The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust

REPORT TO BOARD OF DIRECTORS

SUBMITTED BY:	REPORT FOR:		IMPACT:		
Kate Gordon, Chair	Decision	√	High	Med	Low
CONSULTATION:	Information	√	√		
Executive Directors	REPORT TYPE:		RELATED WORK:		
	Strategic				
	Operational	√			
	Governance	√			

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Monitor Compliance Framework:	
CQC Essential Standard Reference:	16, 17, 20
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Media / Communications:	

Meeting Date: **28th January 2013**
Report Title: **Duty of Candour – Briefing Paper**

Purpose: This paper provides a briefing on the Government's proposal to introduce a contractual Duty of Candour from April 2013 and its possible implications for the Trust.

Summary: The Government issued a consultation paper in October 2011 on introducing a contractual responsibility to comply with a Duty of Candour which would apply to all NHS funded health providers apart from those in Primary Care. This Duty of Candour was described as a duty to ensure full openness and disclosure to patients and their families when something has gone wrong with their care or a mistake has occurred. The Trust contributed to the consultation and the overall results of the consultation were published at the end of November 2012. Although concerns were expressed during the consultation on the actual process of implementation, most respondents agreed with the principle of a contractual obligation and the Government has concluded that it will implement the duty within the NHS Standard Contract for April 2013/14.

This duty will be exercised and monitored by the Clinical Commissioning Group. The details of the implementation process are yet to be clarified but it will require the Trust to ensure that when an incident occurs resulting in moderate or serious harm to a patient, this is communicated promptly to those affected and that a rapid and detailed investigation takes place that is shared with the patient and family concerned. All communication with the family will have to be appropriately documented and available to be audited and reviewed should a challenge of failure of duty occur. The Trust will potentially be subject to a fine if found to have failed in implementing its duty and will be required to publish its failure on the organisation's web site. A fine will be applied by the CCG that is equal to the cost of that episode of care or a £10,000 fine if the cost is unknown. Any failure will be published on NHS Choices by the Clinical Commissioning Group and persistent failures could lead to a referral to the Regulators and potentially withdrawal or suspension of the organisation's contract.

If the findings of the Mid-Staffordshire Inquiry suggest that it would be more effective to have a statutory duty, the Government will take account of these findings and may alter its approach if convinced by the arguments to do so.

Financial Implications / Efficiency Savings / Quality Improvement: This proposal may result in financial losses due to the application of fines and also due to a reduction in contracted services due to loss of reputation.

Risk Assessment (cross-reference with Risk Register where appropriate):

Strategic / External	Operational/ Organisational	Financial	Clinical	Legal/ Regulatory	Reputational / Patient Experience
√	√	√	√	√	√

Recommendations:
The Board is asked to review the proposals and to understand the possible implications of their implementation.

Author **Claire Roberts, Deputy Director of Patient Safety**
Date **14th January 2012**

1 Background

1.1 The Government released a consultation paper in October 2011 on proposals for introducing a new contractual duty on providers of NHS funded health care to operate their services in accordance with a full Duty of Candour. This term is normally associated with a duty to disclose in legal cases but within these proposals it was used to describe a new contractual duty to be applied to NHS funded health care providers to ensure full openness and disclosure to patients and their families when something has gone wrong with their care or a mistake has occurred. The proposal was subject to consultation until January 2012.

1.2 This proposal built on the earlier requirement to 'Being Open' and reflected the Government's commitment in the 2010 Coalition Agreement which stated that, "*we will require hospitals to be open about their mistakes and always tell patients if something has gone wrong".* The consultation document suggested that there was anecdotal evidence to suggest that some health providers were not being open in how they dealt with patient safety incidents and mistakes.

1.3 The consultation did not invite a response on whether this was an appropriate approach to improving the culture of openness within the Health Service but instead invited comment and suggestions on how it should be implemented. The Trust submitted a detailed response to all aspects of the proposal and a number of comments from our response appeared in the analysis of the consultation published by the Department of Health on the 30th November 2012.

1.4 The consultation paper specifically focused on addressing the following four issues:

- What should the contractual requirement look like?
- How will it be monitored, measured and policed?
- How can we support providers to ensure compliance with this requirement?
- How can we support patients, relatives and carers when they feel they are not receiving sufficient information about an incident in their health care?

2 Proposal

2.1 The proposal recommended that a Duty of Candour be incorporated into the standard NHS operating contract from April 2013. The contractual requirement will apply to NHS Acute, Ambulance, Community and Mental Health providers but not to Primary Care. It will also include NHS funded care provided by independent or voluntary providers.

2.2 The contract will require health care providers to be open with patients when things go wrong, apologise for any mistakes that have occurred and provide them with information about any investigations that have taken place and any lessons learned. This commitment will need to be published annually on the Trust's web page.

2.3 A failure to publish this commitment would be treated as a contractual breach and result in a monthly financial deduction from the commissioning contract until it has been implemented.

2.4 Where a provider is found to be in breach of their duty to be open this would also incur penalties which might include:

- A deduction of a percentage of the annual contract up to a capped sum.
- A requirement to implement the lessons learned as part of the contract.
- A requirement to undertake remedial action including:
    - A written apology from the Chief Executive about the lack of openness.

— An independent investigation if the original investigation was felt to be inadequate.
— Publication of the numbers and types of breaches on a prominent site on the Trust's internet site and possibly on NHS Choices.

2.5 A serious breach or persistent breaches would result in an escalation of consequences including notification to Regulators and possible suspension or termination of contract.

2.6 The contractual requirement will apply to all incidents that are graded as causing moderate harm, severe harm or death under the NPSA grading system.

2.7 In all these cases there must be a full investigation and open communication to the patient and/or family that should include:

- A written apology.
- An initial detailed explanation of what has occurred within 5 working days.
- Face to face explanations to support the written communication unless the patient and /or family member refuse to attend a meeting.
- Recording of full minutes of any meeting.
- Disclosure of any new information that might emerge during an investigation within 5 days.

2.8 Providers will be required to inform the Commissioners that such an investigation is taking place and provide them with copies of documentation if requested to do so.

2.9 The proposal suggests that clinicians and specifically GPs would be in an appropriate position to support patients and families in recognising where a breach of duty might have occurred and in reporting it to the Clinical Commissioning Group (CCG). It is also suggested that there would be a role for Patient Advice and Liaison Services and Local HealthWatch Services in providing advice to patients who may feel that a breach has occurred on how to raise their concerns with the CCG. It is envisaged that a roadmap or flowchart will be provided on the NHS Choices site to support the public in understanding how to raise a concern.

2.10 If a particular concern is raised with the CCG by whatever route the Commissioner will be required to contact the Provider through their normal contractual route to request copies of all documents from the incident and investigation including minutes of meetings that may have occurred to determine whether a breach has occurred. The Commissioner will also be subject to the same degree of disclosure and 5 day working targets whilst their investigation takes place.

2.11 The Commissioner will be required to publish any breaches within their Annual Report and preferably more frequently and to forward such information for inclusion on the NHS Choices web site.

3 Results of consultation

3.1 Despite the potential implications of this proposal there were only 122 responses to this consultation. All the professional bodies and trade unions were virtually unanimously against the recommendations whereas two-thirds of NHS organisations were in favour of the principle but felt that the proposed implementation mechanism would be too onerous and difficult.

3.2 The majority supported a range of consequences to failure and these included a percentage deduction of the annual contract up to a maximum capped amount or a proportional repayment on expired contracts plus full implementation of lessons learned. However, NHS Providers voted 2:1 against the possibility of a total loss of contract.

3.3 There was agreement on the proposed remedial action including having to pay for an independent investigation if the organisation's investigation was felt to be inadequate.

3.4 Most saw the 5 day working deadline as unworkable. Particular concerns were raised about the inherent delays in recognising and reporting some incidents and in undertaking any meaningful investigation within that timeframe.

3.5 101 of the respondents felt that GPs should be included in the proposal although there appears to be no appetite within the Department of Health to extend the requirement to Primary Care at present.

3.6 Concerns were raised about equalities issues and in particular that this process would largely be used by articulate, well-educated members of the public to raise concerns but would not be utilised by those with literacy problems, mental health issues, language difficulties or those with a learning disability.

3.7 Only 50% of respondents thought that GPs should be pivotal in identifying failures and all recognised that they would need training and clear guidelines if they take on this responsibility. Some thought it would be helpful if this responsibility was included in their professional code of conduct.

3.8 82% of respondents thought a road map or flow chart would be helpful and there was recognition that Local HealthWatch Services would need resources and guidance to take on a responsibility to provide advice and support.

3.9 All respondents expressed a need for clarity in terms of expectations on Commissioners with respect to proactively advising patients of this new right, referral to Regulators and exercising public reporting requirements.

3.10 Amongst those that supported the proposal there were a number of suggestions from organisations to deliver the same objectives but via different mechanisms:

- That it could be part of Quality Accounts
- Incorporating the requirement into the NHS Constitution
- Compliance should be made part of the audit cycle
- Assurance on compliance could be sought from existing mechanisms such as compliance with NHSLA standards

3.11 The consultation paper concluded with a view that the Government remains of an opinion that the contractual mechanism is still the most appropriate approach to take and that it intends to go ahead with the proposal within the NHS Standard Contract in 2013/14. The conclusion gave no indication as to whether the details will be implemented as originally proposed or whether there will be some modifications in terms of those details that most concerned respondents such as the 5 day reporting period. The final details will be determined by the NHS Commissioning Board and shared with commissioners, health care providers and the public prior to its implementation in April.

3.12 In the final paragraph of the paper there was a suggestion that should the findings of the Mid-Staffordshire Inquiry suggest that it would be more effective to have a statutory duty, the Government would take account of these findings and may alter its approach if convinced by the arguments to do so.

4 Implications for the Trust

4.1 This proposal will go ahead almost immediately and will be included in the forthcoming contract for 2013/14. Dependent on the findings of the Mid-Staffordshire Inquiry, this may also be a statutory duty by the time it is implemented.

4.2 It has been announced that if a breach is identified by the CCG, this will result in a fine equal to the cost of that episode of care or a £10,000 fine if the cost is unknown. The mechanism for investigating and determining that a breach has occurred and the process for appeal are all yet to be confirmed. It is also not clear whether the Government will continue with its proposal to require a 5 working day limit for disclosing an incident as meeting this would be a challenge.

4.3 The Trust does already operate in accordance with its commitment to being open but there are likely to be circumstances where that degree of openness is questioned by patients or relatives. There have been complainants who have taken their complaint to the Parliamentary and Health Service Ombudsman suggesting a lack of openness due to their personal interpretation of events and it is likely that such individuals will avail themselves of this potential new route for raising concerns in the future.

4.4 There will also be resource and process implications for the Trust. During the last year to date the Trust had over 600 incidents that were rated as moderate, serious or catastrophic. Of these some 568 were scored as moderate and would not in normal events have been subject to a full investigation unless it was considered that the incident represented a significant learning event. It would not be possible to undertake a full independent and written investigation of all these incidents, nor would it be appropriate, as the scoring of these incidents may have reflected consequences that did not necessarily cause direct harm to the patient. It is likely that a member of the Patient Safety team will have to review every incident reported within 24 hours and ensure that it is appropriately scored and coded so that all disclosable incidents are identified promptly, appropriate investigations commenced and communication with the patient or family established.

4.5 Meetings with families are not always minuted and are instead usually noted in the patient's health record. The Trust would need to develop a mechanism for ensuring that a separate record of such meetings is kept to an appropriate standard that would ensure an auditable record of communication with families.

4.5 Staff are encouraged to report incidents but the consequence of this is that approximately 6/700 a month arrive in the Risk Management Department. This volume of reporting provides excellent data for analysing risk but does not necessarily create a system in which the significant patient safety event necessarily emerges immediately. There would therefore be a potential for delay that is unintended and does not represent a lack of openness or candour. This may also occur as a feature of the incident itself. For example, a patient may have a fall causing an initial undetected trauma to the head, which then subsequently leads to a deterioration and ultimately death. The initial fall may have appeared uncomplicated and have been rated as low risk but the eventual consequence a few days later is catastrophic.

4.6 In situations in which no incident has been reported but the family claim one has occurred the CCG will be empowered to undertake an independent review of the patient's health record to determine whether one has occurred.

4.7 Incidents that have been considered to be reportable serious incidents are automatically subject to a full investigation utilising a root cause analysis approach and in this organisation there have been 30 reportable incidents during the last year, not all necessarily patient safety events. The Trust policy already requires the results of these investigations to be shared with the families concerned and this would meet the requirements of the Duty of Candour.

4.8 The Trust is committed to openness with patients and their families when incidents have occurred and so this additional contractual requirement is not in itself problematic. However, the finer details of its implementation will determine how much of a bureaucratic burden it is likely to become and the extent to which the Trust is exposed to the risk of fines and to a potential loss of reputation from the publicity arising from a finding that the Trust has been in breach of the Duty.

4.9 If this duty becomes a statutory requirement, this will expose the Trust to the potential for a legal claim if the organisation is found to have been in breach of the duty.