Title: Duty of Candour **IA No:** 6112 **Lead department or agency:** Department of Health **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 29/04/2014 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Jeremy Nolan
	RPC Opinion: GREEN

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
-£49.0m	-£18.2m	£1.0m	Yes	IN

What is the problem under consideration? Why is government intervention necessary?

Although it is widely recognised that providers of health and adult social care should inform and apologise to service users where something has gone wrong in their care, there are many barriers that prevent this from occurring. The existing framework of policies, initiatives and levers designed to encourage candidness is currently not sufficient to overcome these barriers. Current requirements remain fragmented and vary in their effectiveness. Some providers face only weak or no requirements to be candid and there is scope for improvement even where existing levers are strongest. Government intervention is required to create a consistent standard across all providers.

What are the policy objectives and the intended effects?

The policy objective is to place a requirement on all providers of health and adult social care to ensure that they are open and honest with service users where there has been an incidence of serious injury or death. Providers will be expected to encourage and support staff to have open and honest conversations and to create a culture of openness and transparency within the organisation. The intended effect is to reduce the level of upset, anger and frustration that service users experience when they do not get all the information to which they are entitled and to improve reporting and learning from incidences by providers.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do nothing: Under this option there would be no statutory duty of candour that would apply equally to all health and adult social care providers. An assessment of the existing policies and levers to encourage candidness suggests that the current system is likely to leave a significant gap for some health and adult social care sectors and remain weak in others.

Option 2 (preferred option): Introduce a statutory duty of candour on providers: This option would introduce a statutory duty of candour for CQC registered providers of health and adult social care as part of their CQC registration requirements. Where a service user suffers serious injury or death, providers will be expected to inform the service user or their representatives of the events leading to the incident and offer an appropriate apology.

Will the policy be reviewed? It will/will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:  Date: 28/07/2014

Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2014	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised costs by 'main affected groups'

In line with impact assessment guidance the do nothing option has zero costs or benefits as impacts are assessed as marginal changes against the do nothing baseline

Other key non-monetised costs by 'main affected groups'

In line with impact assessment guidance the do nothing option has zero costs or benefits as impacts are assessed as marginal changes against the do nothing baseline

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

In line with impact assessment guidance the do nothing option has zero costs or benefits as impacts are assessed as marginal changes against the do nothing baseline

Other key non-monetised benefits by 'main affected groups'

In line with impact assessment guidance the do nothing option has zero costs or benefits as impacts are assessed as marginal changes against the do nothing baseline

Key assumptions/sensitivities/risks — **Discount rate (%)** 3.5

In line with impact assessment guidance the do nothing option has zero costs or benefits as impacts are assessed as marginal changes against the do nothing baseline. The do nothing option would continue to fail to provide sufficient incentives to ensure that providers inform, explain and apologise to service users where they have suffered serious injury or death as a result of their treatment.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	Yes	Zero net cost

Summary: Analysis & Evidence

Policy Option 2

Description: Duty of Candour on Providers

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2014	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** -£49.0m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	£9.5m		£4.9m	**£49.0m**

Description and scale of key monetised costs by 'main affected groups'

Where providers are not already candid, they will face the costs associated with setting up and running the necessary and appropriate systems to encourage and provide support for staff to be candid. These costs are likely to be hugely variable between organisations depending on the existing systems and processes that they might have in place. CQC would bear increased costs of monitoring providers and enforcing the duty.

Other key non-monetised costs by 'main affected groups'

There may be reputational or other similar intangible costs associated with being candid. For example, it may be embarrassing or reputationally damaging for a provider to admit to their role in a safety incident involving a service user. There may also be costs on the provider in following up incidents with investigations.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	unquantified		unquantified	**unquantified**

Description and scale of key monetised benefits by 'main affected groups'

Benefits have been monetised where possible; however the size of the impact of these benefits could not be estimated, therefore they have not been included in final estimates of the monetised benefit. The monetised benefits explored are the implications for an open and honest culture on the number of patient safety incidents, patient satisfaction, litigation, the number of complaints and reputational benefits to the industry.

Other key non-monetised benefits by 'main affected groups'

Other key benefits of the duty of candour explored are the morality of telling the truth about errors, developing stronger relationships with service users and removing the fact that removing regulation once in place is very damaging both at an industry and provider level.

Key assumptions/sensitivities/risks — **Discount rate (%)** 3.5

There is a risk that the policy will have unintended consequences. Where there is an increase in candidness there is a risk that providing more information to service users about what went wrong in their care will lead to an increase in clinical negligence claims. CQC are also making changes to their regulatory model which will have an impact on the costs of regulation. It has not been possible to take these changes into account as this is still in the development stage.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £1.0m	**Benefits:** £0m	**Net:** £1.0m	Yes	IN

Evidence Base (for summary sheets)

Policy Background

1. The Care Quality Commission (CQC) is the independent regulator of health and adult social care providers in England and has a key responsibility in the overall assurance of safety and quality of health and adult social care services. Under the Health and Social Care Act 2008 all providers of regulated activities, including NHS and independent providers, have to register with CQC and meet a set of requirements of safety and quality.
2. CQC forms part of the wider quality framework, having responsibility for:
    - providing independent assurance and publishing information on the safety and quality of services;
    - registering providers of regulated activities (including NHS, adult social care and independent sector healthcare providers);
    - inspecting and monitoring services against the registration requirements;
    - using enforcement powers (including prosecution) to ensure service providers meet requirements or, where appropriate, to suspend or cancel registrations;
    - undertaking special reviews and investigations of particular services, looking across providers and commissioners of health and adult social care;
    - monitoring the use of the Mental Health Act; and
    - operating a proportionate regulatory system that avoids imposing unnecessary burdens on providers and on the regulator itself, and helping to manage the impact of regulation more generally on health and adult social care service providers and commissioners.
3. CQC's purpose is to improve care by regulating and monitoring services. CQC ensures that only providers who have made a legal declaration that they meet the standards of quality and safety are allowed to provide care. Once services are registered, CQC continues to monitor and inspect them against these standards. It acts quickly in response to any concerns and takes swift enforcement action where services are failing people. This can include issuing a warning notice that requires improvement within a specified time, prosecution, or cancelling a provider's registration and removing its ability to provide regulated activities, or for the NHS, triggering the quality failure regime.
4. On 9th February 2013 Robert Francis QC published his report on the Public Inquiry into the role of the commissioning, supervisory and regulatory bodies in the monitoring of the Mid-Staffordshire NHS Foundation Trust from January 2005 to March 2009. This made a number of recommendations concerning the regulation of healthcare services, which were accepted by the Government in its initial response to the inquiry *"Patients First and Foremost",* and confirmed in its final response *"Hard Truths"*. The proposals to introduce a new duty of candour as a registration requirement and one of the new fundamental standards outlined in this Impact Assessment form one part of the package of changes being brought in as a result of these recommendations. Other measures include:
    - Revising the existing CQC registration requirements to create a set of fundamental standards of care
    - Introducing a new fit and proper person tests for directors and other board level appointments to be enforced via CQC registration requirements
    - Allowing CQC to issue performance ratings to providers
    - Introduction of the three Chief Inspectors of Hospitals, General Practice and Social Care in place since Autumn 2013

5. In addition to these, CQC are also making changes to their regulatory model in order to improve the effectiveness of regulation. This will include changes in their internal practice on how they register, monitor and inspect providers, and will help to shift the burden of regulation away from high performing providers towards those performing at the lower end of the scale in order to drive up quality.

6. The initial policy driver for the new duty of candour came from the Francis Inquiry into the mid Staffordshire Foundation Trust in relation to the NHS hospital sector. The Government response was to introduce a statutory duty of candour across the maximum number of health and adult social care providers, and for that reason to implement the new duty as a CQC registration requirement, and make the duty one of the new fundamental standards, another proposal made by Francis.

7. This Impact Assessment therefore covers the duty of candour in its entirety, as it will be implemented by CQC, covering NHS Trusts, adult social care, independent healthcare, GPs and dentists. The rationale for applying the policy across all sectors is included, because it derives from the NHS but applies to all providers registered with CQC. All costs and calculations have been split according to these different sectors, with the costs on private or third sector providers flagged for ease. The costs to the NHS are provided for information only, and no RPC opinion is being sought for these costs

8. Implementation is expected to be in two stages: NHS Trusts in October 2014, and all other sectors in April 2015, reflecting Ministerial commitments made to the House of Commons when the Francis Inquiry response was made in November 2013. (A similar approach is being taken for the fit and proper persons test, which is also a new registration requirement and a fundamental standard.)

The evidence base of this impact assessment is structured as follows:

- Section A: Definition of the underlying problem and rationale for government intervention
- Section B: Policy objectives and intended effects
- Section C: Description of the options
- Section D: Costs and benefits assessment of the options (including specific impacts)
- Section E: Summary of specific impact tests
- Section F: Summary and conclusion

Section A: Definition of the underlying problem and rationale for government intervention

9. Academic medical ethics literature and health professional bodies agree that when a provider makes a mistake or causes a patient harm, they must be open and honest with the patient about what has happened, offer a sincere apology and take steps to ensure that lessons are learnt for the future. Such a policy is known as open disclosure or being candid. There is evidence to suggest that patients value this. For example, a survey by the Medical Protection Agency in 2011[1] found that 95% of people felt that, in the event of a medical error, it is very important for doctors to give an open and honest explanation of what went wrong.

10. Increased honesty is also associated with better quality of care, as providers are more likely to spend time learning from incidents in an open and transparent culture rather than trying to hide or defend them[2]. The Francis Inquiry Report found that a negative culture of defensiveness and secrecy at Mid Staffordshire contributed significantly to the events that occurred there. For example, the report cited the Trust's lack of openness with the coroner about serious untoward incidents, and

[1] A culture of openness; The MPS perspective, 2011, available at http://www.mps.org.uk

[2] The Health Service Ombudsman 2013 report, '*Designing good together: transforming hospital complaint handling*' found a need for a step change in the culture from defensiveness to welcoming and seeking feedback, including concerns and complaints, to deliver continuous improvement and the best possible patient care.

the failure to inform patients of hospital acquired infections, both of which led to significant distress for the patients and families affected, and prevented proper action being taken to address the underlying quality issues.

11. Although the events that occurred at Mid Staffordshire were extreme, evidence suggests that a lack of openness and transparency with patients continues to be a problem elsewhere in the health and adult social care system. A report in 2009 by the National Audit Office[3] examined two surveys carried out within the NHS, both of which suggested that patients were not always being informed where things had gone wrong, whilst a more recent survey in 2012[4] examined the effectiveness of the NHS 'Being Open' policy and found that 22% of managers reported no increase in the number of candid discussions. A study by the Health Service Ombudsman[5] published in August 2013 also found that a culture of defensiveness still remained within the NHS. 19% of complaints received by the Ombudsman between April 2012 and February 2013 cited a poor explanation as a reason for escalating the issue, whilst 18% cited no acknowledgement of mistakes as a reason. 5% felt that there had been an inadequate apology[6]. Although research tends to be focused primarily on the NHS, it is very unlikely that this is the only sector that suffers from a lack of candour. Evidence from the international literature suggests that a lack of openness and disclosure with patients is also an issue in other countries as well. Birks (2014)[7] reviews this literature and finds estimates of disclosure as low as 2.7% with a figure of 30% for the UK.

12. Francis recommended in the report of the Mid Staffordshire Inquiry in February 2013, that there should be a statutory obligation to observe a duty of candour, policed by the CQC. The government signalled its intention to develop proposals for a statutory duty of candour across the health and adult social care sector in its response to the Francis Inquiry *''Patients First and Foremost' in March 2013. A*n initial consultation examining the principles of introducing a statutory duty of candour via CQC's registration requirements was carried out by the Care Quality Commission between June and August 2013. The Berwick Review, published in August 2013, also recommended that, for serious incidents, CQC regulations should require that the patient or carer affected by a safety incident is notified and supported. However, the Berwick Report did not subscribe to an 'automatic' Duty of Candour, where patients are told about every error or near miss, as this would lead to defensive documentation and large bureaucratic overheads that detract from patient care.

13. In November 2013 in 'Hard Truths' the Government re-affirmed its commitment to the duty of candour, and reflecting on-going discussions, committed to a review of the threshold at which the duty of candour should apply. The Secretary of State for Health Jeremy Hunt asked Professor Norman Williams and Sir David Dalton to undertake this review, which took place between December 2013 and February 2014,. The review sought the views of senior figures from professional regulators, professional representative bodies, patient groups and safety experts. The main recommendation of the review was that that the statutory duty of candour should apply to all cases of 'significant harm' and should cover the National Reporting and Learning System categories of incidents of death, serious injury and moderate harm, but also include 'prolonged psychological harm'. It was also recommended that an environment that allows staff to be trained and supported in admitting and reporting errors and learning fully from mistakes should be encouraged.

14. A parallel piece of work examining the role of candour in the adult social care sector was led by the Think Local Act Personal partnership, which came to broadly similar conclusions. The group recommended that, for adult social care, the harm threshold should include death and serious injury, as outlined in the current CQC notification requirements. This reporting also includes some

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[3] National Audit Office, 2006, A Safer Place for Patients: Learning to improve patient safety, available at http://www.nao.org.uk

[4] Pinto A, Faiz O, Vincent C, 'Managing the after effects of serious patient safety incidents in the NHS: an online survey study' *BMJ Quality Safety* 2012 (**21)** 1001-1008

[5] The Health Service Ombudsman, 2013, Designing good together: transforming hospital complaint handling, available at http://www.ombudsman.org.uk

[6] The Health Service Ombudsman, 2013, The NHS Hospital Complaints system – a case for urgent treatment, available at http://www.ombudsman.org.uk

[7] Birks, Y. 2014, *Duty of Candour and the Disclosure of adverse events to patients and families* Clinical Risk 0(0) 1-5

moderate harm, so the threshold for reporting in adult social care is similar to the NHS. In neither sector will there be a need to devise new reporting classifications, to keep implementation as straightforward as possible.

15. The government accepted these recommendations and consulted on the draft regulations to introduce a statutory duty of candour in March - April 2014.

The case for government intervention

16. Although the large majority of medical professionals agree that being open and candid with patients is the right thing to do, several barriers exist to candid behaviour. Firstly, it is undoubtedly the case that apologising and explaining to someone that something in their care has not gone as planned, especially where harm has been caused, can be a very difficult thing to do. The individuals involved may be worried about how they approach the conversation, and whether they might potentially say the wrong thing and make matters worse. To overcome this personal barrier, the individual requires significant support and encouragement from the provider organisation. Appropriate training and guidance on how to approach the issue must be available and there should be an expectation on staff to behave candidly and hold these types of conversations.

17. There is often a fear among both providers and individual health professionals that being candid and providing more upfront information about patient incidents can lead to a risk of increased litigation, and that offering an apology might be interpreted as an admission of liability. Providers may also fear the potential reputational impact of disclosing that a mistake has been made. As a consequence, individuals may avoid initiating such discussions with patients, and the provider may be reluctant to adopt a policy or clear culture of candour for their organisation. There is a further risk that they may instead actively pursue a policy or culture of secrecy, which would further act as a barrier against individual healthcare professionals being candid.

18. The existence of these barriers means that providers might not always be candid with patients in the event of a patient safety incident. Due to information asymmetries, patients will not necessarily be aware that there has been an incident or what role the provider played in this without such a disclosure being made by the provider. This market failure prevents patients from holding providers to account for these failures to be open through normal market mechanisms. Regulation of health and adult social care is a public good, and as such, the market does not always naturally provide it. Government intervention is required to correct this.

Alternatives to regulation and other options considered

19. This section considers the possible alternatives to regulation and discusses the options that were considered in the development of the policy. Overall, there are a number of different policies and initiatives already being pursued in order to increase openness and transparency in health and adult social care. Against this backdrop, regulation is considered to be an important part of this package of measures. CQC would be responsible for enforcing the statutory duty of candour for all health and adult social care organisations it registers. This will ensure that there is consistency of approach across all provider settings and offer patients equal protection regardless of care setting. This will act as the ultimate backstop by which providers can be held to account for failings.

    - **Improving existing regulation:** We considered whether our aims could be met by improving existing regulation, or improving enforcement against the existing regulations. However, no existing regulation could be identified that made any specific requirement for health or adult social care providers to be open with service users.

    - **Improving legal remedies for individuals who have suffered from a lack of candour:** We considered whether legal remedies for service users could be made more accessible or cheaper. There are currently no specific legal remedies for service users where a provider fails to be honest. In any case, due to information asymmetries, service users would not always be aware that they have not been fully informed, which limits their ability to utilise any legal remedies. The main legal remedy available to service users who suffer harm is via clinical negligence claims. One option to link this to candour might be to create stronger ties between compensation awards and whether the provider acted candidly. Studies also demonstrate that the likelihood of clinical negligence claims might

be linked to whether the service user felt they had received a sufficient explanation and apology.

However, any options that focused on legal remedies for individuals would be likely to increase the risk and size of clinical negligence claims and so was not considered an appropriate policy response. In addition, there is a risk that providers would react to further risks of litigation by becoming more defensive and less open, although similar number of respondents to the recent consultation said that candour could increase or reduce insurance cost to organisations.

- **Improving the provision of information or education for service users**. We considered whether better information provision for service users would have any effect. However, we judged that there would be little benefit from this approach because only the provider organisation would be fully aware of the circumstances surrounding any patient safety incidents. No other body would be able to disclose this information on their behalf, nor would they be able to make statements about the level of openness and candour at different organisations without significant research and investigation costs.
- **Financial incentives** Options involving the use of financial incentives to encourage more openness and transparency amongst providers are being separately considered for the NHS. Following the recommendations of the Dalton Williams Review, the NHS Litigation Authority is considering options to reduce the premium that trusts pay if they are able to demonstrate that they have taken certain steps to improve openness of the organisation. However this will not cover other healthcare sectors. Overall the large number of private insurance providers for clinical negligence insurance makes the coordination of such a scheme very challenging. This has therefore not been taken forward as an option at this stage.
- **Self-regulation by providers** A large number of existing initiatives are already being pursued to improve openness by providers and other non-regulatory bodies:
    - Since 1st April 2013, the NHS Standard Contract has included a direct requirement for providers of NHS funded care to be candid about incidents involving moderate or severe harm or death of a service user (as defined by the previous National Patient Safety Agency). This built on a previous weaker requirement for providers to have regard to the NHS Constitution, which included an expectation for providers to be candid.
    - The professional codes of practice for doctors, nurses and NHS managers all contain duties to ensure that patients who suffer harm are given a prompt apology and full explanation. Other professional codes of conduct such as for dentists and social care workers include a more general requirement to be honest and trustworthy. Following on from the Francis Inquiry, professional regulators will be working to agree consistent approaches to the reporting of candour and errors and to strengthen the references to candour in professional regulation to make a clear requirement to be open. Health professionals will have to be candid with patients about all avoidable harm and the guidance will make clear that obstructing colleagues in being candid will be a breach of their professional codes. The professional regulators will also review their guidance to panels taking decisions on professional misconduct to ensure they take proper account of whether or not professionals have raised concerns properly.
    - In 2009 the then National Patient Safety Agency (NPSA) published policy guidance, called ‘Being Open’, which set out the principles of communication and processes that NHS organisations should follow to ensure mistakes are communicated to patients.
    - The NHS Litigation Authority issued a letter on apologies and openness to all chief executives and finance directors of NHS bodies (reiterated in 2009), which stated that “it is most important to patients that they or their relatives

receive a meaningful apology". This letter also made it clear that an apology does not constitute an admission of liability. Other organisations such as the Medical Defence Union and the British Medical Association endorsed this letter.

- **Using competition to drive openness** Measures to improve competition within the NHS have been actively considered by the Government for a number of years. Within the adult social care sector, it is recognised that this is already a highly competitive market where the scope for further improvements is more limited. However, as discussed above, the existence of information asymmetries limits the ability for market forces to encourage providers to be more open with service users.

20. However, these measures are not consistent across all health and adult social care providers - different types of health and adult social care providers will face different sets of obligations and incentives to be candid. As a result, there are varying levers that can be used to influence providers, and some may be weak, voluntary or poorly enforced.

21. As an example, within the NHS, enforcement against the contractual duty of candour is likely to vary significantly between commissioners. Adult social care providers are likely to use a larger proportion of non-health care professionals, compared to acute hospital providers, and so fewer levers to be candid would apply via professional codes of practice.

22. Overall it was judged that such voluntary initiatives alone would not deliver a fully open and transparent system. As previously discussed, regulation is a public good and thus the market is unlikely to provide the socially optimal level without government intervention. In addition, regulation has an important part to play in ensuring that there is a consistency of approach across all providers and that all service users receive equal protection regardless of care setting. Where providers fail to respond to these initiatives to improve candour, strong enforcement action is required in order to hold them to account and achieve openness for patients and service users.

Section B: Policy objectives and intended effects

23. As discussed above, despite the widely accepted view that patients should receive a full explanation and apology where something has gone wrong in their care, barriers exist which mean that this does not always occur. It can be very difficult for individuals to have to apologise and explain to someone that something has gone wrong in their care, and many individuals will feel like they need additional support to do this. Providers and individual health professionals may fear that being candid and providing more upfront information about patient incidents can lead to a risk of increased litigation. Consequently, it must be the case that health and adult social care provider organisations are encouraged to provide the necessary leadership and support to their staff to ensure that these barriers are overcome.

24. The policy objective is therefore to ensure that all providers of health and adult social care act in an open and transparent way in relation to a person's care or treatment, and that providers are candid with service users where a patient safety incident has resulted in significant harm or death.

25. Providers will need to ensure they establish systems or processes to ensure they can do this. This will encourage provider organisations to ensure their culture is transparent and open. When a service user suffers significant harm or death as a result of the treatment, the provider must ensure that, a member of staff speaks candidly to the service user or family members and give a full explanation of what went wrong, apologise for the harm caused and inform them of the steps being taken to ensure similar incidents are not repeated. The provider will be expected to provide their staff members with the appropriate encouragement, support and guidance to do this. This in turn should lead to an overall improvement in the quality of care, and reduce the number and severity of patient safety incidents. This effect may also be reinforced by a deterrent effect. As providers are obliged to provide more information about adverse safety incidents, which may be reputationally damaging, providers may be incentivised to instead invest more to ensure that fewer avoidable incidents of harm occur in the first place.

26. Overall, the intended effect is to create a more open and transparent culture among providers of health and adult social care, so that patients receive the information that they are entitled to, and the upset, anger and frustration that service users experience when they do not get all the information is reduced. This improvement on organisation culture is also expected to improve the quality of care via the creation of a more open and learning culture that is responsive to mistakes.

Section C: Description of the options

Option 1: do nothing

27. Under this option there would be no statutory duty of candour that would apply equally to all health and adult social care providers. As discussed above, there are a number of existing policies, initiatives and levers to encourage candour, but there still remains a significant role for regulation to play.

28. The majority of existing policies are applicable only to NHS organisations and those providing NHS funded care under the Standard Contract, which excludes NHS primary care. For other healthcare organisations, if the majority of staff are healthcare professionals, such as independent hospitals, GPs and dentists, the existing professional codes of conduct provide some obligations or incentives for these individuals to be candid, but there remains a risk that they will lack support from the provider and so find it difficult to do so in practice. In the adult social care sector the potential gap may be even larger, as these organisations are likely to be private organisations providing a high proportion of non-NHS funded care, with non-health staff who are not subject to a professional duty of candour and not part of a fully professionalised workforce.

29. Even in the NHS there are opportunities for improvement. Recent surveys of the NHS indicate that existing policies may not be having the desired effect and that in some areas a culture of defensiveness may persist. A lack of candour by providers was highlighted as an issue in many of the recent high profile reports into NHS hospitals, such as Mid-Staffordshire and Morecombe Bay. Although the NHS Standard Contract has recently been strengthened to make being candid an explicit requirement for providers of NHS funded care, it is not clear if this has been successfully enforced. NHS commissioners may lack the necessary experience to effectively monitor and enforce a duty of candour and the large number of different commissioners is likely to lead to significant variation in approaches taken.

30. Overall it is judged that the current policies, incentives and levers to encourage providers to be candid are unlikely to be sufficient to achieve the aim that all providers are open and honest with service users in all incidents where serious injury or death occurs in the course of a service user's treatment. Regulation has an important part to play in ensuring that there is a consistency of approach across all providers and that all service users receive equal protection regardless of care setting. Where providers fail to respond to these initiatives to improve candour, strong enforcement action is required in order to hold them to account. Only regulation can provide this on a consistent basis across all health and adult social care providers. It is vital there is consistency in approach to candour given the emphasis on joint working between health and adult social care providers.

Option 2: create a statutory duty of candour for all CQC registered providers of health and adult social care

31. This option would introduce a statutory duty of candour for CQC registered providers of health and adult social care as part of the requirements for registration with CQC. This requirement would be similar in nature to the existing duty for providers of NHS funded care, as currently set out in the NHS Standard Contract, but would be backed by CQCs statutory powers and apply across health and adult social care

32. The Dalton Williams review into the Duty of Candour, whose recommendations were accepted by the government, recommended that, for the NHS, the threshold for harm caused to which the statutory duty of candour would apply should be for moderate or severe harm or death as defined by the National Reporting and Learning System (NRLS). NHS organisations are already mandated by

law to report such instances of patient harm to the NRLS so will be familiar with these definitions. This is also consistent with the thresholds of harm imposed by the contractual duty of candour within the NHS contract. Where providers are already fully compliant with this contractual duty, there should be no new burdens for providers.

33. For adult social care providers, the Think Local Act Personal Partnership recommended that the CQC definitions of serious injury or death for which registered providers are already required to notify CQC of incidents under the Care Quality Commission (Registration) Regulations 2009 should be used. These thresholds have been chosen in order to ensure familiarity with existing reporting processes within the relevant sectors in order to minimise set up and familiarisation costs. There is a high degree of overlap between the two sets of definitions, which currently already form the basis of reporting of patient safety incidents to the CQC within the two sectors.

34. The proposed regulations state that, where an applicable patient safety incident occurs or is suspected to have occurred, the service provider must provide to the relevant person all necessary support and relevant information in relation to that incident as follows:

    - The patient, or their family or carer, should be notified as soon as possible,
    - All information directly related to the incident should be provided, an apology given, and reasonable further support offered
    - The provider should advise and agree with the patient or family what further enquiries are necessary
    - The individual should also be offered the same information in writing
    - A full written record of any correspondence with the relevant persons should be kept.

35. Although CQC will not be able to monitor every single incident, they will be able to require providers to establish systems and processes that encourage and support openness and transparency with service users. As part of their on-going programme of monitoring and inspection of providers against the registration requirements, it is expected that CQC will seek evidence from providers that they are taking all necessary steps to ensure that they are meeting their duty to be candid, as well as gathering information from other sources, which will inform CQC's overall judgement on whether the organisation is compliant. This is similar to the approach CQC takes to monitor and enforce the other existing registration requirements.

36. If a provider is found to be in breach of the duty of candour, CQC will be able to use its existing suite of enforcement actions in order to compel the provider to take action to achieve compliance. These include, issuing a warning notice, placing conditions on a provider's registration, or, in extreme cases, cancelling a provider's registration or prosecution.

Section D: Costs and benefits assessment of the options (including specific impacts)

Costs

Numbers of providers affected

37. All providers registered with CQC will be affected by the statutory duty of candour. Based on analysis of the directory of providers and locations[8] registered with CQC as at 4th April 2014, the following numbers of providers would be affected:

[8] Providers are required to register each location from which they provide regulated activities from. For example, a social care provider might own two separate care homes.

Number of CQC registered providers and locations:

Sector	Registered Providers	Registered Locations
Social Care Org	12,750	25,500
Independent Healthcare Org	1,500	3,000
Primary Dental Care	8,000	10,000
Independent Ambulance	250	250
Primary Medical Services	7,500	8,750
NHS Healthcare Organisation	250	2,000
Total	30,500	49,750

Figures rounded to nearest 250, figures may not sum due to rounding

38. In terms of the split between public and private or voluntary sector providers for the purposes of OITO accounting, we use the following assumptions about the split of public and private organisations within each sector that CQC regulates:

Sector	% public	% private	Rationale
NHS Trusts	100%	0%	Entirely funded and operated by the NHS
Independent healthcare	0%	100%	In the absence of further information it is assumed that 100% of the independent healthcare and private ambulance market is privately run.
GPs	94%	6%	Laing and Buisson 2013/14 Healthcare Market Review found 6% of GPs worked entirely outside of the NHS
Dentists	70%	30%	Analysis of Dental Contracts found that approximately 30% of dental practices did not contract with the NHS
Adult Social Care	10%	90%	Data from 31st March 2010 (under CSA care sector) on providers by ownership type in the adult social suggests that approximately 90% of adult social care providers are voluntary or private organisations. Similarly the Laing and Buisson 2013/14 Healthcare Market Review estimated that between 6% and 13% of adult social care providers were Local Authority or NHS run organisations.

39. In the case of GPs and Dentists, we are aware that the definition of public and private businesses is being reviewed by the Regulatory Framework Group in mid-May. In advance of any decision from this group we have made a best estimate of the potential number of private sector GPs and Dentists using the best available data to hand. Following any further direction on this issue, we will be happy to provide the RPC with further information on how the analysis in this Impact Assessment might be changed as a result.

40. We apply these assumptions to the analysis above in order to estimate the number of private or third sector providers in each case:

Number of CQC registered providers and locations – Private sector:

Sector	Registered Providers	Registered Locations
Social Care Org	11,500	23,000
Independent Healthcare Org	1,500	3,000
Primary Dental Care	2,500	3,000
Independent Ambulance	250	250
Primary Medical Services	500	500
NHS Healthcare Organisation	0	0
Total	16,250	29,750

Figures rounded to nearest 250, figures may not sum due to rounding

41. Where we wish to calculate the impact on private and third sector providers only, these numbers are applied to the unit cost estimates discussed below.

42. As discussed above, there are a number of existing policies, levers and initiatives already in place to encourage candour within the health and adult social care sectors. This suggests that, compared to the do nothing case, different providers might be affected by the proposed statutory duty of candour in different ways, depending on their existing policies on candour. For example, within the NHS there is an existing contractual duty of candour which is very similar to the proposed statutory duty. However, further analysis shows that this might not be implemented all the time. A survey of NHS patient safety managers in 2012 found that only 82% implemented the National Patient Safety Agency Being Open guidance more than half the time when incidents occur. The Think Local Act Personal partnership considered the extent to which adult social care providers already acted candidly in their review into the recommended threshold for a statutory duty of candour[9]. They felt that the framework and regulatory regime within adult social care – particularly in relation to safeguarding – had already driven a culture of candour in adult social care for some time, but that there was a rationale for a statutory duty to drive change where providers do not have such processes in place. This view was also reflected in the consultation responses received. Whilst some providers led the way in the openness and transparency agenda, there was concern that this practice was not universal and further culture change was required across the sectors.

43. This evidence therefore suggests that whilst a significant proportion of providers will need to make changes in their practices to meet the proposed statutory duty of candour, others will already be meeting these requirements. Overall, we received slightly fewer than 50 responses to our call for evidence as part of the consultation. 61% of providers told us that they already had formal policies on candour, although 76% also responded that they anticipated that they would need to make changes as a result of the statutory duty. We therefore use these figures to inform our estimates of the proportion of providers who might already be candid with patients, and the proportion that might make changes to their policies as a result of the duty of candour respectively.

44. Finally, an examination of the number of providers registered with CQC over time suggests that the overall number of registered providers is growing over time. This must be factored into our calculation of the costs and benefits to providers for future years of this Impact Assessment. Analysis from CQC's State of Care report 2013[10] found that over the financial year 2012/13 the numbers of adult social care providers increased by 2% (driven by a growth in at home care, which offset a decline in residential care homes), whilst the number of NHS providers declined 10% as the sector consolidated. The number of independent healthcare providers increased by 9%, and the number of dental providers fell slightly (less than 1%).

45. Overall it is difficult to predict what the long term trend in provider growth rates might be. As CQC was only established in 2009 and the timetable for roll out of the registration process for different provider groups was staggered, there has been limited evidence on steady state growth rates, especially for certain sectors. All NHS trusts had to be registered by 1 April 2010, whilst providers of adult social care and independent health care were to be registered by October 2010. Dentists and ambulance services were required to be registered by April 2011, whilst GPs did not need to register with CQC until April 2013. In addition, we are aware that CQC are exploring options to make the registration process more robust in the adult social care sector, which will likely have a downward pressure on the number of applications and the number of providers registering with CQC. This is balanced by CQC's work to ensure that innovative providers are not put off by this more robust registration process.

46. In spite of these caveats, we have estimated average growth rates for each sector registered with CQC based on information on the number of providers registered with CQC at the end of each of the past three financial years. These growth rates are used to uprate the estimated annual costs to providers for future years of this Impact Assessment to reflect the greater number of providers affected[11].

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[9] See http://www.thinklocalactpersonal.org.uk/_library/The_Duty_of_Candour_-_an_Adult_Social_Care_Perspective_March_2014.pdf

[10] CQC The state of health care and adult social care in England 2012/13
http://www.cqc.org.uk/sites/default/files/media/documents/cqc_soc_report_2013_lores2.pdf

[11] Note that this methodology makes the implicit assumption that the proportion of new relative to existing providers in any given year remains constant, so that both the number of new providers and the number of existing providers grow at the same rate over time. This is one of a number of

Sector	2011/12	2012/13	2013/14[12]	Average growth rate
Social Care Org	12,500	12,750	12750	2%
Independent Healthcare Org	1,250	1,500	1500	10%
Primary Dental Care	8,000	8,000	8000	0%
Primary Medical Services	-	7,750	7500	0%
Independent Ambulance	250	250	250	0%
NHS Healthcare Organisation*	250	250	250	-8%

*Figures rounded to nearest 250

47. However, we do not judge the 8% reduction in NHS trusts to be a sustainable long term trend. Over the past 5 years there has been a trend in consolidation within the NHS, however we judge that this is unlikely to continue for the whole duration of the 10 year period of this Impact Assessment (not least because this would result in more than half of NHS Trusts disbanding in this period). Based on internal advice from the DH provider policy team, it is not possible to accurately predict the likely number of NHS trusts over the next ten years. In the absence of further information, we therefore make the assumption that the number of NHS trusts is likely to remain more or less constant over the period of this Impact Assessment.

Implementation costs

48. In order to implement the new statutory duty of candour, all providers will be required to take similar steps to ensure that there are systems in place to ensure that where moderate or severe harm or death occurs, service users or their families are appropriately informed. How this is achieved will be at the discretion of the provider and it is likely that there will be a large number of different approaches taken, depending on the type of provider and the existing practices and procedures it has in place.

49. In addition to this, it is expected that the statutory duty of candour will also encourage providers to make changes in their culture to improve openness and transparency in accordance with existing best practice. In the consultation stage impact assessment, we made the implicit assumption that all providers would act in according with this best practice. However, we have since undertaken further work with providers to better understand the potential implementation costs, which have allowed us to refine our analysis to better account for the differing approaches that providers could take.

50. Whilst this additional best practice activity is viewed as a key part of driving increases in candour and openness within organisations, there are no specific provisions in the regulations relating to this, beyond a general requirement that providers act in an open and transparent way with service users. We therefore consider it unlikely that all providers would choose to undertake the best practice approach to candour[13]. The costs of the best practice approach are therefore considered separately as an important indirect cost of the policy. For the purposes on OITO, the additional costs associated with implementing the best practice approach are therefore considered to be out of scope, as it is at the discretion of the provider whether they would implement these additional steps.

Direct implementation costs

51. During the consultation, we spoke to a number of provider organisations from different sectors to better understand how the duty of candour might be implemented at their organisation. The consistent picture we received was that the duty of candour should fit into their existing incident reporting and monitoring systems to avoid the creation of additional processes or bureaucracy. Any

possible assumptions that could be made (for example, we could assume that the number of new providers grows at a very high rate, but is also balanced by large increases in the number of providers that de-register each year). In the absence of further information on the exact pattern of new registrations versus de-registrations over time, this appears to be the most sensible and neutral assumption to make, and has the advantage of being the most simple approach

[12] Data for 2011/12 and 2012/13 was obtained from CQC's Annual Reports. Data for 2013/14 was obtained from internal analysis of the directory of providers registered with CQC as at 4th April 2014.

[13] This was clearly demonstrated when we spoke to different providers about the steps that they might need to take to implement the duty of candour – whilst some providers discussed factors such as improved leadership, training and appointing experts by experience, others described a much more minimalist approach to meeting the regulations.

incidents involving patient harm would be identified through the existing reporting channels, and a number of identified individuals would then have responsibility for contacting the service user or their family member and explaining what has occurred in accordance with the proposed regulations. At a large hospital, it is likely that a number of staff would need to be involved in this process. We heard from one NHS trust who already implement a candour policy which use a patient safety team which takes responsibility for this process and, depending on the severity of the incidence and what was felt to be most appropriate, one of the directors in charge of services[14], the clinical director, or a member of the executive team would meet with patients. In the case of adult social care, it was felt that the registered manager at each location would be best placed to have responsibility for this.

52. The main direct costs we consider are thus:

    - Familiarisation costs for the provider
    - Initial set up and training costs
    - The on-going costs associated with speaking to service users, including any additional administrative costs

Familiarisation costs

53. All providers registered with CQC will need to take time to review and understand the change in legislation, and to consider what action they will need to take in order to meet the new requirements. As the introduction of the duty of candour will be made as part of a package of measures to revise the CQC regulations, it is difficult to disentangle the familiarisation costs associated with each separate measure. If these actions were to require one hour of a senior manager's time to carry out, then based on the median gross wage of £24 for a corporate manager or director from the Annual Survey of Hours and Earnings (ASHE) survey 2013[15] (including 15.3% non-wage costs[16]), this would imply a total transitional cost of approximately £730,000 across all 30,500 or so providers that CQC regulates **with around £385,000 cost to private and voluntary sector providers**.

Initial set up and training costs

54. Where providers judge that they will need to make changes to their procedures or policies in relation to the statutory duty of candour, they will incur costs associated with developing and setting up these policies. This is likely to include informing and training staff on the new arrangements and, most importantly, ensuring that those individuals who will be responsible for informing service users have sufficient training and support to be able to carry out this task.

55. As previously discussed, results from the consultation found that approximately 76% of providers anticipated that they would need to make changes as a result of the new policy.

56. It is difficult to predict what these initial set up costs might look like. When we spoke to providers during the consultation, they told us that they are constantly engaging in processes to improve and update their service design, and thus were unable to quantify specific costs relating to the setting up of a new initiative or processes in relation to being candid. Such activity to update and change their processes would be on-going and thus considered as part of the 'business as usual' model of service improvement.

57. As an illustration of the potential costs, we consider two scenarios. Where a provider already has an existing policy on candour, there might be a half an hour discussion during a board meeting to examine the existing policy and consider whether any changes are required. Some subsequent work might then be required by a senior manager to take these changes forward and update the policy, which we assume would take up to half a day (4 hours) of staff time. Based on figures from the 2013 Annual Survey of Hours and Earnings (ASHE), estimated that the median hourly gross income for corporate managers and directors of £24 (including 15.3% non-wage costs), and estimates of the

[14] For example, medicine, surgery etc.

[15] This survey estimates average earnings for the period 2012/13

[16] See http://epp.eurostat.ec.europa.eu/statistics_explained/index.php?title=Wages_and_labour_costs&stable=1

average board size of health and adult social care organisations[17], the cost of updating a duty of candour policy might be £132.

58. Alternatively, if there is no existing policy on candour, there might need to be a longer discussion at board level about what a policy of candour should look like, and more time would be required for such a policy to be developed and drafted. If an hour and a half of time was required at board level, and a further two and a half days to develop the policy, then based on the above assumptions, this might involve an additional cost of approximately £585.

59. Based on the results from our consultation, where 61% of providers indicated that they already had a formal policy on candour, this would suggest that the average cost for creating and setting up a candour policy would be approximately £309.

60. As discussed previously, not all providers anticipate that they will make any changes at all as a result of the new duty of candour. Summing over the 76% of providers who felt that they would need to make changes[18] suggests a total cost of £7.2m, **of which £3.8m would be on the private or voluntary sector**.

61. It is expected that in all cases, providers will have a system of regular meetings and mechanisms to keep staff updated on any organisational developments. It is likely that this would be the primary way in which the new candour policy would be communicated to staff. Thus the additional costs of communicating any new candour policy are expected to be minimal, since these meetings would already be taking place regardless as part of regular contact between managers and staff.

62. It is not clear if providers would need to also provide additional training or support for staff or providing additional information over and above what would reasonably contained within the general communications described in the previous paragraph. As discussed further below, best practice suggests that a key component of creating a culture of openness and change within the organisation is through additional staff training and support. However, for the purposes of purely complying with the proposed regulations, providers would only be required to provide sufficient training and support for staff to ensure that they understand and are able to meet the requirements. At a minimum, the staff would need to understand:

    - When the duty of candour would apply and how such incidents should be identified
    - What is required when such an incidence is identified, including how the conversation with service users should be approached
    - What additional processes would need to be completed, and the next steps following such a discussion

63. Based on the model put forward by providers, whereby it was suggested that a small number of individuals would take responsibility for informing and speaking to patients, we assume that any additional training required would be focused on these individuals. It is not known how much time would be required to provide this additional training for staff, however given the nature of the training topic, and based on our discussions with providers about the potential training arrangements that could arise from a duty of candour[19]; we consider an estimate of two hours additional training to be a reasonable estimate. If a two hour workshop was required, then based on an hourly wage of £24 (including 15.3% non-wage costs) for corporate managers or directors, the cost per individual trained would be £48.

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[17] Research commissioned by the National Leadership Council highlighted that membership of NHS trust boards may range from 8 to 11 members, whilst the Spencer Stuart 2010 UK Board Index, which looks at FTSE 150 companies, found that the average board size was 10. However, the majority of health and social care providers are likely to be small or micro businesses. Evidence suggests that smaller organisations might have significantly smaller average board sizes compared to large organisations. Estimates from the Institute of Directors suggests that in 2012 there were between 200,00 and 5m directors in the UK compared to 2.08m registered businesses from the Office of National Statistics . This suggests that the overall average number of directors across all companies might only be between 2 and 3 at most. We assume that NHS Trusts will have an average of 10 directors per board whilst all other providers would have an average of 3 members per board.

[18] Note that this implies that 50% of those providers who will make changes will update their existing policies and 50% will create new policies where they did not previously exist before.

[19] Whilst some providers felt that training costs might be significant, others felt that they would not since candour itself is a relatively simple concept to explain and for staff to understand and could easily be combined into existing training for staff on communicating with patients or managing patient safety incidences

Sector	Assumption	Total numbers of staff to be trained
Social Care Org	The registered manager at each location would take responsibility for being candid with patients and thus require training	25,500 * 76% = 19,375
NHS Healthcare Organisation	Up to 5 individuals per Trust would have some responsibility for patient discussions	1,250 * 76% = 950
Independent Healthcare Org	This sector is comprised of large acute hospitals plus smaller providers of other healthcare services (e.g. chiropractors and diagnostic and screening services). Laing and Buisson 2013/14 Healthcare Market Review estimates that there were approximately 250 independent acute medical care hospitals as at 1st Jan 2013. We assume that these large hospitals follow the same model as for NHS Trusts, whilst the remainder of the healthcare sector would follow the adult social care model.	1,250 + 2,750 = 4,000 * 76% = 3,100
Primary Dental Care	As is the case for adult social care, we assume that the registered manager at each location would take responsibility for being candid with patients and thus require training	10,000 * 76% = 7,675
Primary Medical Services		8,750 * 76% = 6,575
Independent Ambulance		250 * 75% = 225
Total		37,900

NB Figures may not sum due to rounding

64. As above, we assume that only 76% of providers would need to undertake this additional training for staff. Based on the estimated staff numbers requiring training as above, this would suggest that the total cost of this additional training would be £1.8m, of which, **just over £1.3m would fall on private or voluntary businesses**.

65. Following this initial training, it is likely that any subsequent training for these staff would not need to be as intense or detailed, and may be absorbed into the other ongoing training requirements for staff. We therefore allow for an additional half an hour of training to take this into account. In terms of the frequency that staff would require additional training on being candid, it is unlikely that such training would be provided to staff on an annual basis. An examination of mandatory training policies in the NHS[20] suggests that very few training courses are ever required on an annual basis, rather the majority tend to be required once every three years. We therefore make the similar assumption that any subsequent training on candour would only take place once every three years for staff.

66. Based on these assumptions we estimate that, following the initial training costs, the annual ongoing training costs are likely to be in the region of £150,000 p.a. **with approximately £96,000 p.a. falling on private or voluntary businesses.**

Ongoing costs associated with being candid

67. As a result of the duty of candour there may be some impact on staff time spent informing and discussing incidents with patients. At first glance, it could be the case that every patient safety incidence would require some additional time for staff to discuss the incident with patients. However this does not take into account that, under the do nothing option, there would still need to be conversations between patients and staff to discuss their care. In cases where something has gone wrong it is likely that, in the do nothing option, staff time would still be required to discuss the

[20] For example, see the West Lancashire CCG, 2013. Statutory and Mandatory Training Policy, available at: http://www.westlancashireccg.nhs.uk/wp-content/uploads/sites/4/2013/04/Statutory-and-Mandatory-Training-Policy.pdf, or the training policy for Royal United Hospital Bath NHS Trust http://www.ruh.nhs.uk/Training/Prospectus/mandatory/index.asp?menu_id=7

incident with the service user or their family. Where these conversations do not already meet the criteria described above for being candid and open, the aim of the policy would be the change the nature of the conversation being held rather than impact on the amount of time required for the discussion or to require the provider to hold additional conversations beyond what might be occurring anyway.

68. It is possible that the duty of candour will reduce the total amount of staff time spent dealing with patients' concerns about patient safety incidents by enabling providers to deal with patient complains early and preventing incidents from escalating into formal complaints or litigation cases. These benefits are discussed further in the benefits section of this Impact Assessment. To avoid double counting, however, this section will only examine the impacts on staff time directly related to holding candid conversations with service users.

69. We have already stated that it is likely that managers, as opposed to clinicians, will be those who are required to be candid with patients. As discussed above, a proportion of providers already have active candour policies and will therefore already be conducting candid conversations with patients. For these incidents, we do not expect any change in staff time requirements as a result of the implementation of the new duty. However, estimating this figure is difficult, due to conflicting evidence about the level of openness in organisations. A 2012 survey found that 82% of NHS organisations follow the 'Being Open' guidance more than half of the time[21]. However, 'Building a culture of candour', a 2014 review carried out on behalf of the Department of Health, found that between 5% and 17% of patient safety incidents are reported, a figure which could be reflected in the proportion of candid conversations held[22]. Approximately 61% of providers stated they had a duty of candour already in place in the consultation response to the duty of candour. We will use this as a best estimate of the proportion of patients currently receiving a candid conversation following a patient safety incident, and use 82% and 17% as the lower and upper estimates of costs respectively. From our work with providers at consultation, we are aware that in reality these proportions are likely to differ between sectors – for example we heard from a number of different organisations that the longer term relationships between staff and service users in the adult social care sector meant that candour would be more likely to be already taking place. However, it has not possible to break these estimates down further to take this into account. Thus the additional costs associated with increased candour in the adult social care sector might be overestimated.

70. Even where a candid conversation is not currently taking place, it is likely that in the do nothing case, some type of conversation will still be occurring between the patient and the provider to discuss these incidents. The proposed duty of candour requirement is expected to change the nature of these conversations towards being more open and candid, but it is not known how the average length of the conversation might be affected. It is possible that by providing more information and support, this would require a longer conversation than would previously be the case. However, it is equally possible that there could actually be a reduction in the amount of staff time required, for example if patients or their family feel that an adequate explanation is received up front, they may feel more satisfied with the experience, more willing to accept the explanation and have fewer follow up questions. It is not known what the overall impact of these two competing effects might be.

71. Overall, we consider that in cases of severe harm or death it is highly likely that in the do nothing case there would need to be a relatively long conversation to discuss the incident with the patient. We therefore assume that in these cases there would not be any change in staff time required to discuss these incidents with patients. For incidents of moderate harm, we consider that perhaps providers might have been more able to avoid holding appropriate conversations with service users (for example, because the less serious nature of the incident may mean that service users were unaware of any harm occurring, assuming it was the result of their morbidity). We

[21] Pinto, A., Faiz, O., & Vincent, C. (2013). Republished: Managing the after effects of serious patient safety incidents in the NHS: an online survey study. Postgraduate medical journal, 89(1051), 266-273.

[22] Royal College of Surgeons, 2014. *Building a culture of candour*. [online] Available at: <http://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf>

therefore assume that for these cases, there might be, on average, an increase in the amount of staff time required to discuss these incidents with service users.

72. In terms of the average time required to discuss a patient safety incident with service users, the director of the patient safety team at one NHS Trust estimated that on average he might spend 90 minutes with patients discussing problems with their care. However, as discussed before, it is likely to be the case that, under the do nothing scenario, providers would still have had to spend at least some time discussing incidents with patients. Thus, the average additional staff time required to discuss incidents of moderate harm with patients is unlikely to be high as 90 minutes[23]. In the absence of any information on the average length of time currently being taken to discuss incidents with patients, we make the assumption that a full candid conversation with a service user could double the amount of staff time required. This suggests that there could be an additional 45 minutes of staff time required per case of moderate harm. In the absence of corresponding information specifically for the adult social care sector, we assume that this figure is also applicable to adult social care and other healthcare sectors.

73. In terms of the potential number of patient safety incidences that will require a candid conversation under the proposed regulations, the threshold of harm for which the duty of candour would apply are as follows:

- for the NHS, moderate or severe harm or death as defined by the National Reporting and Learning System (NRLS) and;
- for adult social care the CQC definitions of serious injury or death for which registered providers are already required to notify CQC of incidents under the Care Quality Commission (Registration) Regulations 2009

There is minimal overlap between these two systems of reporting as only providers who do not submit to NRLS are required to report separately to CQC. However, there is a difference in the definitions of harm between the two, as CQC's definition of serious injury will cover similar areas as severe harm in the NRLS and some aspects of moderate harm.

74. In 2012 the following incidents were reported to the NRLS and CQC reporting systems:

NRLS		**CQC**	
Death	3,600	Death	20,300
Severe	7,400	Serious Injury	28,400
Moderate	86,000		
Total	97,000	Total	48,700

75. Applying our estimate that 61% of all patient safety incidents already result in a candid conversation in the do nothing case, suggests that the following number of incidents might require further discussion under the duty of candour:

NRLS		**CQC**	
Death	1,400	Death	7,900
Severe	2,900	Serious Injury	11,100
Moderate	33,500		
Total	37,800	Total	9,000

76. As previously discussed, we assume that for cases of death or severe harm only the nature of the conversation will change due to the duty of candour, rather than the average length of the discussion. For cases of moderate harm, there might be an increase in the amount of staff time required to discuss these incidents with patients. If we assume that all incidents of serious injury

[23] As this would represent a shift from no discussion whatsoever, to a full discussion requiring 90 minutes on average.

reported to CQC would also require additional staff time to discuss with patients[24], this equates to approximately 44,600 incidents requiring an additional 45 minutes of staff time to discuss with patients as a result of the duty of candour. Using the average hourly wage of a corporate manager or director from the 2013 Annual Survey of Hours and Earnings (ASHE) of £24 (inclusive of 15.3% non-wage costs), the total cost of additional time spent with patients would be approximately £800,000 per annum.

77. Using the estimate of 17% and 82% of incidents resulting in a candid conversation, the estimate of costs is £1.7m and £370,000 respectively.

78. The vast majority of NRLS reports are from NHS providers, whilst the CQC reported incidents tend to cover adult social care. It is not possible to further breakdown the number of reported incidents to either system by the type of provider who submitted the report further. As a sensible estimate, we therefore assume that all incidents reported in the NRLS correspond to NHS providers, whilst all CQC reported incidents correspond to private providers[25]. **This produces a best estimate of costs to private providers of just over £200,000.**

79. It is difficult to predict how the number of incidents might change in the future. As health or adult social care activity increases the number of incidents may increase, whilst improvements in patient safety may result in a fall in the number of incidents. Any observed increase in the number of reported incidents might reflect an improvement in reporting rather than an actual increase in the number of cases. It is not possible to take these complexities into account into the analysis, and as such, we make a relatively neutral assumption that the number of safety incidents, in the absence of any other changes, will increase in proportion to the increase in the number of health and adult social care providers entering the market.

80. Finally, we also consider the costs to organisations in administration. As well as spending time with patients, the regulations will also require that providers keep a written record of these conversations. Because at the moment there is no expectation of administration, we expect that all patient safety incidents result in more administrative staff time as a result of the new duty of candour. Estimates from ASHE 2013 suggests that the average hourly wage for administrative staff cost is £12 (including 15.3% non-wage costs). We would expect that the amount of time filing a candid conversation would be minimal. If we assume that all patient safety incidents falling under the duty of candour take up 30 minutes of an administrative staff member's time, the total cost in administration of the new duty of candour would be approximately £860,000 per annum. **Using the same assumptions as before, private providers would bear approximately £290,000 of these costs.**

Indirect costs associated with implementing best practice

81. As discussed above, we separately consider the costs associated with the duty of candour if providers were to follow existing best practice guidance to make further changes to drive increased openness and candour across their organisation. These additional actions are not directly mandated by the requirements and so we consider it to be unlikely that all providers would choose to undertake these additional steps in all instances. However, we continue to assess the potential costs of these additional steps as they will form an important part of achieving the overall policy aim of improving openness and transparency. They are however considered to be out of scope for the purposes of OITO since providers will have discretion on whether they choose to take these additional steps.

82. There are many potential steps providers might take to improve openness across their organisation. As an illustrative example, the best practice guidance, 'Being Open', which was issued for the NHS by the then National Patient Safety Agency, suggests that the following steps should be taken to implement a policy of candour:

[24] this is likely to be an overestimate since serious injury will also include many incidents of harm corresponding to the severe category in NRLS

[25] This was judged to be more appropriate than an alternative option, which would have been to apportion the number of reported incidents equally between all CQC registered providers. This approach would not take into account the varying level of activity and thus potential safety incidents between different types of organisations (e.g. large acute NHS hospitals compared to a small care home)

- Create or review and strengthen local policies identifying how to communicate with patients where serious injury or death has occurred. This policy should be aligned to existing best practice on being candid and should be embedded with the organisation's risk management processes
- The board should make a publicly visible and recordable commitment to implementing a policy of candour.
- Named executive and non-executive leads responsible for the candour policy should be appointed within the organisation
- The new policy should be publicised with staff.
- Advice and training should be given to staff on managing patient safety incidents as part of the general training for all staff.
- Publicise information on the support systems currently available for staff distressed by patient safety incidents

83. Similarly, the Australian Open Disclosure framework makes the following suggestions[26]:

- Leadership - Enlist a clinician leader to champion open disclosure and who will lead the open disclosure process by example. It is also important to have the explicit and vocal support of executive and senior leadership of your organisation.
- Support - Ensuring appropriate support for staff during open disclosure is critical for the individuals involved and for generating support.
- Communication - Look for opportunities to get the message out, including meetings, telephone calls, email, memos and newsletters. Be persistent in order to encourage cultural change.
- Enlist patients - Successes have been found when patients have been asked to become part of the solution. Clinicians often relate better to patients' experiences and explore the issues together.
- Continuous learning - Continue to learn and adapt, and involve clinicians in the learning process.
- Listen - Listen carefully to clinicians' concerns and try to understand their view of your efforts
- Training and development - All staff should be provided with general knowledge and information about open disclosure. This should be part of orientation for all clinical staff.
- Recognising achievement - Recognising the efforts of individual clinicians at all stages of their careers to be open and truthful about adverse events is an important aspect of change management, and cultural transformation.

84. It is difficult to quantify the cost of much of this activity, as many of the recommendations above relate to changes in leadership behaviour or practice, such as ensuring that leaders lead by example and communicate the importance of candour and openness to staff at all times. The main potential cost that we examine is the cost of providing additional training and support to staff, as this is likely to represent the most sizable and quantifiable change for providers.

85. Providers may choose to take various different approaches for training. For example, training might include aspects of (and are not limited to) any of the following:

- a one-off workshop for staff to discuss the importance of openness and how the statutory duty of candour will affect the organisation

[26] Adapted from the Australian Open Disclosure Framework Guidance for Managers, available at: http://www.safetyandquality.gov.au/wp-content/uploads/2013/05/Australian-Open-Disclosure-Framework-Guide-for-Managers.doc

- candour training to be added as part of the induction process for new staff – this could either be incorporated into existing training (e.g. on communication with patients), or serve as an additional stand-alone element
- candour training to be added to the list of mandatory training for all staff – as above this could either be incorporated into existing training, or serve as an additional stand-alone element
- additional voluntary training on candour to be made available to staff
- further written advice and guidance to be made available to staff
- further support to be available for staff via more experienced individuals to act as champions or mentors to other staff

This suggests that the amount of additional training and support to staff and the associated costs could vary significantly between different providers. During the consultation, the providers that we spoke to suggested that it would be likely that any additional training offered would be incorporated into existing training. Although it was difficult for providers to quantify these figures ahead of time, it was suggested that this might perhaps increase the total amount of training offered by approximately half an hour. Overall, we take forward the assumption that additional training costs are significantly lower than we had previously estimated in the consultation stage Impact Assessment.

86. In terms of the costs of training, the consultation stage Impact Assessment had estimated the cost of training per day per employee was approximately £455 based on figures from the UK Commission's Employer Skills (UKCES) Survey 2011. However, when this is compared to estimates of staff costs, this figure appears to be relatively high. Based on hourly earnings for healthcare professionals of £20 (inclusive of 15.3% non-wage costs) from the 2013 ASHE survey, this would suggest that the labour cost of one day of training would only be £160 per member of staff. Assuming that there would be similar costs associated for the time of the individual providing the training is similar, this would suggest that the cost of providing a day's training session for a group of five individuals and with one trainer would be £960 in total or £192 per person in receipt of training. Similarly, we examined the returns from the half year collection of education and training costs in the NHS[27] and found that these figures also tended to suggest a cost of training per FTE per day that was less than half of those originally calculated using the UKCES data.

87. This difference is likely to be because the UKCES survey will include costs such as travel and subsistence costs and fees paid to external training providers. From what we heard from providers during the consultation, it is more likely that any additional training for staff on candour would be incorporated into existing training arrangements and thus the cost of any additional training is likely to be most appropriately measured in terms of additional staff time required.

88. In terms of the number of staff receiving additional training, the 2013 Skills for Care Report on the size and structure of the adult social care sector and workforce in England estimated that there were a total of 1.6m jobs in the adult social care sector[28], whilst NHS workforce statistics showed that as at 30th September 2013, there were approximately 1.4m staff working in the NHS. It is likely that training is likely to be focused on managers and senior clinicians as these staff members are most likely to be involved in responding to patient safety incidents. Within the adult social care sector, it is estimated that approximately 114,000[29] of the 1.6m jobs are managerial or professional roles, whilst in the NHS there were approximately 692,000 professionally qualified

[27] This is the first collect of a new mandatory collection for NHS trusts to estimate the costs of training and education for clinical placements and training posts. For the most part these costs cover a much wider range of training activities than what we are considering in relation to the duty of candour. Nevertheless, these costs act as a useful point of reference for what the costs of training might be. See https://hee.nhs.uk/work-programmes/resources/costing-education-and-training/ for more information

[28] Skills for Care, 2013. The size and structure of the adult social care sector and workforce in England, 2013, Available at: http://www.skillsforcare.org.uk/Document-library/NMDS-SC,-workforce-intelligence-and-innovation/Research/Size-and-structure-2013-vweb2.pdf

[29] Ibid

clinicians and 36,000 managers or senior managers[30]. While no such comprehensive survey is available for the independent healthcare sector, a 2011 report by Skills for Health on the labour market for healthcare in England[31] estimated that the public sector healthcare workforce is approximately three times as large as in the private sector. Overall, this suggests a total of approximately 1.2m staff across the health and adult social care sector who might receive additional training on candour. Based on hourly earnings for healthcare professionals of £20 (inclusive of 15.3% non-wage costs) from the 2013 ASHE survey, this suggests that an extra half an hour of training for all staff would result in an additional cost of £12.1m overall.

89. However, as discussed previously, it is unlikely that training on candour would be annual. Rather, we make the assumption that such training would be made available to staff on average once every three years.It is not known what proportion of providers might choose to undertake this additional training in according with best practice to generate a culture of openness in their organisation. It is likely that the providers who choose to undertake this additional action will be those who assess that the benefits to them of doing so (discussed below) will outweigh the additional costs. From our work with providers during the consultation it is clear that some providers are leading the way in promoting candour and openness in their organisations and so will already be carrying out these types of activities in the do nothing scenario. Nevertheless, we provide some formal assessment of these costs and benefits[32] using the assumption that 50%[33] of providers might carry out some additional training, at an additional annual cost of approximately £2m.

90. **In terms of the costs falling on private or voluntary businesses, using a rough assumption that all costs associated with training staff in the independent healthcare sector and the adult social care sectors fall on the private sector, the additional annual cost would be approximately £775,000. This is however considered to be out of scope for the purposes of OITO, as this training is not strictly required by the regulations**.

91. In terms of the growth in the number of staff over time, we again assume that this will grow in line with the increase in the number of providers in the health and adult social care market.

Costs of enforcing the duty of candour:

92. Although CQC will not be able to monitor every single incident, they will be able to require providers to establish systems and processes that encourage and support openness and transparency with service. As part of their on-going programme of monitoring and inspections of providers against the registration requirements, it is expected that CQC will seek evidence from providers that they are taking all necessary steps to ensure that they are meeting their duty to be candid, as well as gathering information from other sources, which will inform CQC's overall judgement on whether the organisation is compliant. This is similar to the approach CQC takes to monitor and enforce the other existing registration requirements.

93. The additional costs associated with carrying out these checks are expected to be a small marginal cost on existing inspections. It is currently difficult to accurately quantify these costs as the cost of inspections will be driven by the frequency and duration of inspections, and the mix of staff present at the inspection. These factors will not be directly related to the number of requirements, although the more requirements there are, the more there will be for CQC to assess and inspect against. There is unlikely to be a one to one relationship between the number of regulations and the time required for an inspection, as this will depend on the complexity of the requirement, and whether CQC choose to focus on the issue during a particular inspection, which will be in part be driven by their findings and vary between providers. Additionally, the assessment of compliance across a

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30 Health and Social Care Information Centre, 2014. NHS Hospital and Community Health Service (HCHS) Workforce Statistics in England, Summary of staff in the NHS - 2003-2013, Overview, Available at: http://www.hscic.gov.uk/searchcatalogue?productid=14368&topics=2%2fWorkforce%2fStaff+numbers%2fAll+NHS+staff&sort=Relevance&size=10&page=1#top

31 England Skills and Labour Market Intelligence Assessment 2011 available at http://www.skillsforhealth.org.uk/

32 Since it is not possible to estimate what level of benefits might arise due to a 'bare minimum' interpretation of the duty compared to the full approach, this IA considers the both the 'bare minimum' and additional costs of the proposal against all potential benefits.

33 This is roughly in line with the finding from the consultation that approximately 61% of respondents indicated that they already have a formal candour policy – i.e. already take some steps beyond what is required of them to promote openness.

number of different requirements may be based on the same sources of evidence and so require minimal additional inspection time.

94. CQC will be making a number of changes to their regulatory model which will further affect the costs of monitoring, inspecting and enforcing against the registration requirements. It has not been possible to incorporate these cost changes into the analysis, as these proposals are still under development. Thus it is important to note that the costs to CQC quoted below are based on previous CQC cost modelling, and will be subject to change as CQC develop and implement their new regulatory model. CQC will publish separate impact assessments of these changes in due course.

95. If the additional time required came to an average of half an hour per inspection, then based on the average hourly rate of a compliance inspector of approximately £36 supplied by CQC (inclusive of non-wage costs), this implies an additional cost to CQC of approximately £18 per inspection. Based on the 28,000 inspections CQC carried out in 2012, this implies an additional annual cost to CQC of approximately £0.5m for inspection and monitoring. We again assume that over time, the number of inspections increases in proportion to the increase in the number of providers.

96. There may be some transitional costs to CQC associated with producing additional guidance for providers to explain the expectations CQC would have on providers to be candid. CQC estimate that the cost of producing additional guidance is approximately £4,000 based on an assumption that on average guidance requires 3 days to prepare, 2 days to review, 2 days for quality assurance, 2 days for sign-off and 5 days to publish, with a daily staff rate of £277, which includes on-costs and absorbed overheads. This estimate is an average across all types of guidance CQC produce, and does not take into account the differing time requirements that there might be for producing guidance of different lengths or complexity.

97. If a provider is found to be in breach of the duty of candour, CQC will be able to use its existing suite of enforcement actions in order to place sanctions on the provider and compel the provider to take action to achieve compliance. These include issuing a warning notice, placing conditions on a provider's registration, or in extreme cases, cancelling a provider's registration or prosecution. In the absence of better information on the likely rate of non-compliance, we make some crude assumptions based on the fact that in 2012 approximately 4% of all CQC published inspections led to enforcement action. Assuming that this enforcement action was evenly distributed across the 16 registration requirements, this might imply that having an additional registration requirement might increase the rate of non-compliance by a further 0.25 percentage points. Based on the 28,000 inspections CQC published in 2012, this implies an additional 70 enforcement cases. However this is likely to be an overestimate as it does not take into account the fact that one registration requirement is likely to be correlated with breaches in other areas. We expect that some providers who may be found to be in breach of the proposed statutory duty of candour would already face enforcement action for other registration requirements.

98. In addition, we note that the other proposed changes to CQC's regulatory framework are likely to affect the overall pattern of enforcement activity undertaken by CQC in the future. For example the proposed changes to the CQC regulations to enable prosecution without a warning notice, coupled with changes in CQC's method of monitoring and inspecting providers, are expected to improve CQC's ability to detect and take enforcement action against cases of non-compliance. This might in turn improve the deterrent effect on providers to comply with the regulations and so reduce the actual level of enforcement action required. It is not possible to predict what the overall effect of these changes might be, and so we continue to use past rates of non-compliance as the best estimate of future rates of non-compliance.

99. It terms of the cost to CQC of their enforcement action, this has been difficult to estimate because enforcement activity is so widely dispersed across the different CQC functions. Many different members of staff could get involved depending on the specifics of the case and the particular requirements. As a result, the costs of enforcement activity by CQC are tied up within the overall costs of CQC and are difficult to disentangle. It is very difficult to estimate what the additional unit of enforcement activity might cost CQC. CQC advise that the budget for legal fees is £800,000 per annum and that approximately 75% of this might be related to enforcement activity (CQC will also use legal services for other activities such as debt collection). Based on this fairly crude measure of

total enforcement costs, and using the fact that there were approximately 1100 cases involving some enforcement activity by CQC in 2012, we estimate that the average cost of an additional case of enforcement activity could be in the region of £550. Thus the total additional cost of additional enforcement action for CQC might be in the region of £38,000.

Other costs on providers:

100. Where providers hold conversations with patients, it is likely that as part of this conversation they will have to explain to patients what further action is being taken to investigate the incident and ensure that similar incidents do not occur in the future and lessons are learnt. In the regulations providers will be expected to advise and if possible agree with the relevant person what further enquiries into the incident are appropriate. This could potentially lead to an increase in the amount of investigations that providers will need to carry out into incidents and lessons learnt. However, it has not been possible to estimate what this might be. Large NHS hospitals will already have very formalised systems in place to investigate patient safety incidents and complaints whilst for adult social care providers, existing Local Authority safeguarding procedures will already provide the mechanism for investigations where incidents of harm occur. Under this existing framework is it not possible to predict how the duty of candour might influence the level of investigation that occurs. For the purposes of OITO, the costs of any additional investigations are considered to be indirect costs associated with the policy and so out of scope of further analysis. Any additional investigation costs will depend on the expectations of the service user, the existing investigation procedures of the provider and the specific circumstances of the incident. The requirement in the regulations will only be that providers advise and, if possible, agree with service users what further enquiries will be appropriate.

101. There may be reputational or other similar intangible costs associated with being candid. For example, if a provider is obliged to admit to a service user the role that they played in the harm falling on the service user in the course of their treatment, this information may damage the reputation of the provider if it is made publically known. This cost is currently unquantifiable. Providers will be able to mitigate this cost burden by investing in patient safety practices to minimise the number of avoidable mistakes made. On the other hand, it is also possible that being open can have a positive reputational impact, for example if the organisation gains a reputation for being trustworthy. This is examined further in the benefits section.

Litigation and insurance costs

102. During the consultation, the largest cost concern raised by respondents related to the potential impact that increased openness might have on clinical negligence claims and litigation or insurance costs for providers. Providers and insurers have expressed concern that providing an explanation and apology could be seen as an admission of liability, and thus have implications for the outcome and volume of medical negligence claims. Among these providers, these costs were viewed as the most significant potential impact of the policy proposal. However, a competing school of thought is that improvements in candour can actually help to manage and reduce the number of claims by reducing the level of anger, upset or frustration that patients feel when they do not get proper information about their care. During the consultation, approximately 40% of respondents to our call for evidence on insurance costs felt that these were likely to fall or remain the same, whilst just under 40% felt that insurance costs would rise and the remaining 20% did not know. This suggests that opinion on the likely impact of candour on litigation and insurance remains divided.

103. When we followed this issue up with insurance providers, a much more positive view emerged. One insurance broker for the adult social care sector highlighted the potential risks that increased openness could have on insurance costs if providers admit liability without proper investigation or discussion with their insurance providers. However, it was felt that this risk could be mitigated via proper guidance for providers, and overall there was support for a duty of candour as a way of potentially reducing insurance costs by helping to reduce and manage the number of clinical negligence claims. Similarly,, we also heard evidence that some dental insurers are beginning to actively encourage more openness as a way of reducing insurance costs, whilst,, the NHS LA are exploring options to offer financial incentives for NHS providers who take steps to improve the openness and transparency of their organisation, in recognition of the fact that this could reduce their litigation risk. Finally, the Medical Defence Union has also published literature encouraging further openness as a way of reducing litigation claims.

104. The available evidence from international examples also appears to suggest that increased openness reduces litigation (and thus insurance) costs. This is examined in more detail in the benefits section of this Impact Assessment. Overall, we conclude that although it is difficult to draw firm conclusions, the weight of currently available evidence tends to suggest that increased openness and candour is more likely to help to reduce rather than increase litigation and insurance costs.

105. There remains a risk however that, where providers are particularly concerned about the potential liability implications of being open, they may incur significant additional costs in seeking additional advice or assurance about what they should or should not say to patients in relation to a particular patient safety incident. During the consultation, providers suggested that, in order to mitigate this risk, very clear guidance would be required to address these issues.

Costs - Summary

106. The costs above are summarised in the table below;

Summary of societal costs

			Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	
			0	1	2	3	4	5	6	7	8	9	
	Description of Costs		2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23	2023/24	Total
Provider costs	Familiarisation costs		727,000	-	-	-	-	-	-	-	-	-	727,000
	Total		**727,000**	-	-	-	-	-	-	-	-	-	**727,000**
	Initial set up and training costs	Creating a policy	7,160,000	-	-	-	-	-	-	-	-	-	7,160,000
		Training	1,800,000	153,000	155,000	158,000	161,000	164,000	168,000	171,000	175,000	180,000	3,290,000
	Total		**8,970,000**	-	-	-	-	-	-	-	-	-	**10,500,000**
	Ongoing costs of being candid	Staff time for candour	797,000	806,000	815,000	825,000	835,000	846,000	858,000	871,000	885,000	899,000	8,440,000
		Admin time	855,000	865,000	875,000	885,000	896,000	908,000	921,000	935,000	949,000	965,000	9,050,000
	Total		**1,650,000**	**1,670,000**	**1,690,000**	**1,710,000**	**1,730,000**	**1,750,000**	**1,780,000**	**1,810,000**	**1,830,000**	**1,860,000**	**17,500,000**
	Indirect costs of improving culture and promoting openness		2,020,000	2,040,000	2,060,000	2,090,000	2,120,000	2,140,000	2,170,000	2,210,000	2,240,000	2,280,000	21,400,000
	Total		**2,020,000**	**2,040,000**	**2,060,000**	**2,090,000**	**2,120,000**	**2,140,000**	**2,170,000**	**2,210,000**	**2,240,000**	**2,280,000**	**21,400,000**
Total			**13,400,000**	**3,860,000**	**3,910,000**	**3,960,000**	**4,010,000**	**4,060,000**	**4,120,000**	**4,180,000**	**4,250,000**	**4,320,000**	**50,000,000**
CQC costs	Inspection costs		504,000	510,000	515,000	522,000	528,000	535,000	543,000	551,000	559,000	569,000	5,340,000
	Enforcement costs		38,200	38,600	39,000	39,500	40,000	40,500	41,100	41,700	42,400	43,100	404,000
	Producing guidance		4,000	-	-	-	-	-	-	-	-	-	4,000
	Total		**546,000**	**548,000**	**554,000**	**561,000**	**568,000**	**576,000**	**584,000**	**593,000**	**602,000**	**612,000**	**5,740,000**
Total cost (undiscounted)			**13,900,000**	**4,410,000**	**4,460,000**	**4,520,000**	**4,580,000**	**4,640,000**	**4,700,000**	**4,780,000**	**4,850,000**	**4,930,000**	**55,800,000**
Discount adjustment			1.00	0.97	0.93	0.90	0.87	0.84	0.81	0.78	0.75	0.73	
Total Present Cost (discounted)			**13,900,000**	**4,260,000**	**4,160,000**	**4,060,000**	**3,970,000**	**3,880,000**	**3,800,000**	**3,720,000**	**3,650,000**	**3,580,000**	**49,000,000**

NB: figures may not sum due to rounding

Benefits

107. It is expected that increased openness and candour will have multiple benefits to both service users and providers. Although it has been difficult to fully quantify these benefits, we provide some break even analysis to illustrate the potential size of the positive impacts required to outweigh the costs. Based on this analysis we conclude that there is a strong likelihood that the benefits of the proposal would outweigh the costs. In addition, it is likely that the policy would have a net benefit to business. This is discussed further in the sections below. We examine the effects of the duty of candour on; safety, patient satisfaction, clinical negligence claims and insurance costs, complaints, other reputational effects in the health and adult social care market and medical ethics.

Reduction in patient safety incidents

108. The proposed statutory duty of candour is expected to improve and encourage a culture of openness and transparency amongst providers. Increases in openness and transparency are in turn linked to improvements in patient safety. Bierman & Boothman (2006)[34] has stated that disclosure is linked to improving patient safety and active patient safety programmes. For example, a system of open disclosure could lead to increased reporting and investigation of incidents, either as a direct consequence of improvements to the patient safety incident management framework to facilitate or enable candour, or due to any subsequent shift in the culture of the organisation to encourage openness and transparency. It could be the case that more formal investigation procedures are put in place to enable providers to provide better assurances to service users during a candid conversation, which will also enable providers to gain a better understanding of safety issues, allowing improvements to be made. A shift in culture could also impact patient safety via less formal measures, such as changing the attitude of clinicians to learn more readily from others' mistakes. Finally, providers being required to disclose safety incidents to service users might also act as an incentive for providers to reduce the number of incidents.

109. There are many paths and mechanisms by which a robust learning and safety culture can be developed. It is not possible to disentangle the impacts of a duty of candour from the various other initiatives designed to improve patient safety[35]. Although it is unlikely that the introduction of a duty of candour on its own could deliver all desired patient safety improvements, such candour is likely to have an important part to play. We provide some illustrative examples below of the potential patient safety benefits of a duty of candour.

110. A patient safety incident is likely to be costly both to the patient in terms of the adverse health effect, and to the provider in terms of the increase in care they must provide in response to the incidence.

111. In terms of the health impact on the patient, these can be measured in Quality Adjusted Life Year (QALY) terms[36]. We estimate the potential health impact of a patient safety incidence based on the results of a study by Campbell et al. (2009)[37], which uses a systematic review of previous litigation to analyse the impact in QALY terms of various preventable adverse drug events. They are classed as being significant, serious or severe. In the absence of further information, we will assume that these correspond to the low, moderate and severe harm respectively in the NRLS dataset, and that there is a similar impact of QALYs as a result of a preventable adverse drug event is the same as that for all other adverse events.

112. According to data submitted to the National Reporting and Learning Service, between January 2012 and December 2012 there were approximately 1.35 million English patient safety incidents. The majority of these incidents resulted in no harm to the patient, whilst, approximately

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[34] Biermann, J. S., & Boothman, R. (2006). There is another approach to medical malpractice disputes. *Journal of Oncology Practice, 2*(4), 148.

[35] Naveh, E., Katz-Navon, T., & Stern, Z. (2005). Treatment errors in healthcare: a safety climate approach. Management Science, 51(6), 948-960.

[36] The QALY approach weights life years (saved or lost) by the quality of life experienced in those years. Years of good health are more desirable than years of poor health. A value of 1 is equivalent to one additional year of perfect health. Please see Appendix 4 of the supplementary Green Book guidance for more information.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/191503/policy_appraisal_and_health.pdf

[37] Karnon, J., Campbell, F. & Czoski-Murray, C. (2009). Model-based cost-effectiveness analysis of interventions aimed at preventing medication error at hospital admission (medicines reconciliation). *J Eval Clin Pract.*, 15(2):299-306.

430,000 incidents resulted in harm, but not death[38]. In addition approximately 28,500 incidents resulting in serious injury were reported to CQC. As previously discussed, there are some differences in definition between the NRLS and CQC definitions of harm, however if we assume that the same proportions of incidents reported to CQC resulted in moderate and severe harm as in the NRLS this gives an estimate of 26,200 incidents resulting in moderate harm and 2,300 resulting in severe harm in the CQC reporting system.

113. However, these figures will not necessarily reflect the total number of patient safety incidents that occur due to underreporting. By definition it is not possible to determine the degree of underreporting that occurs. Therefore, rather than making an assumption about the true number of patient safety incidents in England, we will take reported incidents as being representative of the number of patient safety incidents. This will therefore be a minimum estimate of the potential number of incidents.

Severity of harm	Estimated number of patient safety events per year ('000s)	QALY loss per event		QALY gain of preventing 1 in 1,000		Monetised QALY gain (£'000s)	
		Min	Max	Min	Max	Min	Max
Low	340	0.001	0.008	0.34	2.72	20	163
Moderate	112	0.061	0.09	6.832	10.08	410	605
Severe	10	1	4.41	10	44.1	600	2,646
Figures may not sum due to rounding						1,030	3,414

114. The table above illustrates the potential QALY gain of preventing 1 in 1,000 events as a result of an improved learning culture derived from introducing a duty of candour for illustrative purposes based on these assumptions.

115. In terms of the costs to providers associated with patient safety incidents, Campbell et al. (2007) once again provides an insight into the probable costs of preventable adverse events. Although its focus is on preventable adverse drug events, one assumes similar costs to the hospital of other adverse events. Using the same assumptions as before that the introduction of a duty of candour induces a fall in the number of preventable adverse events by 1 in 1,000, the following savings to hospitals could be made. These savings are most likely to benefit the NHS rather than all providers. This is because although patient safety incidents can occur in all settings, where there is harm to a patient, the vast majority of the costs of resolving the incident will fall on the hospital.

Severity of harm	Estimated number of patient safety events per year	Cost to the hospital per event (£)		Saving by preventing 1 in 1,000	
		Min	Max	Min	Max
Low	340	70	150	23,800	51,000
Moderate	112	710	1,480	79,520	165,760
Severe	10	1,090	2,120	10,900	21,200
Figures may not sum due to rounding				114,220	237,960

116. Finally, improvements in patient safety are likely to also reduce the number of preventable deaths. Hogan et al. (2012)[39] presents evidence that 5.2% (95% confidence interval (CI) 3.8% to 6.6%) of all deaths were 'more likely than not' preventable from a large representative sample. Given that there were approximately 270,000 deaths in 2012 in English hospitals, this would suggest there were about 14,000 (95% CI 6,000 to 22,000) preventable deaths in 2012 in English hospitals. Hogan et al. (2012) states that for the majority of these patients death is only averted for an average

[38] Although the duty of candour will only apply to cases of significant harm (ie moderate or severe harm and death under current NRLS definitions), the lessons learnt from an open culture will also reduce the chance of low harm events. For a small number of practitioners having to be open to patients might lead to even greater attempts to avoid harm, for fear of having to admit this problem.

[39] Hogan, H., Healey, F., Neale, G., Thomson, R., Vincent, C., & Black, N. (2012). Preventable deaths due to problems in care in English acute hospitals: a retrospective case record review study. BMJ quality & safety, 21(9), 737-745.

of six months, due to multiple comorbidities, frailties and old age. Let us assume therefore that avoiding the death returns the patient to the maximum quality of life achievable for them for six months. Given a willingness to pay for a full QALY of £60,000, preventing 1 in 1,000 preventable deaths would achieve a societal benefit of £420,000 (95% CI £180,000 to £660,000)[40].

117. However, it is not known whether the 1 in 1000 figures quoted above are likely to be a realistic estimate of the reduction in patient safety incidents as a result of the statutory duty of candour or not. Break-even analysis suggests that in order for the (discounted) societal benefit of these prevented patient safety incidents to outweigh the estimated net present cost of the policy of £49m, at least 1 in 250 patient safety incidents (including preventable deaths) would need to be avoided per year. This is equivalent to approximately 0.36% of the total number of reported incidents estimated above. If the costs of taking additional action to improve the culture of the organisation are assumed to already be outweighed by other benefits to the provider, approximately 1 in 440 incidences would need to be prevented by the duty of candour to outweigh the remaining estimated net present cost of the policy. However this does not take into account the other societal benefits of the policy discussed below.

Patient satisfaction

118. It is widely recognised that patients or their families want to be told about patient safety incidents that befall them or one of their family members. O'Connor et al. (2010), a systematic review of the subject of open disclosure of patient safety incidents, details 9 separate papers which make it clear that patients and families report wanting to be told about patient safety incidents. In the UK specifically, a survey by the Medical Protection Agency in 2011[41] found that 95% of people felt that, in the event of a medical error, it is very important for doctors to give an open and honest explanation of what went wrong. Thus any increase in the level of disclosure would result in more satisfied patients or a reduction in the anger, anxiety and frustration that they feel when they do not get the information that they are entitled to. In order to monetise this benefit, we need to first estimate the potential increase in disclosure that might arise, and the potential willingness to pay by patients for improved candour.

119. As discussed previously, we estimate that following number of incidents would fall under the new duty of candour

NRLS		**CQC**	
Death	3,600	Death	20,300
Severe	7,400	Serious Injury	28,400
Moderate	86,000		
Total	97,000	Total	48,700

120. We previously estimated that 50% of these incidents might already result in a candid conversation with patients, with a high estimate of 82% based on the survey of the number of NHS trusts who implement the Being Open guidance[42]. This latter figure provides a prudent estimate on the number of additional candid conversations that might result as a consequence of the duty of candour. Applying this figure to our estimated number of patient safety incidents suggests that there could be approximately 26,250 patient safety incidents each year that are explained candidly to patients.

121. Compared to our best estimate of the net present costs of £49m the average willingness to pay per incidence of improved candour would need to be at least £220 for the benefits of improved patient satisfaction to begin to outweigh the costs. To put this figure into context, we follow the approach of a previous Impact Assessment that examined the case for a contractual duty of candour

[40] Although total deaths are increasing, the proportion of preventable deaths should fall due to the introduction of patient safety programmes and quality measures throughout the NHS, as well as continued endeavour by providers to mitigate avoidable deaths. Given these two opposing actions, we assume that the number of preventable deaths will remain largely constant at the 2012 level.

[41] A culture of openness; The MPS perspective, 2011, available at http://www.mps.org.uk

[42] Pinto, A., Faiz, O., & Vincent, C. (2013). Republished: Managing the after effects of serious patient safety incidents in the NHS: an online survey study. Postgraduate medical journal, 89(1051), 266-273.

for the NHS[43]. This measured the benefits to patients from improved candour in terms of the reduced anxiety resulting from better information using the EQ-5D standard scale of health outcomes[44]. This questionnaire asks individuals to rate their health in five areas including the experience of pain, mobility and anxiety. These scores can then be turned into a health state by assigning values to each of the possible combination of scores and converted into a Quality Adjusted Life Year (QALY) by also considering the duration of the health state. For UK individuals a one point fall on the anxiety/depression scale represents an approximate 12 percentage point fall in health state[45]. Compared to an estimated willingness to pay of £60,000 for each year spent at full health[46], a willingness to pay of £200 corresponds to avoiding one to two weeks of being 'slightly anxious or depressed'[47]. This compares to the 6 months of reduced anxiety estimated in the previous Impact Assessment.

122. In addition, multiple studies cite that many people opt for litigation after a patient safety incident as a result of a desire for further information[48]. This demonstrates further that individuals are willing to pay, in this case paying for litigation processes, for the truth. Again this analysis does not take into account the other benefits associated with candour discussed.

Effect of a duty of candour on litigation and insurance costs

123. The remaining sections consider the potential benefits of candour for providers. One of the most commonly cited barriers to providers being candid is the fear that being candid and providing more upfront information about patient incidents can lead to a risk of increased litigation, and that offering an apology might be interpreted as an admission of liability. On the other hand, it has also been suggested that being candid can actually reduce litigation costs, as often the main motivation for bringing about a medical negligence claim is to seek more information about mistakes in their care, or due to a perceived failure of the provider to apologise. Overall the evidence on the likelihood of litigation is unclear, but tends to point more towards there being a reduction in litigation rather than an increase. Given the large and growing costs of litigation in the healthcare sector especially, this could potentially lead to significant benefits for providers if improved candour is able to reduce these costs.

124. A number of surveys of patients lend evidence to the idea that an important motivation for medical negligence claims is to gain more information about mistakes in their care, or due to a perceived lack of apology by the provider. For example, a study by Hickson et al in 1992 of mothers of infants who had suffered death or permanent perinatal injuries found that 24% reported that one of the reasons they decided to sue was because they realised their physician was not completely honest with them or had intentionally misled them[49]. Getting more information about what happened was cited as a reason by 20%. A more recent survey carried out in 2005[50] examined a number of different scenarios with parents who presented with children at an emergency department and found that 36% of parents thought that they would be less likely to seek legal action if they were informed of the error by the physician although 63% of parents stated that disclosure by the physician of a serious error committed would not change the likelihood of their pursuing legal action in the event of an error in the care of their children.

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[43] Department of Health, 2012. Implementing a Duty of Candour; a new contractual requirement. [online] Available at: <http://www.hsj.co.uk/Journals/2012/12/07/w/b/g/Duty-of-Candour-Impact-Assessment.pdf>

[44] As developed by the EuroQol Group. Please see Appendix 4 of the supplementary Green Book guidance for more information. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/191503/policy_appraisal_and_health.pdf

[45] EuroQoL, 2014. EQ-5D-5L Value Sets. [online] Available at: <http://www.euroqol.org/about-eq-5d/valuation-of-eq-5d/eq-5d-5l-value-sets.html>

[46] Department of Health, 2010. Quantifying health impacts of government policies. [online] Available at: <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216003/dh_120108.pdf>

[47] EuroQoL, 2009. *Health Questionnaire – English Version*. [online] Available at: <http://www.euroqol.org/fileadmin/user_upload/Documenten/PDF/Products/Sample_UK__English__EQ-5D-5L.pdf>

[48] Kraman, S. S., & Hamm, G. (1999). Risk management: extreme honesty may be the best policy. *Annals of Internal Medicine*, *131*(12), 963-967.

[49] Hickson GB, Clayton EW, Githens PB, Sloan FA, 'Factors that prompted families to file medical malpractice claims following perinatal injuries' *Journal of American Medical Association*, 1992, 267(10) 1359-63

[50] Hobgood C, Tamayo-Sarver JH, Elms A, Weiner B. 'Parental preferences for error disclosure, reporting, and legal action after medical error in the care of their children' *Pediatrics* 2005; 116: 1276–1286

125. There have also been a number of case studies looking at the adoption of open disclosure policies across the world. The most commonly cited cases are as follows:

- The University of Michigan Hospital System implemented a full-disclosure programme, which involves thoroughly investigating all incidents, meeting with patients to fully explain and answer all questions, moving to a system of automatic compensation where investigations conclude that the hospital was at fault. A study[51] found that the move to this programme halved the number of pending lawsuits and resulted in a total average annual savings of $2 million. However, causality could not be established as malpractice claims were found to have generally declined in Michigan during the latter part of the study period.
- The Veterans Affairs Medical Center (VAMC) in Lexington, Kentucky, introduced a policy of full-disclosure in the 1980s which involved informing patients and/or their families of adverse events known to have caused harm or injury to the patient as a result of medical error or negligence. The disclosure includes discussions of liability and also includes apology and discussion of remedy and compensation. By 1999 it was found that the hospital had liability costs that were moderate and comparable to those of similar facilities[52].
- The '3Rs' programme was put in place by the medical malpractice insurer COPIC. The program emphasises disclosure, transparency, apology, and patient benefits and has been credited with reducing adversarial litigation in Colorado[53]. However, as the openness programme is linked with a 'no fault' compensation programme it is difficult to determine whether the reduced litigation costs are related to this aspect, or the increase in openness.

126. Overall, although all of these case studies indicate that a policy of candour may be associated with a reduction in litigation costs, none of them offer conclusive proof of a causal link. In all of the cases above, an increase in openness was accompanied by other changes in policies to consider the case for compensation up front, which would also have an impact on total litigation costs. Other external changes that might have influenced medical malpractice claims were not fully taken into account. Kachalia et al (2003)[54] conducted a comprehensive literature review of more than 5000 citations and concluded that there was very little evidence that directly links the effect of a policy of candour to litigation costs. On the other hand a paper by Berlin (2006)[55] notes that no published evidence (at the time) suggested that more open disclosure of errors and apologising increased liability dramatically.

127. Moreover, during consultation both providers and their representative bodies pointed out that some insurers are now encouraging openness as a way of reducing litigation costs. The Medical Defence Union, an organisation which provides professional medical indemnity, explicitly states that 'if more doctors said 'sorry' and said it sooner then there would be fewer claims and complaints'[56]. The NHS Litigation Authority (NHS LA), which pools risk from NHS trusts, employs the 'Being Open' guidance, which also encourages candour. In the adult social care market, patients are largely protected by safeguarding arrangements, which attempt to instigate similar openness.

128. Based on the evidence available, it is not possible to quantify the overall impact that the proposed statutory duty of candour might have on litigation costs. However the following paragraphs

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51 Boothman RC, Blackwell AC, Campbell DA Jr, Commiskey E, Anderson S. 'A better approach to medical malpractice claims? The University of Michigan experience' *Journal of Health and Life Sciences Law* 2009; 2: 125-159

52 Kraman SS, Hamm G, 'Risk Management: Extreme Honesty May be the Best Policy' *Annals of Internal Medicine* 1999; 131(12): 963-967

53 Quinn RE, Eichler MC, 'The 3Rs program: the Colorado experience' *Clinical Obstetric Gynecology* 2008; 51: 709-718

54 Kachalia A, Shojania KG, Hofer TP, Piotrowski M, Saint S, 'Does Full Disclosure of Medical Errors Affect Malpractice Liability? The Jury Is Still Out' *Joint Commission Journal on Quality and Patient Safety* 2003 29(10) 503-511(9)

55 Berlin L, 'Will saying "I'm sorry" prevent a malpractice lawsuit? Malpractice issues in Radiology' *American Journal of Roentgenology* 2006;187: 10-15.

56 MDU, 2009. 'How to avoid claims and complaints'. [online] Available at: <http://www.acutemedicine.org.uk/index.php?option=com_docman&task=doc_download&gid=67&Itemid=21>

provide some additional analysis on the potential size of these benefits using illustrative examples and break even analysis.

129. Data is most readily available on litigation costs for the NHS via the NHS Litigation Authority (NHSLA). From their Annual Report 2012/13, 10,129 claims were received compared to 9,143 in the previous financial year representing a 10.8% increase. This is similar to the picture for the past 5 years:

Figure 1: New claims reported (all Trusts)

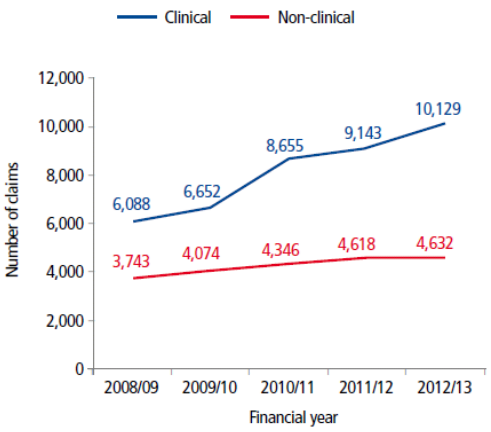
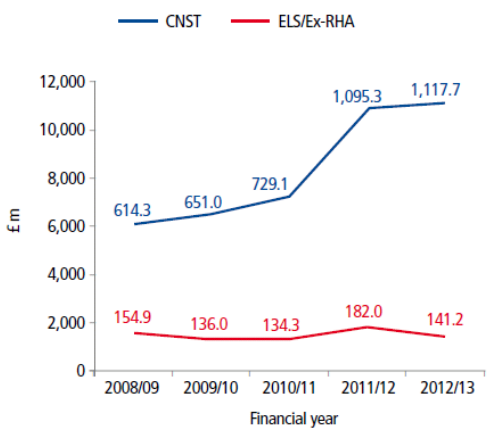


Figure 6: Expenditure on clinical claims



130. In terms of the total expenditure on claims, this was approximately £1.1bn in 2012/13, representing a 2% growth compared to the previous financial year. Over the past 5 years, the average growth rate of expenditure was 20%, mainly driven be a sharp increase in expenditure between 2010/11 and 2011/12, as a result of a change in regulations, not a change in demand.

131. However this expenditure will include expenditure relating to new claims, as well as ongoing expenditure relating to past claims (e.g. the ongoing payment of compensation for malpractice in obstetrics) and thus it is not possible to estimate the average cost per claim from these figures. Nonetheless, we can calculate the estimated potential saving to the NHSLA associated with a change in the growth rate of expenditure over time. Compared to total expenditure on clinical claims in 2012/13 a 0.1 percentage point decrease in the growth rate of expenditure would result in a saving of £1.1m in the following year. Over the ten years of the impact assessment, and assuming that claims expenditure would have continued to grow by 2% p.a. this would result in a total saving of £69m (or £56m following discounting). If there were a 0.5 percentage point decrease in the long term growth rate, this would give a saving of £5.7m in the next financial year, or £340m (£280m discounted) over the 10 years of the impact assessment.

132. While these cost savings relate mainly to the NHS, it is likely that private hospitals will experience similar types of litigation costs. It has not been possible to obtain figures on the total litigation expenditure for this sector since there no central body that collects this information in the same way as the NHS LA. From 2012/'13 independent sector providers of NHS care were also able to join the NHS LA's Clinical Negligence Scheme for Trusts however, but given the time delay between a claim being made and the actual legal procedures it is unlikely that any costs associated with these providers will have been captured in the data as of yet. Laing and Buisson estimate in their 2013/14 Healthcare Market Review that the independent sector supplies approximately 15.5% of UK elective surgical admissions[57]. We will assume therefore that the private hospital market has litigation claims 18.3%[58] as large as those managed by the NHS LA. Given that most litigation claims occur as a result of surgical as opposed to medical procedures, this claim seems valid. Thus, we estimate that total litigation expenditure might have been in the region of £200m for the independent hospital sector in 2012/'13. A 0.1 percentage point reduction in the growth rate would therefore reduce litigation costs by just under £13m over the ten-year period (£10m discounted). Similarly, a

[57] Laing and Buisson *Healthcare Market Review 2013/14* <Not available online>

[58] In other words, independent hospitals litigation claims are 18.3% the size of those for the NHS because activity is also 18.3% that observed in the NHS (15.5% divided by 84.5% is 18.3%)

0.5 percentage point reduction in the growth rate will reduce costs by £63m (£51m discounted). Although these litigation costs would ultimately be paid by insurance companies rather than providers, a reduction in litigation costs would ultimately lead to a reduction in premiums. Assuming a perfectly competitive insurance market where super-normal profits cannot be made, in the long run we would expect all savings to be passed onto providers in the form of lower premiums.

133. In the primary care market, insurance costs amongst GPs have risen at an even faster rate in recent years. Over the past two years the average rise in indemnity costs has been approximately 10% for partners and salaried GPs to an average premium of £7,000 in 2013[59]. There are approximately 40,000 GPs nationally, according to 2012 data[60]. We will use the previous assumption that 6% of GPs are private[61] and therefore total insurance costs for this group might be approximately £16.8m. As discussed above the introduction of a duty of candour may reduce total litigation costs, which would be reflected in insurance prices, assuming a competitive market. If the annual rate of increase in insurance prices fell by between 0.1% and 0.5% per year from 10% as a result of the duty of candour, the undiscounted savings over ten years could range from £1.7m to £8.3m (£1.3m to £6.6m discounted).

134. These figures above compare to an estimated business net present cost of between £17.3m and £10m, depending on whether the additional costs of culture change are included or not and so suggest that overall, a decrease of at least 0.16 percentage points in the growth rate of litigation (or insurance) costs would result in the benefits outweighing the costs to business. This analysis does not include the adult social care sector as it has not been possible to obtain any estimates of the total size of litigation or insurance costs for this sector. As is the case for the independent hospital sector, there is no central organisation that collects these figures. However, evidence suggest that litigation costs will be a significant pressure for this sector, as is the case for acute hospitals and GPs. During the consultation, one insurance broker suggested that they might receive notification of between 80-100 new claims per day in relation to this sector.

Fewer complaints

135. As already discussed, a policy of candour is expected to improve patient satisfaction. This is also expected to benefit the provider as it is likely to reduce the number of patient complaints. Holden (2009) states 'saying sorry and providing an explanation to a patient or relative seldom does any harm and can often avoid a complaint'[62]. It is difficult to ascertain the exact number of complaints as many complaints may be dealt with informally. In 2012/'13, however, there were 162,019 written complaints to the English NHS[63]. Communication was the third most commonly cited reason for complaint, after 'all aspects of clinical treatment' and 'attitudes of staff'. This strongly suggests that the proposed duty of candour could have an impact on the number of complaints made to health and adult social care organisations. In the NHS, 11,606 formal complaints related to communication in hospital and community health settings and 10,110 in general practice and dentists[64].

136. It is difficult to approximate the cost of a complaint, since there is little data on the time taken by providers to rectify these problems and what level of administration is required to see the complaint through. In an article by a consultancy company specialising in complaints management, Complaint is Great, they examined some case studies for public sector complaint costs and found that a study carried out during the late 1990s of complaint handling costs at stages 1 and 2 of a local authority complaint scheme showed that the average cost of a stage 1 investigation was £57.00 and

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59 Pulse, 2013. 'GP medical defence costs to rise to almost £7,000 per year'. [online] Available at: <http://www.pulsetoday.co.uk/your-practice/practice-topics/legal/gp-medical-defence-costs-rise-to-almost-7000-per-year/20002646.article>

60 HSCIC, 2013. NHS Staff – 2002-2012 – General Practice. [online] Available at: <http://www.hscic.gov.uk/searchcatalogue?productid=10382&topics=2%2fPrimary+care+services%2fGeneral+practice%2fGeneral+Practice+workforce&sort=Relevance&size=10&page=1#top>

61 This is equivalent to assuming that there is an even spread of GPs between all different GP practices

62 Holden, J. (2009). Saying sorry is not the same as admitting legal liability. *BMJ* 338: 370.

63 HSCIC, 2013. Data on Written Complaints in the NHS – 2012-13, [online] Available at: <http://www.hscic.gov.uk/searchcatalogue?productid=12245&q=complaints&sort=Relevance&size=10&page=1#top>

64 Ibid.

a stage 2 investigation had an average cost of £153.20[65]. The cost of handling a complaint at Chief Executive or Ombudsman stage will increase the costs to somewhere between £300 and £1000[66]. They also cited a further study by the National Audit Office found that complaints to Ofwat cost from £5, if they were quickly resolved, up to £1,500 when escalated to the ombudsman[67].

137. Guidance on complaints handling for the NHS gives three stages of complaint handling – local resolution, independent review or referral to the Parliamentary and Health Service Ombudsman. When a complaint is first received by the Trust, they must; acknowledge the complaint, investigate and respond to the issues in the complaint, and provide a formal response. This might include further meetings with the complainant to discuss the complaint, and offers of remedial action, in addition to a formal written response. It is recommended that boards and practitioners work together to fully resolve a complaint by responding to every point outlined in the complaint, and giving full explanations for any shortcomings[68].

138. We will assume that, in line with the guidance cited above, in a hospital setting both board time and practitioner time is set aside to deal with complaints. We will also assume that senior members of staff take on the responsibility for dealing with complaints of their team and will therefore use the costs of nurse team leaders and consultants. Each complaint will also incur the cost of an administrative staff member's time. The mean gross hourly pay for those in Administrative Occupations from the 2013 Annual Survey of Hours and Earnings (ASHE) was estimated to be £12 and for corporate managers and directors £24. Research commissioned by the National Leadership Council[69] highlighted that membership of NHS trust boards may range from 8 to 11 members, and thus we assume an average of 10 board members. Specific information about staff costs in health and adult social care suggest that the hourly cost of a nurse team leader is £49 in a hospital, whilst for a consultant it is approximately £140, regardless of speciality[70]. It is assumed here that half of complaints will concern doctors and half will concern nurses. If the board and the practitioner require a quarter of an hour to discuss the complaint, the practitioner takes a further half an hour to resolve the complaint and a member of the administrative staff takes half an hour to file the complaint, the cost of an average hospital complaint can be assumed to be £136. Across the estimated 11,606 formal complaints relating to communication in hospitals this suggests a total cost of £1.6m in 2012/13. This should be treated as a very low estimate, because costs of escalating complaints, as already demonstrated, leads to much higher costs; however it is not possible to say what proportion of communication related complaints are escalated.

139. In general practice and dentistry, it is likely that the doctor involved will be the sole individual dealing with the complaint, again with administrative support. Including non-wage costs the hourly cost is estimated to be £58 for an advanced nurse in a GP practice, whilst the hourly cost for a GP is approximately £147[71] and for a dentist, £163[72]. One cannot work out which of the 11,110 fall upon dentists and which fall upon GP surgeries. Given that there are an almost equal number of primary medical and dental services, we assume an equal number of complaints for GPs and dental surgeries. If half of GP complaints are dealt with by an advanced nurse and half by a GP and all

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[65] Complaintisgreat, 2012. The costs of complaint handling. [online] Available at: <http://www.complaintsmanagementexpert.com/cms/content/costs-complaint-handling>

[66] Ibid.

[67] Ibid.

[68] Please see: Hodgson, R., Mendis, S., & Storey, S. (2011). When things go wrong: a practical guide to dealing with complaints. Advances in Psychiatric Treatment, 17(2), 122-130. The NHS Guide for Complaints Handling for CCGs available at http://www.england.nhs.uk/wp-content/uploads/2012/03/20130513-Good-complaints-handling-for-CCGs-FINAL-version-for-publication.pdf,
'Complaints in the NHS: A guide for handling complaints in Wales' – the Welsh Government available at: http://www.wales.nhs.uk/documents/nhs-complaints-guide.pdf
Principles of Good Complaints Handling – the Parliamentary and Health Services Ombudsman, available at http://www.ombudsman.org.uk/__data/assets/pdf_file/0005/1040/0188-Principles-of-Good-Complaint-Handling-bookletweb.pdf

[69] National Leadership Council. , 2010. The Healthy NHS Board: A review of guidance and research evidence, available at http://www.foresight-partnership.co.uk/downloads

[70] Curtis, L. (2013). Unit costs of health and social care 2013. Personal Social Services Research Unit.

[71] Curtis, L. (2013). Unit costs of health and social care 2013. Personal Social Services Research Unit.

[72] Tan, S. S., Ken Redekop, W., & Rutten, F. F. (2008). Costs and prices of single dental fillings in Europe: a micro-costing study. *Health Economics*, *17*(S1), S83-S93.

dentistry complaints are dealt with by a dentist, each complaint receiving forty five minutes of their time, the average minimum cost of a complaint in primary medical or dentistry care is approximately £105 including half an hour of administrative staff's time in all cases. Again, summing over the 10,110 formal complaints relating to communication in GP and dental practices, this equates to a total cost of approximately £1.1m. Again, this should be taken as an absolute minimum estimate of costs, given that many complaints are escalated and require further time to be resolved.

140. It is not possible to estimate similar figures for adult social care or independent healthcare providers. As discussed previously, information about the volume of complaints is not collected by any central organisation, and there is also likely to be more variation in the complaints handling process. However, if we were to assume that the average cost of a complaint was roughly in line with the estimates calculated above for GPs and Dentists, then compared to a calculated EANCB of approximately £1m, this would suggest that there would need to be a reduction in complaints of at least 10,000 per year for this particular benefit to outweigh the EANCB figure. Although we do not know the total number of complaints made to the sector, there are approximately 12,750 private or voluntary sector providers registered with CQC; this is therefore equivalent to a reduction of less than one complaint per organisation in a year.

Reputational benefits

141. Introducing a duty of candour will also lead to reputational benefits for providers. There are two ways this might happen. Firstly, as discussed before a duty of candour might actively increase quality as a result of a learning culture. Secondly, as previously discussed, increased candour is likely to improve patient satisfaction. Both of these factors might lead to providers being given higher ratings by inspectors or by service users, who can convey their opinions to others through websites or word of mouth. Overall this might serve to improve the reputation of the provider or even the sector as a whole, helping to attract more patients and increase revenues.

142. This effect is likely to be strongest for adult social care. Although all health and adult social care markets are likely to have a degree of elasticity of demand with respect to quality, it is unlikely to be high for hospitals, GPs and dentists because choice is likely to be limited in these markets due to other factors. Overall demand for care in these sectors is likely to be driven by need for these services. Thus even if certain providers are able to gain reputational benefits and increase their market share, this will be at the expense of other providers.

143. Adult Social care, however, has a substitute good in the form of the informal care market. This suggests that the total size of the adult social care market is likely to respond to overall perceptions about the quality of the service on offer – as the perceived quality and thus value for money of the service on offer increases, providers might choose to move from informal to formal care earlier than they would otherwise. Although not all people who require adult social care will have the ability to get informal care; however, many do. It is estimated that there are 1.6 million people who require care but do not receive it from the formal market[73]. A study by Kemper (1992)[74] finds that amongst the disabled elderly, the use of formal home care increases and the use of informal care decreases with income. Similarly, the availability of immediate family increases reliance on informal care and reduces reliance on formal care. Although this study did not directly consider whether the perceived quality of care in the formal care market would similarly induce a substitution effect, other studies have estimated that the elasticity of demand with respect to quality in care homes may be as high as 0.44[75]. This suggests that it is possible that the duty of candour might result in a small number of individuals choosing to use more formal care.

144. The average fee charged for a private nursing care home place is £750[76] whilst the average cost for a private residential home place is £532[77]. We average between these two estimated based

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[73] Deloitte, 2008. *Mapping care of older people*. [online] Available at: <https://www.deloitte.com/assets/Dcom-UnitedKingdom/Local%20Assets/Documents/UK_GPS_MappingCareMarkets1.pdf>

[74] *The use of formal and informal home care by the disabled elderly;* P Kemper; Health Serv Res. Oct 1992; 27(4): 421–451

[75] *Quality Change and the Demand for Hospital Care*; Feldstein, M. Econometrica, Vol. 45, No. 7 (Oct., 1977), pp. 1681-1702 estimates the long run elasticity of hospital admissions with respect to quality is 0.44

[76] Curtis, L. (2013). Unit costs of health and social care 2013. Personal Social Services Research Unit.

on the assumption that individuals with higher needs would require nursing home care whilst the remainder require residential home care only. Given that 'high need' individuals make up 40% of the market[78], the average price of private home places is £641. Compared to the estimated EANCB figure of £1m, this suggests that if an additional 1600 service users began to demand care home services due to the reputation effects associated with the duty of candour, the additional benefits to business would outweigh the costs. This would equate to approximately 0.1% of those individuals estimated above who have care needs but do not receive care from the formal market. It is difficult to argue whether the duty of candour might influence this proportion of people to purchase formal care; however, it is possible that such a small proportion being influenced by changes in perception of quality is reasonable. It is also worth noting that this analysis has not considered domiciliary care, due to less evidence and more variation in their costs.

Other Benefits

145. Finally, we note that the benefit that is cited most often in consultation with providers is that being candid about medical errors is the 'right thing to do', an opinion backed up by evidence from the literature[79]. Ethical guidelines often cite open disclosure as an obligation for doctors[80]; however, the barriers to open disclosure are too high for this moral benefit to be achieved in some cases. A review of the duty of candour cited multiple reasons for this failure to report, including fear of litigation, fear of excessive regulatory response and bureaucratic burden[81]. By enforcing a duty of candour practitioners have the ability to embrace their ethical duties. This would lead to higher staff satisfaction amongst practitioners. Moreover, doing the right thing has a social value, as a result of increased trust in the healthcare sector and greater comfort with the idea of health and adult social care. Naturally, it is impossible to quantify the size of this benefit.

146. During the consultation, many adult social care providers also pointed out that being candid was a natural part of their organisations. Many service users stay in adult social care for an extended period of time and therefore the relationship between the provider and the service user is vital to ensure that the service user is happy and comfortable. They argued that having open and honest conversations with not only the service user, but their relatives, helped to strengthen the relationships between service user and provider. This allowed for a more open discussion on other topics, such as what the service user requires or enjoys, giving the provider vital information about what they can do to give better care.

147. CQC recently commissioned some work to understand providers' attitudes towards regulation.[82] This involved interviews with 59 providers of a variety of different sizes, including large NHS hospitals, single-location care homes and private dental practices. All providers viewed such regulation as an essential part of running a health or adult social care service, with an unregulated world being unimaginable. For example, during the consultation, many adult social care providers made reference to existing Local Authority safeguarding practices, which oblige many adult social care providers to report incidents and be open about errors (although being candid with service users is not an obligation). These practices were seen as an integral part of the learning, monitoring and improvement process in their organisation.. One might also cite the safety practices in the airline industry that have grown up since mass travel became typical in the early 1970s (the first 747 as introduced in 1970) and aeroplane capacity enlarged to meet demand as being similar: the standardisation of safety checks and reporting of incidents may be considered a regulatory impact worth paying for to ensure the high levels of safety that characterise that industry..

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[77] Ibid.

[78] Deloitte, 2008. *Mapping care of older people*. [online] Available at: <https://www.deloitte.com/assets/Dcom-UnitedKingdom/Local%20Assets/Documents/UK_GPS_MappingCareMarkets1.pdf>

[79] Smith, M. L., & Forster, H. P. (2000). Morally managing medical mistakes. *Cambridge Quarterly of Healthcare Ethics*, *9*(01), 38-53.
Kraman, S. S., & Hamm, G. (1999). Risk management: extreme honesty may be the best policy. *Annals of Internal Medicine*, *131*(12), 963-967.
Mazor, K. M., Simon, S. R., & Gurwitz, J. H. (2004). Communicating with patients about medical errors: a review of the literature. *Archives of internal medicine*, *164*(15), 1690-1697.

[80] Wu, A. W., Cavanaugh, T. A., McPhee, S. J., Lo, B., & Micco, G. P. (1997). To tell the truth. *Journal of General Internal Medicine*, *12*(12), 770-775.

[81] Royal College of Surgeons, 2014. *Buidling a culture of candour*. [online] Available at: <http://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf>

[82] *Health and Social Care Regulation: A study of Provider Attitudes and Behaviours*, A report for CQC, November 2013, available at http://www.cqc.org.uk/content/health-and-social-care-regulation-study-provider-attitudes-and-behaviours

The wider policy context

148. The proposals discussed in this Impact Assessment are part of a package of measures in response to Francis to improve the quality and effectiveness of regulation. In addition to the legislative changes described in this and other related Impact Assessments, CQC are currently introducing changes in their inspection regime designed to coincide and work alongside these legislative changes. The aim of CQC's new inspection regime is to create a more effective and proportionate regulatory system. They will make better use of the data they already collect to develop an intelligent monitoring system to allow them to better target their inspection activity in areas of greatest risk. As a result high quality and compliant providers should face fewer inspections. The burden of regulation should as a result shift from high quality and well performing providers onto the poorer quality and potentially non-compliant providers. CQC also anticipate that by providing a more robust and broader assessment of provider performance, this will benefit providers by giving them a clearer view of the quality of their services and their strengths and weaknesses, which assists providers in designing their services[83]. The overall impact of these changes will be discussed in more detail within CQC's Accounting for Regulator Impact (ARI) process.

149. In addition to the direct impacts on business that these additional changes might have, overall improvements to the effectiveness of CQC regulation may also have additional benefits for business. For example, CQC state in their interim Impact Assessment for Adult Social Care Services[84] "*Better performing providers may also find reduced levels of scrutiny from commissioners. In addition it is likely that providers will benefit from not having to facilitate multiple inspections by different organisations or provide the same information twice as local authorities have more confidence in the way CQC assesses care provided through our inspections and ratings*." In evidence supplied to the Red Tape Challenge and the Focus on Enforcement it has been estimated that Local Authority duplication CQC activity resulted in approximately £30 million of additional burdens just in the Care Homes sector, so the potential impact on this sector from any reduction in duplication could be significant. However, this is considered to be an indirect benefit to business as it is dependent on additional action being taken by local authorities in response to the changes being made in the regulation of health and adult social care. In addition, it is not possible to attribute this effect to any one particular measure within the package of legislative and operational changes to CQC as described above.

Risks

150. As previously discussed, the largest concerns raised by providers were around the potential litigation and insurance consequences of increased openness and candour. Overall, our assessment of the evidence from the insurance sector and the international evidence suggests that it is more likely for openness to reduce litigation costs rather than increase them, but we acknowledge that this issue remains a risk. Mitigation of this risk will be through clear guidance for providers on these issues. This will reiterate the provisions of the Compensation Act 2006, which clearly states that an apology should not be treated as an admission of liability.

151. Finally, there remains the risk, as with any new policy, that there could be unintended or unanticipated consequences associated with the policy, or for any other reason the policy does not achieve its aim. We have mitigated these risks through the policy development process. We have sought views and advice from various groups such as the Dalton Williams Review, the Berwick Review and the work with the Think Local Act Personal partnership, as well as from other stakeholders during the consultation period. This has allowed us to address any concerns raised and ensure that the final proposed policy will achieve its objectives.

Value for money

[83] This is a key benefit of CQC as identified by providers in a recent report on provider attitudes to CQC regulation, as carried out by Research Works Ltd on behalf of CQC. See http://www.cqc.org.uk/content/health-and-social-care-regulation-study-provider-attitudes-and-behaviours

[84] CQC "Changes to the way we regulate and inspect adult social care - Interim regulatory impact assessment". Available at: http://www.cqc.org.uk/sites/default/files/media/documents/20140409_asc_ria_for_april_2014_consultations_-_final.pdf

152. The tables below show the profile of expected costs and benefits over the next ten years:

Overall Net Present Value

			Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
Description of Costs			**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**2022/23**	**2023/24**	**Total**
Provider costs		Familiarisation costs	727,000	-	-	-	-	-	-	-	-	-	727,000
		Total	**727,000**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**727,000**
	Initial set up and training costs	Creating a policy	7,160,000	-	-	-	-	-	-	-	-	-	7,160,000
		Training	1,800,000	153,000	155,000	158,000	161,000	164,000	168,000	171,000	175,000	180,000	3,290,000
		Total	**8,970,000**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**10,500,000**
	Ongoing costs of being candid	Staff time for candour	797,000	806,000	815,000	825,000	835,000	846,000	858,000	871,000	885,000	899,000	8,440,000
		Admin time	855,000	865,000	875,000	885,000	896,000	908,000	921,000	935,000	949,000	965,000	9,050,000
		Total	**1,650,000**	**1,670,000**	**1,690,000**	**1,710,000**	**1,730,000**	**1,750,000**	**1,780,000**	**1,810,000**	**1,830,000**	**1,860,000**	**17,500,000**
	Indirect costs of improving culture and promoting openness		2,020,000	2,040,000	2,060,000	2,090,000	2,120,000	2,140,000	2,170,000	2,210,000	2,240,000	2,280,000	21,400,000
	Total		**2,020,000**	**2,040,000**	**2,060,000**	**2,090,000**	**2,120,000**	**2,140,000**	**2,170,000**	**2,210,000**	**2,240,000**	**2,280,000**	**21,400,000**
	Total		**13,400,000**	**3,860,000**	**3,910,000**	**3,960,000**	**4,010,000**	**4,060,000**	**4,120,000**	**4,180,000**	**4,250,000**	**4,320,000**	**50,000,000**
CQC costs	Inspection costs		504,000	510,000	515,000	522,000	528,000	535,000	543,000	551,000	559,000	569,000	5,340,000
	Enforcement costs		38,200	38,600	39,000	39,500	40,000	40,500	41,100	41,700	42,400	43,100	404,000
	Producing guidance		4,000	-	-	-	-	-	-	-	-	-	4,000
	Total		**546,000**	**548,000**	**554,000**	**561,000**	**568,000**	**576,000**	**584,000**	**593,000**	**602,000**	**612,000**	**5,740,000**
Total cost (undiscounted)			**13,900,000**	**4,410,000**	**4,460,000**	**4,520,000**	**4,580,000**	**4,640,000**	**4,700,000**	**4,780,000**	**4,850,000**	**4,930,000**	**55,800,000**
Discount adjustment			1.00	0.97	0.93	0.90	0.87	0.84	0.81	0.78	0.75	0.73	
Total Present Cost (discounted)			**13,900,000**	**4,260,000**	**4,160,000**	**4,060,000**	**3,970,000**	**3,880,000**	**3,800,000**	**3,720,000**	**3,650,000**	**3,580,000**	**49,000,000**
Description of Benefits													
Patient benefits	Reduction in patient safety incidents							Unquantified					
	Patient satisfaction							Unquantified					
Provider benefits	Effect of a duty of candour on litigation and insurance costs							Unquantified					
	Fewer complaints							Unquantified					
	Reputational benefits							Unquantified					
Total Benefit								Unquantified					
Net Present Value			**-** **13,900,000**	**-** **4,260,000**	**-** **4,160,000**	**-** **4,060,000**	**-** **3,970,000**	**-** **3,880,000**	**-** **3,800,000**	**-** **3,720,000**	**-** **3,650,000**	**-** **3,580,000**	**-** **49,000,000**

NB: figures may not sum due to rounding

Net Present Value associated with introducing the policy for NHS providers only

NB: figures may not sum due to rounding

			Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
Description of Costs			**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**2022/23**	**2023/24**	**Total**
Provider costs	Familiarisation costs		5,880	-	-	-	-	-	-	-	-	-	5,880
	Total		**5,880**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**5,880**
	Initial set up and training costs	Creating a policy	85,600	-	-	-	-	-	-	-	-	-	85,600
		Training	11,000	3,730	3,730	3,730	3,730	3,730	3,730	3,730	3,730	3,730	44,500
	Total		**96,600**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**130,000**
	Ongoing costs of being candid	Staff time for candour	599,000	599,000	599,000	599,000	599,000	599,000	599,000	599,000	599,000	599,000	5,990,000
		Admin time	569,000	569,000	569,000	569,000	569,000	569,000	569,000	569,000	569,000	569,000	5,690,000
	Total		**1,170,000**	**1,170,000**	**1,170,000**	**1,170,000**	**1,170,000**	**1,170,000**	**1,170,000**	**1,170,000**	**1,170,000**	**1,170,000**	**11,700,000**
	Indirect costs of improving culture and promoting openness		1,240,000	1,240,000	1,240,000	1,240,000	1,240,000	1,240,000	1,240,000	1,240,000	1,240,000	1,240,000	12,400,000
	Total		**1,240,000**	**1,240,000**	**1,240,000**	**1,240,000**	**1,240,000**	**1,240,000**	**1,240,000**	**1,240,000**	**1,240,000**	**1,240,000**	**12,400,000**
Total			**2,510,000**	**2,410,000**	**2,410,000**	**2,410,000**	**2,410,000**	**2,410,000**	**2,410,000**	**2,410,000**	**2,410,000**	**2,410,000**	**24,200,000**
CQC costs	Inspection costs		4,080	4,080	4,080	4,080	4,080	4,080	4,080	4,080	4,080	4,080	40,800
	Enforcement costs		309	309	309	309	309	309	309	309	309	309	3,090
	Producing guidance		4,000	-	-	-	-	-	-	-	-	-	4,000
Total			**8,390**	**4,390**	**4,390**	**4,390**	**4,390**	**4,390**	**4,390**	**4,390**	**4,390**	**4,390**	**47,900**
Total cost (undiscounted)			**2,520,000**	**2,420,000**	**2,420,000**	**2,420,000**	**2,420,000**	**2,420,000**	**2,420,000**	**2,420,000**	**2,420,000**	**2,420,000**	**24,300,000**
Discount adjustment			1.00	0.97	0.93	0.90	0.87	0.84	0.81	0.78	0.75	0.73	
Total Present Cost (discounted)			**2,520,000**	**2,330,000**	**2,250,000**	**2,170,000**	**2,100,000**	**2,020,000**	**1,950,000**	**1,880,000**	**1,820,000**	**1,750,000**	**20,800,000**
Description of Benefits													
Patient benefits	Reduction in patient safety incidents		Unquantified										
	Patient satisfaction		Unquantified										
Provider benefits	Effect of a duty of candour on litigation and insurance costs		Unquantified										
	Fewer complaints		Unquantified										
	Reputational benefits		Unquantified										
Total Benefit			Unquantified										
Net Present Value			**- 2,520,000**	**- 2,330,000**	**- 2,250,000**	**- 2,170,000**	**- 2,100,000**	**- 2,020,000**	**- 1,950,000**	**- 1,880,000**	**- 1,820,000**	**- 1,750,000**	**- 20,800,000**

NB: figures may not sum due to rounding

			Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	
Description of Costs			**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**2022/23**	**2023/24**	**Total**
Provider costs	Familiarisation costs		386,000	-	-	-	-	-	-	-	-	-	386,000
	Total		**386,000**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**386,000**
	Initial set up and training costs	Creating a policy	3,780,000	-	-	-	-	-	-	-	-	-	3,780,000
		Training	1,300,000	95,600	98,200	101,000	104,000	107,000	110,000	114,000	118,000	122,000	2,270,000
	Total		**5,090,000**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**6,060,000**
	Ongoing costs of being candid	Staff time for candour	198,000	202,000	207,000	211,000	217,000	222,000	228,000	234,000	240,000	247,000	2,210,000
		Admin time	286,000	292,000	299,000	305,000	313,000	321,000	329,000	338,000	347,000	357,000	3,190,000
	Total		**484,000**	**494,000**	**505,000**	**517,000**	**529,000**	**542,000**	**556,000**	**571,000**	**587,000**	**604,000**	**5,390,000**
	Indirect costs of improving culture and promoting openness		778,000	795,000	812,000	831,000	851,000	872,000	894,000	918,000	944,000	971,000	8,670,000
	Total		**778,000**	**795,000**	**812,000**	**831,000**	**851,000**	**872,000**	**894,000**	**918,000**	**944,000**	**971,000**	**8,670,000**
Total cost (undiscounted)			**6,730,000**	**1,380,000**	**1,420,000**	**1,450,000**	**1,480,000**	**1,520,000**	**1,560,000**	**1,600,000**	**1,650,000**	**1,700,000**	**20,500,000**
Discount adjustment			1.00	0.97	0.93	0.90	0.87	0.84	0.81	0.78	0.75	0.73	
Total Present Cost (discounted)			**6,730,000**	**1,340,000**	**1,320,000**	**1,300,000**	**1,290,000**	**1,270,000**	**1,260,000**	**1,250,000**	**1,240,000**	**1,230,000**	**18,200,000**
Description of Benefits													
Provider benefits	Effect of a duty of candour on litigation and insurance costs		Unquantified										
	Fewer complaints		Unquantified										
	Reputational benefits		Unquantified										
Total Benefit			Unquantified										
Net Present Value			**- 6,730,000**	**- 1,340,000**	**- 1,320,000**	**- 1,300,000**	**- 1,290,000**	**- 1,270,000**	**- 1,260,000**	**- 1,250,000**	**- 1,240,000**	**- 1,230,000**	**- 18,200,000**

		Year 0	Year 1	Year 2	Year 3	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9		EANCB
	Description of Costs	**2010/11**	**2011/12**	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**2022/23**	**2023/24**	**Total**	
Provider costs	Familiarisation costs					386,000	-	-	-	-	-	-	-	-	-	386,000	
	Total					**386,000**	-	-	-	-	-	-	-	-	-	**386,000**	
	Initial set up and training costs – Creating a policy					3,780,000	-	-	-	-	-	-	-	-	-	3,780,000	
	Initial set up and training costs – Training					1,300,000	95,600	98,200	101,000	104,000	107,000	110,000	114,000	118,000	122,000	2,270,000	
	Total					**5,080,000**	-	-	-	-	-	-	-	-	-	**6,060,000**	
	Ongoing costs of being candid – Staff time for candour					198,000	202,000	207,000	211,000	217,000	222,000	228,000	234,000	240,000	247,000	2,210,000	
	Ongoing costs of being candid – Admin time					286,000	292,000	299,000	305,000	313,000	321,000	329,000	338,000	347,000	357,000	3,190,000	
	Total					**484,000**	**505,000**	**517,000**	**529,000**	**542,000**	**556,000**	**571,000**	**587,000**	**604,000**	**5,390,000**		
	Indirect costs of improving culture and promoting openness					Out of Scope											
	Total					-	-	-	-	-	-	-	-	-	-	-	
	Total cost (undiscounted)					**5,960,000**	**590,000**	**668,000**	**618,000**	**633,000**	**649,000**	**667,000**	**685,000**	**705,000**	**726,000**	**11,800,000**	
	Deflated to 2009 prices					**5,560,000**	**551,000**	**564,000**	**577,000**	**592,000**	**607,000**	**623,000**	**640,000**	**659,000**	**678,000**	**11,100,000**	
	Discount adjustment	1	0.97	0.93	0.90	0.87	0.84	0.81	0.79	0.76	0.73	0.71	0.68	0.66	0.64		
	Total Present Cost (discounted)					**4,850,000**	**464,000**	**459,000**	**454,000**	**449,000**	**445,000**	**442,000**	**438,000**	**436,000**	**434,000**	**8,870,000**	**1,030,000**
	Description of Benefits																
Provider benefits	Effect of a duty of candour on litigation and insurance costs									Unquantified							
	Fewer complaints									Unquantified							
	Reputational benefits									Unquantified							
	Total Benefit									Unquantified							
	Net Present Value					**4,850,000**	**464,000**	**459,000**	**454,000**	**449,000**	**445,000**	**442,000**	**438,000**	**436,000**	**434,000**	**8,870,000**	

NB: figures may not sum due to rounding

153. These costs are based on information from a number of different sources and assumptions about what the likely impacts of the policy might be. We have highlighted the fact that providers

could choose to take a huge variety of different approaches to implement the duty of candour, which will depend on the existing systems and policies that are in place to support a duty of candour, and what further action the provider feels would be most appropriate for the organisation. As such the true implementation costs of the policy cannot be known precisely although we have worked with providers during the consultation stage to generate as accurate estimates of the potential costs as possible.

154. We provide some sensitivity testing below under the other different scenarios examined:

- If all providers had an existing candour policy and judged this to be sufficient, there would be no costs associated with any additional activity to create or update their candour policy or provide additional training to staff on this basis. The implementation costs of the policy would be limited to the staff costs associated with holding additional candid conversations with patients, and any indirect costs associated with providers choosing to take further steps to implement best practice. The overall net present cost would decrease to £38.8m and the EANCB to £473,000.
- If all providers elected to undertake additional activity to create or update their candour policy and provide additional training to staff on this basis, the overall net present cost would increase to £52.2m and the EANCB to £1.2m
- If all providers were already undertaking fully candid conversations with patients so that there were no additional staff time requirements for these conversation (but assuming all other implementation costs associated with updating policies and training are as before), the overall net present cost would decrease to £41.8m and the EANCB to £850,000
- If no candid conversations already took place with patients, so that all incidents of moderate harm required an additional 45 minutes of staff time, the overall net present cost would increase to £60.2m and the EANCB to £1.3m
- If no providers undertook any additional best practice activity to improve the culture of their organisation and further encourage openness and transparency, the overall net present cost would be £30.8m, and the business net present cost would be £10.9m. The EANCB would not change since these costs are already considered to be out of scope.
- If, as in the first scenario, no providers incurred any set up costs in revising or setting up a candour policy or providing training for staff AND no providers chose to undertake further additional steps in accordance with the best practice to promote candour, the overall net present cost would be £20.5m and the EANCB £472,000.
- If the time requirements for training to familiarise managers with their new duties under the duty of candour were half those estimated, the overall net present cost would fall to £47.5m. The EANCB would be £930,000.
- If the time requirements for training to familiarise managers with their new duties under the duty of candour were double those estimated, the overall net present cost would increase to £52m. The EANCB would be approximately £1.2m.

155. Overall, it is expected that there will be some initial high set up and transitional costs associated with the policy. However, we estimate that the steady state costs of the policy are likely to be low. The overall net present cost of the policy is highly dependent on what additional activity providers might choose to undertake in order to further promote openness and transparency in their organisations. It is a key policy intention that the statutory duty of candour will act as a signal of the importance of openness and transparency and thus encourage providers to make further changes in their organisations to achieve this. However, such action would not strictly be required if providers were to take a ‘bare minimum’ interpretation of the regulations.

156. The net present value is negative as it only includes the quantifiable identified costs. It has not been possible to quantify the benefits of the policy. However, we have carried out some break even analysis which suggests that under, relatively modest assumptions, the benefits of the policy would outweigh the costs to society. For example, if as a result of the duty of candour there were:

- A reduction in the number of patient safety incidents of 1 in every 2,500 (equivalent to 0.04% of the number currently reported)
- An increase in the number of candid conversations by 26,000 (this assumes an additional 18% of patient safety incidences are discussed candidly as above), with an associated willingness to pay for increased candour of £60 per incidence (this equates to approximately a three day reduction in anxiety as measured on the EQ-5D scale).
- A reduction in the growth of litigation or insurance costs for private hospitals and GPs on 0.1 percentage points per year
- A reduction in the growth of litigation or insurance costs for NHS Trusts of 0.002 percentage points per year
- A reduction in complaints of 6,750 per year to private or voluntary sector CQC registered providers (this equates to approximately one fewer complaint made per year for half of providers)
- A reduction in complaints relating to communication of 1% for NHS hospitals, GPs and Dentists per year
- An increase in the number choosing to use care home services of 150 per year

then the overall benefits to society would exceed the costs. The estimated NPV would be approximately £0.5m. The NPV for businesses would show a net benefit of approximately £82,500. The estimated EANCB would show a much larger net benefit to business since the indirect costs of improving organisational culture are excluded. The EANCB would show a net benefit of £700,000.

157. If the indirect costs of improving organisational culture are excluded from the analysis altogether, the following impacts would be required for the benefits of the proposal to outweigh the costs:

- A reduction in the number of patient safety incidents of 1 in every 10,000 (equivalent to 0.01% of the number currently reported)
- An increase in the number of candid conversations by 13,000 (this assumes an additional 9% of patient safety incidences are discussed candidly compared to the do nothing scenario), with an associated willingness to pay for increased candour of £60 per incidence (this equates to approximately a three day reduction in anxiety as measured on the EQ-5D scale).
- A reduction in the growth of litigation or insurance costs for private hospitals and GPs on 0.05 percentage points per year
- A reduction in the growth of litigation or insurance costs for NHS Trusts of 0.002 percentage points per year
- A reduction in complaints of 5,500 per year to private or voluntary sector CQC registered providers (this equates to approximately one fewer complaint made per year for half of providers)
- A reduction in complaints relating to communication of 1% for NHS hospitals, GPs and Dentists per year
- An increase in the number choosing to use care home services of 75 per year

158. The estimated NPV would be approximately a £550,000 net benefit. The NPV for businesses would show a net benefit of approximately £130,000. The EANCB would show a net benefit of £9,000.

159. In terms of views from the consultation overall there was strong support for the duty with candour, with many respondents simply stating that it is ‘the right thing to do’. A number of respondents raised concerns about the potential costs of implementation, but the view overall was that these costs would depend significantly on the existing practices in organisations, which we have tried to reflect in the analysis above. On the overall balance of costs and benefits, a significant

proportion of respondents were of the view that the benefits were likely to outweigh the costs. Others reflected the view that there should be no costs associated with candour as this is something that providers should already be doing.

One-In, Two-Out

160. It has only been possible to quantify the costs of the business associated with this policy. We estimate an Equivalent Annual Net Cost to business of approximately £1m. Consequently the policy is considered to be a net IN for business.

161. However, as the analysis above suggests, the potential benefits to business associated with improved honesty are likely to be significant. As demonstrated in the break even analysis above, only very moderate assumptions are required for the policy to demonstrate an overall net benefit to business. The overall position for business is therefore likely to be in fact ZERO NET COST. However, as we have been unable to gather sufficient evidence to confirm this position, we have rated the policy as an IN.

Section E: Summary of specific impact tests:

Equality Impact Assessment

162. This policy proposal impacts all CQC registered health and adult social care providers. The costs will not impact service users or any group of individuals. The benefits of improved quality of care through increased openness and transparency with service users and improved learning from patient safety incidents will be realised by users of health and adult social care services equally. This policy will not disproportionately affect any one demographic or social group. In general, the users of healthcare services tend to be people from older age groups, lower income distribution and those with disabilities or long term conditions.

Competition

In any affected market, would the proposal:

- Directly limit the number or range of suppliers?

163. No. The proposals do not involve the award of exclusive rights to supply services, procurement will not be from a single supplier or restricted group of suppliers.

- Indirectly limit the number or range of suppliers?

164. CQC ensures that only providers who have made a legal declaration that they meet the standards of quality and safety are allowed to provide care. The proposed policy will increase the standards that providers must meet before they are able to enter the market.

- Limit the ability of suppliers to compete?

165. This duty is not expected to have any impact on suppliers. It will impact all CQC registered providers of health and adult social care and impose the same conditions for all providers.

166. This duty does not limit the scope for innovation for the introduction of new products or supply existing products in new ways. It does not limit the sales channels a supplier can use, or the geographic area in which a supplier can operate. It does not limit the suppliers' freedoms to organise their own production processes or their choice of organisational form. It does not substantially restrict the ability of suppliers to advertise their products.

- Reduce suppliers' incentives to compete vigorously?

167. The proposal does not exempt the suppliers from general competition law. It does require providers to be more open and honest with service users in the event of a patient safety incident. Where this information would otherwise not be available, competition is likely to increase as information asymmetries are reduced.

Small and Micro Business Assessment

How does the proposal affect small businesses, their customers or competitors?

168. Although CQC do not collect information about the size of the organisations it regulations, it has been possible to gain a sense of the size distribution of providers it regulates from other sources. The 2013 Skills of Care report on the size and structure of the adult social care workforce[85] used ONS data to estimate that there were a total of 17,100 adult social care providers, of which 86% would be considered small or micro businesses.

	Size group (employees)							
Service type	Total	0 - 4	5 - 9	10 - 19	20 - 49	50 - 99	100 - 249	250 +
Residential services (SIC2007 87)	7,900	1,600	900	1,600	2,300	1,000	400	200
Non-residential (SIC2007 88)	9,200	4,000	2,000	1,300	1,100	500	200	100
Total adult social care	**17,100**	**5,600**	**2,800**	**2,900**	**3,400**	**1,400**	**700**	**300**

Individual rows may not sum to totals due to rounding

169. This estimate is similar to that obtained from the BIS Annual Business Population Survey, which found that in 2013, there were approximately 50,000 employers in England with the Standard Industrial Classification (SIC2007) Human Health and Social Work Activities, of which 94% would be considered a small or micro business.

Count of number of private businesses within SIC2007 Q - Human Health and Social Work Activities in England

All employers	50,295
1	5,285
2-4	14,305
5-9	10,025
10-19	9,505
20-49	8,115
50-99	1,975
100-199	650
200-249	110
250-499	175
500 or more	150

Source 2013 BIS Business Population Survey

170. Thus, it is likely that the large majority of private providers registered with CQC will be small or micro businesses.

171. As is the case with the existing CQC regulations, the proposed duty of candour requirement would apply equally to providers of all sizes. The rationale for this approach is because the risks associated with health and adult social care that CQC regulation is designed to mitigate is unlikely to vary significantly with the size of the organisation. For example, it is likely that the potential risks to a service user from a residential care home owned by a large national chain will be much the same as from a much smaller local provider. This is because the key determinants of risk in health or adult social care are the type of service provided and the potential for patient harm or adverse consequences associated with this, and the vulnerability of people using the service rather than the size of the organisation providing the service. In the example of residential care homes, the potential consequences for service users from poor quality care might include pressure ulcers and the potential for abuse, whilst the vulnerability of service users will be determined by factors such as disability status and whether they have mental capacity. These factors are likely to remain the same across the care home sector, and as a result, it is important that there is the same assurance of levels of safety and quality wherever people access services.

[85] Skills for Care, *The size and structure of the adult social care sector and workforce in England,* 2013

172. In terms of the statutory duty of candour discussed here, it is likely that large and small providers are equally at risk of lacking openness and transparency. For example, at consultation stage many providers expressed concern that whilst large providers were likely to have formal policies and procedures in place regarding candour, the culture of the organisation may still be lacking. On the other hand, smaller providers were considered a risk as it was thought that they would lack any formal policies or procedures to support candour.

173. However, this is not to say that CQC does not take into account regulatory burden. Under the 2008 Health and Social Care Act, CQC has a duty to ensure that any action it takes is proportionate to the risks to which it is addressed and is targeted only where it is needed. As a result, CQC takes into account and makes adjustments in how it monitors and inspects providers of different sizes in order to minimise regulatory burden.

174. As discussed above, providers are required to meet the same set of standards, as set out by the regulations, and will judge compliance and rate providers based on this same set of criteria. However, what this means in terms of inspection length and/or frequency, and the amount of evidence providers will be expected to provide will vary as follows:

- The methodology by which CQC inspect compliance and construct provider ratings is likely to vary by sector and in accordance with the nature and the complexity of the service provided. For example, a large NHS hospital is likely to undertake a wider range of regulated activities involving a greater number of staff and patients compared to a small care home, which might provide a single regulated activity with a handful of staff. It is clearly the case that CQC would need to spend longer inspecting and considering the available evidence where providers provide a more complex and larger range of services. As an illustration of this, CQC anticipate that, under their new regulatory model, a typical inspection at an Acute Hospital might take up to 22 days whilst the typical inspection at a care home would more likely take between 3 to 5 days. In terms of the impact on small and micro businesses, it is likely that, subject to the factors below, they would face shorter and less intensive inspections due to the nature of the services that they would be providing.

- CQC operate a regulatory model that is proportionate to risk. Where CQC have existing concerns about a provider, they will focus more regulatory activity here for example by conducting a more intensive and lengthy inspection, asking to see more evidence from the provider, or inspecting on a much more frequent basis. On the other hand, where providers have a good history of compliance, they would face less scrutiny from CQC. Under CQC's new regulatory model, it is proposed that inspection frequency will be linked to provider ratings, so that providers who are found to be high performing will be inspected less frequently than is currently the case. This approach suggests that a provider of any size will face a lower regulatory burden associated with monitoring and enforcement against the regulations, provided that they maintain a high quality and compliant service.

- Finally, in terms of how CQC will judge compliance against any requirement, CQC are not prescriptive in terms of the evidence that providers would need to supply. Rather than CQC specifying what providers must provide, it is the duty of the provider to be able to demonstrate to CQC how it is meeting the standards. For example, whilst a large provider might be able to demonstrate how it is meeting the registration requirement on complaints with reference to the work being carried out by the dedicated complaints manager, CQC would not expect a smaller provider to also have such a person in place. Instead, a small provider might demonstrate compliance by being able to provide written records of the complaints it received and what subsequent action was taken. Similarly for the proposed statutory duty of candour, whilst a large provider might have a dedicated patient safety manager who is able to provide all the documentation relating to the development and implementation of a formal candour policy, there is no expectation that a smaller provider would need to do the same so long as they were able to provide alternative evidence to demonstrate to CQC that they were meeting the requirement.

175. CQC recently commissioned some work to understand providers' attitudes towards regulation.[86] This involved interviews with 59 providers of a variety of different sizes, including large NHS hospitals, single-location care homes and private dental practices. Although providers did identify some burdens associated with managing the regulatory requirements, all providers viewed such regulation as an essential part of running a health or adult social care service, with an unregulated world being unimaginable. Overall, whilst this suggests that providers of all sizes are supportive of regulation, it is important to ensure that this regulation is carried out in a way to minimise the potential burdens. On the back of this work, CQC are committed to doing more to understand the burden of regulation on providers, and to work continually to reduce the burdens of regulation on providers as part of the duty for non-economic regulators to have regard for growth.

Legal Aid/ Justice Impact

176. The following have been considered in the main impact assessment above and in the Ministry of Justice impact test provided alongside this document:

- Will the proposals create new civil sanctions, fixed penalties or civil orders with criminal sanctions or creating or amending criminal offences? **Yes – a separate Justice Impact Test has been prepared which assesses the impact on the Justice System of the whole package of CQC policies.**
- Any impact on HM Courts services or on Tribunals services through the creation of or an increase in application cases? **No**
- Create a new right of appeal or route to judicial review? **No**
- Enforcement mechanisms for civil debts, civil sanctions or criminal penalties? **No**
- Amendment of Court and/or tribunal rules? **No**
- Amendment of sentencing or penalty guidelines? **No**
- Any impact (increase or reduction on costs) on Legal Aid fund? (criminal, civil and family, asylum) **No**
- Any increase in the number of offenders being committed to custody (including on remand) or probation? **No**
- Any increase in the length of custodial sentences? Will proposals create a new custodial sentence? **No**
- Any impact of the proposals on probation services? **No**

Sustainable Development

177. The proposals are not expected to have a wider impact on sustainable development. There will be no impact on climate change, waste management, air quality, landscape appearance, habitat, wildlife, levels of noise exposure or water pollution, abstraction or exposure to flood.

Health Impact

Do the proposals have a significant effect on human health by virtue of their effects on certain determinants of health, or a significant demand on health service? (primary care, community services, hospital care, need for medicines, accident or emergency services, social services, health protection and preparedness response)

178. The potential impacts on health have been considered above in the cost benefit analysis of this impact assessment, see Section D above

[86] *Health and Social Care Regulation: A study of Provider Attitudes and Behaviours*, A report for CQC, November 2013, available at http://www.cqc.org.uk/content/health-and-social-care-regulation-study-provider-attitudes-and-behaviours

179. There are no expected health risks in association with, diet, lifestyle, tobacco and alcohol consumption, psycho-social environment, housing conditions, accidents and safety, pollution, exposure to chemicals, infection, geophysical and economic factors, as a result of the proposals

Rural Proofing

- Rural proofing is a commitment by Government to ensure domestic policies take account of rural circumstances and needs. It is a mandatory part of the policy process, which means as policies are developed, policy makers should: consider whether their policy is likely to have a different impact in rural areas because of particular circumstances or needs, make proper assessment of those impacts, if they're likely to be significant, adjust the policy where appropriate, with solutions to meet rural needs and circumstances.

180. The proposals will not lead to potentially different impacts for rural areas or people.

Wider impacts

181. The main purpose of the proposed duty and offence is to incentive all providers of health and adult social care services to be open and honest with patients where they have suffered serious injury or death, providing the patient will all the necessary facts and an apology where appropriate. This is intended to reduce the level of distress and harm felt by patients in the event of a serious patient safety incident, and improve the culture of healthcare organisations to be more open and transparent.

Economic impacts

182. The costs and benefits of the proposals on businesses have been considered in the main cost benefit analysis of this impact assessments, see Section D above.

Environmental impacts and sustainable development

183. The proposals have not identified any wider effects on environmental issues including on carbon and greenhouse gas emissions.

Social impacts

184. No impact has been identified in relation to rural issues or the justice system

Section F: Summary and Conclusions

185. Based on the above impact assessment, the preferred option is Option 2: Introduce a statutory duty of candour on providers of health and adult social care via a new registration requirement in the CQC regulations. This would require all providers registered with CQC to take steps to ensure that, where things go wrong, the patient is properly informed and an appropriate apology is given. This policy will send a strong signal to providers of the importance of openness and transparency and thus further encourage providers to make changes to ensure that their organisational culture promotes these values.

186. The main costs associated with this proposal are the initial set up costs for providers in developing a policy on candour and ensure that the relevant staff are made aware of and have the ability to meet their new responsibilities. We anticipate some moderate costs associated with any additional staff time or admin costs associated with properly informing patients. We also consider the potential costs associated with further training and support to drive organisation and cultural change, but these are not considered to be strict direct costs of the proposal.

187. The benefits of the proposal are likely to include improvements in patient satisfaction, in patient safety, a potential reduction in medical negligence claims, a reduction in patient complaints, and reputational benefits for providers. In addition, there are ethical benefits associated with being open and honest, and these have been reflected by the wide support this policy has received during the consultation stage. The majority of providers were of the view that being open and honest was simply the right thing to do.

188. Although it has not been possible to quantify these benefits, break even analysis has suggested that, even under very modest assumptions, the benefits of the proposed policy are likely to outweigh the costs. The main risk associated with this policy remains the potential impact on litigation and insurance costs. During our consultation, respondents remained divided on whether the duty of candour would cause these costs to increase or decrease. Overall we have considered that, based on the international evidence, costs would be more likely to decrease rather than increase, however further options are being explored with insurers on how this risk could be further mitigated, and to provide further reassurance for providers.