Title: Duty of Candour on Providers **IA No:** **Lead department or agency:** Department of Health **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 20/09/2013 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Jeremy Nolan/Tongtong Qian

Summary: Intervention and Options

RPC Opinion: Awaiting Scrutiny

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**
-£87.5m	-£31.7m	£3.7m	Yes	IN

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

Although it is widely recognised that providers of health and 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 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 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 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 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 SELECT SIGNATORY: ..... Date: .....

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:** -£87.5m

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	£10.9m		£8.5m	**£87.5m**

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

Where providers are not under an existing obligation to be candid under the NHS standard contract, 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.

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'

It has not been possible to monetise any benefits

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

The main benefits to service users will be to reduce the level of anger, upset and frustration that they experience when they do not get all the information to which they are entitled. There may also be increases in the quality of care due to better reporting and learning practices to ensure that avoidable patient safety incidences are minimised, which is more likely to occur in an open and transparent culture.

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

There is a risk that increasing the expectation of staff to be candid 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 medical 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.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £3.7m	**Benefits:** unquantif	**Net:** -£3.7m	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);
    - monitoring compliance with a set of registration requirements;
    - using enforcement powers (where appropriate) 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.

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

4. 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

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

open and honest explanation of what went wrong. Increased honesty is also associated with better quality of care, as providers are more likely to spend time learning from incidences rather than trying to hide or defend them in an open and transparent culture[2].

5. However, several barriers exist that may prevent 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.

6. There is often a fear among both providers and individual health professionals that being candid and providing more upfront information about patient incidences can lead to a risk of increased litigation, and that offering an apology might be interpreted as an admission of liability. 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 candidness for their organisation. There is a further risk that they may instead actively seek a policy or culture of secrecy, which would further act as a barrier against individual healthcare professionals being candid.

7. As a consequence of these barriers, a number of policies, initiatives and levers are already in place to encourage more candid behaviour. These policies have both originated from Government and from inside the health and social care system, and cover a range of different organisations and health professionals. For example:

   - Since 1st April 2013, the NHS Standard Contract has also 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 for 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.

   - 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 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 also endorsed this letter.

   - The Care Quality Commission's Guidance about Compliance suggests that implicit to complying with the standards on quality and safety, providers should ensure that service users are informed of any adverse events, incidents or errors that have occurred in their care.

8. However, it is not clear if this framework of policies and levers is currently strong enough to ensure that all health and social care providers and organisation types are being appropriately candid. The very fact that there are a large number of separate policies, initiatives and levers designed to encourage candidness implies that different types of health and social care providers 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. In these situations, whether a provider is candid is at their own discretion.

9. Further, many of the existing policies and levers are applicable only to NHS organisations and those providing NHS funded care under the Standard Contract, excluding NHS primary care. For other

[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.

healthcare organisations, where the majority of staff are healthcare professionals, such as independent hospitals, GPs and dentists, the existing professional codes of conduct may encourage these individuals to be candid, but there remains a risk that they will lack support from the provider organisation 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 professionals who are not subject to a professional duty of candour.

10. It is difficult to gain evidence on the lack of candidness that might exist across different providers within the health and social care sector, as, by definition, it is not possible to know where and when patient incidences have not been disclosed. However, the limited evidence that we have suggests that more needs to be done to encourage candidness. 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. While a lot of subsequent work has occurred in the NHS to further encourage trusts to be candid since these surveys, these results may provide a useful illustration of the possible situation in other sectors where the levers encouraging candidness still remain weak.

11. Even in the NHS there may be opportunities for improvement. A 2012 survey[4] examined the effectiveness of the 'Being Open' policy that was subsequently introduced in the NHS, and found that here there was still room for improvement, with 22% of managers reporting 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. A lack of candidness by providers has also been highlighted as an issue in many of the recent high profile reports of NHS hospitals, such as Mid-Staffordshire and Morecombe Bay.

12. Although the NHS Standard Contract has recently been strengthened to make being candid an explicit requirement for providers of NHS funded care, there is still room for improvement around how this is enforced. The large number of commissioners and the different local approaches that they may take means that there would not be a nationally consistent approach to enforcement, and some providers may therefore face weaker obligations or incentives to be candid than others, creating variation between Trusts. It is important that there is a mechanism by which it can be ensured that a nationally consistent approach is adopted for the health and social care sector. The recent inquiry at Mid Staffordshire suggested that a statutory duty of candour should be introduced for healthcare providers and individual healthcare professionals. The subsequent Berwick Report also considered this issue and came to the recommendation that there should be a duty on providers to be candid for serious incidences.

13. The above demonstrates that there are currently issues with the level of candour providers are attending service users and care quality is likely to suffer as a result. As discussed above, it is widely acknowledged that being open and honest with patients, especially when something has gone wrong with their care, should be part and parcel of providing a high quality service. Service users have a right to be informed if something goes wrong in their care and to have access to all the relevant facts concerning the incident and insensitive or inadequate handling of the incident can lead to further trauma[6]. As a lack of openness with service users is often associated with a general lack of transparency within the organisation, this inhibits the ability of the provider organisation to learn from patient safety incidences and to make improvements to care quality by reducing the number of preventable mistakes. In a defensive and secretive culture, providers may be more preoccupied with avoiding information about patient safety incidences rather than taking the time to learn from them. A blame culture in health care has been suggested as a major source of medical errors[7].

14. The government signalled its intention to develop proposals for a statutory duty of candour in its initial response to the Francis Inquiry *'Patients First and Foremost*', and an initial consultation examining the principles of introducing a statutory duty of candour via CQC's registration

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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] Vincent CA and Coulter A, 'Patient Safety: What about the Patient?' *Quality and Safety in Health Care* 2002, 11: 76-80

[7] Khatri, Naresh; Brown, Gordon D.; Hicks, Lanis L. 'From a blame culture to a just culture in health care' *Health Care Management Review* 2009, 34 (4) 312-322

requirements was carried out by the Care Quality Commission between June and August 2013. The consultation accompanying this impact assessment now focuses on the draft regulations that will introduce this duty.

The case for government intervention:

15. It is important that providers are candid and inform service users where there has been a problem with their treatment, and surveys of patients demonstrate that this is valued by them. Information asymmetries between service users and providers of health and social care mean that service users will not always be aware if something has gone wrong in their treatment, and whether the provider played a role in this, unless the provider chooses to inform them. Providers may have an incentive to deliberately mislead, and/or other barriers may prevent frank and candid conversations taking place. As a consequence there is a market failure which could be addressed through independent regulation. Regulation of health and social care is a public good, and as such, the market does not always naturally provide it. In this case, the level of regulation delivered by the market is insufficient to fully induce the desired behavioural change, and a lack of coordination has led to a fragmented system of regulation with differing levels of obligations or incentives placed on different provider types. Government intervention is required to correct this.

Section B: Policy objectives and intended effects

16. 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 incidences can lead to a risk of increased litigation. Consequently, it must be the case that health and social care provider organisations are encouraged to provide the necessary leadership and support to their staff to ensure that these barriers are overcome.
17. The policy objective is therefore to ensure that all providers of health and social care are required to have the system management and organisational arrangements in place that will encourage and support staff to be candid with service users where a patient safety incident has resulted in serious injury or death.
18. This will compel provider organisations to ensure their culture is transparent and open. There will be an expectation put on staff by the provider that when a service user suffers serious injury or death as a result of the treatment, they will speak 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 incidences are not repeated. The provider will 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 incidences. This effect may also be reinforced by a deterrent effect. As providers are obliged to provide more information about adverse safety incidences, which may be reputationally damaging, providers may be incentivised to instead invest more to ensure that fewer avoidable incidences of harm occur in the first place.
19. Overall, the intended effect is to create a more open and transparent culture among providers of health and 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.

Section C: Description of the options

Option 1: do nothing

20. Under this option there would be no statutory duty of candour that would apply equally to all health and 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 social care sectors and remain weak in others.

21. 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 may provide 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 professionals who are not subject to a professional duty of candour.

22. Even in the NHS there may be opportunities for improvement. Recent surveys of the NHS indicate that existing policies may not be having the desired level of effect and that in some areas a culture of defensiveness may persist. A lack of candidness 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, there is still room for improvement around how this is enforced. CQC would be able to offer a nationally consistent approach to enforcement across all health and social care sectors, and use its expertise as an existing regulator of quality in health and social care.

23. Overall the current policies, incentives and levers in place to encourage providers to be candid are unlikely to be sufficient to fully achieve the aim that all providers are open and honest with service users in all incidences where serious injury or death occurs in the course of a service user's treatment.

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

24. This option would introduce a statutory duty of candour for CQC registered providers of health and social care as part of their CQC registration requirements. This requirement would be similar to the existing duty for providers of NHS funded care, as currently set out in the NHS Standard Contract.

25. The threshold for harm caused for which the duty of candour would apply will be based on CQC definitions of serious injury or death for which registered providers are already required to notify CQC of incidences under the Care Quality Commission (Registration) Regulations 2009. This provides a consistent definition of harm which is applicable and already in use for all CQC registered providers. For NHS bodies, who are able to submit these notifications through the National Reporting and Learning System (NRLS), the definition of serious injury will not directly match the definitions of moderate or severe harm as defined in the NRLS. However there will be no new burdens for these providers as they are already expected to be candid under the conditions of the NHS Standard Contract. The proposed statutory duty will not increase the scope of incidences for which providers are expected to be candid about beyond this.

26. Thus, where a patient safety incident resulting in serious injury or death 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,
    - At this stage all the facts that the provider knows about the incident should be provided
    - The individual should also be offered the same information in writing
    - A full written record of the notification and any meeting or other contact with the relevant persons should be kept.

27. Thus, for providers of NHS funded care, the will be no change in the requirements placed on providers. The only difference will be the change in how the duty will be enforced. In addition to the role commissioners play, CQC will now also be responsible for monitoring and enforcement of the duty as part of its existing regulatory model. This will enable a stronger and more consistent approach to be taken nationally. For non-NHS providers, and others not subject to the NHS Standard Contract, these requirements will be new, and will strengthen the weak levers currently in place to encourage candidness.

28. Although CQC will not be able to monitor every single incident, they will be able to require providers to be taking steps to ensure that there is good organisational management and leadership in place to encourage and support staff to be open with service users and to drive a culture change towards more openness and transparency. 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.

29. 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.

Alternative options:

30. Only the proposal to introduce a statutory duty of candour in CQC's registration requirements has been considered in this Impact Assessment. The government has signalled its intention to develop proposals for a statutory duty of candour in its initial response to the Francis Inquiry *'Patients First and Foremost*', and an initial consultation examining the principles of introducing a statutory duty of candour has already been carried out between June and August 2013. The consultation accompanying this impact assessment now focuses on the draft regulations that will introduce this duty, and as such, no other options are considered in this impact assessment.

31. The wide range of voluntary and non-regulatory levers already in place to encourage providers to be candid suggest that further non-regulatory levers are unlikely to be effective and stronger levers are required to compel providers to be candid.

32. Although it would be possible to extend further contractual requirements to be candid to other areas of the health and social care sector (such as primary care), the analysis above in paragraph 12 suggests that this would not be an optimal approach. Being candid should be considered a national quality issue and so calls for a nationally consistent approach led by a single organisation.

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

Costs:

Costs of implementing the duty of candour:

33. CQC registers providers in the following sectors:

Location Type/Sector	Number of CQC registered providers[8]
Adult Social Care	12,500
Independent Healthcare	1,500
Dentists	8,000
GP services	7,500
Independent Ambulance	250
NHS Trusts	250

34. Following BIS convention, we consider NHS trusts, GPs and dentists as public sector organisations. 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. For independent healthcare and independent ambulance service providers, we assume that all providers are private or voluntary sector organisations since the other major ownership type identified for social care services was local authorities, which is not likely to be applicable for these remaining organisation types. This suggests that of the 30,000 providers

[8] From CQC's Annual Report 2012/13, figures rounded to nearest 250

registered by CQC, approximately 13,000 are private or voluntary organisations, whilst the remaining 17,000 are public.

35. Where providers are not under an existing obligation to be 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.

36. As the proposed statutory duty of candour is similar to the expectations of the duty set out in the NHS Standard Contract, we do not expect that there would be any additional cost burdens for most providers providing NHS funded services under this contract as they should already be meeting this requirement. While the statutory nature of the proposed new duty and likely better enforcement by CQC compared to commissioners might create stronger incentives for providers to meet the duty, we do not consider the additional costs associated with this change in behaviour as a burden on these providers, as they are already under existing obligations to meet this requirement, the costs of which have previously been impact assessed. However, there does remain a risk that the potentially stronger incentives to be candid of the proposed policy could cause some already compliant provides to take additional unnecessary action and go over and above to ensure that they are compliant with the new statutory duty. Although it is not possible to quantify this risk, we consider the potential likely impact via sensitivity analysis on the estimated costs of implementing the duty of candour below.

37. There is no available data on how many providers have signed an NHS Standard Contract. The contract is likely to cover all NHS trusts and may cover some Local Authority funded adult social care, and some NHS funded independent healthcare and independent ambulance services. Providers of primary care, such as GPs and dentists, are covered by separate primary care contracts. Where the terms of the NHS Standard Contract only apply to part of a provider's activity, it is not clear how the duty of candour requirement might be implemented, and whether the provider would face any additional costs to roll out the duty of candour to all service users under the new proposals. As an upper bound estimate of implementation costs, we assume that all providers apart from NHS Trusts face additional implementation costs due to the new proposals.

38. In order to implement the new statutory duty of candour, providers will be required to take steps to ensure that there are systems in place to encourage and support staff to be open with service users and to take steps to drive culture change towards more openness and transparency. 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. However, 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 candidness:

    - 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 candidness.
    - Named executive and non-executive leads responsible for the candidness 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 incidences as part of the general training for all staff.
    - Publicise information on the support systems currently available for staff distressed by patient safety incidences

39. The amount of resources required by an organisation to implement the above steps is likely to vary, and will depend on the existing arrangements already in place for each of these areas. Providers are likely to take different approaches to achieve each of these steps and so the costs associated are likely to vary. Below we provide some illustrative examples of the possible costs that could arise. The consultation accompanying these impact assessments will seek provider's views on the assumptions below and additional evidence on the potential costs and benefits of the proposals.

40. Costs associated with creating or strengthening and publicising the provider's policy on candidness are likely to be mainly transitional costs. This might involve a discussion during a board meeting on whether the existing policy on being candid is fit for purpose and some subsequent work by the responsible senior manager to improve and update the policy. Based on figures on the total number of director and company registrations at Companies House as of April 2012, we estimate that the average number of directors per organisation is approximately 2[9]. If the discussion during the board meeting required half an hour of extra time, and the senior manager took half a day to update (4 hours) to update the policy, then the total additional time requirement from senior management would be 5 hours. The 2012 Annual Survey of Hours and Earnings (ASHE) suggests that the median hourly gross income for corporate managers and directors (as defined by the Standard Occupational Classification 2010) is £26 (including 30% on costs), thus giving an overall additional cost of £130.

41. Alternatively, if there is no existing policy on candidness, there might need to be a longer discussion at board level about what a policy of candidness 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 and draft the policy, then based on the above assumptions, this might involve an additional cost of approximately £600. Taking the midpoint of these two estimates (equivalent to assuming 50% of providers have existing policies, whilst 50% would develop new ones), gives a best estimate of £364 per provider or £10.9m in total across all affected providers, of which £4.75m would fall on private or voluntary providers.

42. If NHS organisations were to also exhibit behaviour change as a result of this policy, we would expect that the majority would have existing policies on candidness, so the time requirements of updating the policy would be lower, but there might be higher costs, due to the larger average size of the board of directors. Based on an assumption of 10 board members per NHS trust, and the time requirements outlined in paragraph 41 above, the total additional cost to NHS trusts might be £59,000. However, as discussed above, as NHS providers already have existing requirements to be candid under the NHS standard contract, we should expect little additional behavioural change from these providers.

43. The second main category of costs will be associated with ensuring that staff have the necessary support and training to be able to hold candid discussions. This could take the form of a number of different arrangements, and might involve both one-off costs and on-going changes in practice. For example, providers could offer additional formal training for staff on how to be candid, either on an on-going basis or as a one off exercise, or they could undertake more informal on-the-job training via experienced individuals who could act as 'candour champions' and offer specific guidance and advice to staff as necessary. Alternatively, providers might choose to only issue written guidance on how to be candid, and strengthen existing support networks (such as professional counselling and mentoring) to ensure that staff are supported. In other cases, providers may feel that their systems of training and support are already adequate and so no additional action is required. These providers may instead focus on doing more to promote and encourage use of these systems.

44. We estimate the cost of formal training based on the UK Commission's Employer Skills Survey 2011, which suggests that the average cost of training per employee for health and social care organisations (including indirect costs such as the wage costs of staff undertaking training) is approximately £2,300. As the average number of days spent training per employee was estimated to be 5.2 in the health and social care sector by the same survey, this implies that the cost per day of training in 2011 was approximately £450. Uprating this to 2012 prices using the latest GDP deflator figures from June 2013, gives a cost per day of training for providers of almost £454 per employee.

45. Training is most likely to focus on those staff who will be directly involved in holding conversations with service users, i.e. senior health professionals and managers directly involved in dealing with clinical operations and/or patient complaints. As discussed above, providers may choose to target additional training (if it is not already provided) on all staff in these categories, or may choose to provide more intense training and support to key individuals, who would be able to provide support and guidance to others. This training might be on-going for all staff, or be a one-off exercise, or there

[9] While this figure might appear low for large organisations (for example, an examination of NHS trust websites show that these organisations typically have more than 10 directors and non-executive directors on their boards), for smaller organisations this figure is likely to be more realistic. For example, we expect that the large majority of adult social care providers will be small organisations consisting of a single care home and so would not have a large board of directors. Thus the overall average number of directors per organisation is expected to be relatively low.

might be some other combination for example, with more intense one off courses initially offered, and shorter refresher courses thereafter. The large variety of approaches that providers could take means that costs are likely to be highly variable.

46. In terms of estimating the potential numbers of senior healthcare professionals who would be involved in conducting or leading conversations with patients, the Skills for Care 2012 report on the State of the Adult Social Care Sector and Workforce in England estimates that there are approximately 93,000 'professional' jobs (such as social workers or nurses) in the social care sector. With no further information about the relative seniority of these individuals, we could make an assumption that approximately a third of these individuals might be sufficiently senior to conduct or lead candid conversation with patients. While no such comprehensive survey is available for the independent healthcare sector, estimates from the Labour Force Survey as reported in a 2011 report by Skills for Health on the labour market for healthcare in England[10], suggested that the public sector healthcare workforce is approximately three times as large as in the private sector. If this ratio was applicable for the different types of staff needed to deliver healthcare, we might be able to estimate the number of senior health professionals and managers working in the independent sector based on estimates of the NHS workforce. Estimates from the 2012 NHS staff census showed that as at 30 September 2012 there were approximately 40,000 consultants working in the NHS. If, it is the case that this is three times the number that would be in the private sector, this would imply that approximately 13,000 health professionals of equivalent seniority in the independent healthcare sector. The NHS staff census also estimated that there were approximately 35,000 GPs, whilst the 2011/12 NHS dental statistics compiled by the Health and Social Care Information Centre estimated that there were approximately 23,000 dentists who carried out at least some NHS activity in 2011/12.

47. In terms of estimating the number of managers who would require training, we take a slightly different approach and assume that there would be one or at most two managers who would be involved in holding conversations with patients at each provider location registered by CQC (taken from CQC's 2012/13 annual report). This approach is taken as it is not possible to separately count the number managers who might be involved in discussions with patients against those who would not (such as HR or finance managers). We assume that there will be an average of 1.5 managers involved with holding conversations with patients per location.

48. The following table sets out the final assumptions we have made about the numbers of staff that might require additional training and support to be candid:

Location Type/Sector	number of locations	number of managers	number of health professionals	total staff
Adult Social Care	25,250	38,000	31,000	69,000
Independent Healthcare	3,000	4,500	13,000	17,500
Dentists	10,000	15,000	23,000	38,000
GP services	8,750	13,250	35,000	48,250
Independent Ambulance	250	500	assumed to be captured as part of independent healthcare	500
NHS Trusts	2,250	3,500	40,000	43,500

NB: figures may not sum due to rounding

49. Based on these estimates of the potential numbers of staff who might be involved in conducting or leading candid conversations with patients, we estimate that if all providers were to provide all of these staff members with an additional half day of training, the additional cost could be as high as £40m. If only an additional hour of training were required (based on the argument that most healthcare professionals should already receive training on how to talk to patients and deliver bad news) the additional cost of providing additional training for all staff would be £10m (assuming an 8 hour day).

50. As an alternative to providing training for all of the above staff, providers might choose to provide more intense training for a smaller proportion of staff who would act as 'candour champions' and have responsibility to lead on all candid discussions and provide on-the-job guidance and support for other staff as necessary. If providers provided a day of training for 5% of the staff discussed above, the cost would be £4m. In terms of the on-the-job support and guidance for other staff, we would expect that this would be related to the number of incidences of moderate or serious harm or death that occur. Based on figures from the previous National Patient Safety Agency on their

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

National Reporting and Learning System (NRLS), this suggested that for the NHS there were approximately 90,000 incidents of moderate or severe harm or death between June 2011 and June 2012 (we use NHS figures as these figures are most readily available for illustrative purposes, and could be argued to provide an upper bound on our estimates since hospital care is considered to be more risky and hence lead to a higher proportion of incidences occurring). Compared to 40,000 consultants we estimate to be working in the NHS, this implies that at best, each consultant might be expected to be involved in 3 incidences per year. If 5% of senior staff were to be candour champions this would suggest that they would provide support to an average of 19 other members of staff. If each then required half an hour of support and guidance from the candour champion, this would suggest that the overall annual time requirement would be just under 30 hours a year per champion. Using estimates of the median gross hourly wage from ASHE 2012 for health professionals of £32 and for corporate managers and directors of £26 (both including 30% on costs), this gives an annual cost of £7.6m across the sector. As noted above, other members of staff are likely to continue to receive day to day training, which, for medical staff, is likely to include training relating to holding discussions with patients and delivering bad news.

51. Overall, it is not possible to determine what approach providers might adopt to provide additional support and guidance to staff on being candid, and it is likely that different providers are likely to differing approaches based on their existing practices and what might best fit their circumstances. It is likely that for some providers, they will already by providing sufficient support and training for staff and no further action is necessary. Our best estimate of the potential costs of support and training are based on the champion model as outlined above, as this provides a convenient mid-point between the high costs associated with training all staff, and the potentially very low costs if the majority of providers judge that they already have sufficient training and support for staff.

52. Applying the above discussion on the split between private/voluntary and public sector organisations to the estimates of staff numbers above, we estimate that if providers adopt approaches that are, on average, similar to the ‘candour champion’ model above, approximately £1.8m of the initial training costs and £3.5m of on-going support costs would fall on the private or voluntary sectors.

53. In terms of additional sensitivity testing for NHS organisations, based on the same methodology as above and assuming that all trusts were to also choose to adopt an approach similar to the ‘candour champion’ model described above, we estimate that there would be approximately £1m in additional transitional costs, and £2m in on-going support costs. However, as there is an existing requirement on NHS providers to be candid via the NHS Standard Contract, we do not expect there to be any additional burdens for these providers. Even if the more effective and potentially stronger enforcement afforded by the proposed statutory duty were to induce some additional behavioural change for these providers, it is unlikely to be of the scale described above due to the fact that we expect that these organisations will already be taking some action based on their existing duties.

54. Lastly, by implementing a policy of candidness, staff employed by the provider organisation will be expected to change their behaviour to ensure that where a service user suffers serious injury or death, a candid conversation takes place to notify the service user of all the relevant facts, and an apology made if appropriate. We do not expect this to place a significant burden on providers because when a service user suffers serious injury or death we would expect that all providers are likely to have some existing procedure in place, which is likely to include holding a conversation with the service user or their representatives and keeping a record of what has occurred. The policy intention is to change the nature and content of the conversations that do take place to ensure that they are open and informative, rather than defensive in nature.

55. Although we have examined previous case studies where a policy of open disclosure or candour has been adopted, there is little evidence available to suggest what effect this might have on the amount of clinician and/or manager time required to discuss, explain and otherwise manage any adverse patient events. From a purely intuitive perspective, it could be possible to make the case that being candid could potentially both increase or decrease the amount of time required. For example, it will take additional time for clinicians and managers to investigate and determine the course of events that occurred to be able to effectively explain what occurred to patients. More time might be required to discuss these issues in detail with patients and answer their questions. On the other hand, it might be the case that avoiding the issue and attempting to evade responsibility requires more time and effort than being truthful. Patient are less likely to be satisfied with the content of the discussions held and so could be more likely to pursue the issue, potentially leading to a rise in formal complaints, thus requiring greater time and input from staff. Overall as it is not

possible to determine which of these scenarios might be more likely to occur, we continue to assume that the overall net effect on providers is minimal.

56. The proposed statutory duty also requires that written notification be made available if required, and a record of the conversation kept. This change of practice may potentially generate additional cost burdens, as it is less likely that the provider organisation already carries out these tasks. However, these costs are unlikely to be large as we expect that most organisations will already have some existing administrative processes to record incidences of serious injury or death, which these requirements can feed into. For example, there is an existing statutory obligation for CQC registered providers to inform CQC where an unexpected death of a service user has occurred, or if severe injury has been suffered.

57. There is little evidence to suggest what the additional time requirements might be for a provider to make and keep a record of the conversations held with service users following an incident of serious injury or death. To illustrate the potential costs involved, we assume that an additional 30 minutes of administrative staff time is required. Based on the mean gross hourly pay for those in Administrative Occupations (as defined by the Standard Occupational Classification 2010) from the 2012 Annual Survey of Hours and Earnings (ASHE) of £13 (including 30% on costs), this would be an additional cost of £6.50 per incident of serious injury or death that occurs.

58. In order to estimate the number of incidents of serious injury or death that have occurred at organisations who are not already under the existing duty of candour in the NHS Standard Contract, For non NHS organisations the number of incidents of death or serious injury reported to CQC in 2012 was approximately 49,000, although it is not clear exactly what organisations might be included in this sample. Additionally the National Reporting and Learning System (NRLS) estimated that almost 400 patient safety incidences resulting in moderate or serious harm or death were reported in 2011/12 relating to primary care dentistry and general practice.

59. Using these two figures gives a total additional annual cost associated with extra administrative and recording practices associated with being candid of just under £325,000. It is difficult to further split this figure out to take into account the costs that would fall on the private or voluntary sector only, as it is not currently clear which of the 49,000 non NHS reported incidences might relate to activity in the private sector. As a prudent assumption, we consider the costs to business assuming that all reported incidences relate to private or voluntary sector organisations, as this provides an upper bound on the potential costs estimates.

Potential effect of a duty of candour on litigation costs:

60. One of the most commonly cited barriers to providers being candid is the fear that being candid and providing more upfront information about patient incidences 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.

61. 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 because they realised their physician was not completely honest with them or had intentionally mislead[11]. Getting more information about what happened was cited as a reason by 20%. A more recent survey carried out in 2005[12] 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.

[11] 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

[12] 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

62. 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 incidences, 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[13] 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[14].
    - 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[15]. 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.

63. 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)[16] 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 candidness to litigation costs. On the other hand a paper by Berlin (2006)[17] notes that no published evidence (at the time) suggested that more open disclosure of errors and apologising increased liability dramatically.

64. Based on the evidence available, we take forward the assumption that the proposed statutory duty of candour is unlikely to affect litigation costs, as the evidence to suggest that litigation costs will fall is too tentative to be conclusive, and there are also no firm indications that litigation costs are likely to increase. This latter possibility is retained as a potential risk of the proposed policy.

Distributional impacts:

65. A provider's litigation costs consist of both the legal costs involved in a claim and the cost to the provider of any compensation payments they would have to make in the event of a successful claim against the provider.

66. Compensation payments are a transfer payment between the provider and the service user. There is no overall net effect on society stemming from such a payment as the gain by one party is equal to the cost on the other. However, there could be distributional impacts if there is evidence to suggest that the compensation payment is valued more (or less) by those in receipt of the payment compared to those making the payment. The Green Book suggests that additional income is more highly valued by those with lower incomes.

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[13] 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

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

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

[16] 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)

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

67. For profit-making providers, the owners of the organisation might be argued to be of higher income than service users and so value the compensation payment less. However, there is little evidence to suggest what the relative income difference might be between these two groups. It is likely that there would be wide variation in circumstances within the two groups that make overall conclusions difficult to draw.

68. For non-profit healthcare providers, compensation payments would be more likely to impact on other service users through the effect on the level of resources available for treatment, rather than affecting provider profits. Thus, a distributional adjustment is unlikely to be required as the same group of individuals bear the costs and benefits of the compensation payment, although it may be necessary to consider how service users value health outcomes relative to additional income. However, as the analysis above does not suggest that it is likely that there would be any change to compensation payments as a result of the proposed policy, any such further investigation into this issue is unlikely to be proportionate.

69. Legal costs can be seen as the transaction cost associated with determining what, if any, the correct level of compensation should be in the event of an accident. These costs will be incurred by both the provider and the claimant and it may be possible that as part of any agreed settlement, one party would pay for the legal costs incurred by the other. Thus distributional effects may also be of importance here. However, as discussed above, there is insufficient evidence available to suggest what appropriate distributional weights might be, and so no distributional adjustments are considered.

Additional risks:

70. The possibility of increased candidness leading to an increase in litigation costs remains a potentially significant risk due to the potentially large consequences of such an increase, even though the evidence so far suggests that the likelihood of it occurring is low. The argument was put forward in a paper by Studdert et al (2007)[18], who warned that, because the majority of medical errors do not currently result in a claim, there is a large reserve of possible claimants. Even if only a very small proportion of these potential claimants were induced to make a claim due to increased openness, this could create a potentially very large effect, which would dwarf any reduction in the number of claims made elsewhere due to increased candidness. However, while the authors did construct a model to illustrate this, they did not test the model using real world data. As discussed previously, there is little evidence to suggest that such an impact has been observed in reality.

71. Secondly, there is a risk that the size of compensation claims may increase due to the statutory duty of candour because individuals will start to seek additional remedies as part of their claim if the provider fails in their duty to be candid. Although increased compensation payments have no net effect on society as a whole, the actual implications for any provider might be large and so should be considered as a risk. However, there is little evidence to suggest that this is likely to occur. The level of compensation is mainly based on the level of damages experienced and the level of past compensation awarded historically for similar incidences. Any damages associated with a failure of the provider to be candid are likely to be a very small component of this. Where providers or healthcare professionals already face existing duties to be candid, no significant increases in the size of compensation payments have been observed.

72. Lastly, we note that most providers are unlikely to directly pay for their litigation costs. In reality the majority will be members of risk sharing or other insurance scheme designed to mitigate the financial risks of public liability for providers. Our underlying assumption in the discussions above was that if there is any change in litigation risks or costs, insurance organisations will adjust the their insurance premiums to reflect this. Thus, providers would bear the cost of any increased litigation costs and insurers would be unaffected. However, there is a risk that the actual effect on the insurance market is more complex, leading to unanticipated consequences. For example, if insurers over-estimate the risk of litigation and increase insurance premiums accordingly, this would create additional cost burdens on providers.

Other costs on providers:

[18] Studdert DM, Mello MM, Gawande AA, Brennan TA, Wang YC, 'Disclosure of Medical Injury to Patients: an Improbable Risk Management Strategy' *Health Affairs* 2007, 26(1): 215-226

73. 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.

74. 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 below.

Costs of enforcing the duty of candour:

75. CQC will take on responsibility for monitoring and enforcing the proposed statutory duty of candour on providers. Although CQC will not be able to police every single incident individually, they will be able to require providers to be taking steps to ensure that there is good organisational management and leadership in place to encourage and support staff to be open with service users and to drive a culture change towards more openness and transparency. 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.

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

77. 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.

78. 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 on 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.

79. 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.

80. 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 71 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.

81. It is difficult to determine what the additional cost of this enforcement action might be. Enforcement activity is widely dispersed across the different CQC functions and 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 different 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 might be in the region of £39,000.

Costs - summary:

82. The costs above are summarised in the table below:

	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	
£('000)s	**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 of developing policy on candour	10,900	-	-	-	-	-	-	-	-	-	10,900
Provider costs of training and supporting staff	11,550	7,600	7,600	7,600	7,600	7,600	7,600	7,600	7,600	7,600	80,150
Provider costs of holding candid conversations	325	325	325	325	325	325	325	325	325	325	3,250
Impact on litigation costs	Likely to be zero										zero
Reputational and other costs on providers	UNQUANTIFIED										
Monitoring and inspection costs: CQC	505	505	505	505	505	505	505	505	505	505	5,050
Enforcement costs: CQC	39	39	39	39	39	39	39	39	39	39	390
Transitional costs: CQC	4	-	-	-	-	-	-	-	-	-	4
Total cost (undiscounted)	23,300	8,500	8,500	8,500	8,500	8,500	8,500	8,500	8,500	8,500	99,700
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)	23,300	8,200	7,900	7,650	7,350	7,100	6,850	6,600	6,400	6,150	87,500

NB: figures may not sum due to rounding

Benefits:

Increased disclosure and honesty:

83. The objective of the statutory duty of candour is to make providers of health and social care make changes to their culture and increase transparency and openness in their organisation. Staff will be encouraged and supported to speak candidly to service users or family members when a service user suffers serious injury or death as a result of the treatment, and give a full explanation of what went wrong and apologise for the harm caused.

84. This will 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. Although this benefit is unquantifiable, surveys of patients have shown that honesty, openness and apologies are highly desired by patients where there has been an error in their treatment, and thus should be part and parcel of delivering high quality care. For example, a survey by the Medical Protection Agency in 2011[19] 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. Additionally, a survey[20] of parents presenting at an

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

[20] 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

emergency department with their children in 2005 found that 99% wanted physicians to inform them about error involving their children no matter the severity.

85. Even where service users do not experience frustration or anger when they do not receive an explanation (for example, if the service user has no wish for a further explanation, or had no knowledge that an incident took place), increased openness and honesty might still be seen as a benefit in its own right. The academic literature on medical ethics has put forward a number of theories examining this. Overall Smith and Forster (2000) [21] argue that as a starting point, increased disclosure should always be considered as desirable unless strong reasons exist otherwise (such as where patients explicitly state that they do not wish to be informed). It is expected that the proposed duty of candour will achieve this by placing a duty on the provider to ensure that there are systems in place to support staff to be open and encouraging a culture of transparency. However, in the case of exceptional circumstances where it might not be appropriate to be candid room would remain for providers to exercise discretion.

Potential health benefits:

86. By encouraging a culture of transparency and openness within organisations, it is expected that the level of reporting of patient safety incidences will increase, and there will be greater opportunities for providers to learn when things go wrong, which will reduce the level of avoidable patient safety incidences arising. This effect may also be reinforced by a deterrent effect. As providers are obliged to provide more information about adverse safety incidences, which may be reputationally damaging, providers may be incentivised to instead invest more to ensure that fewer avoidable incidences of harm occur in the first place.

87. Although these benefits are difficult to quantify, to provide an illustrative guide on the potential size of these benefits, we can calculate the impact of a small change in health outcomes using the EQ-5D framework for calculating health states[22]. This framework asks individuals to rate their health from 1 to 3 in five different domains, including the experience of pain, mobility and anxiety. A score of 1 means the individual has no problems whereas a response of 3 indicates serious or severe problems. 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) [23] by also considering the duration of the health state. Based on this methodology, any move away from perfect health in any of the five domains leads to a reduction in an individual's health state of at least 0.155 points. Thus if one service user is able to avoid one month's worth of less than perfect health due to poor quality care, there would be a 0.013 QALY gain.

88. Applying this figure to the number of providers registered with CQC who we assume not to be under the existing duty of candour from the NHS Standard Contract, and assuming that at half of these there would be the minimal improvement described above, this would lead to a total QALY gain of 193. Based on a societal willingness to pay of £60,000 per QALY, the total societal value of this modest change in health outcomes would be approximately £11.6m.

Other benefits:

89. Being candid may have additional benefits, for example there could be increased trust and honesty between patients and healthcare providers that benefits society as a whole. The provider might experience other benefits associated with having a more open culture, such as increases in staff satisfaction. These benefits cannot be quantified.

Risks:

90. In addition to the risks associated with medical negligence costs discussed previously, there remains a risk that introducing a statutory duty of candour on providers of health and social care might produce unintended consequences that lead to additional burdens on the healthcare system

[21] Smith, M. and Forster, H. 'Morally Managing Medical Mistakes' *Cambridge Quarterly of Healthcare Ethics* 2000; 9: 38-53

[22] 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

[23] 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

or mean that the above benefits are not realised. For example, if increasing the expectation that clinicians are open and honest with service users where a patient incidence occurs leads to less reporting of incidents. These risks will be mitigated be placing the duty to be candid on the provider rather than on individuals, so that the provider is able to take a flexible approach to ensure that a culture of openness and honesty is created and staff feel supported to speak candidly to service users. As part of our consultation on these regulatory changes, we will invite further comments and evidence on the potential impacts of the proposed duty, which will further mitigate the risks of unintended consequences.

Value for money:

91. The below table shows the profile of the net present value of identified impacts over a 10 year period. All figures are based on assumptions and should be treated as such, however this represents our best understanding of the likely impacts:

	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	
£('000)s	**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 of developing policy on candour	10,900	-	-	-	-	-	-	-	-	-	10,900
Provider costs of training and supporting staff	11,550	7,600	7,600	7,600	7,600	7,600	7,600	7,600	7,600	7,600	80,150
Provider costs of holding candid conversations	325	325	325	325	325	325	325	325	325	325	3,250
Impact on litigation costs	Likely to be zero										zero
Reputational and other costs on providers	UNQUANTIFIED										
Monitoring and inspection costs: CQC	505	505	505	505	505	505	505	505	505	505	5,050
Enforcement costs: CQC	39	39	39	39	39	39	39	39	39	39	390
Transitional costs: CQC	4	-	-	-	-	-	-	-	-	-	4
Total cost (undiscounted)	23,300	8,500	8,500	8,500	8,500	8,500	8,500	8,500	8,500	8,500	99,700
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)	23,300	8,200	7,900	7,650	7,350	7,100	6,850	6,600	6,400	6,150	87,500
Reduction in patient anxiety	UNQUANTIFIED										
Improvements in care quality	UNQUANTIFIED										
Other benefits e.g. staff satisfaction	UNQUANTIFIED										
Total benefit	UNQUANTIFIED										
Net Present Value	- 23,300	- 8,200	- 7,900	- 7,650	- 7,350	- 7,100	- 6,850	- 6,600	- 6,400	- 6,150	- 87,500

NB: figures may not sum due to rounding

92. The table below reflects the direct impacts to businesses only. The figures are presented in 2009 prices and the present value base year is 2010/11 as required for the One In Two Out initiative. Similarly the costs associated with non-compliance with the regulation are excluded.

	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year		
£('000)s	0	1	2	3	4	5	6	7	8	9	10	11	12	13		
Description of Costs/Benefits	**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**	**EANCB**
Provider costs of developing policy on candour					4,750	-	-	-	-	-	-	-	-	-	4,750	
Deflated to 2009 prices					4,450	-	-	-	-	-	-	-	-	-	4,450	
Provider costs of training and supporting staff					5,300	3,450	3,450	3,450	3,450	3,450	3,450	3,450	3,450	3,450	36,550	
Deflated to 2009 prices					4,950	3,250	3,250	3,250	3,250	3,250	3,250	3,250	3,250	3,250	34,150	
Provider costs of holding candid conversations					325	325	325	325	325	325	325	325	325	325	3,250	
Deflated to 2009 prices					300	300	300	300	300	300	300	300	300	300	3,000	
Impact on litigation costs					Likely to be zero											
Reputational and other costs on providers					UNQUANTIFIED											
Total cost (undiscounted)					9,700	3,550	3,550	3,550	3,550	3,550	3,550	3,550	3,550	3,550	41,600	
Discount adjustment	1	0.97	0.93	0.90	0.87	0.84	0.81	0.78	0.75	0.73	0.70	0.68	0.65	0.63		
Total Present Cost (discounted)					8,400	2,950	2,850	2,750	2,650	2,550	2,500	2,400	2,300	2,250	**31,650**	**3,700**

NB: figures may not sum due to rounding

93. 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 are not known. Our best estimates of the potential costs are based on the mid-point of a range of potential costs that could arise, based on a number of different scenarios. We will undertake more work at consultation to gather evidence from providers of the likely costs of the proposed policy.

94. As such the quantified costs are estimates only, and we provide some sensitivity testing below under the other different scenarios examined:

- If all providers had to develop a candour policy from scratch, this would cost £17.9m and the overall net present cost would increase to £94.5m. The EANCB would be £4m.
- If all providers were to train all relevant staff for half a day as a one off, this would cost £40m and the overall net present cost would fall to £57.6m if we assume there would be no on-going support costs. The EANCB would fall to £2.4m.
- If all providers were to provide annual half day of training to all staff at a cost of £40m p.a. then the overall net present cost would increase to £355m and the EANCB to £15m.
- If all providers were to provide an additional hour of training to staff annually, the annual cost would be £10m and the overall net present cost £102m. The EANCB would be £4.4m.
- If providers already had adequate training and took no further action, there would be no additional cost of training and the overall net present value would fall to only £18.3m and the EANCB would be £0.7m.

95. In addition, we note that other uncertainties with the analysis also remain. For example there is a risk that increased candidness could lead to additional litigation costs on providers, which given the volume and size of claims could be a significant additional cost. However, academic literature examining previous case studies has so far found no evidence that it would occur. The estimated costs to CQC of the policy are also expected to change, as CQC will be making a number of changes to their regulatory model which will affect the costs of monitoring, inspecting and enforcing the registration requirements. It has not been possible to incorporate these new cost implications into the analysis above, as CQC are still in the process of developing and testing these proposals. Overall, it has been difficult to quantify the additional costs to CQC. Due to the nature of CQC's operating model it is difficult to attribute costs directly to a specific activity or registration requirement as is required for this analysis.

96. The net present value is negative as it only includes the quantifiable identified costs. Other costs, such as the potential reputational effects that being candid might have could not be quantified at this stage. In addition, it has not been possible to quantify the benefits of this policy, although the desirability of openness and candidness has been well documented and evidence continues to show this is still lacking amongst health and social care providers. A lack of candidness by providers has been highlighted as an issue in many of the recent high profile care failings in NHS hospitals, such as Mid-Staffordshire and Morecombe Bay. As this policy will require providers to make changes to their culture to become more open, transparent and candid, it is expected that candidness will increase as a result and there will be benefits to service users accordingly. Increased openness and transparency is also expected to improve learning from incidences, which will have health benefits. The illustrative example provided above shows that even very modest health improvements could lead to a large societal gain.

Section E: Summary of specific impact tests:

Equality Impact Assessment

97. This policy proposal impacts CQC registered health and social care providers who do not provide NHS funded care under the NHS Standard Contract. 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 incidences will be realised by users of health and 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

98. In any affected market, would the proposal:
    - Directly limit the number or range of suppliers?

99. 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?

100. 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?

101. This duty is not expected to have any impact on suppliers. It will impact all CQC registered providers of health and social care who do not currently provide NHS funded care under the NHS Standard Contract, and impose the same conditions on these providers that already exist for all other CQC registered providers.

102. 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?

103. 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 serious 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?

104. The duty would apply to all CQC registered providers of health and social care of all sizes and the impacts are as described above. Only small or micro business providers who do not currently provide NHS funded services under the NHS Standard Contract will be affected. These organisations are likely to include a mixture of small and large organisations, and the likely impacts are described in section D above.

105. However, we note that regulation tends to have a disproportionate impact on smaller firms. The impact of this regulation on small businesses by allowing providers discretion in how they meet the new requirements and through CQC's proportionate and risk based regulatory approach, which seeks to minimise the burdens of regulation on providers.

Legal Aid/ Justice Impact

106. 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? **No**
- 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

107. 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 affects 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)

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

109. 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.

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

Wider impacts

111. The main purpose of the proposed duty and offence is to incentive all providers of health and 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

112. 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

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

Social impacts

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

Section F: Summary and Conclusions

115. Based on the above impact assessment, the preferred option is Option 2: Introduce a statutory duty of candour on providers via a new registration requirement in the CQC regulations. This would require all providers registered with CQC to take steps to ensure that there is good organisational management and leadership in place to encourage and support staff to be open with patients and to drive a culture change towards more openness and transparency.

116. The main costs associated with this proposal are those falling on the provider to put in place and ensure that they have adequate systems of support and guidance in place to encourage and support staff to be candid, and to create a culture of openness. Although we have considered the potential for there to be increased costs to providers associated with increased medical negligence claims as a result of the proposal, we have found no evidence to suggest that it would increase. The costs of monitoring and enforcing the policy would fall to CQC. The main benefits that we have identified from the proposed duty are the increase in open and honest conversations that take place between clinicians and service users, and accompanying benefits that this might have for patients, and the potential for increased reporting and learning following patient safety incidences that might arise from having a culture of increased openness. While it has not been possible to quantify these benefits, illustrative examples of the potential size of these benefits suggest that they could be sizeable.