4. Findings

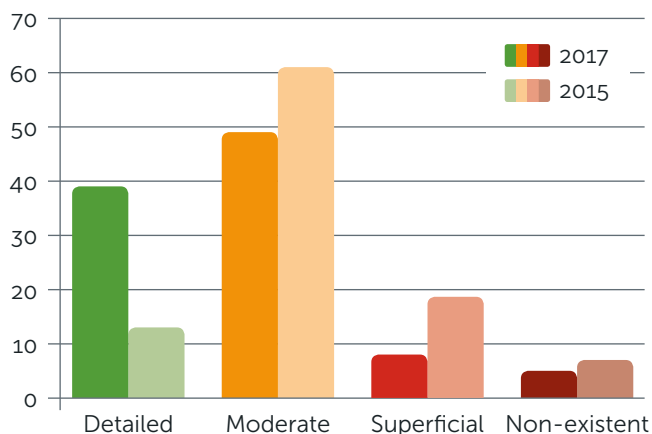
Figure 1, below, gives a picture of our findings regarding the reports on 2017 inspections. We have used the assessment standard, explained in section 3, to categorise the reports and evidence appendices. [Appendix 1](#) has the list of CQC reports we analysed, with the final column indicating the assessment standard in each report.

Figure 1: Duty of candour reporting standards – 2017 inspections



Using our assessment standard and categories we have been able to compare reports from 2015 and 2017. This has allowed us to see whether there has been an improvement in the inspection and reporting of the duty of candour. This comparison can be seen in figure 2 (below). It is important to note that the samples used, in the 2016 report, are larger than this 2018 report. Due to this we have compared the data using percentages.

Figure 2: A comparison of 2015 and 2017 reporting standards on the duty of candour



In 2015, six reports (7%) didn't mention the duty of candour at all. In 2017, three reports (5%) don't mention the duty of candour in the report or the evidence appendix thus placing them in the non-existent category. This shows improvement in the inspection and reporting of the duty of candour.

Four reports (8%) had a 'superficial' analysis of the duty of candour in 2017. It was briefly mentioned in a sentence or two that functioned to simply acknowledge that the duty of candour should be mentioned. This superficial assessment of the duty of candour doesn't demonstrate the relevant NHS body's actions regarding compliance nor does it highlight areas for improvement.

29 reports (49%) had a moderate degree of analysis in 2017 and 23 reports (39%) had detailed analysis. There has been improvement in the number of reports with detailed analysis since the publication of the 2016 report, which only showed 12 reports (13%) with detailed analysis. This shows positive improvement not only in the inspection of the duty of candour but also in the thorough interpretation and reporting of findings by the CQC.

In a number of reports, the duty of candour was superficially assessed or wasn't included in the inspection report itself but was included in the evidence appendix. The inclusion of

the duty of candour in evidence appendices and not the report is problematic, especially if problems are identified in the appendix. This is discussed further later when we look at what recommendations or actions arise as a result of problems with complying with the duty of candour.

Examples of 'non-existent' analysis

Inspection reports have been classified as 'non-existent' if the duty of candour wasn't mentioned in the main report or the evidence appendix. It is worth noting, however, that Oxleas NHS Foundation Trust and Hounslow and Richmond Community Healthcare NHS Trust both mention the duty of candour in specific ward or service reports. Nonetheless these two trusts have been classified as 'non-existent' due to the absence of the duty of candour in the main report or an evidence appendix.

Example 1: Oxleas NHS Foundation Trust (www.cqc.org.uk/provider/RPG/reports)

The duty of candour wasn't mentioned in the trust level report, which is a report on the quality of care at this provider. It was mentioned superficially in the report on the forensic inpatient/secure wards, which stated that "managers and senior staff knew about the duty of candour. They were aware that an apology should be made when mistakes were made and were open and transparent when this happened". Nevertheless, this provider has been classified as 'non-existent' due to the lack of any mention of duty of candour in the main report or evidence appendix.

Example 2: Hounslow and Richmond Community Healthcare NHS Trust
(www.cqc.org.uk/provider/RY9/reports)

Like the Oxleas NHS Foundation Trust, the duty of candour wasn't mentioned in the trust level report. However it is mentioned superficially in the report on the community health inpatient services where it is held that "staff... were able to tell us when they would apply the duty of candour by being open and transparent with patients, or relatives of a patient, about a safety incident". The duty of candour should be assessed and reported on within each service and the provider overall, therefore despite its inclusion in the community health inpatient services report, this provider has been marked as 'non-existent'.

Examples of 'superficial' analysis

Example 1: Barts Health NHS Trust
(www.cqc.org.uk/provider/R1H)

This report had only a superficial analysis of the duty of candour despite having detailed analysis of incidents. The report showed Barts Health had an "electronic incident system to report, investigate and act upon incidents and adverse events". The inspector was assured that staff knew how to report an incident and reviewed several incidents to ensure action had been taken and lessons learnt. However, although the report states "saw examples of where staff applied the principles of the duty of candour", it doesn't provide details or statistics to show how many incidents triggered the duty.

The report raised more questions than it answered. Did the trust have a policy in place to ensure the duty of candour was complied with? Did the inspector offer recommendations to ensure the application of duty of candour wasn't delayed? Overall the report contained vague assurance that the duty of candour

was being adhered to but the exclusion of recommendations to remedy delays is worrying.

Examples of 'moderate' analysis

Moderate analysis is the most varied category. The duty of candour may be mentioned throughout the report but without the detailed analysis and statistics required to be categorised as 'detailed'.

Example 1: Southern Health NHS Foundation Trust
(www.cqc.org.uk/provider/RW1)

Southern Health NHS Foundation Trust has a 'being open' procedure, which was ratified in 2016. In that year, the CQC highlighted improvements that needed to be made, some of which the trust has implemented (*for example at the time of the inspection, in March 2017, the trust was developing a training package that focused on the duty of candour*). Further evidence of improvement in the trust was shown by a follow-up audit in March 2017 (the original audit occurred in 2016/17).

The employment of audits and the improvements made are promising and show that the trust understands the fundamental importance of the duty of candour. However, the CQC found gaps in the records of duty of candour application.

The CQC had highlighted that Southern Health NHS Foundation Trust did not consistently record a patient's next of kin on their records, hindering the trust's ability to carry out the duty of candour in a timely manner. Despite the use of audits, the trust still hadn't improved in their recording of next of kin details (*for example, the CQC highlighted that in older person's mental health only 47% had next of kin recorded*). This must be improved and the CQC's criticisms should have been coupled with recommendations.

Example 2: Cumbria Partnership NHS Foundation Trust
(www.cqc.org.uk/provider/RNN)

Cumbria Partnership NHS Foundation Trust has duty of candour principles in place. The report showed that in wards for older people with mental health problems, staff were able to respond to and report incidents. There were de-brief sessions after incidents and lessons were learnt.

These are positive findings and the inclusion of patients' views in the investigation shows the CQC were thorough. However the lack of evidence of the application of duty of candour is worrying. Also, when recommending action to take, the CQC stated the trust 'should improve'. The use of "should" instead of "must" isn't appropriate language for the failure to comply with the duty of candour (a fundamental standard).

Examples of 'detailed' analysis

Example 1: King's College Hospitals NHS Foundation Trust
(www.cqc.org.uk/provider/RJZ)

The report had only a superficial overview of the duty of candour that suggested compliance. However, the evidence appendix showed a detailed inspection, which flagged issues.

In April 2017, the trust employed a rigorous process to ensure the duty of candour was being appropriately applied. This is a positive step but there are still worrying reports. Between April and June 2017, 107 incidents occurred which met the duty of candour threshold. Of these 10 incidents (10%) had no conversation documented and a further 4% didn't include a written letter.

The evidence appendix shows that investigation findings had been shared in only 23% of incidents (although we acknowledge

that many investigations hadn't been completed). In spite of these findings the CQC didn't appear to give recommendations (at least none recorded in the report or evidence appendix).

The evidence appendix showed the trust utilised many avenues to share incident learning: these included handovers, emails and staff noticeboards. This shows an open and transparent trust that promotes compliance with the duty of candour.

Example 2: University Hospitals of North Midlands NHS Trust
(www.cqc.org.uk/provider/RJE)

The report had only a superficial analysis of the duty of candour but the evidence appendix held a detailed one. The trust had a "robust electronic system" for complaints which aided staff in ensuring the duty of candour was carried out. The trust had a duty of candour policy that included training at induction, and further statutory and mandatory training both online and in person. Furthermore training sessions were also provided on request.

The trust's incident reporting forms and root cause analysis (RCA) documents demanded the duty of candour be recorded. However, in serious incident breakdowns it wasn't explicitly stated that the duty of candour was applied. The staff's understanding and application of the duty of candour suggests that it was applied.

Example 3: Portsmouth Hospitals NHS Trust
(www.cqc.org.uk/provider/RHU)

The report contains detailed analysis of the duty of candour. It flags the out-of-date duty of candour policy but doesn't query a renewal date or offer detail of the policy itself. The report doesn't assess the policy's definitions of harm against those included in regulation 20 but it does state non-compliance with

the National Patient Safety Agency's '[Seven steps to patient safety](#)' tool. The trust must be compliant with regulation 20.

The report stated that the CQC were "provided with examples of where duty of candour had been applied" and gave evidence regarding the failure to apply the duty of candour to relevant incidents. It found that duty of candour wasn't applied in 24 out of 305 incidents (7%). The report includes recommendations but there isn't evidence that there was follow up to ensure that the problem was rectified.

This report has a detailed assessment of the duty of candour and good use of statistics. However it fails to mention staff training and simply holds that staff are "aware of duty of candour".

5. Recommendations to improve

Since our 2016 report the CQC has improved in their inspection and reporting on compliance with the duty of candour. However, our analysis showed that even where problems were found with trusts' compliance with the duty of candour and are mentioned in the inspection report or the evidence appendix, often this still was not leading to a recommendation to address it.

For example, the report on Weston Area Health NHS Trust criticises staff's inconsistent knowledge of the duty of candour but no recommendations followed. The CQC could have included recommendations of mandatory training or the use of leaflets in the wards to improve knowledge.

The CQC point out that King's College Hospital NHS Foundation Trust hasn't applied the duty of candour in 10% of cases but doesn't provide suggestions for improvements or recommendations.

West Suffolk NHS Foundation Trust was criticised for a lack of mandatory training on the duty of candour but did not follow it up with a recommendation (However the CQC did acknowledge that the trust appeared to be complying with the duty of candour when appropriate).

Southern Health NHS Foundation Trust was criticised in January 2016 and again in 2017 for failing to consistently obtain the patient's next of kin details, thus hindering their ability to comply with the duty of candour. However recommendations weren't given as the CQC acknowledged that improvements were being made (*for example, the trust was developing a duty of candour training package*).

Seven reports did have both criticisms and recommendations to improve but the recommendations were inconsistent and often vague. In some reports the recommendations appeared specific to the issues at hand. For example, the CQC recommended that Portsmouth Hospitals NHS Trust must take action to improve the identification and management of incidents. This would allow them to highlight incidents that trigger the duty of candour.

In contrast, Northern Devon Healthcare NHS Trust were simply told they must take action to ensure the duty of candour is complied with and that evidence of this is recorded. Although somewhat vague, this does address the trust's failure to keep records of duty of candour compliance. However, the recommendation doesn't specifically address the criticism that staff weren't always given sufficient time to complete mandatory training.

Actions trusts 'should' or 'must' take

Our 2016 report analysed the CQC's language when giving recommendations. The recommendations were divided into two types: action the trust "**should** take" and action

the trust “**must** take”. The distinction between should and must shows a clear divide in the importance of improvement.

In 2016, we found that the importance placed on recommendations regarding the duty of candour was inconsistent. The use of ‘should’ highlights the CQC simply suggesting improvement rather than insisting on the improvement of a fundamental standard of care.

In this report we have found a significant change in the language used by the CQC. The 2017 inspection reports used the word ‘must’ when requesting specific action to improve. This shows a consistent respect for the duty of candour and is evidence that the CQC uniformly views the duty of candour as a fundamental aspect to healthcare.

We are pleased that the CQC has shown improvement through its consistent use of ‘must’ when giving recommendations. However, action must be taken to ensure that recommendations accompany all criticisms.

6. Issues of implementation and non-compliance

The duty of candour has many aspects that need to be fulfilled in order to be compliant with regulation 20. Through inspections, both announced and unannounced, the CQC highlights issues of implementation and non-compliance. Since 2015, there has been significant improvement not only in the inspection of the duty of candour but also, it would seem, in its application by NHS trusts. However there are still problems with compliance. These are included in the reports and evidence appendices and should be followed by recommendations.

Staff training

In order for the duty of candour to be applied, staff must have knowledge and be trained; this wasn’t always evident in trusts. This issue was flagged in the CQC’s inspections and trusts were called to improve. For example, at the Northern Devon Healthcare NHS Trust, staff weren’t always given adequate time to complete mandatory training nor were they up-to-date with training. When highlighting areas for improvement in the report, the CQC held the trust must improve and ensure compliance. The lack of training was only in certain sectors of the trust but this is still problematic as there needs to be compliance across the whole trust.

The inclusion of the duty of candour in mandatory training is important and should be done at all trusts. However, this can only be successful if all staff complete mandatory training. At Whittington Health NHS Trust training for the duty of candour was at 87% completion (152 out of 175 staff had been trained).

Knowledge of the duty candour was varied as well. For example, at Weston Area Health NHS Trust, medical staff were knowledgeable but the nursing staff had inconsistent knowledge. Furthermore the staff were unaware the trust was providing training or support for the duty of candour.

Categorisation of incidents

A triggering incident can be death, serious or moderate harm, or psychological harm. The correct categorisation of incidents is essential to the application of the duty of candour. During inspections, CQC inspectors weren’t always assured that incidents were correctly categorised. For example, the end-of-life care service at George Eliot Hospital NHS Trust couldn’t assure the CQC of this despite staff being aware of their responsibility to report incidents.

CQC inspections found varied application of the duty of candour within trusts. The duty of candour may have been applied to serious incidents but not moderate or psychological incidents. This raises questions of the understanding of the duty of candour but also the monitoring of incidents to ensure all incidents that trigger duty of candour are flagged.

For example, at Portsmouth Hospitals NHS Trust 7% of incidents showed the duty of candour hadn't been completed. In the CQC inspection reports and evidence appendices, there is a focus on the application of the duty of candour in death and serious incidents. Although this doesn't show that moderate and psychological incidents are not being inspected, the findings should be as openly displayed and discussed.

In Warrington and Halton Hospitals NHS Foundation Trust, the CQC found the duty of candour hadn't been applied in some moderate incidents. The CQC also requested evidence of duty of candour for serious and moderate incidents but only serious incidents were available.

Evidence of the application of the duty of candour should be available for all appropriate incidents, not merely serious incidents. The issues of application across all incidents of significant harm (death, serious, moderate and psychological) highlight that trusts must not only improve monitoring of incidents but also staff training. Staff must be aware of all aspects of significant harm to ensure they can pinpoint incidents that may have caused it.

Inspections and monitoring

The quality of inspections and the detail of analysis in the reports was varied, highlighting a need for a standard approach that inspectors can use to gather evidence and analyse the duty of candour. The KLOEs (key lines of enquiry) created by the CQC ensure the inspectors focus on, for example, how well-led

or safe the provider/service is. This is positive and seemingly more focused than the 2015 inspections. However the inspectors are still relying on the examples and data given by the provider. Only a few reports show evidence of independent analysis of random selection of incidents. Inspections and the degree of analysis have improved since 2015 but there needs to be a more detailed inspection guide for the duty of candour as two sets of KLOEs do not appear sufficient.

Trusts must have rigorous systems to monitor the application of the duty of candour. These systems ensure not only that the duty is applied but that it is done so in a timely manner. The CQC found many trusts lacked such systems or these systems were insufficient. For example, Warrington and Halton Hospitals NHS Foundation Trust had a duty of candour monitoring process but it "lacked rigour". The ten-day timescale for initiating the duty of candour wasn't monitored and the board didn't receive information regarding the duty of candour regulatory requirements.

During inspections the CQC assesses recorded compliance of the duty of candour. Trusts must keep a record not only of compliance but also of evidence of compliance (for example, conversations and letters of apology). This wasn't always done which makes it difficult to assure us of compliance. For example, Tees, Esk and Wear Valleys NHS Foundation Trust hadn't kept records of attempts to contact the relevant person (necessary to show why duty of candour wasn't carried out) and didn't have evidence that written notification was given to patients or their relatives in each incident.

7. Active implementation of the duty of candour

The CQC reports have shown a number of trusts employing active methods of duty of candour implementation. Most trusts have

a duty of candour policy that sets out the duties and responsibilities of staff. In order to ensure that their policies fulfil the legal requirements, set out in regulation 20, some trusts undertook an audit of compliance. This was seen, with positive results, in the Cornwall Partnership NHS Foundation Trust. This is good practice and should be standard procedure among trusts to ensure they fulfil their legal requirements. For example, Portsmouth Hospitals NHS Trust has a duty of candour process but there has been no quality audit “to assess the openness and transparency of the trust”.

Some trusts have ensured both staff and patients are aware of the duty of candour. These measures close gaps in knowledge and allow for up-to-date training. For example; University Hospitals of North Midlands NHS Trust provided patients with duty of candour leaflets. Humber Teaching NHS Foundation Trust has utilised multi-media training sessions for staff. These included podcasts for refresher courses, interactive training sessions and practice notes regularly sent to clinical teams.

George Eliot Hospital NHS Trust had created a ‘compact to excel’ for staff that set out the expected behaviours and standards; this is an excellent method of implementation. Croydon Health Services NHS Trust’s use of duty of candour explanatory guides attached to staffs’ payslips is an innovative method of ensuring all staff become aware of the duty of candour.

Reports showed that many trusts employed the use of an electronic reporting system to record and monitor duty of candour compliance. These systems had a section for the duty of candour that served to remind staff of their duties and ensure they were completed. Incident reporting systems are alerted when an incident triggers the duty of candour (as seen in Walsall Healthcare NHS Trust). Methods have to be developed to ensure all steps of the duty of candour are completed. For example, Northampton General Hospital NHS Trust

has developed a simple yet effective method to display when duty of candour has been completed. The trust uses stickers placed on patient’s notes, which include an account of incidents, details and an apology.

A common practice across trusts is the use of governance teams or designated senior leaders that ensure duty of candour compliance. This ensures individuals can be trained to handle emotionally and socially difficult situations that may arise. For example, West Hertfordshire Hospitals NHS Trust had nominated an ‘executive leader’ to ensure compliance. Walsall Healthcare NHS Trust had divisional governance teams who monitored every significant harm incident. The use of governance teams across most trusts is a positive sign of active implementation.

These aren’t all of the methods of active implementation or good practice but they do show an improvement in the implementation of the duty of candour since 2015.

8. Action taken regarding the duty of candour

After looking at the CQC’s inspection reports we looked at whether any regulatory action followed breaches of the duty of candour by NHS trusts, primary care and private care. A Freedom of Information (Fol) request ([appendix 2](#)) was submitted and the CQC was able to provide some of the relevant data. However the extent of the data we received was limited due to the absence of a central recording system at the CQC and the cost of finding the information.

We were astonished that the CQC were initially unable to tell us about any regulatory action taken with regard to NHS trusts. Thankfully, staff at the CQC rectified this on request and we are grateful for them taking the trouble to collate it for us. However, the fact that no

central record was being kept is worrying. We are assured that the CQC is improving its reporting system as part of a duty of candour review (to which AvMA has been invited to contribute).

The CQC has developed an enforcement policy¹ which concerns the enforcement of the Health and Social Care Act 2008 and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The enforcement policy is used to protect individuals from harm or risk of harm and to hold providers accountable. The CQC employs a four-step operating model that is used to hold providers to legal standards of care.

The main enforcement actions open to the CQC are a requirement notice; a warning notice; an urgent suspension or urgent imposing condition. However, it can also cancel registration and even prosecute for breach of duty of candour.

The CQC has created a 'decision tree' ([appendix 3](#)) that allows inspectors to apply consistent and proportionate enforcement action when standards aren't met. Inspectors utilise many tools to assess services and providers: for example, complaints and information received from staff, patients and members of the public may influence the timing of inspection.

The reliance upon external complaints and information is problematic as the CQC doesn't centrally record alleged breaches of the duty of candour. This hinders its ability to use appropriate enforcement action. For example, enforcement action (including prosecution) would be taken if there had been a continuous failure to adhere to regulatory standards. However without access to complaints or an ability to realise patterns of breaches, the CQC can't be relied upon to ensure the duty of candour is adhered to.

Action taken with NHS trusts

Upon our request the CQC searched reports and identified actions taken regarding the duty of candour with regard to NHS trusts. In total 18 actions were found, 15 under regulation 20 and three under regulations 17 and 18. Further details can be seen in [appendix 4](#).

The main issues found across the NHS trusts were: incomplete application of the duty of candour; lack of staff knowledge; and partial adherence to the duty of candour. Although it is positive to see that regulatory action is being taken in some cases, which was not the case when we reported in 2016, these issues also appear in many inspections reports on trusts that have not been subject to enforcement action. It is possible that those who had action against them had more serious issues across the board, whereas ones who did not receive enforcement action had more localised issues. This isn't clear from reports but most, regardless of action taken, hold recommendations and areas for improvement, which is important for development.

We also looked at whether there had been follow-up inspections or reports on trusts following regulatory action. Of the 18 examples, ten (56%) did not record any follow up. As most trusts were inspected in 2018 or late in 2017, it is possible that the CQC is allowing time for improvements to be made. However for five (28%) of the reports, the inspections were carried out in 2015 and 2016.

This leaves adequate time not only for improvements to be implemented but also for results to be assessed in follow up inspections. The CQC may have inspected the trusts without publishing their findings but this seems unlikely considering other follow up reports were published on the CQC's website. The lack of follow up with these five trusts is worrying and doesn't portray a high standard of inspection from the CQC.

¹ www.cqc.org.uk/sites/default/files/20150209_enforcement_policy_v1-1.pdf (February 2015)

Enforcement action requires the trust to report back to the CQC, setting out the actions planned in order to improve and comply with legal requirements. These action plans may influence follow up investigations as it could cause them to be more focused. It wasn't clear that the CQC received responses however it is more important that there was evidence of improvement when follow-up inspections occurred.

There were common issues throughout the trusts, namely a lack of staff knowledge and training. For example, Isle of Wight NHS Trust didn't include the duty of candour as part of mandatory staff training. The outpatients sector didn't hold regular staff training and in diagnostic imaging there was no evidence that staff understood the duty of candour or when to apply it. The duty of candour wasn't referred to in serious incident investigation reports, which is likely a result of the lack of staff knowledge and training.

Incidents are likely to go unreported if the staff are unaware of when to apply the duty of candour, meaning patients will be uninformed and the trust will be unable to act in the open and transparent manner required of it. The Isle of Wight NHS Trust was given a requirement notice, as were the other trusts, however there doesn't seem to be a time limit for when a follow up has to occur.

Of the 18 actions, requirement notices are the most common form of enforcement. The CQC employs them when there has been a breach of or poor ability to maintain compliance with regulations but there is no immediate risk of harm. The CQC uses this enforcement power to extract a report from the offending provider; who must show the actions it will take to comply with the regulation. A follow-up inspection should logically ensue.

Examples of regulatory actions taken with trusts

Example 1: The Nuffield Orthopaedic Centre of the Oxford University Hospitals NHS Foundation Trust – no follow up
(www.cqc.org.uk/sites/default/files/new_reports/AAAH1928.pdf)

An inspection on 9 August 2017 showed that the trust hadn't adhered to all aspects of the duty of candour regulation (*for example, conversations with relevant individuals weren't recorded and documented*). This inspection was unannounced and was carried out in response to a Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) notification concerning an incident that occurred on 8 July 2017.

The specific incident showed that the duty of candour had been applied, including a letter of apology to the patient, but there was no evidence of a conversation with the family. The CQC's response of a focused inspection is a positive reassurance in light of issues of complaint records, namely the lack of a central recording system. The CQC issued the Nuffield Orthopaedic Centre with a requirement notice. The report sufficiently highlighted issues of compliance; however, it didn't mention a duty of candour policy, nor did it discuss staff awareness or understanding of the duty of candour.

On 8 November 2017, Nuffield Orthopaedic Centre was subject to another unannounced inspection. This was a follow-up from the August inspection. Surprisingly this report gave more information on what was found in August, namely that the duty of candour wasn't included in mandatory training, staff knowledge was limited and duty of candour compliance was incomplete. The report from the November inspection doesn't address whether there were plans for improvement after the previous inspection. However it does

issue another requirement notice this time with regard to staff knowledge of the duty of candour.

The report states that Nuffield Orthopaedic Centre has continuously struggled with duty of candour compliance, most notably in the medical care unit. This is due to unclear definitions and formal requirements of the duty of candour. Perhaps this can be rectified with the creation of pamphlets or flyers, which can be easily circulated, that contain definitions² of candour and a brief explanation of moderate, serious and psychological harm. This in conjunction with a clear and concise step-by-step guide to the duty of candour may ensure an increase in full compliance.

Example 2: Royal Cornwall Hospitals NHS Trust – follow up
(www.cqc.org.uk/provider/REF)

The inspection report highlighted an excellent two-route compliance method used by the trust. These methods were divided into: significant/major harm or death; and minor harm. Although this process to ensure compliance is commendable it wasn't operating effectively. The CQC flagged incorrect classification of incidents so that moderate/major or catastrophic incidents were overlooked as 'no harm' incidents.

When incidents were correctly classified and serious incident forms filled out, the trust often marked 'Yes' in sections where a detailed overview of the duty of candour is expected. The trust didn't consistently adhere to all aspects of the duty of candour; on occasion there was evidence of an apology given to patient but no evidence that it had been followed up by a written apology.

Royal Cornwall Hospitals NHS Trust had included duty of candour in their mandatory training and set a training target of 95% completion. Unfortunately duty of candour training was only at 92.2% and only 43.5% of required medical staff had up-to-date duty of candour training.

The trust had attempted to actively implement the duty of candour through mandatory training, two-route compliance system and new serious incident template. Unfortunately the trust hadn't fulfilled mandatory training goals and there wasn't complete compliance with the duty of candour; therefore a requirement notice (regulations 18 and 20) was issued. Furthermore, due to failings in governance systems and ineffective processes, the trust received an s29A³ warning notice.

The CQC have stated in their enforcement policy⁴ that they aim to follow up a warning notice (s29A or otherwise) within three months of issue. We can't be sure that this wasn't achieved but the next published inspection was on 15 January 2018. This was only six months after issue – displaying assuring procedural rigour by the CQC.

Royal Cornwall Hospitals NHS Trust had responded to both the requirement notice and warning notice with an action plan, on 30 November 2017, which included the must do/should do improvements highlighted in the July 2017 inspection. The CQC were informed of 'random audits of the grading of incidents' that commenced in December 2017. In January 2018, the trust planned to begin incident reporting refresher training, which would include the duty of candour.

These appear to be positive changes in response to the CQC's enforcement action. However upon inspection, it was found that the trust's duty of candour systems and processes

² The CQC have committed to using Robert Francis' definitions (used in the Mid-Staffordshire NHS Foundation Trust report) of openness, transparency and candour.

³ A s29A warning notice can only be given where significant improvement is required of an NHS Trust

⁴ www.cqc.org.uk/sites/default/files/20150209_enforcement_policy_v1-1.pdf - February 2015

still weren't operating effectively nor were all duty of candour requirements being complied with. Furthermore the trust still didn't have an adequate process for recording the duty of candour and there were gaps in evidence of duty of candour application.

The CQC issued a second s29A warning notice on 1 March 2018, which called for significant improvements to be made by April 2018. There is no available information to assess if improvements have been made at the time of writing.

Example 3: Southampton General Hospital of the University Hospital Southampton NHS Foundation Trust – follow up
(www.cqc.org.uk/location/RHM01/reports)

The inspection of Southampton General Hospital took place between December 2014 and January 2015; the report showed the hospital had a culture of openness and transparency that met the general principles of the duty of candour. Awareness and understanding of the duty of candour was evident but staff weren't fully informed of duties. For example local leaders didn't fully understand their duties beyond ward level such as record keeping.

The hospital used policies, staff handbooks and induction meeting presentations to inform staff of responsibilities. However these didn't contain comprehensive information of staff's duty of candour responsibilities and duties. Despite the positive culture of the hospital there wasn't always evidence of learning from incidents, often patients were told of incident but the duty of candour's formal procedure to inform wasn't followed. Services within the hospital hadn't fully adhered to the statutory regulations of the duty of candour following an incident.

The CQC issued the hospital with a requirement notice in response to regulation 20 breaches. A follow up inspection took

place between January and February 2017. It is positive to see follow up even if it is after two years. We can't be sure inspections or queries didn't occur in the interim but, if not, inspection should ideally follow sooner.

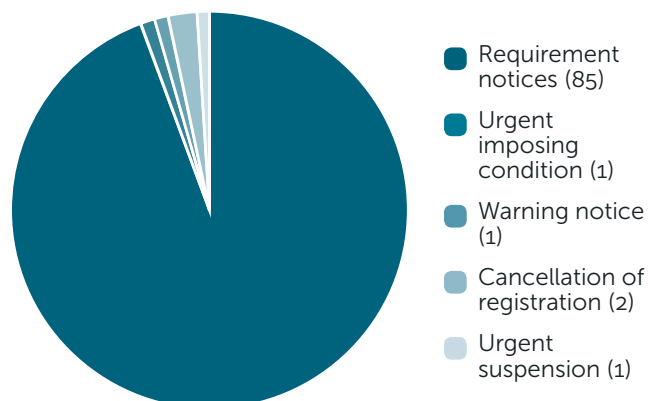
The CQC found significant improvements had taken place; the trust had a 'being open' policy, which supported the duty of candour and ensured it was monitored through an online incident reporting system. Staff had a good understanding of the duty of candour and could provide examples of when they had applied it following an incident. Furthermore there was evidence that all aspects of the duty of candour had been applied and documented such as; letters of apology, explanations and offers to view investigation findings. These positive improvements and the removal of the requirement notice demonstrate that the CQC's enforcement procedures can be a successful tool in ensuring the application of the duty of candour.

Examples of regulatory action in primary care and private care

This report is mostly focused on NHS trusts, looking at the CQC's inspections and action taken over the duty of candour. However we have briefly looked at regulatory action taken by the CQC over the duty of candour with regard to primary and private care. A list of the actions can be found in [appendix 5](#).

There have been 90 published regulatory actions served against regulation 20. Requirement notices accounted for 85 of these. Additionally, there were two cancellations of registration, one urgent suspension, one urgent imposing condition and one warning notice.

Figure 3: Enforcement action taken: primary care & private care



A majority of the reports had a superficial analysis of the duty of candour: this could be indicative of the services' failure to comply with regulations or the CQC's quality of reporting. For example, Dr Sibani Basu (inspection in January 2015) and Wayside Residential Care Home (inspection in April 2017) only included the phrase 'duty of candour' when stating that a requirement notice was given. St Clements Courts, inspected in December 2016, had their registration cancelled. This measure was taken in light of a lack of staff training or knowledge and absence of a policy for guidance. Despite the superficial analysis in reports, each action showed the CQC's response and in some cases subsequent improvement.

Enforcement procedures are effective only if the CQC follows up its recommendations to ensure that improvements have been made. If no improvements follow from the actions then further action should be taken. Of the 90 actions, 20 (22%) resulted in the service being de-registered. It wasn't clear in the reports whether this was a direct consequence of their failure to comply with the duty of candour regulations specifically; but it is reassuring to know continuous failure to comply with any regulations is acted upon by the CQC.

The CQC followed up on 44 (49%) actions to see if improvement had occurred. A number of these services were inspected in late 2017 or 2018 and therefore it is understandable that follow-up is yet to occur, however, improvements need to be made. For example, a warning notice should have follow up three months after the date of issue – as is a goal of the CQC.

Many of the follow-up inspections showed apparent improvement. The improvement is only apparent as a majority of reports had only a superficial analysis of the duty of candour and some didn't mention it in subsequent reports. For example, the Katharine House Hospice received a requirement notice after an inspection in March 2016 but in an inspection report from June 2017 the duty of candour isn't mentioned. It is important to note that it does state required action to improve had been achieved.

The CQC may have included a superficial analysis of the duty of candour in the inspection reports but it is more important that they took appropriate enforcement action in response to non-compliance. The enforcement actions under the duty of candour in primary and private care appear to show success. Of the actions with follow up inspections, a majority showed improvement although this wasn't specifically mentioned to be improvement in the duty of candour.

9. Conclusions

Although this report focuses mainly on the regulation of the duty of candour by the CQC, it also gives an indication of how well the duty is being implemented by NHS trusts. The inspection reports suggest that implementation of the duty of candour by NHS trusts has improved.

There is evidence of duty of candour policies and processes that promote an open and honest culture within trusts and ensure patients are informed when notifiable incidents occur. However it is worrying to see that many reports show incomplete compliance with the duty of candour (for example conversations aren't recorded or there is evidence of an apology but not a written one). The duty of candour must be adhered to in full.

The CQC's standard of reporting has significantly improved since 2015. There were only three reports (5%) that didn't mention the duty of candour at all. However it should be noted that 12 reports (20%) didn't mention the duty of candour in the report but solely in the evidence appendix. This demonstrates that it has been inspected and assessed but was omitted from the final report. This is problematic as the duty of candour is one of the 13 fundamental standards and should be openly displayed in the report.

There was a moderate degree of analysis in 27 reports (46%) and detailed analysis in 23 reports (39%). This shows positive improvement not only in the inspection of the duty of candour but also the thorough interpretation and reporting of findings by the CQC. The varying degree of duty of candour analysis highlights the fact that existing arrangements, including the use of KLOEs, need to be improved and applied consistently. It appears from the reports that not all inspections included an analysis of randomly selected sample of incidents.

The continuing absence of a central recording system and the CQC's inability to gather reports on all regulatory action was disappointing. We are assured that the CQC intends to address this.

The information eventually provided to us on regulatory action taken under the duty of candour with NHS trusts, primary care and private care was relatively assuring. It demonstrated that the CQC is now using its enforcement powers and procedure. Often follow-up inspections demonstrated improvements had taken place.

We understand that the CQC might follow up concerns by means other than inspections and NHS Improvement also has a role. However, it is not always apparent from the inspectors' reports or the CQC website that concerns were being followed up.

The superficial analysis of the duty of candour found in primary and private care reports must be rectified in order to have a more effective enforcement procedure.

The CQC had done very little itself to raise awareness of the fact that it was taking regulatory action regarding non-compliance with the duty of candour. It is not easily apparent from reading the website information on trusts. It should not have taken our research to unearth this information.

The reports highlighted varying levels of knowledge and awareness among staff and patients in private care, primary care and NHS trusts. Some providers are combating this through the use of mandatory training and refresher courses or the distribution of duty of candour leaflets. Action needs to be taken across the UK to ensure improvement of duty of candour knowledge – one of the 13 fundamental standards of care.

The continuing lack of clarity about how the CQC deals with individual allegations / reports of potential breaches of the duty of candour is very worrying. The CQC was unable to provide

any information on how many such reports it receives or what had been done about them. This was in spite of us highlighting this problem in our last report. Furthermore, there is no assurance from the inspection reports that even when an organisation is found not to have complied in individual cases, that the organisation has gone back to the patient/family concerned to rectify the situation and ensure they have what happened in their or their loved one's care fully explained.

Concerns have been raised and areas of improvement highlighted throughout this report. However it is important to underline that the CQC has improved in its inspections, reporting and follow-up as well as the use of enforcement procedures. Inspection reports have shown many examples of good practice and positive implementation; some have shown simple yet effective methods of ensuring duty of candour awareness among staff and patients.

The duty of candour is fundamental to healthcare and the CQC is fundamental in ensuring nationwide compliance.

10. Recommendations

1. The CQC should develop a more robust framework for inspections to assist with assessing compliance with the duty of candour. This must be consistently applied and include an analysis of a reasonable sample of incident reports, safety investigations and complaints.
2. The CQC should improve how it deals with reports received alleging individual breaches of the duty of candour. These should be assessed and centrally recorded. If they seem to indicate there has been a breach, immediate action should result. A serious breach of the duty in an individual case should be accorded the same seriousness as an alleged incident of neglect or abuse.
3. The inspection reports themselves should report consistently on the duty of candour (and the other fundamental standards), even if it is say that inspectors were confident it was being complied with well. Concerns about implementation of the duty of candour should not be buried in the evidence appendix. If there is evidence that the duty is not being fully complied with, this should always result in at least a recommendation to improve, or in serious or persistent cases, regulatory action.
4. The CQC should be much more proactive in publicising the fact that is taking regulatory action with regard to the duty of candour. Press releases should be issued when this occurs and examples should be given in CQC's communications with registered organisations and the public. This will act as a powerful incentive for organisations to comply and assure the public that the duty of candour is being taken seriously.
5. The CQC should work with other statutory bodies and stakeholders including AvMA to ensure there is consistently high quality training on duty of candour rolled out across England. Publication of the guidance currently being reviewed provides a perfect opportunity to launch this. It would significantly help improve understanding of the requirements and iron out any 'grey areas' and confusion that still exists.

Appendix 1: CQC reports (NHS trusts)

Trust	Link	Rating
Avon and Wiltshire Mental Health Partnership NHS Trust	www.cqc.org.uk/provider/RVN	Moderate
Barnet, Enfield and Haringey Mental Health NHS Trust	www.cqc.org.uk/provider/RRP	Moderate
Barts Health NHS Trust	www.cqc.org.uk/provider/R1H	Superficial *
Birmingham and Solihull Mental Health NHS Foundation Trust	www.cqc.org.uk/provider/RXT	Moderate
Bradford District Care NHS Foundation Trust	www.cqc.org.uk/provider/TAD	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	Detailed
County Durham and Darlington NHS Foundation Trust	www.cqc.org.uk/provider/RXP	Detailed
Coventry and Warwickshire Partnership NHS Trust	www.cqc.org.uk/provider/RYG	Moderate
Croydon Health Services NHS Trust	www.cqc.org.uk/provider/RJ6	Moderate
Cumbria Partnership NHS Foundation Trust	www.cqc.org.uk/provider/RNN	Moderate
George Eliot Hospital NHS Trust	www.cqc.org.uk/provider/RLT	Detailed
Gloucestershire Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RTE	Moderate
Great Western Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RN3	Detailed
Greater Manchester Mental Health NHS Foundation Trust	www.cqc.org.uk/provider/RXV	Moderate
Hounslow and Richmond Community Healthcare NHS Trust	www.cqc.org.uk/provider/RY9	Non-existent
Humber Teaching NHS Foundation Trust	www.cqc.org.uk/provider/RV9	Detailed
Imperial College Healthcare NHS Trust	www.cqc.org.uk/provider/RYJ	Superficial
Ipswich Hospital NHS Trust	www.cqc.org.uk/provider/RGQ	Superficial
Kent and Medway NHS and Social Care Partnership Trust	www.cqc.org.uk/provider/RXY	Detailed
King's College Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RJZ	Detailed
Leeds Community Healthcare NHS Trust	www.cqc.org.uk/provider/RY6	Detailed
Lewisham and Greenwich NHS Trust	www.cqc.org.uk/provider/RJ2	Superficial
Lincolnshire Partnership NHS Foundation Trust	www.cqc.org.uk/provider/RP7	Detailed
Mersey Care NHS Foundation Trust	www.cqc.org.uk/provider/RW4	Detailed
Norfolk and Suffolk NHS Foundation Trust	www.cqc.org.uk/provider/RMY	Moderate
North Cumbria University Hospitals NHS Trust	www.cqc.org.uk/provider/RNL	Non-existent
North East London NHS Foundation Trust	www.cqc.org.uk/provider/RAT	Superficial
North Staffordshire Combined Healthcare NHS Trust	www.cqc.org.uk/provider/RLY	Moderate
Northampton General Hospital NHS Trust	www.cqc.org.uk/provider/RNS	Detailed
Northamptonshire Healthcare NHS Foundation Trust	www.cqc.org.uk/provider/RP1	Detailed
Northern Devon Healthcare NHS Trust	www.cqc.org.uk/provider/RBZ	Moderate *

* The report includes a detailed analysis of incidents but the duty of candour was only superficially discussed

† On 1 July 2018 Colchester Hospital University NHS Foundation Trust merged with The Ipswich Hospital NHS Trust to form East Suffolk and North Essex NHS Foundation Trust.

Trust	Link	Rating
Nottinghamshire Healthcare NHS Foundation Trust	www.cqc.org.uk/provider/RHA	Moderate
Oxleas NHS Foundation Trust	www.cqc.org.uk/provider/RPG	Non-existent
Poole Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RD3	Moderate
Portsmouth Hospitals NHS Trust	www.cqc.org.uk/provider/RHU	Detailed
Royal Berkshire NHS Foundation Trust	www.cqc.org.uk/provider/RHW	Moderate
Royal Cornwall Hospitals NHS Trust	www.cqc.org.uk/provider/REF	Detailed
Sandwell and West Birmingham Hospitals NHS Trust	www.cqc.org.uk/provider/RXK	Moderate
Somerset Partnership NHS Foundation Trust	www.cqc.org.uk/provider/RH5	Detailed
Southern Health NHS Foundation Trust	www.cqc.org.uk/provider/RW1	Moderate
Surrey and Borders Partnership NHS Foundation Trust	www.cqc.org.uk/provider/RXX	Moderate
Sussex Partnership NHS Foundation Trust	www.cqc.org.uk/provider/RX2	Moderate
Taunton and Somerset NHS Foundation Trust	www.cqc.org.uk/provider/RBA	Detailed
Tees, Esk and Wear Valleys NHS Foundation Trust	www.cqc.org.uk/provider/RX3	Detailed
The Mid Yorkshire Hospitals NHS Trust	www.cqc.org.uk/provider/RXF	Moderate
The Pennine Acute Hospitals NHS Trust	www.cqc.org.uk/provider/RW6	Detailed
The University Hospitals of North Midlands NHS Trust	www.cqc.org.uk/provider/RJE	Detailed
University Hospital Southampton NHS Foundation Trust	www.cqc.org.uk/provider/RHM	Superficial
Walsall Healthcare NHS Trust	www.cqc.org.uk/provider/RBK	Moderate
Warrington and Halton Hospitals NHS Foundation Trust	www.cqc.org.uk/provider/RWW	Detailed
West Hertfordshire Hospitals NHS Trust	www.cqc.org.uk/provider/RWG	Detailed
West Suffolk NHS Foundation Trust	www.cqc.org.uk/provider/RGR	Moderate
Weston Area Health NHS Trust	www.cqc.org.uk/provider/RA3	Moderate
Whittington Health NHS Trust	www.cqc.org.uk/provider/RKE	Detailed
Worcestershire Acute Hospitals NHS Trust	www.cqc.org.uk/provider/RWP/reports	Detailed
Wrightington, Wigan and Leigh NHS Foundation Trust	www.cqc.org.uk/provider/RRF	Moderate
York Teaching Hospital NHS Foundation Trust	www.cqc.org.uk/provider/RCB	Moderate

* Requirement notice given to this trust - it is included in the section 'Duty of candour action against NHS Trusts'

Detailed 23

Moderate 26

Superficial 6

Non-existent 3

Appendix 2: Freedom of Information response and request



Response issued under the Freedom of Information Act 2000

Our Reference: CQC IAT 1718 0898

Date of Response: 25 April 2018

Information Requested:

“Please provide the following information for each year (2015, 2016 and 2017) as follows:

- 1. The number of reports received of alleged breach of your registration regulation 20: Duty of Candour by a registered organisation.**
- 2. The number of a) recommendations b) warnings c) other regulatory actions issued to registered organisations with respect to regulation 20: Duty of Candour.**
- 3. For each of the above provide the type of organisation concerned (e.g. NHS acute trust/GP practice/private healthcare) and the name of the organisation.**
- 4. Any other information you wish to provide with regard to how you promote and uphold regulation 20: Duty of Candour.”**

The Information Access team has now coordinated a response to your request.

CQC has considered your request in accordance with the Freedom of Information Act 2000 (FOIA). Our main obligation under the legislation is to confirm whether we do or do not hold the requested information.

In accordance with section 1(1) of FOIA we are able to confirm that CQC does hold some recorded information in relation to this matter, however we consider that the cost exemption set out at section 12 of the FOIA to be engaged.

Where this exemption applies, a public authority does not have to comply with any part of a request for information. However, in this case, we have endeavoured to provide as much information as possible, within the limit.

We have addressed each of your points in turn in the ‘Your request for information’ section below, but first it may be of assistance to provide some information in relation to CQC’s powers of enforcement.

Actions CQC can take

We have a wide set of powers that allow us to protect the public and hold registered providers and managers to account. Our enforcement policy sets out in full the approach that we take to address breaches of regulations. It also reflects how we may work with other organisations to make sure that people are protected from harm, for example, through special measures regimes.

Since the introduction of Duty of Candour Regulation CQC has not prosecuted any provider for breaching of the regulation.

However, in line with our enforcement policy CQC can use our full range of enforcement powers. We may issue a 'Requirement Notice', which notifies a provider that we consider they are in breach of legal requirements and should take steps to improve care standards. It may be issued in circumstances where a registered person is in breach of a regulation or has poor ability to maintain compliance with regulations, but people using the service are not at immediate risk of harm. If we have more serious concerns about a provider's capacity to deliver safe and effective care we can take further enforcement steps such as issue warning notices, issue fixed penalty notices, suspend and cancel registrations and more.

To read our enforcement policy in full, please visit:

www.cqc.org.uk/sites/default/files/20150209_enforcement_policy_v1-1.pdf

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20

The 'Duty of Candour' applies to all providers registering or registered with CQC from 1 April 2015. It applied to NHS bodies (NHS trusts, NHS foundation trusts and special health authorities) from 27 November 2014. 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 with care and treatment, causing harm, the regulation defines the harm thresholds that trigger the duty of candour. The regulation identifies specific action to be taken to notify the relevant person, as soon as is reasonably practicable after becoming aware that a notifiable safety incident has occurred.

The intention of this regulation is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.

The regulation applies to registered persons when they are carrying on a regulated activity and not individual employees (for example, a nurse).

CQC can prosecute for a breach of parts 20(2)(a) and 20(3) of this regulation and can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take other regulatory action. See the offences section of this guidance for more detail.

You can find out more about the duty of candour on our website:

<http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour>

Your request for information

“Please provide the following information for each year (2015, 2016 and 2017) as follows:

- 1. The number of reports received of alleged breach of your registration regulation 20: Duty of Candour by a registered organisation.***

We do not log the numbers of Duty of Candour reports centrally. We would have to manually interrogate each enquiry that held the key words ‘duty of candour’ to identify which related to an actual report of an alleged breach of regulation 20. This would exceed the cost limit set out at s12 of the FOIA. This exemption is explained in full in the ‘Freedom of Information and Exemptions on disclosure’ section below.

- 2. The number of a) recommendations b) warnings c) other regulatory actions issued to registered organisations with respect to regulation 20: Duty of Candour.***

The Table below contains the Number of Published Actions, by type for social care, primary medical services, independent ambulance services and independent healthcare.

However, please note that all actions served on NHS healthcare organisation locations in inspections conducted under the new approach prior to 1 April 2017 and urgent cancellations, simple cautions, fixed penalty notices and prosecutions served on all sectors prior to 1 April 2017 are not held centrally and are excluded from this data. We are unable to provide this data to you as we would have to manually interrogate the records for each NHS healthcare provider and this would exceed the cost limit set out in the FOIA. For more information please see the ‘Freedom of Information and exemptions on disclosure’ section below.

	Number of Published Actions, by Type					Total
Year Inspection Published / Management Review	Cancellation of registration	Requirement	Urgent imposing condition	Urgent suspension	Warning notice	

Decision Issued						
2015		11	1			12
2016		16			1	17
2017	2	49		2		53
Total	2	76	1	2	1	82

We can also confirm that there have been no prosecutions with respect to regulation 20: Duty of Candour.

3. For each of the above provide the type of organisation concerned (e.g. NHS acute trust/GP practice/private healthcare) and the name of the organisation.

Please see document 1 which contains names of providers, service type and whether the service is active or de-registered. The information relates to published actions and does not include NHS healthcare for the reasons explained in question 2.

4. Any other information you wish to provide with regard to how you promote and uphold regulation 20: Duty of Candour.”

Duty of Candour is one of our fundamental standards (Regulation 20, Duty of Candour (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20). The purpose of this fundamental standard is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong. During an inspection we would look at how this fundamental standard is being addressed by the provider organisation. This is applicable across all providers registered with CQC including NHS organisations, those in Primary Care and Adult Social care. Further information about Duty of Candour can be found at the below website along with a link to a patient pamphlet that we have developed with Action against Medical Accidents AvMA .

<http://www.cqc.org.uk/content/regulation-20-duty-candour>

CQC have undertaken work during the past year to improve our response to Duty of Candour. This has been included our new approach to Well led as part of our hospital inspections and an improved approach to how we report against Duty of Candour in our inspection reports. During 2018/19 we will be updating all guidance for both internal staff and for provider organisations.

The Freedom of Information Act 2000 – and exemptions on disclosure

The purpose of FOIA is to ensure transparency and accountability in the public sector. It seeks to achieve this by providing anyone, anywhere in the world, with the right to access recorded information held by, or on behalf of, a public authority.

The main principle behind FOIA is that people have a right to know about the activities of public authorities, unless there is a good reason for them not to.

A disclosure under FOIA is described as “applicant blind” meaning that it is a disclosure into the public domain, not to any one individual.

FOIA also recognises that there may be valid reasons for withholding information by setting out a number of exemptions from the right to know, some of which are subject to a public interest test.

Exemptions exist to protect information that should not be disclosed into the public domain, for example because disclosing the information would be harmful to another person or it would be against the public interest.

A public authority must not disclose information in breach of any other law.

When a public authority, such as CQC, refuses to provide information, it must, in accordance with section 17 of FOIA, issue a refusal notice explaining why it is unable to provide the information.

Section 12 Requests where the cost of compliance exceeds the appropriate limit set out in the Act

We consider that the information requested is currently exempt under section 12 of the FOIA. 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 do not log reports of allegations of regulation 20: duty of candour breaches, centrally. Any such enquiries would be logged in our customer database. The only way of identifying enquiries relating to 'duty of candour' is by a key word search for that term and we have identified over 1200 enquiries where this term is used. Many of these could be general enquiries about the regulation rather than actual reports of alleged breaches, or enquiries seeking updates on allegations. The only way to identify enquiries relating to the original reporting of an alleged breach would be to manually interrogate each of these enquiries. As you can imagine, this would far exceed our limited resources.

Given the scope of your request we estimate it will take far longer than 18 hours and cost more than £450 to perform an interrogation of all of the records held to gather the requested information and formulate a response to your request.

In fact, to conduct such an exercise would far exceed the appropriate limit; currently £450 or 18 hours, as defined under regulation 3(3) of the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004.

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:

www.ico.gov.uk/for_organisations/freedom_of_information/guide.aspx

Advice and assistance

Under section 16 of the Freedom of Information Act 2000 (and in accordance with the section 45 code of practice) we have a duty to provide you with reasonable advice and assistance.

If you need any independent advice about individual's rights under information legislation you can contact the Information Commissioner's Office (ICO).

The ICO is the UK's independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals.

The contact details for the ICO are detailed below.

There is useful information on the ICO website explaining how individuals can access official information:

www.ico.org.uk/for-the-public/official-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.

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/contact-us

To request a review please contact:

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

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

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

The contact details are:

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

Telephone Helpline: 01625 545 745

Website: www.ico.org.uk

Appendix 3: CQC's operating model and decision tree

Figure 3: Enforcement decision tree



Appendix 4: Duty of candour action against NHS trusts

Action under regulation 20			
Provider name	Inspection date	Report URL	Follow up
East Lancashire Hospitals NHS Trust	20-21 September 2016	www.cqc.org.uk/sites/default/files/new_reports/AAAE3927.pdf	No
Isle of Wight NHS Trust	23 to 25 January and 20 to 22 February 2018	www.cqc.org.uk/sites/default/files/new_reports/AAAH3952.pdf	No
Isle of Wight NHS Trust	22-24 November 2017	www.cqc.org.uk/sites/default/files/new_reports/AAAG3063.pdf	No
Kingston Hospital NHS Foundation Trust	12 - 14 January 2016	www.cqc.org.uk/sites/default/files/new_reports/AAAF0780.pdf	No
London North West Healthcare NHS Trust	19 - 23 October 2015; unannounced visits 3 - 7 November 2015	www.cqc.org.uk/sites/default/files/new_reports/AAAE4700.pdf	No
Northern Devon Healthcare NHS Trust	4 October to 25 October 2017	www.cqc.org.uk/sites/default/files/new_reports/AAAG9892.pdf	No
Oxford University Hospitals NHS Foundation Trust	8 November 2017	www.cqc.org.uk/sites/default/files/new_reports/AAAH1928.pdf	No
Oxford University Hospitals NHS Foundation Trust	9 August 2017	www.cqc.org.uk/sites/default/files/new_reports/AAAG9831.pdf	Yes
Royal Cornwall Hospitals NHS Trust	4,5,6 and 7 July 2017	www.cqc.org.uk/sites/default/files/new_reports/AAAG6979.pdf	Yes
Royal Liverpool and Broadgreen University Hospitals NHS Trust	15 - 18 and 30 March 2016	www.cqc.org.uk/sites/default/files/new_reports/AAAF2722.pdf	No
Sheffield Children's NHS Foundation Trust	14 to 17 and 30 June 2016	www.cqc.org.uk/sites/default/files/new_reports/AAAF6506.pdf	No
Southend University Hospital NHS Foundation Trust	12-14 January and unannounced 24 January 2016	www.cqc.org.uk/sites/default/files/new_reports/AAAF0756.pdf	Yes
Southport and Ormskirk Hospital NHS Trust	20 November 2017	www.cqc.org.uk/sites/default/files/new_reports/AAAH2412.pdf	No
The Royal Orthopaedic Hospital NHS Foundation Trust	28-29 July and 05 August 2015	www.cqc.org.uk/sites/default/files/new_reports/AAAE2059.pdf	Yes
United Lincolnshire Hospitals NHS Trust	10-14, 18,19, 26, 27 October 2016	www.cqc.org.uk/sites/default/files/new_reports/AAAG3119.pdf	Yes
University Hospital Southampton NHS Foundation Trust	9-11 December 2014 and between 5 -15 January 2015	www.cqc.org.uk/sites/default/files/new_reports/AAAB8995.pdf	Yes
West Hertfordshire Hospitals NHS Trust	6 - 9 and 19 September 2016	www.cqc.org.uk/sites/default/files/new_reports/AAAG0227.pdf	Yes

Action in relation to duty of candour under other regulations			
Provider name	Inspection date	Report URL	Follow up
Gateshead Health NHS Foundation Trust	07-09 December 2016	www.cqc.org.uk/sites/default/files/new_reports/AAAF8016.pdf	No
Hull and East Yorkshire Hospitals NHS Trust	19 – 21 May 2015	www.cqc.org.uk/sites/default/files/new_reports/AAAD5172.pdf	Yes
Portsmouth Hospitals NHS Trust	19 July 2017	www.cqc.org.uk/sites/default/files/new_reports/AAAG9180.pdf	Yes

Appendix 5: Duty of candour action against primary and private care

Table 1 - Number of published regulatory actions served against Regulation 20 of the HSCA RA Regulations 2014, Duty of Candour



Table 2 - Data relating to summary in Tab 1

Source: CQC database (Data Requests Team/Digital Directorate) at 4 June 2018

To Note: All actions served on NHS healthcare org locations in inspections conducted under the new approach prior to 1 April 2017 and urgent cancellations, simple cautions, fixed penalty notices and prosecutions served on all sectors prior to 1 April 2017 are not held centrally and are excluded from this data.

Disclaimer: Please note that the data we have provided can be used in accordance with the Open Government Licence for Public Sector Information by acknowledging CQC as the data source. CQC does not however hold any responsibility for subsequent analysis done from raw data provided as this is seen as creating new information; CQC should not be quoted as the source of the analysis and/or interpretation of transformed data.

[Open Government Licence for Public Sector Information](#)

Table 1		Number of published actions, by type					Number of actions, total
Location type	Year inspection published or carried out / management review decision issued	Cancellation of registration	Requirement notice	Urgent imposing condition	Urgent suspension	Warning notice	
Independent ambulance	2017		9		2		11
	2018		2				2
Independent ambulance total			11		2		13
Independent healthcare org	2015		1				1
	2016		8				8
	2017	1	13				14
	2018		2				2
Independent healthcare org total		1	24				25
Primary dental care	2018		1				1
Primary dental care total			1				1
Primary medical services	2015		5				5
	2017		3				3
Primary medical services total			8				8
Social care org	2015		5	1			6
	2016		8			1	9
	2017	1	23				24
	2018		5				5
Social care org total		1	41	1		1	44
Grand total		2	85	1	2	1	91

Table 2 Location name	Location status	Regulatory response	Inspection date/ management review meeting date	Follow-up
Abbey Care Home	Active	Requirement notice	13/01/2016	No
Acacia Court	Active	Requirement notice	05/04/2016	No
Ambuline Chesterfield	Inactive-dereg	Requirement notice	13/03/2017	Yes
Ambuline Leicestershire	Inactive-dereg	Requirement notice	13/03/2017	Yes
Ambuline Nottinghamshire	Inactive-dereg	Requirement notice	13/03/2017	Yes
AmbuServ Limited Nottinghamshire	Active	Requirement notice	14/02/2017	Yes
Arbour Lodge Independent Hospital	Active	Requirement notice	04/07/2016	Yes
Ascroft Medical	Active	Requirement notice	15/11/2017	Yes
Ashfield House - Annesley Woodhouse	Active	Requirement notice	10/03/2015	Yes
Beacon House	Active	Requirement notice	10/04/2017	Yes
Bigfoot Independent Hospital	Inactive-dereg	Requirement notice	21/03/2016	No
Birchwood	Active	Requirement notice	01/08/2017	No
Blue Sky Orthopaedic	Active	Requirement notice	26/06/2017	No
BMI Fawkham Manor Hospital	Active	Requirement notice	05/04/2017	No
Buckingham House	Active	Requirement notice	08/02/2016	No
Burlam Road Care Home	Inactive-dereg	Requirement notice	14/10/2015	No
Cale Green Nursing Home	Active	Requirement notice	27/04/2015	No
Cameron House	Active	Requirement notice	06/02/2017	Yes
Cartello Ambulance	Active	Requirement notice	17/01/2017	No
CC Kat Aesthetics	Active	Requirement notice	08/08/2017	Yes
Chandlers Ford Dialysis Unit	Active	Requirement notice	26/04/2017	Yes
Cherry Blossom Care Home	Active	Requirement notice	25/05/2017	Yes
Cherry Garden	Active	Requirement notice	26/07/2016	Yes
Dalton Court Care Home	Active	Requirement notice	14/12/2015	Yes
Dr D J Corlett and Partners	Active	Requirement notice	12/02/2015	Yes
Dr Sarman Bapodra	Inactive-dereg	Requirement notice	20/01/2015	Yes
Dr Sibani Basu	Inactive-dereg	Requirement notice	21/01/2015	No
Eleanor Palmer Trust Home	Active	Requirement notice	29/11/2016	No
Eleanor Palmer Trust Home	Active	Requirement notice	18/09/2017	Yes
EMC Medical Services - Blewbury	Active	Requirement notice	15/09/2016	No
Forget Me Not Residential Home	Active	Requirement notice	25/11/2014	No
Grace House	Active	Requirement notice	18/03/2016	No
Greengables Care Home	Active	Requirement notice	09/08/2017	Yes
Guardian House	Active	Requirement notice	04/11/2015	Yes
Haven Lodge	Active	Requirement notice	19/04/2017	Yes
Heathgrove Lodge Care Home	Active	Requirement notice	27/04/2017	No
Hull NHS Dialysis Unit	Active	Requirement notice	10/05/2017	Yes
Jigsaw Independent Hospital	Active	Requirement notice	21/03/2016	No
Lakeside Healthcare Stamford	Active	Requirement notice	02/02/2015	No
Larchfield House	Active	Requirement notice	27/02/2017	Yes
Larchfield House	Active	Requirement notice	01/11/2017	No

Table 2 Location name	Location status	Regulatory response	Inspection date/ management review meeting date	Follow-up
Lent Rise House	Active	Requirement notice	13/12/2017	No
Lent Rise House	Active	Requirement notice	31/01/2018	Yes
LIFELINE Medical Transport Service Limited	Active	Requirement notice	21/11/2017	Yes
Lifeways Community Care (New Barnet)	Active	Requirement notice	16/01/2017	No
Linia Bristol	Active	Requirement notice	11/10/2016	No
Medisec Ambulance Service Limited	Active	Requirement notice	14/09/2016	No
Miss Bridget Jane Marshall - 43 Freeman Street	Inactive-dereg	Requirement notice	07/02/2018	No
Motorsport Vision - Snetterton Circuit	Active	Requirement notice	22/03/2017	Yes
Nationwide Pharmacies Ltd	Active	Requirement notice	06/02/2017	No
Newbus Grange	Active	Requirement notice	19/01/2016	Yes
Nightingales Care Home	Active	Requirement notice	02/03/2017	Yes
North Ormesby Dialysis Unit	Active	Requirement notice	04/04/2017	No
Northern Community Careline Services	Active	Requirement notice	03/01/2018	No
Norwood House	Active	Warning notice	11/04/2016	Yes
PrivateDoc Limited	Active	Requirement notice	10/05/2017	Yes
ProCare Solutions	Inactive-dereg	Requirement notice	07/03/2017	No
ProCare Solutions	Inactive-dereg	Requirement notice	08/06/2017	No
Pudding Pie Lane Surgery	Active	Requirement notice	15/08/2017	No
Rascasse	Active	Requirement notice	20/03/2017	Yes
Renal Services (UK) Limited- Havant	Active	Requirement notice	20/06/2017	Yes
Richmond House Surgery	Inactive-dereg	Requirement notice	25/05/2017	No
Ridgewood	Active	Requirement notice	19/10/2017	Yes
Ridley Villas	Active	Requirement notice	05/12/2016	Yes
Riviera Ambulance Service Limited	Inactive-dereg	Urgent suspension	07/09/2017	No
Rosewood Court	Inactive-dereg	Requirement notice	11/07/2017	No
Rushyfield Residential and Nursing Home	Active	Cancellation of registration	17/03/2017	Yes
Scunthorpe NHS Dialysis Unit	Active	Requirement notice	23/05/2017	Yes
Seeleys House Short Breaks Centre	Active	Requirement notice	27/06/2017	Yes
Seeleys Respite Centre	Inactive-dereg	Requirement notice	14/11/2016	No
Shardale Specialised Therapeutic Community	Inactive-dereg	Requirement notice	03/05/2016	No
Simply Together Limited	Active	Requirement notice	08/03/2017	No
SMART Windsor and Maidenhead	Inactive-dereg	Requirement notice	11/05/2016	Yes
Sparkhill Dialysis Unit	Active	Requirement notice	30/05/2017	Yes
Spring Tree Rest Home	Active	Urgent imposing condition	12/05/2015	No
St Clements Court	Inactive-dereg	Cancellation of registration	05/12/2016	Yes
St Hugh's Hospital	Active	Requirement notice	25/08/2015	Yes
St Margarets Residential Care Home	Inactive-dereg	Requirement notice	11/10/2016	No
Station House	Active	Requirement notice	30/06/2017	No
The Foscoate Private Hospital	Active	Requirement notice	19/08/2015	Yes
The Gateway	Inactive-dereg	Requirement notice	21/10/2015	No
The Katharine House Hospice	Active	Requirement notice	09/03/2016	No

Table 2 Location name	Location status	Regulatory response	Inspection date/ management review meeting date	Follow- up
The Leonard Pulham Nursing Home	Active	Requirement notice	27/09/2017	Yes
The Old Vicarage	Active	Requirement notice	24/09/2015	No
UKSAS Regional Headquarters Hampshire	Inactive-dereg	Requirement notice	23/08/2016	Yes
Wayside Residential Care Home	Inactive-dereg	Requirement notice	18/04/2017	Yes
Western Medical Ambulance Services	Active	Requirement notice	07/11/2017	No
Windsor Park Nursing Home	Active	Requirement notice	30/08/2017	No
Winfield Hospital	Active	Requirement notice	27/02/2018	Yes
Wood Street Health Centre - Dr. Raghav Prasad Dhital	Active	Requirement notice	19/07/2017	No

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