Title:	Impact Assessment (IA)
Implementing a 'Duty of Candour'; a new contractual requirement on providers	**Date:** 10/10/2011
IA No: 5100	**Stage:** Consultation
Lead department or agency:	**Source of intervention:** Domestic
Department of Health	**Type of measure:** Other
Other departments or agencies:	

Summary: Intervention and Options

RPC: RPC Opinion Status

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, One-Out?**	**Measure qualifies as**
-£48.30m	£0m	£0m	No	NA

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

The Government expects the NHS to admit to errors, apologise to those affected, and ensure that lessons are learned to prevent them from being repeated. Ensuring staff are open with patients when mistakes happen is crucial. There is anecdotal evidence from individual cases however that suggests NHS organisations are not as open as they should be. When openness fails to happen, it can have a real, sometimes tragic impact on people's lives. The Government has committed to strengthen the transparency of organisations and increase patient confidence by introducing a "duty of candour": a new contractual requirement on providers to be open and transparent in admitting mistakes

What are the policy objectives and the intended effects?

The leadership of an organisation has the overall responsibility for creating a strong culture of reporting and learning from incidents in the organisation, and therefore also in encouraging workers to tell patients about incidents. We therefore need to establish a mechanism to encourage organisational management and leadership to support health professionals in being open. The Government believes the most appropriate and effective way to improve openness would be to impose a contractual requirement on NHS providers to be open. This should encourage NHS organisations to focus on ensuring they encourage and foster a culture of openness, particularly with patients and their families/carers when things go wrong.

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

The Department has considered a wide range of views covering a number of different options, from doing nothing to creating a new law. This led the Government to conclude that the most appropriate and effective way to improve openness would be to impose a contractual requirement on NHS providers to be open with patients and their relatives/carers when things go wrong. This consultation does not re-open this debate and the decision to impose a contractual requirement is set. However we need to consult on the detail of this proposal. The options considered were; Option 1: Do Nothing. There are a number of 'requirements' in place already. Nothing more is needed Option 2 (Preferred): Contractually require openness with incidents involving moderate and severe harm and death

Option 3: Contractually require openness with all incidents, from no harm to death.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 10/2014

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** No	**< 20** No	**Small** No	**Medium** No	**Large** No
What is the CO2 equivalent change in greenhouse gas emissions? (Million tonnes CO2 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: 10.10.11

Summary: Analysis & Evidence

Policy Option 1

Description: Do Nothing

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m) Low: 0	High: 0	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0	10	0	**0**
High	0		0	**0**
Best Estimate	0			

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

As the 'do nothing' option there are no direct costs of the policy

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

By definition there will be no improvement in the openness of NHS-funded providers using this option. The status quo will be maintained.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0	10	0	**0**
High	0		0	**0**
Best Estimate				

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

As the 'do nothing' option there are no direct benefits to this option

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

By definition there will be no change in the openness of NHS-funded providers using this option. The status quo will be maintained.

Key assumptions/sensitivities/risks **Discount rate (%)** n/a

This option clearly does nothing to alleviate a problem which the Government has made clear it wishes to address. Doing nothing allows non-disclosure to continue as at present, potentially risking anxiety and uncertainty for patients and their loved ones, and doing nothing to promote an open learning culture in the NHS

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	Benefits: 0	Net: 0	No	NA

Summary: Analysis & Evidence

Policy Option 2

Description: Contractually require openness with incidents involving moderate and severe harm and death

FULL ECONOMIC ASSESSMENT

Price Base Year **2011**	PV Base Year **2011**	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: -£10.54	**High:** -£86.07	**Best Estimate:** -£48.30

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	0	10	£2.73	**£27.32**
High	0		£22.31	**£223.08**
Best Estimate	0		£12.52	£125.20

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

Costs are related to the increased activity in NHS-funded provider organisations required to apologise and provide explanations for patient safety incidents over and above the current assumed activity, plus the additional work by NHS commissioners and providers to undertake appropriate contract management activity in a proportion of cases where a failure to be open is identified.

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

There may be additional costs that we have not estimated for to health care workers such as GPs and other clinicians, plus HealthWatch or other sources of information and support providing advice to potential victims of non-disclosure. These will be variable and depend on local and individual circumstances.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	0	10	£1.68	**£16.78**
High	0		£13.70	**£137.01**
Best Estimate	0		£7.69	£76.89

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

The benefits estimated relate to the assumption that improved disclosure is likely to result in fewer people experiencing anxiety or nervousness around the lack of information for a particular patient safety incident. The estimates are therefore the benefit for patients (based on QALYs) who experience a patient safety incident and who will now receive a timely and sincere apology and explanation of the incident who would not have previously.

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

There are other non-monetised benefits, for clinicians who will receive more support from their employers to disclose incidents thereby reducing subsequent anxiety, for all patients who will potentially be subject to fewer incidents due to improved reporting and learning, and to the taxpayer in general in terms of reduced costs overall from safety incidents.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.50%

The benefits assume most people will experience reduced anxiety and nervousness from being told about an incident in their health care. There is a risk however that disclosure of an incident will actually increase anxiety. The costs assume costs are limited to implementing the policy. There is a risk that the policy will lead to increased litigation and/or decreased reporting and learning, both of which will increase costs to the system overall. We believe that these impacts are unlikely though.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs: 0	**Benefits: 0**	**Net: 0**	No	NA

Summary: Analysis & Evidence

Policy Option 3

Description: Contractually require openness with all incidents, from no harm to death.

FULL ECONOMIC ASSESSMENT

Price Base Year **2011**	PV Base Year **2011**	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: -£158.80	**High:** -£1,296.	**Best Estimate:** -£727.85

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	0	10	£41.16	**£411.61**
High	0		£336.14	**£3,361.44**
Best Estimate	0		£188.65	£1,886.52

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

The costs are as for option 2 but recognising the greatly increased activity in disclosing all incidents that are reported, including no and low harm incidents, and the greatly increased cost of contract managing breaches of this new requirment

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

There are potentially large additional costs associated with increased anxiety and loss of trust in the health service by patients due to them being told about every no and low harm event being subject to a full 'being open' style disclosure process.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	0	10	£25.28	**£252.80**
High	0		£206.46	**£2,064.55**
Best Estimate	0		£115.87	£1,158.68

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

The benefits are the same as for option 2 but assuming a greatly reduced level of anxiety and nervousness due to all incidents being disclosed to the affected people. Please see assumptions/risks as to why this may not be the case.

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

There are potentially the same benefits as described in option 2, but scaled up proportionately.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.50%

The key assumption is that both costs and benefits rise proportionally with the increased amount of disclosure activity. This is far from certain. It is quite possible implementing this option will prove impossible in practice therefore undermining the whole principle of being open and actually reducing disclosure. It is alos possible there will be far greater costs to the health service in terms of loss of confidence and far greater costs to patients and the public due to increased anxiety.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs: 0	**Benefits: 0**	**Net: 0**	No	NA

Evidence Base

A. What is the problem under consideration?

1. Openness When Things Go Wrong

1.1 Over one million patient safety incidents are reported to the National Patient Safety Agency's National Reporting and Learning System (NRLS) every year. Of the patient safety incidents reported,

- Almost 764,000 (70 per cent) resulted in no harm to the patient;
- 260,000 (24 per cent) resulted in low harm;
- 65,000 (6 per cent) resulted in moderate harm;
- 8,200 (0.7 per cent) resulted in death or severe harm[1].

1.2 The Government expects the NHS to admit to errors, apologise to those affected, and ensure that lessons are learned to prevent them from being repeated. There is anecdotal evidence from individual cases that suggests NHS organisations are not as open as they should be.

1.3 We do not know how often non-disclosure happens or how systemic it is. It is very difficult simply to gather statistical information on the number of incidents in which openness does not occur as they are, by definition, not openly disclosed.

1.4 There is no doubt that apologising to someone for a mistake, especially where harm has been caused, and explaining what has happened, is a very difficult thing to do. For this reason, organisations must do all they can to support their staff to be open and this means openness must be a leadership issue. The leadership of an organisation has the overall responsibility for creating a strong culture of reporting and learning from incidents in the organisation, and therefore also in encouraging workers to tell patients when mistakes are made.

1.5 The way to enable a genuine culture change and really increase openness is to establish a mechanism to encourage organisational management and leadership to support health professionals in being open and fully deliver the Coalition Government's requirement.

1.6 Different people have different views on how best to do this. The Department has considered a wide range of views ranging from doing nothing to creating a new law. This led the Government to the conclusion that the most appropriate and effective way to improve openness would be to impose a contractual requirement on NHS providers to be open with patients and their relatives/carers when things go wrong. This means that this policy will be public sector specific and should have no impact on the private sector unless a private sector provider chooses to enter into a contractual agreement with an NHS body using the NHS Standard Contract.

1.7 This impact assessment looks at various options for implementing the contractual requirement.

2. The analytical narrative

2.1 There are at present a number of initiatives, policies and levers in place to encourage openness.

2.2 The Health Act 2009 requires all NHS organisations to '*have regard'* to the NHS Constitution[3]. The Constitution places the following expectation on NHS staff;

> ''*The NHS also commits…when mistakes happen, to acknowledge them, apologise, explain what went wrong and put things right quickly and effectively (pledge)…*''

All providers of NHS funded care have an obligation under the NHS Standard Contract to have regard to the NHS Constitution.

2.3 The professional codes of practice for doctors, nurses and NHS managers contain similar duties:

- The General Medical Council sets out in its Good Medical Practice: '*If a patient under your care has suffered harm or distress, you must act immediately to put matters right, if that is possible.*

You should offer an apology and explain fully and promptly to the patient what has happened, and the likely short-term and long-term effects'.[4]

- Similarly the Nursing and Midwifery Council states in its code:[5] '*You must act immediately to put matters right if someone in your care has suffered harm for any reason…You must explain fully and promptly to the person affected what has happened and the likely effects'*
- The code of conduct for NHS Managers states[6]: '*I will accept responsibility for my own work and the proper performance of the people I manage. I will seek to ensure that those I manage accept that they are responsible for their actions to: patients, relatives and carers by answering questions and complaints in an open, honest and well researched way and in a manner which provides a full explanation of what has happened, and of what will be done to deal with any poor performance and, where appropriate giving an apology'.*

2.4 The National Patient Safety Agency (NPSA) has published policy guidance, called *Being Open*[7], which sets out the principles of communication and the processes that organisations should follow to ensure mistakes are communicated to patients.

2.5 The Care Quality Commission registration requirements as detailed in *Guidance about compliance: Essential standards of quality and safety* [8] place a number of requirements on providers to be open with service users about the care they receive;

- they require providers to analyse incidents that could have caused harm;
- require providers to involve service users in making decisions about their care;
- requires providers to have an effective complaints procedure;
- require providers to notify CQC of a range of incidents resulting in harm to service users or with the potential to harm service users;
- and crucially require providers to reflect, where appropriate, published research evidence and guidance issued by the appropriate professional and expert bodies as to good practice in relation to such care and treatment. This final duty therefore means that providers should comply with the '*Being Open'* policy published by the National Patient Safety Agency, which makes the requirement to tell patients when something goes wrong quite clear.
- CQC's *Guidance about compliance: Essential standards of quality and safety* further details that people who use services should benefit from a services which ''*informs them, or others acting on their behalf, if an adverse event, incidents or error has occurred in their care, treatment or support that has caused, or may result in, harm and offers a full explanation of what happened along with an appropriate apology or expression of regret.''*

2.6 The NHS Litigation Authority issued a letter on apologies and openness to all chief executives and fiance directors of NHS bodies, reiterated in May 2009. The letter states that 'it is most important to patients that they or their relatives receive a meaningful apology'.[9] Additionally, the letter makes it clear that an apology does not constitute an admission of liability.

2.7 The Data Protection Act 1998[10] also gives individuals the right to access information that is held about them. Under the Act, individuals are entitled to access any personal information that is held about them and to be given a copy of the information and an explanation of any technical or complicated terms. This would include written information regrading an error in their healthcare or an investigation into their care following an error.

2.8 Despite the existence of these levers and policies, there is unfortunately very little evidence available about the actual incidence of non-disclosure. Most available evidence is anecdotal, from organisations such as Action against Medical Accidents (AvMA)[1]. There are also stories in the press from time to time, most recently in relation to Ambulance Trusts[11]. There is no definitive evidence as to the prevalence of non-disclosure, only the underlying acknowledgement that it does happen, in an unknown number of cases.

2.9 The NAO report, *A Safer Place for Patients: Learning to improve patient safety*[18] referenced data from a survey they conducted that suggested only 24 per cent of Trusts routinely informed patients when they were involved in a reported incident and 6 per cent did not inform patients at all. This is cited by some commentators as demonstrating the scale of the problem of non-disclosure. However, looking at the survey data in detail reveals that in addition to the 24% of Trusts that routinely inform patients thy had been involved in an incident a further 52% did so depending on the severity of the incident, which is consistent with the *Being Open* policy. A further 17% of Trusts did so depending on

other (unspecified) criteria. Therefore, at the time of this survey in 2006 it was likely that organisationally at least, lack of disclosure was limited to 6% of Trusts. It should also be noted this was before the NPSA undertook a large programme of work including producing and promoting *Being Open* and providing training for the NHS. Therefore, the proportion or Trusts not informing patients when they have been involved in an incident is likely to have decreased further.

2.10 The same NAO report also used evidence from a patient survey to explore openness from patients' perspectives. This reported that 51% of patients were informed when 'something had gone wrong with their treatment' (of 2061 members of the public surveyed, 881 had been in hospital in the previous 2 years and 97 of them had suffered harm, of which 51% were informed). Unfortunately, the survey does not appear to have defined 'something going wrong' or asked about the severity of harm caused by the incident in question, therefore we cannot rely on this alone as a true reflection of disclosure following a patient safety incident. Equally, it does not correlate with the figures from the survey of Trusts cited in the same report unless we assume that a lot more disclosure is taking place than suggested by the conclusion that only 24% of Trusts routinely inform patients involved in an incident. Again, this data pre-dates much of the work to improve disclosure that has been undertaken.

2.11 Moving away from the issue of defining how big the problem is, we have a slightly clearer picture on the importance that patients place on being told when they are involved in a patient safety incident. For example, the Medical Protection Society recently conducted a survey of 2028 members of the public in conjunction with ComRes. This survey demonstrated that 95% of the people surveyed feel it is very important for doctors to given an open and honest explanation of what went wrong or ensure that the problem is corrected[14]. Indeed it is generally accepted that being open with patients is quite simply the right thing to do.

2.12 As well as being desirable for patients, another commonly cited benefit of open disclosure is that it leads to fewer people seeking to litigate or claim for negligence. This is based on the premise that many people litigate or make a claim to obtain information about the mistakes in their care. Alternatively, they may be prompted to claim by what they see as a failure to apologise. This effect could potentially mean that increased openness will lead to fewer claims for clinical negligence and a reduced burden of negligence payments.

2.13 Evidence for this view comes from a study by Hickson et al.[15] that involved a survey of mothers of infants who had suffered death or permanent perinatal injuries and had closed medical malpractice claims in Florida. In response to the question "why did you sue?" respondents gave 179 reasons (1.4 per respondent). The leading reasons were as follows.

- Advised to sue by someone outside of their immediate family **33%**
- Needed money for long-term care **24%**
- Realized physician was not completely honest with them or intentionally misled them **24%**
- Realized their child would have no future **20%**
- Sued to get more information about what happened **20%**
- Sued to get revenge or deter future errors **19%**

2.14 These findings suggest litigation is often the result of a desire to obtain more information or to overcome a perceived lack of openness by a medical professional. While there are some limitations with this study, it could be assumed that increasing openness could lead to fewer cases of litigation. However, evidence for this reduction in litigation is not conclusive.

2.15 A study undertaken at the Veterans Affairs Medical Centre in Lexington, Kentucky[19] has been cited as evidence for a likely reduction in litigation due to increased openness. However, the main conclusions from this work are that '*Despite following a policy that seems designed to maximise malpractice claims* [i.e. open disclosure]*, the Lexington facility's liability payments have been moderate and are comparable to those of similar facilities'*. This in fact suggests there was no impact on litigation caused by moving to a full disclosure policy, rather than any decrease in litigation.

2.16 Another source of evidence is a paper by Hilary Clinton and Barack Obama in the New England Journal of Medicine[20]. This reported that the University of Michigan Health System's annual litigation costs dropped from about $3 million to $1 million after it began to;

- acknowledge cases in which a patient was hurt because of medical error and compensate these patients quickly and fairly;

- aggressively defend cases that the hospital considered to be without merit;
- and study all adverse events to determine how procedures could be improved.

While the effects of the latter two interventions cannot be separated from the implementation of the disclosure policy, the report is consistent with openness reducing litigation.

2.17 Similarly, another disclosure programme, the '3Rs' programme at COPIC, is credited with reducing adversarial litigation in Colorado[16]. However, again this does not provide clear evidence for the reduction in litigation as a result of openness as the disclosure programme is linked with a 'no fault' compensation programme, meaning the apparently diminished costs of litigation cannot be attributed clearly to the effects of open disclosure.

2.18 There are those who argue that increased openness and disclosure will actually result in increased litigation. This is based on the observation that the vast majority of errors do not currently result in a claim, and that even a relatively small proportional increase in the percentage of errors that result in a claim due to the patient being made aware of an error will dwarf the number of claims that would not happen if a patient received full and open disclosure. In other words, with an increase in disclosure across a healthcare system, the number of people who are prompted as a result of the information they receive to make a claim against the hospital responsible, will outweigh the number who would have claimed but decide not to once they receive information about what went wrong.

2.19 This effect was modelled by Studdert et. al.[21] who estimated a 95% chance that disclosure would increase the total number of claims made (and a 5% chance it would decrease the number), with a 60% chance the annual number would at least double. They further estimated a 94% chance the costs would increase (and a 6% chance they would decrease), with a 45% likelihood they would double.

2.20 These findings are based purely on modelling using a survey of 78 selected patient safety, risk management, legal and medical experts, who were asked to estimate the percentage of patients likely to be prompted to make a claim who would not otherwise have claimed, or dissuaded from making a claim who would otherwise have claimed, if they received full disclosure. Therefore, the findings are theoretical and based on opinion. However, they provide a striking alternative view to the idea that openness reduces litigation.

2.21 Overall, the most we can really say at this point is that while '*disclosure may quell some patients' interest in litigating, it will* [may] *ignite interest in others, particularly those who would never have known of their injury in the absence of the disclosure. The net impact of disclosure on the size and cost of litigation ultimately depends on the balance between these two effects*'*'*[16]. And we do not know the balance between these effects.

2.22 In terms of enforcement of current requirements, the professional regulators, the GMC and the NMC, told us that they do take action against professionals who do not abide by their regulations. In particular, the GMC informed us that they have looked into the categories of allegations that they have investigated covering the period April 2006 - April 2008. This review demonstrated that they did consider allegations of poor practice related to the issue of being open when things go wrong. Their information shows that over this period, 93 allegations related to a failure to be open were investigated (failure to offer an apology, failure to explain an error/issue, failure to respond to concerns). This amounts to 1.5% of allegations (not cases) considered. The analysis of allegations shows that complaints about lack of openness were relatively small in number, but were treated seriously, and were represented roughly proportionately in the cases where a finding of impaired fitness to practise was made.

2.23 Overall, the evidence base on this issue is patchy and does not lend itself to firm conclusions being made. What we can say with some certainty is that;

- Patients (for the most part) want to be told when something has gone wrong
- There has been a large amount of work to encourage openness, but the problem still seems to persist at least in some places
- There are clearly examples where the NHS has failed to be open with patients regarding patient safety incidents, and as such further measures to improve openness should be beneficial at least in terms of providing patients with the openness they desire.

B. What are the policy objectives and the intended effects?

1. The Coalition Government has made clear its commitment to openness. The 2010 Coalition Agreement states "… *we will require hospitals to be open about mistakes and always tell patients if something has gone wrong*"[12].

2. More recently in its response to the Future Forum[13] the Government signalled it would require openness through a contractual mechanism;

   ''We also heard through the listening exercise the suggestion that we could strengthen transparency of organisations and increase patient confidence by introducing a ***"duty of candour"****: a new* ***contractual requirement on providers*** *to be open and transparent in admitting mistakes. We agree. This will be enacted through contractual mechanisms…''*

3. As mentioned already, there is anecdotal evidence from individual cases that suggests NHS organisations are not as open as they should be. Organisations must do all they can to support their staff to be open and this means openness must be a leadership and management issue. The leadership of an organisation has the overall responsibility for creating a strong culture of reporting and learning from incidents in the organisation, and therefore also in encouraging workers to tell patients when mistakes are made.

4. The way to enable a genuine culture change and really increase openness is to establish a mechanism to encourage organisational management and leadership to support health professionals in being open and fully deliver the Coalition Government's requirement.

5. Subject to the passage of the Health and Social Care Bill, in the new arrangements for NHS commissioning, Clinical Commissioning Groups will buy services for their local populations from provider organisations like hospitals based, in part, on the quality of care those organisations provide.

6. The NHS Standard Contracts set out standard terms and conditions that all organisations providing NHS-funded community and secondary care must agree to. This therefore includes the providers of NHS acute hospital, community, ambulance and mental health services. The NHS Standard Contracts are therefore the system of rules used to manage the relationship between the commissioners and the providers of NHS funded services and provide the correct vehicle for incentivising whole organisations to deliver improvements in quality such as being open.

7. Another key issue with openness is actually detecting incidents of non-disclosure. One of the fundamental challenges with implementing a requirement for NHS organisations to be open with patients when things go wrong is the difficulty in detecting when patients are not told about a mistake. This sits at the heart of the issue and is a major barrier to putting in place any kind of requirement or duty of openness. By definition, a lack of openness involves a lack of information about an incident. So how can you monitor the performance of an organisation and know when it has not been open*?*

8. A solution may be offered by the move to put patients and clinicians at the heart of commissioning and to make health services more locally accountable and responsive.

9. Under the proposed new arrangements for commissioning, clinicians will be fundamentally involved in commissioning services for their patients, through Clinical Commissioning Groups. GPs providing primary medical care for example are at the centre of the NHS, acting as the gateway to NHS services and referring their patients to hospital. Following a patient's treatment in hospital, GPs receive discharge letters, detailing the care their patient has received. They then provide follow-up care, as necessary. Therefore, the GP, together with the patient or their representatives, should be well positioned in the new system to identify when things have gone wrong in particular instances where the patient does not know the facts or has not been given sufficient explanation and apology. GPs are in a strong position provide medical expertise and knowledge to support the patient in identifying that something has gone wrong with their care but they have not been told.

10. It is equally possible of course, that patients may be aware or suspect that something has gone wrong without the help of a clinician. In this scenario, patients must still be able to raise a concern or complaint. Patients or their representatives can do this by raising the issue with either the organisation that was treating them or the commissioner of that treatment. Local Patient Advice and Liaison Services (PALS) and in future Local HealthWatch services (subject to Parliament) will be able

to provide information and/or assistance with raising concerns, how to complain, and how to access NHS complaints advocacy, and all providers of NHS-funded care are under a duty to make information available on their arrangements for dealing with complaints. This should include information on what patients can expect in terms of openness, and how they can purse concerns.

11. If a patient is satisfied with the local response to a concern, perhaps because it demonstrates no breach of the contractual requirement has occurred, no further action would be required. Where the response is not satisfactory to the patient, they would be able to raise it with their Clinical Commissioning Group - regardless of whether there is involvement or interest from any clinician, such as their GP.
12. What this new mechanism should do therefore is provide both an incentive to an entire organisation to improve its culture and increase transparency and openness. This in turn will lead to all patients who have suffered an error in their health care being given all the appropriate facts about the incident, including explanations of what went wrong, apologies for the harm caused and details of the steps being taken to ensure similar incidents are not repeated.
13. On a personal level, this will undoubtedly reduce the amount of anguish, upset, anger and frustration that some people experience when they do not get all the information to which they are entitled. On a national level, a shift towards a more open and transparent culture will lead to improved reporting and learning from incidents and therefore will likely lead to a reduction in the number and severity of patient safety incidents overall.

C. What policy options have been considered?

1. Option 1 - Do Nothing

1.1 As outlined in section 2 above, a number of requirements or guidance already exist which promote openness. Some may therefore argue that an additional requirement may not be strictly necessary. In addition, we do not know how widespread or systemic non-disclosure is. We know it happens through anecdotal evidence[1, 11] but there remains the possibility that further action may be disproportionate.

1.2 That said however, the very fact that there is anecdotal evidence and information from individual cases demonstrates NHS organisations are not always as open as they should be. Given the configuration of the NHS is changing, particularly with respect to the commissioning of services, it is timely to consider options that could increase the frequency with which organisations are open.

1.3 It must also be noted that doing nothing does not deliver the Coalition Government commitment nor fulfil the commitment made in the Government's response to the NHS Future Forum report.

2. The other options considered

2.1 Two further options are considered in this Impact Assessment.

2.2 Option 2 is to contractually require that organisations comply with the *Being Open* policy in relation to all patient safety incidents that occur during care provided under the NHS Standard Contracts and that result in moderate harm, severe harm or death (using NPSA definitions). On an annual basis, all organisations would have to publish a "declaration of a commitment to openness" including a commitment to always tell patients if something has gone wrong during their care. This declaration could be required to be published on the organisation's web page and/or on their NHS Choices page. Under this mechanism, where a provider breaks their openness commitment by not being open with a patient or their representatives about a moderate or severe harm or death incident, the commissioner could take action through the contract management processes.

2.3 The failure to publish the 'commitment to openness' would be treated as a contractual breach, resulting in a possible financial deduction from each monthly payment until the declaration is published.

2.4 Where a provider is found to have failed to be open, through a direct or indirect notification received from the patient or someone acting on their behalf (including a clinician) or through any other means, the commissioner shall implement the consequences set out in the contract.

2.5 Option 3 builds on option 2 but extends the contractual requirement to all incidents reported to the NPSA's NRLS, that is all near miss, low, moderate, or severe harm incidents and those where death results.

2.6 We are consulting on these options now in order to determine which is the most viable and effective option or indeed to identify if there are additional options for a contractual mechanisms that we have not considered. This consultation will include equality groups.

3. How the listed options were selected:

3.1 The listed options were selected as a basis for discussion on possible contractual mechanisms to employ. The evidence base in relation to the issue of openness is not extensive and is centred around qualitative and anecdotal data. However, all stakeholders accept the benefits of being open with patients when things go wrong. It is the case that the benefits are often described in very qualitative ways, the possible exception being some survey work carried out by the Medical Protection Society[14] mentioned earlier, but the evidence still serves to emphasise the importance to the public of doctors being open with patients. The options presented are therefore based on the opinion of the Government that a contractual requirement is an important lever for stimulating the cultural changes necessary to improve openness.

3.2 It was decided that a relatively straightforward option for requiring openness would be chosen as option 2, based on the existing '*Being Open*' policy. Alongside this we have looked at a more

stretching option 3 based on the principle that patients must be provided with all the information that is relevant to their care including where something has gone wrong even if no or low harm has been caused. As mentioned the final contractual mechanism(s) chosen is not necessarily limited to one of these two. This will be determined by the responses received to the consultation.

3.3 If necessary, piloting of a new contractual requirement could take place, even if this means delaying implementation in order to ensure the most effective mechanism is chosen. Pilots could be conducted with selected commissioners to investigate the practicality and efficacy of a contractual requirement for openness. This would allow evaluation of both the contractual mechanisms, including the precise requirements and consequences of breach, as well as the behaviour of patients and their representatives when presented with this option for pursuing openness in cases where they feel they have not received full disclosure. Ultimately pilots could determine what a contractual requirement might add to the levers that already exist

3.4 It should be noted however, there are a number of arguments against piloting. There are no identified resources at present to fund a pilot study. The organisation of commissioning in England is also undergoing a period of transition, which may limit the accuracy of pilot findings or indeed the ability to identify participant commissioners. It would also of course delay the implementation of any requirement by a significant period.

4. Summary of the options;

Option 1

Do nothing. Rely on the current requirements for openness that already exist (professional regulations, Data Protection Act, CQC registration requirements and guidance).

Option 2

Implement a contractual duty of openness in the NHS Standard Contracts, setting out clear expectations for conforming with the duty in relation to moderate and severe harm and death incidents, and outlining a framework for enforcement by commissioners backed by conventional contractual sanctions that escalate to potential withholding of a percentage of the contract income or contract termination

Option 3

Implement Option 2 in full but in addition, require that all incidents, regardless of harm, are reported to patients or the representatives and that it will be a contractual breach to not do so.

D. Option 2 Impacts, Costs and Benefits

1. How will Option 2 work?

1.1 Where a provider is found to have failed to be open, through a direct or indirect notification received from the patient or someone acting on their behalf (including a clinician) or through any other means, the commissioner shall implement the consequences set out in the contract.

1.2 The consequences would be :

- A deduction of a percentage of the annual contract value (capped to a maximum sum) or where the contract has expired or terminated prior to the failure being identified, a substantial repayment proportionate to the overall size of the contract; and
- Implementation of any lessons learned following a review of the failure, on the basis of the contract management provisions.
- Requiring the provider to undertake specific remedial action depending on circumstances. Initially we suggest;
  - A written apology to the patient from the Chief Executive regarding the lack of openness alongside a full explanation of the facts as set out in the *Being Open* guidance
  - An independent investigation of the facts at the expense of the provider where it is felt the providers investigation was inadequate
  - Publication of number or type of breaches of a provider in a prominent place on their website

1.3 Ultimately, a serious breach of the contractual requirement or persistent breaches would have escalating levels of consequence that would include notification being sent to the Regulators, suspension and/or termination of the organisation's contract.

1.4 The way that organisations should behave when it comes to explaining to patients and their loved ones that a patient safety incident as occurred in their healthcare is set out in the '*Being Open'* guidance produced by the National Patient Safety Agency. We think this document continues to provide an excellent reference point and all organisations should follow the procedures it sets out. The contractual requirement will therefore require that organisations comply with the *Being Open* policy.

1.5 However, the *Being Open* policy rightly leaves a number of issues open to local interpretation depending on circumstances, and is therefore not, in itself ideal for setting out firm contractual expectations. So, to ensure that Commissioners and organisations providing health care are clear on the expectations that the contractual requirement will set out, and importantly what would count as a failure to be open, we want to define a list of basic contractual requirements for all organisations. These are entirely derived from *Being Open* and impose no new expectations on the NHS. We propose setting these expectations out in a separate guidance that will be issued to support the contractual obligation.

1.6 As mentioned, one of the fundamental challenges with implementing a requirement for NHS organisations to be open with patients when things go wrong is the difficulty in detecting when patients are not told about an incident. Section B above however outlines how a solution may be offered by the move to put patients and clinicians at the heart of commissioning and to make health services more locally accountable and responsive.

1.7 Briefly, we think that GPs and other clinician will be in a strong position to identify problems with openness. They could then take up the issue with the relevant Clinical Commissioning Group (often the Clinical Commissioning Group they are part of), or advise their patient to do so. The commissioners could then take action under the NHS standard contract if it was found to be appropriate. We would also predict that clinicians particularly GPs may wish to pursue any concerns more actively within their Clinical Commissioning Group, given they will be uniquely placed to demand higher quality care for their patients, especially if they suspect repeated breaches of the openness requirement.

1.8 It is equally possible of course, that patients may be aware or suspect that something has gone wrong without the help of a clinician. In this scenario, patients must still be able to raise a concern or

complaint. Patients or their representatives can do this by raising the issue with either the organisation that was treating them or the commissioner of that treatment. Local Patient Advice and Liaison Services (PALS) and in future Local HealthWatch services (subject to Parliamentary process) will be able to provide information and/or assistance with raising concerns, how to complain, and how to access NHS complaints advocacy, and all providers of NHS-funded care are under a duty to make information available on their arrangements for dealing with complaints. This should include information on what patients can expect in terms of openness, and how they can purse concerns.

1.9 If a commissioner receives a report of a breach, we would expect the commissioner to contact the provider in question and request copies of the relevant documentation in relation to the patient safety incident and the subsequent communication between the provider and the patient and their family/carer. The commissioner should already have this documentation if the provider has fulfilled the contractual requirement appropriately. If there is no documentation of the communication between the provider and patient, but there is a record of a patient safety incident, this would clearly indicate a breach.

1.10 If there is documentation of the communication with those affected by an incident, the commissioner should review this against the contractual requirements to determine if a breach has occurred. This review should involve discussions between provider and commissioner and the affected patient and their family/carer and the commissioner. This should also involve any other relevant people as appropriate, such as the patient's GP if they are involved in identifying the potential breach.

1.11 The commissioner will have the final say on whether to declare a breach and implement the contractual processes that are relevant. Any dispute about the commissioner's decision by the provider would be dealt with in the same way as any other contractual dispute. If the patient or their family/carers dispute the decision, they could make a complaint about the process the commissioner has undertaken to the commissioner and if they are not satisfied with the response, to the Parliamentary and Health Service Ombudsman.

1.12 In keeping with the principles of *Being Open* we would expect the commissioner to provide the patient and their family/carer with written and if requested face-to-face updates on the investigation into a possible breach, including a detailed explanation in plain english of the final decision and any action the commissioner decided upon.

2. Specific Impact Tests

2.1 Health Impact Assessment

As mentioned previously, there is the possibility that the introduction of the contractual requirement will indirectly lead to increased reporting and learning from patient safety incidents, particularly locally and to the NRLS. This in turn could lead to a reduced incidence of patient safety incidents and therefore improve the safety of those who would otherwise have experienced and adverse incident. This impact is theoretical but it is reasonable to suggest it could occur. It is impossible however to estimate the scale of this impact, especially in the context of the numerous other initiatives designed to reduce the incidence of patient safety incidents. Regardless it is a positive effect and is likely to only increase in its positive effect the more successful the contractual requirement is.

2.2 Competition and Small Firms, Environmental, Justice, Human Rights, Rural Proofing and Sustainable Development Impact Assessments

There are not anticipated to be any additional impacts on small firms, competition, the environment, the justice system, human rights, rural proofing or sustainable development.

With respect to the Justice Impact Assessment, we are not aware of any previous appeals to the Courts around contract disputes between NHS commissioners and providers related to any of the current provisions in the NHS Standard Contracts. This suggests there is not likely to be any increase in applications to the Courts due to this requirement. It is possible in the future that an increased plurality of providers outside the NHS (i.e. including the independent sector) could increase the likelihood of contract disputes in general, but this effect is not specific to this requirement, so it is not considered further here.

3. Costs and Benefits of Option 2

Benefits

3.1 Qualitatively, the benefits of more openness are undeniable. The Medical Protection Society recently conducted a survey of 2028 members of the public in conjunction with ComRes. This survey demonstrated that 95% of the people surveyed feel it is very important for doctors to given an open and honest explanation of what went wrong or ensure that the problem is corrected[14]. Therefore improving openness should result in greater satisfaction with healthcare.

3.2 Using this finding, we can reasonably assume that the vast majority of people will benefit from increased openness, given that it is what they want. This benefit is at least in part derived from the idea that improved disclosure is likely to result in fewer people experiencing anxiety or nervousness around the lack of information for a particular patient safety incident. Openness may indeed ultimately improve their trust and reassurance in the health system. Quantifying an individual's trust and reassurance is not straightforward but the analysis below attempts to put an indicative valuation on this benefit.

3.3 One of the most widely-used frameworks for calculating health states is the EQ-5D framework developed by EuroQol. The framework asks individuals to rate their health from 1 to 3 in five different domains; a response of 1 means the individual has no problems whereas a response of 3 indicates serious or severe problems. One of the five domains in the EQ-5D system is for anxiety/depression.

3.4 For the purpose of this assessment, we assume that implementing a requirement for openness will increase the health state of individuals who have little confidence or trust in the health system compared to a scenario where they are not informed fully about their patient safety incident.

3.5 The EQ-5D scores can be turned into a health state (measured between 0 and 1, where 1 represents perfect health and 0 represents death) using regression analysis. The difference in health state between a person recording 1 and 2 on the anxiety/depression scale is 0.071[22].

3.6 We can convert this figure into a QALY valuation by considering the duration of time this change in health state would last for. For the purpose of this assessment, we assume that improved disclosure will see an improvement in their health state of patients for one month. This is then multiplied by the valuation of a QALY (£60,000) to give a value of £355 per patient.

3.7 It is now necessary to consider how many people will experience this change in health state and experience this £355 benefit. From above we estimate the total number of moderate, severe and death category patient safety incidents as 73,000. Furthermore, there is evidence to suggest that 6%-49% of patient safety incidents are not disclosed in full, thus giving 4,400 – 36,000 non-disclosed incidents.

3.8 We multiply this figure by the QALY increase (£355) to give a range of £1.6m - £12.7m. Our best estimate is the mid-point of this range, creating £7.1m per year. These figures are only an indication of the benefit of patient confidence and it is for this reason that we must consider such a large range to our estimate to accommodate for uncertainties.

3.9 Beyond reduction in anxiety, there is also an argument that improving openness with patients and their relatives/carers can only improve incident reporting overall to the NRLS and within organisations. An open culture should mean incidents are more openly investigated and learned from leading to a reduction in the likelihood of incidents being repeated. This will again benefit patients. However, for reasons discussed later there may also be a negative effect of requiring openness on reporting and so we have not attempted to quantify the benefit here.

3.10 There is also a common perception that increased openness with patients, particularly when combined with an apology, will lead to decreased levels of clinical litigation. This was discussed earlier, but as we explained, the research evidence for any effect of disclosure on litigation is conflicting and by no means conclusive, and to estimate with any certainty what impact disclosure may have on litigation is not possible. We have therefore not included the effect on litigation as either a cost or a benefit.

Costs

3.11 Estimating the costs of implementing Option 2 are subject to similar problems with a lack of evidence of the extent of non-disclosure. What we can do, however, is to estimate the costs to those involved of a single case of non-disclosure and extrapolate some overall costings from there.

3.12 In order to implement the NPSA's *Being Open* Policy, following a patient safety incident, we would expect (for a straightforward case) that two patient meetings would take place. The initial 'being open' discussion with the patient and/or relatives takes place where an apology is offered for the harm has been done and the patient is informed that an incident investigation is being carried out. Secondly, a follow up discussion would provide information on the findings of the investigation. On average, we expect at least two people from the hospital to attend; the Being Open lead in the organisation and the healthcare professional responsible for treating the patient. If we assume each meeting to last 30 minutes, and each professional to be of AfC band 8c, paid at approximately £50 per hour. This equates to approximately £100 for providing an apology in total.

3.13 We currently propose that the requirement will apply to all incidents involving death, severe and moderate harm. The most recent NPSA figures available suggest around 73,000 such events per annum[1] are reported. There is a general acceptance of a level of under-reporting to the NRLS. The NAO's 2006 report estimated this level at 22%. This would suggest a 'true' figure of 89,000 such incidents. However it is also reasonable to assume that incidents that are not reported for any reason will also not be disclosed. While this is not ideal, it is realistic.

3.14 Using this 73,000 figure, the total cost for apologies annually would be 73,000 x £100, totalling approximately £7.3m. The *Being Open* policy was introduced in 2005. The policy was re-launched in 2009, with an implementation date of 23 November 2010. Therefore, this is not a new policy requirement, but rather the requiring of an existing policy via a new mechanism, and we expect that in most cases, patients will receive an apology already. Therefore, these are not additional costs.

3.15 However, it is reasonable to assume that disclosure is not happening in some cases, otherwise there would be no need for any change in policy. As such, we must assume that the policy will have some impact in terms of increasing the amount of disclosure that occurs and therefore the costs of delivering that disclosure. As discussed in the analytical narrative above, work in 2006 by the NAO suggests around 51% of patients were informed when something had gone wrong with their treatment. While we have already discussed the accuracy of this figure, it does provide a starting point for estimating the additional amount of disclosure that could result from a contractual requirement. Assuming the situation has not got worse and has probably improved since 2006 given the NPSA's focus on the issue of disclosure, we can estimate that the number of incidents reported that are not disclosed to the patient is less than 35,770 (49% of 73,000). Therefore, the additional cost of disclosure as a result of the requirement will be under £3.6m per year.

3.16 The alternative figure provided by the NAO work was that 6% of organisations do not inform patients they had been involved in an incident. We could use this as a proxy in assuming that they will report an equivalent proportion of incidents to the NRLS as other comparable Trusts but then therefore use this 6% as a proxy for the proportion of patients nationally who are not told when something goes wrong, assuming elsewhere, all other patients are told. This would lead to a lower bound estimate for the additional cost of disclosure being £438,000.

3.17 There will of course be costs involved in implementing the option 2. When it comes to identifying cases of non-disclosure, costs are unclear. We have suggested two possible routes for non-disclosure to come to light, either through a patient their relative or carer being aware of an error that is not accompanied by open disclosure, or through another health care professional such as a GP involved in a patient's care realising an error has occurred but the patient does not know about it. In either case, the costs associated with notifying the commissioner are not identifiable. They could be very low, and simply related to a health care professional or local information source such as HealthWatch providing a patient with information about how to raise the issue with the relevant commissioner. They may, however, be more substantial if a GP chooses to devote more time to supporting a patient or their relatives/carers in reporting a potential breach. Due to this lack of clarity we have not attempted to estimate these costs.

3.18 We are more clear however that additional contract management activity will be required whenever a potential breach of the openness requirement is reported. On receipt of a report of non-disclosure from a patient/clinician we would expect the commissioner and provider to review the case, and implement the consequences of a breach if appropriate. We estimate that the time required to discuss each report of non-disclosure will be approximately 1 hour per report involving up to 5 people, (2 provider representatives, 2 commissioner contract managers and a clinician) at an average of AfC band 8c, paid at £50 per hour (£250).

3.19 If a breach is demonstrated via this discussion, action should be taken probably in the form of remedial action plan being established. We estimate the costs of producing this as the equivalent of

0.5 days work of an AfC band 8c (£200). Implementation of the plan is, in essence, implementation of existing policy requirements and is therefore not costed here for the reasons explained above. Therefore, most incidences of breach may lead to additional costs of around £450.

3.20 In some cases a plan may not be agreed, or the remedial action plan itself be breached. This triggers the implementation of a stronger contractual sanction where the commissioner can withhold a proportion of the monthly sums payable by the commissioner to the provider. Commencing this will likely require an additional meeting between provider and commissioner (£250) plus 15 minutes of the commissioner contract manager's time liaising with their provider counterpart (both AfC band 8c) followed by 15 minutes for the commissioner's finance/contracting lead to implement the sanction (AfC band 6, paid at £18 per hour). Therefore, we can estimate a cost per incident of non-disclosure followed by an action plan breach of £730 (excluding the cost to the provider of withholding payment, which is not a loss to the system).

3.21 It is unlikely that breach of an action plan of failure to agree one will happen very often. If we assume that 10% of breaches will result in this additional activity, we can estimate the average cost of a typical breach to be £478.

3.22 The potential cost to the NHS as a whole will be dependent on the number of incidents of non-disclosure reported. As discussed, we have no firm data on the incidence of non-disclosure. What we do have is the NAO's estimate of the number of patients who were informed something had gone wrong with their treatment by their provider as a percentage of the total who said something had gone wrong with their treatment (51%). We also have the NAO estimate that 6% of Trusts do not inform patients that they were involved in an incident at all, which we can use as a proxy for 6% of patients not being informed. Again, applying this to our estimate of the total number of relevant incidents (73,000) suggests between 4380 and 35,770 are undisclosed.

3.23 The upper figure here is clearly an overestimate, as the NAO disclosure figure covers all levels of incident harm and it seems clear that moderate and severe harm and death incidents will be disclosed to a far greater level than low harm incidents. In addition, this takes no account of the level of improvement in the NHS that will have resulted from the NPSA's activity in developing and promoting the *Being Open* policy. Even so, it provides us with an upper estimate of the level of non-disclosure in the NHS and allows us to calculate a maximum cost of resolving all these breaches of disclosure via contract management of £17.1m. This cost is in addition to the additional higher estimate for disclosure costs (£3.6m), which must still happen. The upper limit for the total cost is therefore £20.7m.

3.24 Doing the same calculation but using the lower estimate of non-disclosure (6%) we can calculate a lower estimate for the total cost as (4380x£478 + 4380x£100) £2.5m. Again, it is highly likely that this lower estimate is an underestimate as it is likely non-disclosure is not limited to a small number of organisations who simply refuse to undertake disclosure. The true figure therefore must lie between these two bounds, so we will estimate it as the mid-point - £11.6m.

3.25 An alternative proposal to the one outlined where commissioners can penalise the provider by withholding a proportion of the overall contract payment is the introduction of a standard ('flat rate') fine for breaches of the requirement. The simplicity of a flat rate fine may be attractive as this reduces the contract management activity involved in responding to a breach. Either way however, the financial penalty is not lost to the NHS, as the commissioner holds it.

4. The exchequer costs of option 2 falling upon the public sector

4.1 Table 1 below identifies the annual profile of costs and benefits of option 2 per year in constant prices assuming the number of incidents rises by 10% for the first 3 years then stays level. We have taken the mid-point between our two estimates of non-disclosure (6% and 49%) as the level of non-disclosure assumed.

Year	1	2	3	4	5	6	7	8	9	10
Incidence of Moderate, Severe and Death incidents	73000	80300	88330	97163	97163	97163	97163	97163	97163	97163
Total annual costs (m)	**£11.60**	**£12.33**	**£13.11**	**£13.93**	**£13.46**	**£13.00**	**£12.56**	**£12.14**	**£11.73**	**£11.33**
Total annual	**£7.13**	**£7.57**	**£8.05**	**£8.56**	**£8.27**	**£7.99**	**£7.72**	**£7.46**	**£7.20**	**£6.96**

benefits (m)										
Net benefits (m)	**-£4.47**	**-£4.76**	**-£5.06**	**-£5.37**	**-£5.19**	**-£5.01**	**-£4.84**	**-£4.68**	**-£4.53**	**-£4.37**

4.2 As explained in section 2 above, the costs we have calculated relate to contract management activity when incidents of breach are notified to the commissioner. We are not able to estimate costs in relation to health care workers such as GPs, HealthWatch or other sources of information and support providing advice to potential victims of non-disclosure. These will be variable and depend on local and individual circumstances.

4.3 There should be no additional costs for Local Authorities and Government Offices. The burden on the Department in introducing this requirement will be borne as part of normal activity. There are no capital costs.

4.4 Note the NHS costs above are not presented on an opportunity cost basis. This can be achieved for NHS costs by multiplying the costs shown by 2.4.

5. Risks and Assumptions

5.1 As discussed earlier these cost estimates are based on a relatively poor evidence base. We do not know how often non-disclosure occurs. We have based our estimate on the number of moderate harm, severe harm and death incidents reported to the NRLS. This assumption is debatable as incident reporting is unlikely to represent a full picture of the number of incidents that actually occur. All CQC-registered providers must report severe harm and death incidents to the CQC via the NRLS, but it is not an explicit requirement to report moderate harm events. In addition, the reporting of incidents is not comprehensively and independently audited. Therefore, these figures may not represent the true level of harm experienced by patients. However, there are no other reliable sources of information. Reports based on retrospective reviews of medical and nursing records that indicate up to 10% of patient admissions may result in an adverse event[17], suggest that harm may be more widespread than NRLS figures suggest. However we cannot use these figures given they are based on a small survey of a single hospital and do not provide a reliable breakdown of the severity of harm caused. Therefore, the NRLS appears to be the best proxy available.

5.2 The next major assumption is around how many incidents are not disclosed to patients. As discussed we have relied on low and high estimates of non-disclosure contained in the NAO report *A Safer Place for Patients* – that is between 6% and 49% non-disclosure. This report and the estimates it contains have their limitations however.

5.3 In calculating costs, we have made broad assumptions about the people and activity involved in contract management. These are based on feedback from PCT commissioners, but it should be noted the there is no mandatory process that must be followed and therefore local commissioning practices may vary from those assumed above.

5.4 We have assumed that only 1 in 10 reports of an openness breach will result in withholding of payment, the rest being satisfactorily resolved via drafting and implementation of an action plan. This assumption is not based on evidence but reflects a view that most providers will likely seek to satisfactorily address any concerns raised by their commissioners and prevent recurrence of problems.

5.5 In calculating costs over time we have assumed a roughly 10% increase in the number of incidents reported year on year for 3 years followed by reporting staying constant. This is not inconsistent with current reporting patterns as the increase in reporting year on year does appear to be reducing in magnitude. This may herald a levelling-off of reporting hence the assumption made here. It should also be noted that policy changes such as the introduction of the Outcomes Framework domain 5 overarching indicator looking at reporting rates and severe harm and death incidents may result in greater scrutiny on patient safety and therefore more focus on preventing incidents, reducing the upwards trend in reporting.

5.6 Given the above, great care should be taken in using these figures. They are only illustrative and are based on a particular scenario, which may not happen.

5.7 We must acknowledge a risk of implementing this requirement for openness that could have wider costs. This applies to whatever mechanism of requiring openness is chosen, provided it involves some form of punitive consequence, for individuals or organisations, from not being open.

5.8 When an error is occurs, in many cases the clinicians involved will be faced with a choice, to either report the error to their organisation's incident management systems or not. We expect and wish to encourage reporting, as it is the primary mechanism by which learning and improvement will occur. At present, there is a further expectation that when an incident is reported, the patient involved is also informed. This is reinforced by the variety of levers discussed earlier. Informing the patient is not an easy thing to do though. Admitting to making a mistake or being involved in an error or incident is difficult at the best of times, and this is much more difficult when admitting involvement in an incident to a person who has been or cares about someone who has been harmed because of that incident.

5.9 While it is contrary to national policy and runs counter to various requirements in regulation, a health care worker involved in a patient safety incident could choose to report the incident to their local incident management system, but not tell the patient or their loved one. The health care worker could essentially take the risk that the benefit to them of not having to have a very difficult conversation with an affected individual outweighs the risk of falling foul of one of the existing requirements that apply regarding openness. If a health care worker knows there are even more negative consequences to not telling affected people about an incident having reported it to their local systems (i.e. this new contractual requirement), they may be even more likely to decide that the risk of the consequences outweigh the positive benefits of reporting the incident to their organisation's incident management system. Put simply, the more potential punishments that are associated with an error or incident, the more likely a person is not to report it at all – therefore not only does the patient not get told, the incident may not even be reported. The introduction of an additional requirement could therefore result in a reduction in overall reporting. This could have knock-on effects on learning, improvement and ultimately the safety of health care.

5.10 While we cannot discount this risk, there are a number of mitigating factors that should reduce it. Reporting is a key facet of building a safety culture. Its importance has been clearly and unambiguously communicated over a number of years. We intend to re-emphasise its importance by including a measure of overall levels of reporting, which we want to see increase, in the overarching indicator of Domain 5 of the Outcomes Framework. Reporting serious incidents to CQC is an explicit CQC registration requirement.

5.11 The proposed mechanism for requiring openness is also organisational, rather than individual. The proposed consequences of not being open are for the organisation as a whole, not the individual involved. This means there are no more potential punishments associated with an incident for the individual than there are now. Instead, the organisation is itself incentivised to ensure its employees are fully supported to be able to have those difficult conversations with affected patients and their families. This should mean that there is no additional consequence for individuals and any consequences are for the whole organisation, which is unlikely to be collectively disincentivised by the prospect of disclosure as the disincentive is only an individual one.

5.12 In any case, due to the lack of information on the current level of openness and disclosure, and the lack of any evidence for the above potential risk about additional requirements leading to reduced reporting, we are unable to quantify this theoretical risk.

5.13 Because of the uncertainties with the extent of non-disclosure, we must acknowledge two further risks with this policy. At one extreme, it may be that there is almost no problem with non-disclosure in the NHS. Commissioners may receive hardly any reports of non-disclosure and this could mean that the policy is redundant. Alternatively, we may have underestimated the scale of the issue and discover that non-disclosure is a significant problem. This could result in there being a substantial cost to the NHS in implementing this policy that we have not anticipated. Both these risks support implementation of a policy of this type however. The contractual requirement is responsive to the scale of the problem that exists. If there is no problem, there will be relatively little activity required to implement it and the costs will be very low (as will the benefits). If on the other hand, the problem is significant, there will be large costs in requiring openness, but there will also be considerable benefits, both in terms of reduced personal anxiety and concern, but also in the wider development of an open reporting and learning culture.

6. Equality Impact Assessment

6.1 See separate document for equalities impact assessment

6.2 There are no anticipated disproportionate impacts on rural communities, or impacts on human rights

E. Option 3

1. Mechanism

1.1 The policy requirements for option 3 are the same as for option 2, including the mechanism, evidence base and specific impact tests. The difference in option 3 lies in the contractual requirements and therefore the costs and potential benefits that could be achieved.

1.2 Option 3 would require all incidents that qualify for reporting to the NPSA via its NRLS to also be disclosed to the patient involved (and/or their family/carer/representative). This means moderate and severe harm and death incidents as with option 2, but also any incident involving low or no harm. It is in essence a simple principle in that if an incident is considered to meet the criteria that mean it should be reported to the NRLS (via local risk management systems if appropriate) then it is also considered to be something that should be shared with the patient involved.

2. Option 3 Impacts, Costs and Benefits

Benefits

2.1 To gain an indication of what the benefits of Option 3 might be in terms of reassurance and reduced anxiety, we adopt the same approach as that in Option 2. We multiply the £355 estimate on QALY for decreased anxiety (see earlier) by the number of estimated non-disclosed incidents, which we estimate as 6% - 49% of 1.1 million. This gives an estimate of 66,000 – 539,000 non-disclosed incidents. Multiplying by £355 per incident gives a range of £23.4m - £191m, with a best estimate (mid point) of £107m per annum.

2.2 We have already discussed the issues with quantifying the other possible benefits of increased openness due to the lack of reliable baseline data on the extent of non-disclosure and the issues with the evidence base. Again, there is a potential benefit from increased reporting and learning leading to safer healthcare, and a possible link to reduced litigation. However, the uncertainties about the effects here mean we cannot quantify any particular benefits in these areas.

Costs

2.3 All the costs outline for option 2 apply to option 3 but with an additional burden in relation to the greatly increased activity required to meet the requirement. There is also a possible detrimental impact or cost associated with this increased openness as outlined below.

2.4 Turning to the quantifiable additional burden on the NHS first, we have already explained how the number of moderate and severe harm and death incidents reported to the NRLS indicates around 73000 such events per annum[1]. There were in the same period 259,455 low harm incidents and 763,487 near miss incidents. Using the NAO's 2006 report, we could estimate under-reporting and therefore estimate a 'true' figure for such incidents. However as argued earlier, if an incident is not reported it is very unlikely it would ever come to light, either in the form of being disclosed to the patient or as a contract breach. This is even more unlikely with low and no harm incidents, so we will use the NRLS figures as our estimate. This gives a total number of incidents of almost 1.1 million

2.5 Using the same cost assumptions as in option 2, which suggest a cost of up to £100 per apology, the overall burden of option 3 would be over £110 million. (It could of course be the case that if the volume of apologies becomes very large then there may be some economies of scale and therefore the unit cost could reduce from £100, but we cannot really estimate how much this might fall by). As detailed in option 2, however the actual additional burden of the requirement only relates to those cases where there is no openness already. For moderate, severe harm and death incidents, this additional burden assumed due to the impact of the requirement itself, was between £0.4m and £3.6m (an additional 6%-49% of moderate, severe and death incidents apologised for). Factoring in low and no harm incidents on top of this however is a completely new requirement and so the additional burden is actually around £103-106 million ((4380 or 35,770+259,455+763,487)x£100).

2.6 Turning to the costs associated with breaches of the requirement, we will again use the same assumptions outlined in option 2, which suggested a cost of £478 in resolving each breach of the requirement. Again using the NAO estimate of 6%-49% non-disclosure as our range for the total number of breaches, this suggests a possible total range of 66,000 to 539,000 breaches and therefore a cost of between £31.5m and £258m to resolve these breaches via contract management.

This is in addition to providing the disclosure, which still must happen, bringing the total to between £38.1m and £311.5m.

2.7 In addition to these monetary costs, feedback to the NPSA when they were developing their *Being Open* policy [7] identified several problems if it became necessary for low and no harm incidents to be discussed with patients, their families and carers, including:

- added stress to patients and potential loss of confidence in the standard of care;
- negative effects on staff confidence and morale;
- decreased public confidence in the NHS.

2.8 In addition, it was widely believed that communicating prevented and 'no harm' patient safety incidents was impractical, adding to staff workload and potentially interrupting their ability to provide patient care. We have not attempted to quantify these additional costs.

3. The exchequer costs of Option 3 falling on the public sector

3.1 Table 2 below identifies the costs of option 3 per year assuming the number of incidents rises by 10% for the first 3 years then stays level. We have taken the mid-point between our two estimates of non-disclosure (6% and 49%) as the level of non-disclosure assumed.

Year	1	2	3	4	5	6	7	8	9	10
Incidence of all incidents	1100000	1210000	1331000	1464100	1464100	1464100	1464100	1464100	1464100	1464100
Total annual cost (m)	**£174.85**	**£185.83**	**£197.50**	**£209.90**	**£202.80**	**£195.94**	**£189.32**	**£182.91**	**£176.73**	**£170.75**
Total annual benefit (m)	**£107.39**	**£114.13**	**£121.30**	**£128.92**	**£124.56**	**£120.35**	**£116.28**	**£112.34**	**£108.54**	**£104.87**
Net benefit (m)	**-£67.46**	**-£71.69**	**-£76.20**	**-£80.98**	**-£78.24**	**-£75.60**	**-£73.04**	**-£70.57**	**-£68.18**	**-£65.88**

3.2 There should be no additional costs for Local Authorities and Government Offices. The burden on the Department in introducing this requirement will be borne as part of normal activity. There are no capital costs.

3.3 Note the NHS costs above are not presented on an opportunity cost basis. This can be achieved for NHS costs by multiplying the costs shown by 2.4.

4. Risks and Assumptions

4.1 The risks and assumptions set out in relation to option 2 apply here, but noting the basic assumption that an increase in the number of incidents that are subject to the openness requirement will produce a linear increase in both the costs and the benefits of the policy. This assumption seems reasonable but is not based on direct evidence and may prove false. For example, there may actually not be a linear increase in benefits due to reduced anxiety for patients as in many cases, particularly with no harm incidents, patient anxiety may well increase once they are made aware of an incident that they would otherwise have been oblivious to.

4.2 An underlying risk with this option is that the large increase in burden represented by option 3 in terms of the activity that is required to meet the contractual terms will prove impossible for organisations to deliver. If this is the case and breach of the requirement becomes widespread it is likely that both commissioners and providers will come to perceive the requirement as undeliverable and will cease to take it seriously. This will mean the benefits of the policy will no longer be realised and indeed there may be detrimental impacts on openness even in cases of more significant harm. This could have knock on effects on the overall culture of open reporting and learning, and therefore detrimental effects on patient safety in general. Given the size of the burden that option 3 represents this is not an unrealistic scenario.

5. Equality Impact Assessment

5.1 See separate document for equalities impact assessment

5.2 There are no anticipated disproportionate impacts on rural communities, or impacts on human rights

F. SUMMARY AND WEIGHING OF OPTIONS

1. Option 1 will cost nothing but will have no impact on the problem of non-disclosure therefore potentially leading to continuing distress, anxiety and damage to patients their families and carers as well as potentially damaging the ability of the NHS to learn from errors

2. Option 2 will involves a cost to the NHS of £11.6m in the first year and £125.2m over 10 years. These incorporate the cost of contract management and an estimated increase in activity to reflect additional disclosure of incidents and are a pressure on the NHS. Balanced against these are benefits of £7.7m in year one and £76.9m over 10 years due to reduced anxiety and uncertainty for patients. It should be noted these benefits are not NHS-specific. There could also be unquantifiable benefits in terms of increasing reporting and learning leading to reductions in patient safety incidents, and reducing anxiety and increasing satisfaction amongst staff due to greater support being received from their employers.

3. Option 3 will involve a cost to the NHS £175m in year one and £1,887m over 10 years (depending on the prevalence of non-disclosure). It will, if we assume a linear relationship between the number of relevant incidents and the level of disclosure that will happen, have the greatest impact on non-disclosure and therefore the greatest benefit as all incidents will be disclosed. The benefits are estimated as £116m in year one and £1,159m over 10 years (note these are not direct benefits to the NHS). However, it is arguable that this additional disclosure of low and no harm incidents is not necessarily beneficial as set out in the section above. In particular, there are likely to be some patients who would not wish to be made aware of near miss incidents that may only serve to increase anxiety at no extra benefit, as well as impacting on staff morale etc. In addition, the huge burden of option 3 seems likely to undermine the practicality of actually delivering the requirement, leading to widespread breach. This will likely lead both commissioners and providers to view the requirement as undeliverable leading to openness actually decreasing as people cease to take the issue seriously.

G. Conclusions

Option 2 is currently the preferred option. It is represents a significantly lower cost to the NHS than option 3, but delivers the coalition agreement and the commitment to implement a contractual requirement for openness unlike option 1. It also stands a good chance of delivering improvements in disclosure. It builds on tried and tested contract management processes and is therefore likely to be relatively simple to implement, especially if supported by clear guidance from the Department.

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No.	Legislation or publication
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