Building a culture of candour

A review of the threshold for the duty of candour and of the incentives for care organisations to be candid

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ADVANCING SURGICAL STANDARDS

Executive Summary

1. Put simply, candour means the quality of being open and honest. Patients should be well-informed about all elements of their care and treatment and all caring staff have a responsibility to be open and honest to those in their care. It follows then that care organisations should have and sustain a culture which supports staff to be candid.

2. Medical treatment and care is not risk free. Errors will happen and nearly all of these will be due to failures in organisational systems or genuine human errors. A duty of candour on organisations, registered with the Care Quality Commission, means that they must ensure that patients, and where appropriate their families, are told open and honestly when unanticipated errors happen which cause a patient harm above a predetermined threshold.

3. The evidence we have heard reaffirms what we already know: that when things do go wrong, patients and their families expect three things: to be told honestly what happened, what can be done to deal with any harm caused, and to know what will be done to prevent a recurrence to someone else. Health and care organisations have a responsibility to ensure that all of these are reliably undertaken.

4. Candour cannot be an 'add on' or a matter of compliance; candour will only be effective as part of a wider commitment to safety, learning and improvement. This will require a considerable commitment to supporting staff through induction, training, and processes of review and implies inculcating a 'just culture' focused on learning and improvement and avoiding the temptations of defensiveness and blame.

5. Leaders within health and care organisations have a responsibility for ensuring that both the organisational commitment and the resources for building a culture of candour as part of a wider culture of safety, learning and improvement are in place. This means:

    a. Developing or adopting a process for ensuring candour / open disclosure. The Australian model process set out in chapter one is, we believe, a good basis for developing local approaches.

    b. Putting in place systems and processes for 'closing the audit loop' to ensure that concrete action follows on from learning.

c. Training and supporting staff in disclosing unanticipated events in patient care.

6. It is vital that this happens across primary and community care settings as well as secondary care. It applies to mental health as well as to physical health. We are aware that the rate of reporting of unanticipated events which cause harm to patients is significantly variable across these care settings and it also our view that the systems for learning from these events are not yet strong enough for there to be confidence that organisations are doing all that they can to improve reliability and reduce the risk of harm to patients.

7. Our first recommendation is therefore:

Recommendation 1: A duty of candour requires a culture of candour, and this requires all organisations registered by the CQC to:

- **Train and support staff to disclose information about unanticipated events in a patient's care and to apologise when appropriate;**
- **Improve the levels and accuracy of reporting patient safety incidents so that this information is used as the basis for organisational learning and not for criticism of individuals; and**
- **Close the 'audit loop' by spreading and applying lessons learned into practice and publicly report these.**

8. There are a number of definitions of 'harm' that are used for different purposes. This can lead to confusion and some of the language of definitions can be positively unhelpful for talking to patients. We would like to see greater alignment of definitions over time. Ahead of that, we believe that it is in the interests of patients, families and providers of care that the organisational duty of candour applies to all harm that is not defined as 'low'. Our second recommendation is therefore:

Recommendation 2: The duty of candour should apply to all cases of 'significant harm'. This new composite classification would cover the National Reporting and Learning System categories of 'moderate', 'severe' and 'death'; harm that is notifiable to the Care Quality Commission; and would include 'prolonged psychological harm'. This is in line with the 'Being Open' guidance.

9. We recognise that identifying harm can be a matter of judgement and interpretation, particularly at the lower end of the scale. Arrangements should

already be in place locally for providers to work with commissioners to agree the response to harm events, and where these arrangements are not in place or need to be reinforced, this should be addressed urgently in order to support implementation of the duty and of the wider safety culture to which it contributes.

10. A statutory duty on organisations is an important step forward. The duty should bear consequences, and the Care Quality Commission will have an important role to play in ensuring that it regulates care providers in respect of candour in a thorough and proportionate manner. This is likely to mean looking at a number of different sources of evidence, including how well an organisation identifies and responds to harm, and how it supports staff to disclose harm to patients and their carers. It is also likely to mean looking for patterns in organisational behaviour rather than one-off breaches (though stark cases will of course merit particular scrutiny).

11. Over the long term, we would encourage the Government to consider how it can ensure that the legal system is most able to support a culture of candour. In particular, it could be helpful to minimise the possibility that explanations given as part of a process of candour or open disclosure are then used in evidence to support an admission of negligence.

12. It will be important for national organisations to work closely together, and we think there is scope for closer co-operation at national level to promote candour and to ensure the duty is being discharged well. We believe that one of the most powerful drivers of organisational behaviour is reputation, and national bodies should make use of this in their work. This is likely to be a relatively stronger force for change than adjustments to liability cover. Our final recommendation is therefore:

> **Recommendation 3: The focus of any sanctions on organisations found to be in breach of the duty should have impact on the provider's reputation. The various options for involving the NHS Litigation Authority, including but not limited to reimbursement, should be explored in consultation. National organisations (including the NHS Litigation Authority, the Care Quality Commission and NHS England) should set out how they will:**
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> - **Share intelligence about breaches of the duty of candour;**
> - **Incentivise candid behaviour by organisations through co-ordinated action, including commentary within published reports on the findings for individual care organisations;**

- **Ensure proportionate enforcement action is taken by commissioners and the Care Quality Commission in the event of breach; and**
- **levy any financial sanctions on organisations who fail to be candid.**

In consulting on incentives relating to reimbursement of litigation costs, the Government should take account of the advantages and disadvantages outlined in this report, and work to ensure that future incentives form part of a coherent framework. These measures should be subject to an appraisal of how they have affected the behaviour of decision-makers in provider organisations.

13. Candour is essential for patients and their families. It is the responsibility of professionals, care organisations and the national bodies that support them to ensure that they have in place, and can sustain, a culture of candour.

14. The statutory duty on organisations provides a powerful signal of what is considered essential and should act as an important catalyst for care organisations to improve their systems and commit to a learning culture for their staff.

Introduction

Dear Secretary of State,

When you asked us to undertake this review, we began with two questions.

1. Should the threshold for the statutory duty of candour for organisations be linked to serious injury and death or to serious injury, death and moderate harm?

2. How might the proposal that the NHS Litigation Authority be given the discretion to reduce or remove indemnity cover in cases where a Trust has not been candid with patients or their families be made to work?[1]

As the thoughtful and often passionate contributions of our expert witnesses have helped us to understand, these apparently simple questions harbour a number of complex issues. Along with many of those who provided evidence to the review, we believe that a duty of candour can make an important contribution to creating a culture of openness and honesty which always places the safety and the needs of the patient and family above the reputation of the organisation.

This culture requires organisations to support their staff to report unanticipated events which may have harmed a patient and for staff to know that when they do so, they will not be blamed or penalised. It also means that when something has happened which has harmed a patient, the patient is given full disclosure of what happened and staff are supported in how to provide a sincere apology, if that is what is required, and to put it right if at all possible.

We were mindful of the Professor Don Berwick's report to the government last year, *A Promise to Learn. A Commitment to Act*. We see many parallels in his advice and the work of our group. We want to build on his recommendations and reaffirm that a culture of openness and honesty requires a full commitment from our health and care organisations to create and maintain effective systems of learning and improvement. We do not underestimate how difficult it can be to take the learning from a single event and spread this across a large organisation which may have a staff of many thousands. Similarly spreading such important lessons across the wider healthcare system is daunting. These challenges cannot ever be a justification to hold back from placing the highest expectations on organisations and their leaders to commit through their behaviour and actions to place learning and improvement amongst their highest priorities. Patients and their families want to know that when things do go wrong not only is every effort made to put them right for them but every effort is made to prevent similar incidents happening again to somebody else.

[1] See Annex A for our terms of reference.

We should be ambitious about what can be achieved for patients. That is why the first part of the report is about 'what we should aim for'. It is unashamedly aspirational. Achieving a culture of candour also means recognising the challenges and the day to day realities of providing care: ambition requires realism, and an understanding (but not an acceptance) of the issues captured in the second part of the report under the heading 'what we must reckon with'. In this part of the report we also address the important question of definitions as it relates to the setting of thresholds.

We have been very fortunate in having support from a number of colleagues from across the NHS and a number of other organisations in developing this report. The witnesses to the review gave generously of their time, and a list of them can be found at Annex B. We would also like to thank those people who directly supported us in our review.

Much (but by no means all) of the discussion and evidence for this review concerned care in the NHS and in secondary settings, and this is reflected in the report. We are also, however, keen to underscore the importance of candour in other healthcare settings and in social care. It is our view that patients and service users in primary, community and social care should be treated with candour just as much as those in secondary care. We therefore support the Government's approach of doing this through the Care Quality Commission registration process. It is important that all registered organisations recognise their responsibility for upholding the duty of candour. In parallel with this review, the 'Think Local, Act Personal' Quality Forum has been developing advice to support the Care Quality Commission in applying the duty of candour in social care.

We are at a historic crossroads for patient safety. There are a number of respects in which our health and care system leads the world in its approach to safety, and we have a lot that we can build upon. It is, however, also the case that we are only in the foothills of achieving a truly comprehensive, systematic culture of safety, learning and improvement in England. There are some basic things that still need to be improved: the levels and accuracy of reporting of safety incidents are far from where they need to be; all too often the audit loop is not closed and safety lessons are not acted upon; and we need to do far more to make discussion of harm a much more usual part of the way we think and talk about health and care services with the people who use and work in them. We are, however, encouraged by the attention now being given to assuring high standards of care and safety and by the progress which is being made.

What is needed is a culture of openness and honesty, stimulated by a duty of candour, which is wholeheartedly adopted by organisations and individuals. This will enable our patients to be reassured that when things do go wrong, we will learn and we will improve.

Sir David Dalton **Prof. Norman Williams**

Chapter one

What we should aim for: a culture of candour

1. To understand the importance of candour in healthcare, we need to take a step back and look at how society has changed in recent decades, and at the effects this has had and is still having on the services we provide. Our focus is on the duty of candour that the Government has decided to put in place for organisations registered by the Care Quality Commission (ie those providing health and adult social care services) and so we need to begin with the changing place of institutions within our society.

A changing society

2. It is commonplace that we now live in a 'post-paternalist' age; one that is less trusting of authority and of institutions, and which places a greater value on self-determination and choice than was once the case. This is broadly true, although the reality is perhaps a little less clear-cut than the labels suggest. Just as the imagined 'age of paternalism' was never quite as closed off to individual decisions as some might think, so our apparently 'post-paternalist' age contains some important remnants of its predecessor. It would not be right to say that trust in institutions has ended; but there is no doubt that institutions and those who oversee them recognise the need to look again at how trust is earned and maintained, and recognise the need to question some of the assumptions they once held about how best to do that.

3. In part this has been driven by technological change: we are able to access more information and opinion than was once the case, and so some of the older hierarchies of understanding and insight do not hold true: it is no longer clear who always 'knows best'. These changes have also made it far less easy to hide away or avoid confronting failures in our public institutions, caught as they are in the persistent gaze of a 24-hour, web-enabled media serving a public eager to know more, and to know instantly.

4. The change in our society is, however, about more than how we use technology. There is a greater willingness to question and to challenge authority, and to doubt its pronouncements. Throughout the public sector and beyond this is leading to an understanding of the need for new forms of public engagement – different types of conversations – with individuals and with groups of people.

5. These changes are to be welcomed. Trust that is earned rather than assumed is likely to be stronger and more enduring; and for many people in clinical and managerial roles, a relationship with patients and the public that is about partnership rather than paternalism accords more readily with their life experience

and values. That said, there is no doubt that these wider changes in social attitudes, which are likely to intensify as time goes on, present challenges and will require us to change the ways in which services are organised and delivered.

Society, candour and care services

6. This shifting landscape of ideas and relationships is the context for 'candour'. Much of what is changing and needs to change in the way health and care services work with the people they care for is reflected in the idea of candour. A critical test for our trust in any institution is what happens when things go wrong. Openness is easy enough when all is well, but far more challenging in cases of actual or possible harm. Candour has therefore become an important – for some even an emblematic – issue.

7. When we look specifically at trust in the medical profession, candour seems all the more important. Levels of trust in doctors are extremely high. An IPSOS-MORI survey in 2011, found 88% of people surveyed said that they trusted doctors to tell the truth[2]. Many other professions lagged a long way behind. It would, however, be dangerous to interpret these results complacently. While they show that the NHS is clearly doing a great deal to earn and keep the trust of patients – a tribute to the hard work and also the integrity of clinicians and those who support them – it also shows that expectations of candid behaviour are very high.

8. This may also help to explain why some people react very strongly when they feel that clinicians and the healthcare providers they work for have <u>not</u> been candid with them. The high level of trust in doctors that IPSOS-MORI identified (and have mapped over a number of years) intensifies the sense of disappointment when things go wrong. A number of witnesses to the review commented that it can be the way that a complaint or dispute is handled as much or even more than the original fault that creates the breakdown of trust. This leads us to the somewhat paradoxical conclusion that the high levels of trust in clinicians makes it even more important to ensure higher levels of candour than might otherwise be the case.

9. As we know, a number of high-profile failures in care services in recent years – most obviously the case of Mid Staffordshire NHS Foundation Trust – have led to profound questions being asked by the NHS itself but also by the public about the ways in which harm in healthcare can be prevented and about how, when that is not possible, it can be acknowledged and act as a source of learning and improvement.

10. In short, the specific questions we have been asked about candour form part of a wider context of reflection and change. We will need to test the answers we come

[2] See http://www.ipsos-mori.com/researchpublications/researcharchive/2818/Doctors-are-most-trusted-profession-politicians-least-trusted.aspx

up with against a number of the most important elements of this process of wider change. First, the need to reinforce a 'conversation of equals' between people using services and those providing them. Second, the need to promote a culture of safety and learning rather than defensiveness and blame. Finally, and perhaps most challenging of all, candour needs to form part of the commitment of organisations to act with humanity rather than narrowly perceived self-interest.

Candid conversations- treating patients as equals

11. A culture of candour will not be brought about by legislative requirements and duties alone. If we are to see the kind of sensitive, clear and candid conversations that patients deserve, that is most likely to happen as part of a wider commitment to having good conversations of all kinds with patients. A number of witnesses to this review commented that having a candid conversation when something went wrong was far easier if it formed part of an ongoing clinical relationship in which issues of risk and consent had been clearly discussed from the outset.

12. Modern medicine offers an abundance of hope, but very few absolute certainties. One of the comforts (some would say benefits) of paternalism was to obscure this lack of certainty for patients. This is no longer sustainable, and it means that being candid when things go wrong needs to be grounded in being honest about what could go wrong from the start. Better conversations about risk and the potential for harm are essential for fostering a culture of candour, both as a means of preparing patients should something bad happen, and to encourage clinicians and healthcare organisations to do the right thing when errors occur.

13. One of the possible consequences of a stronger role for candour in healthcare is greater openness and public understanding about the risks of harm inherent in clinical care. . This can only be a good thing. Clinical care is inherently risky, and while organisations and individual clinicians must do all they can to minimise those risks, it will never be possible to eliminate them fully. Candour will therefore always be necessary, and most clinicians and all organisations will find themselves in the difficult position of having to discuss harm or potential harm with a patient.

14. Making candid conversations good conversations depends on recognising the different perspectives of patients and providers of care. In one sense this is simply a matter of being open to the different ways in which different people find it helpful to communicate and receive information about their care. There are also, however, some important differences in relation to the perception of 'harm'.

Different understandings of 'harm'

15. The evidence we have heard from a number of different organisations has challenged some of the assumptions we began with about what counts as 'harm'. We will consider this issue in the round in the next chapter; but in thinking about 'what we should aim for' in respect of candour, we need to consider the perspective of patients and the public.

16. There is one obvious and important difference when it comes to the ways in which patients and clinicians perceive harm. By and large, and as a natural and expected aspect of their working life, clinicians and the people who support them see far more cases of harm than most patients. When a patient is harmed or a carer or family member sees someone close to them harmed, this is usually a unique or near-unique event for them, and they are not usually in a position to 'contextualise' such an event relative to other cases; nor should we expect them to do so. For clinicians there can be the opposite risk of over-familiarity, as even the most successful clinical teams will be responsible for errors that lead to harm. This means that while thresholds and definitions are a helpful support for healthcare organisations and their regulators to understand how well an organisation is doing in relation to safety, they are not a helpful way of starting a conversation with patients and carers when something has gone wrong.

17. As well as different perceptions of harm, there can be different pathways to a candid conversation. In the following chapter we will look at the most common clinical route to a situation requiring a candid conversation: the detection of patient harm as defined in clinical terms. This is not, however, the only scenario in which candour is required (although the most commonly cited models of candour tend to focus on clinician-perceived harm of this sort). Some harm is more easily perceived by patients and carers than by clinicians. This is particularly true of psychological and emotional harm, though this is by no means the only type. Patients and carers will almost always have something to say about harm that has been done to them that would add to the understanding of the incident. In situations where patients or carers initiate the conversation, whether as a formal complaint or as something less formal, it is vital that their perception of harm is taken seriously. While organisations and clinicians may not always agree that harm has been done, it is essential that they treat any patient-generated perception of harm as worthy of consideration, discussion and, potentially, further investigation.

18. We believe that the duty of candour must also be a duty to disclose information in cases where a patient or carer believes that harm has been done. Patients and service users have a right to a copy of the information held about them via a request

under the Data Protection Act to any organisation processing their personal data[3]. Candour goes wider than disclosure on request, but the attitude of an organisation to the disclosure of information that a patient requests is an important test of its overall attitude to candour, not least because this is one of the aspects of an organisation's culture of candour that is most visible to patients. Any request for information about potential harm should therefore be handled sensitively and candidly: the provider organisation, on being told that harm has potentially occurred, should be as concerned as the person who believes they have been harmed to establish the facts of the case and the lessons to be drawn from them. This approach provides a solid foundation for working in partnership with patients, family and carers to find the truth and, where necessary, to restore trust.

Candour, safety and improvement

19. A culture of candour is a culture of safety, and vice-versa. This fundamental interdependence helps to demonstrate the wider importance of candour, and the benefits it can bring to health and care organisations. By being honest with patients and carers, providers of care are far more likely to be honest with themselves; and that is the foundation for a culture of improvement. A recognition that it is right to apologise and explain when things go wrong requires, in turn, the ability to discern harm. Once organisations are explicit in their commitment to identifying harm and apologising for and explaining it to patients and carers, they are much more likely to want to learn from it. Apart from anything else, it is a whole lot easier to be candid with patients and carers about harm if an organisation is able to demonstrate that it is able to learn from what has happened. A common feature of complaints is that complainants want to be assured that what happened to them does not happen to others. We believe that candour can therefore act as a catalyst to 'close the audit loop' in relation to patient safety incidents so that lessons are learned and- crucially – applied.

20. We know that levels of reporting do not reflect the actual level of harm that occurs in healthcare, and that there are significant differences in reporting culture between different kinds of health care services – for example primary care shows particularly low rates of reporting considering the level of activity in this sector. The National Reporting and Learning System (NRLS) receives around 1.4 million reports a year (including 'no harm' incidents), with around 75% from secondary care. On average, most studies have found that reporting systems only receive reports of around 7–15% of all incidents that are identified through more intensive retrospective review processes. There are 4,000-5,000 reports annually from GP practices to the NRLS,

[3] For further details see the guidance issued by the Information Commissioner at http://ico.org.uk/for_the_public/personal_information.

which as a proportion of care episodes is low; although we know that many practices undertake significant event audits to learn from both positive and negative examples of care. For all these reasons it is clear that levels of reporting do not provide an accurate measure of the actual amount of harm that occurs in healthcare- indeed they are not designed to measure the level of actual harm. It is also clear, however, that to make a serious shift to a culture of candour would require a significant increase in the level of reporting of patient safety incidents, both to patients and to reporting systems.

21. For candour to perform this role, and to act more widely as a catalyst for improvement, it is vital that candour is understood in context by staff and by board members as an integral part of a culture of safety. This will not happen spontaneously. Time, money and effort have to be invested in education and training to reinforce the importance of candour and to provide clinicians and others with the skills and confidence to have good candid conversations based on insight and experience, and with the support of their peers and their organisation. As we have said, candid conversations are just one of the many 'good conversations' that the quality of health and care services depends upon. In training staff to have those conversations, provider organisations, Royal Colleges, Health Education England and others with a responsibility for ensuring excellence in education and training should ensure that situations requiring candour are well represented. Indeed, such a culture should be instilled at undergraduate level and we would urge medical and nursing schools to include appropriate modules in their curricula.

22. A culture of safety depends upon clinical and other staff in health and care services; and they in turn depend on organisational and peer support that is there for them when times are difficult and when mistakes are made. We endorse the general distinction between 'errors and violations' that is often made in the academic literature that distinguishes between genuine unintentional acts of omission or commission that can lead to harm (errors) and the much rarer acts of wilful neglect or deliberate breach of acceptable practice (violation)[4]. When mistakes are made and harm is caused, the primary duty of clinicians and their organisations is to put things right and to be open and honest with the patient and their family and carers. In addition to this primary responsibility, a provider organisation also has a responsibility to look after the person or team that has made the mistake or mistakes in question. The impact of such errors can be devastating on individuals and teams. Organisations need to put in place arrangements to support staff in this unfortunate position. They should do this because it is the right thing to do, and

[4] See *Errors, Medicine and the Law* by Merry and McCall Smith, 2001 and also *A promise to learn – a commitment to act: Improving the Safety of Patients in England,* Berwick and the National Advisory Group on the Safety of Patients in England, 2013, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf .

they should recognise that this means supporting staff emotionally as well as in more formal terms. An additional

23. benefit of behaving in this way is that staff and teams will be far more likely to behave in a candid way.

24. Leadership is vital. A consistent and visible commitment to support and learning rather than blame and punishment from the leaders of health and care organisations and from regulators is likely to lead to a far greater willingness from staff to act in a candid manner when something goes wrong. Inevitably a statutory duty of the kind we are discussing is going to be seen in quite negative terms – the focus will be upon 'breaches' and 'consequences' and that is no bad thing. The challenge for leaders, however, is not just to ensure that they have the arrangements in place to ensure that their organisation is prepared against breaches of the duty, it is also to translate the requirements of the duty into actions that form part of a positive culture of learning, safety and improvement throughout their organisation[5].

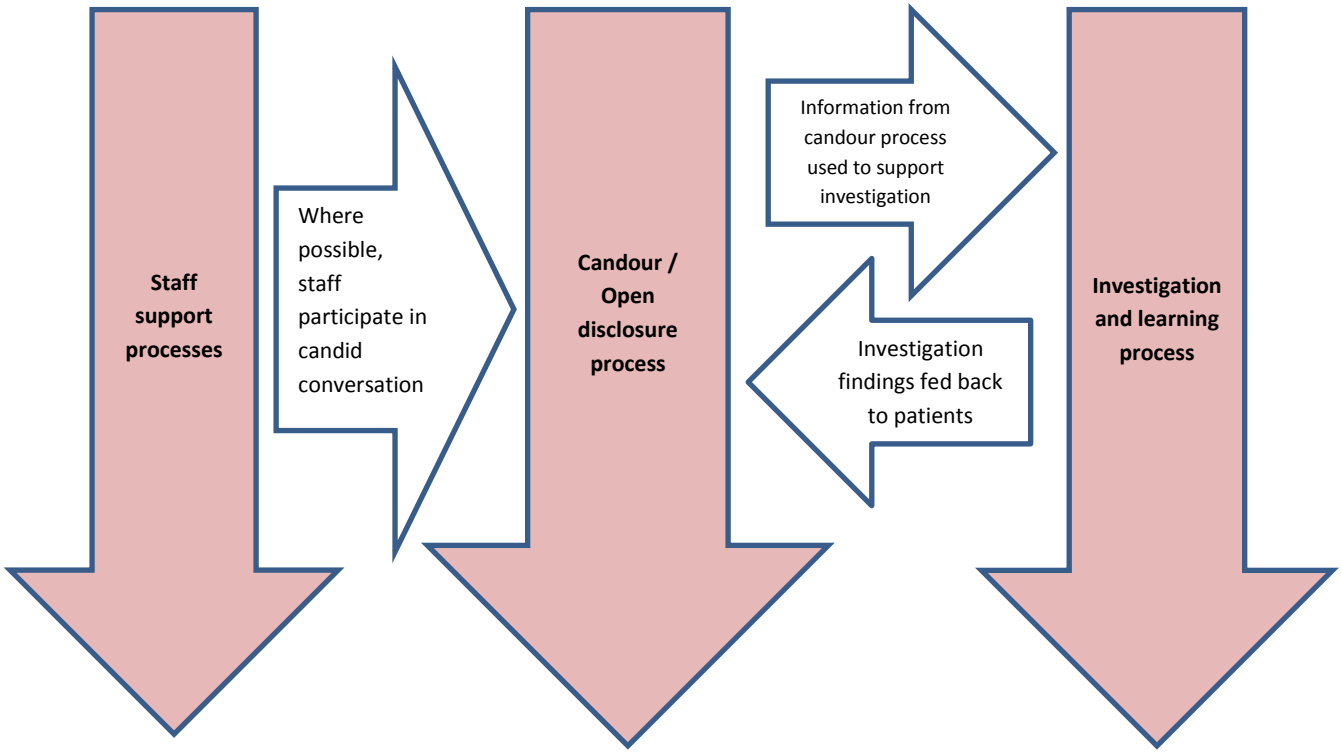
25. In addition to leadership, a candid culture requires strong peer support to function effectively. We believe there is a lot to be said for locally developed means of supporting candour and openness about harm, including mechanisms to ensure constructive review and challenge of decisions about disclosing harm as a basis for further learning and improvement. We also believe that where practitioners are isolated, they are likely to need support to ensure that they are candid. We believe there is a particular need to ensure that single-handed general practitioners are supported to be candid and to learn lessons from incidents of harm.

26. Where an incident is a case of 'violation' rather than 'error', it is right that the necessary regulatory and possibly legal consequences flow from that for the individuals and organisations concerned. A wider culture of candour is likely to make it far less easy to keep such cases quiet, as it should become far more normal to discuss situations where actual or possible harm has been done. If we are able to put in place a culture which is more open to the possibility of error and harm, and where concerns raised by staff are heard and taken seriously in a balanced and open manner as part of a broader commitment to learning and safety, these are more likely to be dealt with in a more constructive and less adversarial manner than is often the case currently. We believe it is right that when problems are raised, they are heard, addressed and acted upon, and seen as vital information for improvement, rather than as irritation to be managed defensively. Even in a culture of greater candour, effective whistleblowing and complaints systems would continue

[5] The experience of six early adopters of 'communication-and-resolution' programmes in the United States provides evidence for the importance of leadership and of senior champions. See Mello, Boothman et al 'Communication-And-Resolution Programs: The Challenges And Lessons Learned From Six Early Adopters', *Health Affairs,* January 2014, pp20-29.

to be vital parts of an open and transparent culture that is committed to improvements in safety and quality.

27. International evidence reinforces the importance of seeing candour (or 'open disclosure' as it is often termed in other countries) as part of a wider culture of safety and improvement[6]. Of the different models and processes we have seen from around the world, one of the most thorough and well-structured was the Australian Open Disclosure Framework. We were particularly impressed by the way in which the Australian framework explicitly integrates the candour (or 'open disclosure') process with both support to staff and the investigation and organisational learning processes. The diagram below (which is a simplified version of the Australian Framework) highlights the benefits for learning and for candour of thinking of candour as part of a wider system of learning, improvement and support[7].



[6] For a helpful summary of recent evidence on candour / open disclosure, see *Open Disclosure: A Review of the Literature,* Australian Commission of Safety and Quality in Health Care, 2008 see http://www.safetyandquality.gov.au/wp-content/uploads/2012/02/Open-Disclosure-A-Review-of-the-Literature.pdf. *Literature review: incident disclosure research, policy and legal reforms since 2008,* Australian Commission of Safety and Quality in Health Care, 2011 see http://www.safetyandquality.gov.au/wp-content/uploads/2012/02/Literature-review-incident-disclosure-research-policy-and-legal-reforms-since-2008.pdf. For a specific case study from the United States, see Kraman, Cranfill, Hamm and Woodard (2002) 'The Lexington Veterans Affairs Medical Center', *Journal of Joint Commission on Accreditation of Healthcare Organizations,* 2002, pp646-650.

[7] See the *Australian Open Disclosure Framework,* Australian Commission on Safety and Quality in Health Care, 2013 - http://www.safetyandquality.gov.au/wp-content/uploads/2013/03/Australian-Open-Disclosure-Framework-Feb-2014.pdf. The detailed schematic can be found on page 16.

28. Candour can be a powerful catalyst for improvement and safety. If an organisation takes the need for candour seriously, it will soon discover that it needs to do a lot more beside writing a policy and disseminating it. The duty is the starting point, and both a very helpful prompt to the majority of willing organisations and a means of tackling the unwilling; but no legal duty will ever produce by itself the necessary skill, commitment and support to make a culture of candour a reality for patients. Providers of health and care services registered by the Care Quality Commission, and those who lead them therefore need to take ownership of this agenda for themselves.

29. An important advantage of thinking of candour in the manner suggested above is that it emphasises the link between individual errors and the organisational factors that can often lay behind them[8]. While there can be a degree of individual responsibility when something goes wrong (and that is certainly how it feels to the practitioners concerned) it is vital for investigations of harm to consider the human factors in the context of team, organisation and system factors. This is not only because it is a fair and balanced way of understanding individual responsibility, but also because it provides a far firmer basis for understanding why harm has occurred and therefore of preventing future harm. Individual cases of harm, rightly considered, can provide insights into wider organisational issues that can contribute to harm, such as loss of notes, the poor management of resource pressures, and shortcomings in discharge processes.

30. These issues may not present an immediate and obvious impact on safety in themselves (and may even seem rather trivial in specific instances) but with the right understanding of the 'latent' factors that can be so critical to patient outcomes, they can be shown to be significant. A commitment to candour must mean a commitment to understanding and sharing the truth about a case of harm at an organisational as well as an individual level.

31. We believe that a particular focus should be given to taking action to improve safety in the light of incidents of harm: 'closing the audit loop' should mean putting in place a sustained improvement in safety for patients. This is something we believe that providers, commissioners and the CQC should look for when assessing how well an organisation is doing to create a culture of safety and improvement. At an organisational level, true candour entails a willingness to learn; and a true

[8] For the links between systems, organisations, teams and individual errors, see James Reason 'Understanding adverse events: human factors' in *Clinical Risk Management,* Vincent, C (ed) (1995). See also Vincent, C (2003) 'Understanding and responding to adverse events' *New England Journal of Medicine,* 348(11), 1051-1056. Walshe K, Shortell, S (2004) 'When things go wrong: how health care organizations deal with major failures' *Health Affairs,* 23(3): 109-118.

commitment to learning entails a willingness to change in the light of what is learned.

Compassion, humanity and candour

32. The obligations and challenges of candour serve to remind us that for all its technological advances, healthcare is a deeply human business. Systems and processes are necessary supports to good, compassionate care, but they can never serve as its substitute. It follows from this that making a reality of candour is a matter of hearts and minds more than it is a matter of systems and processes, important as they can be. A compliance-focused approach will fail. If organisations do not start from the simple recognition that candour is the right thing to do, systems and processes can only serve to structure a regulatory conversation about compliance. The commitment to candour has to be about values and it has to be rooted in genuine engagement of staff, building on their own professional duties and their personal commitment to their patients[9].

33. It is, of course, right to be clear about thresholds and about the enforcement of the duty, and we will have much to say on these matters in the following chapter; but we must not lose sight of the fundamental purpose of candour, which is to do the right thing for patients. It is that which must always come first.

Recommendation 1: A duty of candour requires a culture of candour, and this requires all organisations registered by the CQC to:

- **Train and support staff to disclose information about unanticipated events in a patient's care and to apologise when appropriate;**
- **Improve the levels and accuracy of reporting patient safety incidents so that this information is used as the basis for organisational learning and not for criticism of individuals; and**
- **Close the 'audit loop' by spreading and applying lessons learned into practice and publicly report these.**

[9] For the impact of a lack of an enabling environment for candour / open disclosure, see Mazor et al (2004) 'Communicating with patients about medical errors', *Archives of Internal Medicine* 164, pp1690-1697; Vincent (2003) 'Understanding and responding to adverse events' *New England Journal of Medicine* 348 (11) pp 1051-56.

Chapter 2

Making candour happen: what we must reckon with

Introduction

1. There are a number of challenges to implementing a culture of candour. There is the basic fact of human psychology and of organisational culture that it is often hard and unpleasant to admit that you have (or may have) done something wrong, especially when that has led to harm. It is precisely because this is often so difficult that leaving it to happen by itself can never work as a strategy for improvement. The statutory duty on organisations has the potential to be of great benefit as a means of reinforcing the commitment of organisations and individuals to doing the right thing.

2. Our purpose, then, in setting out some of the challenges to a culture of candour is not to provide excuses or to induce despair. We believe that it is possible for individuals and organisations to be candid when things go wrong. The challenges are real, but they can and should be overcome provided that they are recognised and actively tackled. This requires attention and action throughout an organisation. It also requires a real desire by an organisation – and in particular its leadership – to embrace a culture of candour, as set out in the previous chapter, and to do this as part of a wider commitment to a culture of safety and continuous improvement.

3. This doesn't mean that fulfilling the duty of candour should be voluntary or discretionary. The Government's choice of a statutory duty sends an unequivocal signal to the health and care system that this matters, a position that we resolutely endorse. Our hope is that organisations respond to this signal wholeheartedly, and make a reality of candour for themselves and the people they serve, and that they do this not simply because the law is changing, but because they see the value of it for the people who use their services. Bare compliance and vague endorsement will not be sufficient: a determination to really tackle the challenges will be required.

4. There are two broad types of challenge: those at the organisation / system level and those at the individual level. We take these in turn, dealing with the threshold issue in the first category.

System / organisation challenges

5. With the help of the witnesses to the review, we have identified the following challenges at system and organisation levels:

    - Definitions and thresholds (including what counts as a safety incident);
    - Ascription;
    - Bureaucratic burden;
    - Fear of litigation;
    - Potential for / fear of excessive regulatory response; and
    - Organisational reputation.

6. We will work through each in turn.

Definitions and thresholds

7. As we have seen, the differing perspectives of patients and clinicians can lead to very different understandings of what counts as 'harm', and this can make the use of thresholds, and terms such as 'low' or 'moderate' harm unhelpful as a way of structuring a conversation with a patient or their carer.

8. This does not mean that differentiating levels of harm is always unhelpful. There are legitimate reasons for grading harm, including supporting the analysis, categorisation and interrogation of incident report data and, therefore, the facilitation of learning. This has been recognised by the National Reporting and Learning System which uses such categorisations of harm. When it comes to learning and improvement, the fact that there are cases on the borderlines of the categories employed (an inevitability of any classification system) does not in itself invalidate the usefulness of the categorisation.

9. A number of different categorisations of harm exist and are employed for different purposes.

10. The National Reporting and Learning Service uses the following framework:

Grade	Definitions	Average annual figure reported to NRLS rounded
No harm	Impact prevented – any patient safety incident that had the potential to cause harm but was prevented resulting in no harm to people receiving NHS funded care. Impact not prevented - any patient safety incident that ran to completion but no harm occurred to people receiving NHS funded care.	900,000
Low	Any patient safety incident that required extra observation or minor treatment (first aid, additional therapy, additional medication) and caused minimal harm.	335,000
Moderate	Any patient safety incident that resulted in a moderate increase in treatment (return to surgery, unplanned readmission, prolonged episode of care, extra time in hospital) and which caused significant but not permanent harm.	85,000
Severe	Any patient safety incident that appears to have resulted in permanent harm (permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of wrong limb or organ or brain damage).	7,500
Death	Any patient safety incident that directly resulted in the death (related to the incident rather than to the natural course of the patient's illness or underlying condition) of one or more persons.	3,500

11. This framework has been designed to support reporting and learning. It therefore includes 'no harm' events, and while we would not expect organisations and practitioners in such cases to disclose the incident to patients, we would expect them to use such incidents as the basis for learning so that future harm is avoided.

12. One feature of this set of definitions that has been much discussed by the review group is the idea of 'permanence' to separate moderate from severe harm. While there is some value from a clinical perspective in making such a distinction, we do not think it is helpful from a patient perspective. Non-permanent harm can last a long time and can have a significant effect on the life of a patient (for example, by keeping them from working for a long time). In some cases 'moderate' harm of this kind does not seem very moderate in reality.

13. A broader, and simpler categorisation has been developed by the World Health Organisation.

Term	Definition
Harmful incident	A patient safety incident that resulted in harm to the patient. Replacing adverse event and sentinel event (e.g., the wrong unit of blood was infused and the patient died from a haemolytic reaction).
No harm incident	A patient safety incident which reached a patient but no discernible harm resulted (e.g., if the unit of blood was infused, but was not incompatible).
Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological.

14. There are two broad differences here to the NRLS categorisation. First, there is a single differentiation between incidents with harm and with no harm. Second, harm explicitly includes 'psychological' harm. While it potentially adds complexity, we think that it is important that prolonged psychological harm is included within the scope of the organisational duty.

15. The Care Quality Commission requires notifications from English NHS providers when certain incidents occur. The relevant regulations state that notification should apply to:

    a. any injury to a service user which, in the reasonable opinion of a health care professional, has resulted in—

        i. an impairment of the sensory, motor or intellectual functions of the service user which is not likely to be temporary,
        ii. changes to the structure of a service user's body,
        iii. the service user experiencing prolonged pain or prolonged psychological harm, or
        iv. the shortening of the life expectancy of the service user;

    b. any injury to a service user which, in the reasonable opinion of a health care professional, requires treatment by that, or another, health care professional in order to prevent—

        i. the death of the service user, or
        ii. an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).

16. The CQC notification definitions favour the use of the broader concept of 'prolonged' rather than 'permanent' and therefore appear to include at least some of the harm that the NRLS would categorise as 'moderate'. It also includes prolonged psychological harm[10].

17. Finally, we think there is a lot to commend the Australian Commission for Quality and Safety's set of definitions.

Term	Definition
Harmful incident	An incident that led to patient harm. Such incidents can either be part of the healthcare process, or occur in the healthcare setting (i.e. while the patient is admitted to or in the care of a health service organisation).
No harm incident	An error or system failure that reaches the patient but does not result in patient harm.
Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological.
Higher Level Response	A comprehensive open disclosure process usually in response to an incident resulting in death or major permanent loss of function, permanent or considerable lessening of body function, significant escalation of care or major change in clinical management (e.g. admission to hospital, surgical intervention, a higher level of care or transfer to intensive care unit), or major psychological or emotional distress. These criteria should be determined in consultation with patients, their family and carers. A higher-level response may also be instigated at the request of the patient even if the outcome of the adverse event is not as severe.
Lower Level Response	A briefer open disclosure process usually in response to incidents resulting in no permanent injury, requiring no increased level of care (e.g. transfer to operating theatre or intensive care unit), and resulting in no, or minor, psychological or emotional distress (e.g. near misses and no harm incidents). These criteria should be determined in consultation with patients, their family and carers.

[10] See *Notifications required by the Health and Social Care Act 2008,* Care Quality Commission, July 2013 - http://www.cqc.org.uk/sites/default/files/media/documents/statutory_notifications_for_nhs_bodies_-_provider_guidance_v6.pdf. For the relevant regulations see http://www.cqc.org.uk/sites/default/files/media/documents/care_quality_commission_registration.pdf

18. The division into 'higher level' and 'lower level' responses and the relatively broad nature of the 'higher level' response (inclusion of psychological harm and the avoidance of permanence as a criterion) is a helpful model. The 'higher level' category maps quite closely onto the NRLS categories of 'Moderate', 'Severe' and 'Death', though with the added advantage of including psychological harm and emotional distress. We were also attracted to the way in which the Australian model makes it possible for patients who are judged to require a lower level response to demand a higher level response if they believe it is merited, although we recognise that a measure of this kind could add to the complexity of a statutory regime.

19. At the level of individual professionals, the definitions are simpler. The regulatory codes essentially require the regulated professionals to disclose to patients and service users all incidents where harm is done regardless of the severity of the harm. One of the challenges for the organisational duty of candour is that it is framed in a way that serves to support and reinforce the discharge of the professional duty, even if its scope is not quite as wide.

20. As this brief tour of the terrain illustrates, there are a number of definitions available, and there is clearly the potential for confusion for individuals and organisations. We need greater consistency of definitions and their application if the new duty is to have the impact we all want to see, although we also recognise that even with a single set of definitions, it is not always straightforward or simple to categorise the harm caused by a patient safety incident.

21. The point of these definitions is to allow organisations to identify and manage risks and to learn when things go wrong. They are not specifically designed to promote or ensure candour. They are, however, established definitions and the NRLS definitions in particular are now widely used in the NHS, especially in secondary and tertiary care. Primary, community and social care are far less frequent users of such definitions, whether the NRLS or any others. One of the considerations that has preoccupied us has been the need to avoid excessive bureaucracy, and this has been an important factor in developing our view of definitions and thresholds. We believe that the threshold for the duty of candour should be rooted in the existing NRLS and CQC definitions, with some modifications that import features of some of the other definitions that will support the development of a culture of candour.

22. Our advice is that the threshold for the duty of candour should include what is classified as 'moderate' harm in the NRLS definitions. The territory we think that the organisational duty of candour should cover includes the 'moderate', 'severe' and 'death' categories as set out by the National Reporting and Learning System

and the incidents notifiable to the Care Quality Commission. These should be merged into a single category of 'significant' harm. In line with the CQC's definitions, this category would also include 'prolonged psychological harm'

23. This would give us a model as follows:

Term	Definition	Consequence for organisational duty of candour and for patient safety
No harm incident	An error or system failure that reaches the patient but does not result in patient harm – a 'near miss'.	No consequences: these incidents should be used for learning, but do not need to be disclosed to patients / service users.
Low harm	Corresponds with NRLS 'low' harm: Any patient safety incident that required extra observation or minor treatment (first aid, additional therapy, additional medication) and caused minimal harm.	Disclosure would be required under the professional duty of candour and in line with the 'Being Open' guidance. The incident should also be reported to the NRLS for NHS care. There would be no regulatory consequence on an organisation for a failure to disclose.
Significant harm	Corresponds with NRLS 'moderate', 'severe' and 'death', and with incidents notifiable to CQC with harm explicitly defined to include 'prolonged psychological harm' in line with CQC reporting practice. Any patient safety incident that resulted in a moderate increase in treatment (return to surgery, unplanned readmission, prolonged episode of care, extra time in hospital) and which caused significant but not permanent harm. Any patient safety incident that appears to have resulted in permanent harm (permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of wrong limb or organ or brain damage). Any patient safety incident that directly	Disclosure would be required under both the professional and the organisational duties of candour, with proportionate regulatory consequences for a failure to disclose harm of this kind.

	resulted in the death (related to the incident rather than to the natural course of the patient's illness or underlying condition) of one or more persons.	

24. Some witnesses to the review have argued strongly for including all harm within the organisational duty of candour. While this question was not in our original terms of reference, we think it is important to address it in our report. The main argument for this position is that it gives a clear and simple alignment with the professional duty (which applies to all harm). With organisations 'on the hook' for the same thing as the professionals who work for them, there will be a clear incentive for organisations to support the people who work for them to be candid at all times.

25. While we recognise the force of this argument, we do not accept it. It is possible for the professional and organisational duties to be mutually supportive without applying to exactly the same incidents. We have also been mindful of the fact that the organisational duty will provoke a regulatory response, and therefore needs to be applied in a proportionate way. While the level of harm is not a perfect measure of 'what counts', it does, if set at 'significant', help us to strike a reasonable balance between organisational initiative and commitment and regulatory oversight. It is, however, extremely important to be clear that in drawing the threshold at 'significant' we do not in any way think it is right for organisations to avoid, either actively or by neglect, supporting professionals to be candid in respect of all types of harm. The absence of a regulatory sanction for organisations should not be an excuse for a failure to provide the support and leadership required for candour to become a much more normal feature of care services.

26. We were attracted by the option within the Australian Framework for a patient to instigate a higher-level response at their request. We recognise that this would be difficult to replicate within the proposed statutory framework given that a breach of candour under such a framework could result in a sanction. We also do not have as formalised a set of procedures as appear to be in place in Australia. We would, however, welcome measures that provided something of the same spirit of openness to patient views and preferences. One of the benefits of local measures to ensure that there is effective peer review and external challenge (with a key role for commissioners) to decisions about candour is that such a mechanism could act as a source of assurance and challenge when patients took the view that harm classed as below 'significant' under our proposed classification was in fact 'significant'. We would also expect the Care

Quality Commission over time to build up an understanding of best practice and of borderline cases to support local organisations to make good decisions about candour and linked processes. In cases that are particularly difficult to resolve, we would expect the Care Quality Commission to then be able to act as an arbiter if local agreement is not possible. In cases of doubt where patients and / or their families believe that harm is 'significant', providers should treat them as such and act accordingly rather than wait for a verdict from local discussions or from the Care Quality Commission.

27. Definitions and thresholds matter: they provide the clarity and the prompts for action that organisations and individuals need. In answering the core question set for us by the review, we have sought to set out a threshold that provides the clarity organisations need, and a basis for proportionate regulatory action by the CQC. We have sought to align our approach with existing frameworks and reporting systems so that organisations are able to graft their approach to candour onto existing processes and systems. In this way, we think it should be possible to put in place an organisational duty of candour that can be clearly understood and applied by care organisations, and used as a catalyst or reinforcement for developing a wider culture of safety, learning and improvement.

    Recommendation 2: The duty of candour should apply to all cases of 'significant harm'. This new composite classification would cover the National Reporting and Learning System categories of 'moderate', 'severe' and 'death'; harm that is notifiable to the Care Quality Commission; and would include 'prolonged psychological harm'. This is in line with the 'Being Open' guidance.

Ascription

28. A number of witnesses raised the issue of ascribing harm. For example, a patient with a pressure sore that is discovered in an acute setting may in fact have developed the sore in a care home. In what sense is the hospital under a duty to be 'candid' with a patient in this situation? They should of course make it clear to the patient that they have a pressure sore, but should the duty of candour apply?

29. If we start from the patient's perspective, they clearly should not be at a disadvantage simply because their care pathway takes them from one organisation to another. They have just as much of a right to a candid conversation as someone whose pressure sore was generated while under the care of the hospital. The difficulty is that the duty applies to registered

organisations, and, as a result, it can be difficult for organisations to be candid 'on behalf' of another organisation.

30. We do not, however, believe that this problem is a justification for avoiding or ignoring the obligations of candour. It is better to view it as a symptom of a failure to integrate services for patients and service users. Where providers of care frequently find themselves in a position where harm caused elsewhere is discovered while someone is in their care, they should explore with other organisations how such an issue can be both disclosed to those who are its victims, and prevented in future.

31. The right reaction to borderline cases of this kind is to do something about them: complexity should not be an excuse for inaction. It would probably not be a useful or proportionate measure to attempt to set out in law how harm should be ascribed and how the duty of candour should therefore flow from that. However, we think there is merit in the CQC looking at how well organisations that are likely to be in the position of discovering harm done elsewhere in the system are set up to ensure that these safety issues are managed, and in particular, how well disclosure to patients and service users is done in cases of this kind[11].

Bureaucratic burden

32. As we have discussed elsewhere in this report, we have been conscious of the need to avoid a bureaucratic burden in putting the duty of candour in place. All of the elements we have included in our description of 'significant harm' already have to be reported to either NRLS or the CQC. The professional duties of candour already require open conversations when things go wrong. There is no doubt, given the current levels of underreporting, that the organisational duty will reinforce obligations, and that these are not currently complied with as much as ought to be the case.

33. While there is therefore likely to be a need for increased activity in the care system to meet the duty of candour, this is activity that should already be happening, and which brings enormous benefits when it does happen. Given the fundamental importance of learning when things go wrong, and of being open and honest with patients and service users, the role of the duty in reinforcing such activity can only be a good thing. While we have not been asked to undertake a cost-benefit analysis in relation to candour, it seems likely to us that

[11] For a discussion of this issue from the more individual perspective of one clinician disclosing harm caused by another which argues along similar lines to this review, see Gallagher, Mello et al 'Talking with Patients about Other Clinicians' Errors', *New England Journal of Medicine,* October 31, 2013, pp1752-1757 - http://www.nejm.org/doi/full/10.1056/NEJMsb1303119.

the benefits of introducing a culture of candour as part of a wider culture of safety, learning and improvement will more than repay the initial costs for an organisation. We also believe that setting the threshold so that it includes 'moderate' harm would require less bureaucracy than a system that asked organisations to distinguish between 'moderate' and 'severe' on a regular basis.

34. We therefore are of the view that the CQC should think hard about how it will monitor and enforce the duty in a way that maximises the use of existing data and systems and which avoids burdens.

Fear of litigation

35. The fear of litigation and some of the defensive behaviour it provokes can serve to undermine the development of a culture of candour. The international evidence does not provide a conclusive verdict on the impact of increasing open disclosure on litigation. There are some cases where greater openness has been followed by a reduction in litigation, although we acknowledge that it is difficult to ascribe a causal role to greater openness in such cases. Despite this evidence, there are some organisations and individuals that are likely to avoid behaving in a candid manner in order to avoid the perceived threat of litigation.

36. In the context of the NHS, the NHS Litigation Authority has done a lot to emphasise the importance of apologising and explaining to patients when things go wrong, and it has made it clear that it will continue to indemnify organisations that apologise and explain to patients. This is a very helpful position. However, it is the case under the current law that explanations can be used as evidence of admissions of liability which can have the effect of discouraging candour because of the fear that what is said can be used in negligence litigation. Commercial insurers are often reluctant to allow their insured to be fully candid where this can result in an admission of legal liability.

37. Fear of litigation is clearly not a principled argument against candour: something that is not in your interests can still be the right thing to do, and candour can clearly fall into this category in some cases. We also believe that it is a bad practical argument as well. While individual acts of candour may encourage others to legal action, the aggregate effect of greater candour on levels of litigation is unlikely to be significant. It is difficult to quantify the effect precisely, but it seems likely that if organisations really put candour into practice, there will be real gains in preventing drawn-out cases where legal action is really an expression of the intensity of the desire to know what happened rather than an attempt to secure financial redress.

38. Over the long term, we would encourage the Government to consider how it can ensure that the legal system is most able to support a culture of candour. In particular, it could be helpful to minimise the possibility that explanations given as part of a process of candour or open disclosure are then used in evidence to support an admission of negligence. This has been put in place in a number of other countries / territories (including Canada, Australia, parts of the United States and Denmark) and the English health system could usefully learn from this approach. [12].

Potential for / fear of excessive regulatory response

39. This 'barrier' is similar to the fear of litigation. It is clearly not a good excuse to avoid acknowledging harm because of a fear that the CQC will react strongly as a result; but we must acknowledge that this inhibitor can exist even if it is not justified.

40. Our expectation is that the CQC will look at the duty of candour in the same way as it looks at other fundamental standards. Its interest will therefore be in how well an organisation has done against the standard, which is usually assessed in terms of patterns of behaviour, processes and outcomes rather than in individual cases or 'breaches', although exceptions may of course be made for particularly serious cases.

41. It is certainly true that a great deal rests on the way in which the Care Quality Commission elects to regulate provider organisations in respect of the duty. It is vital that the Commission takes a proportionate approach, and that it provides clear guidance and information setting out its expectations of organisations. We have provided some suggestions in this review of the things we believe organisations should focus on. It will be important not only to ensure widespread and thorough implementation of the duty, but also to avoid the clumsy or insensitive implementation of it. Candour that does not work for patients and families does not work at all, and this is something we would encourage providers, commissioners and the Care Quality Commission to build into their evaluation of how well the duty is being upheld. It is likely that the CQC's approach to regulating the duty will need to adapt as it learns and as organisations become more used to the duty. It may therefore want to consider how to phase its approach to maximise learning and improvement for providers and for itself. As the CQC develops its approach, it would be very helpful for it to share this with providers and others.

[12] For a helpful study of how one health system (University of Michigan) used disclosure to improve patient safety see Boothman, Imhoff and Campbell 'Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk Through Disclosure: Lessons Learned and Future Directions', *Frontiers of Health Services Management,* 28:3, pp13-28 - http://www.med.umich.edu/news/newsroom/Boothman-ACHE-Frontiers.pdf.

Organisational reputation

42. The argument in this case will be familiar from the previous two sections. A likely inhibitor of candour is the potential impact of the disclosure of harm on the reputation of the organisation. Again, this is not a valid justification for avoiding or underplaying candour; and, again, we should do all we can to demonstrate that this is a poor strategy in practice as well. This is why it is important to recognise the role of candour as part of a wider commitment to a culture of safety that understands the inevitability of harm even as it tries to do all it can to avoid it. A good organisation is not one that never does any harm, as such an organisation is likely to be unable or unwilling to see the harm for which it is responsible. Reputation should not, therefore, rest on being free of harm, but on swift, thoughtful and practical responses to cases of harm. This is clearly not something that is solely within the gift of any organisation. Among others, the media have a part to play in representing failures in care fairly and with an understanding of the realities of care.

Individual challenges

43. Our focus is the organisational duty of candour, but organisations are made up of individuals and so we cannot ignore some of the factors that inhibit individuals from being candid. This is in part because one of the ways that leaders of organisations should discharge their duty of candour is by supporting – which can also mean challenging – the people in their organisations.

44. We have identified the following issues at an individual level that can inhibit candid behaviour and which therefore place organisations at risk of not meeting the duty.

    a. Reputation;
    b. Fear of professional regulatory consequences;
    c. Misplaced paternalism; and
    d. Re-interpretation of situation or seeing in an excessively clinical way.

Reputation

45. There are similar points to be made in relation to reputational impact and the fear of litigation at an individual level as at an organisational level. Clearly concerns about either of these issues cannot be used as a justification for avoiding candour. We think it is important to emphasise that a good reputation for an individual professional should not be about infallibility but about the ability to learn when things go wrong. It would be helpful if these messages

could be reinforced by organisations with a responsibility for professional regulation and indemnification – and by care providing organisations as well.

Fear of professional regulatory consequences

46. There is an important responsibility for organisations providing care to work closely with professional regulators to ensure that the right support and training are put in place so that individual professionals have the confidence to be candid.

47. Fear of regulatory consequences on an individual level is not a justification for failing to be candid, but this fear clearly has the potential to act as a powerful inhibitor. The professional regulators are leading a parallel process to look at aligning and strengthening their guidance and codes in order to reinforce the importance of candour as a fundamental of professional practice. Our review has maintained close contact with the professional review, and we have found the insights offered by our professional regulatory colleagues to be very helpful in framing our thoughts.

48. We expect the work being undertaken by the professional regulators to reinforce the importance of candour, and it is likely that, as at an organisational level, the increased focus on safety and openness will lead to a stronger regulatory interest in issues of candour. As now, these are likely to emerge in particular cases as part of a broader set of issues relating to fitness to practise.

Misplaced paternalism

49. One argument for not being candid with a patient or service user is that 'it can do them no good to know'. This is less commonly used than in earlier, more paternalist times, but it is worth addressing not least because it can most often be employed in relation to people who lack (or are perceived to lack) the ability to understand or deal with what they are being told. While it is clearly important to disclose harm in a sensitive manner, and in a way that is appropriate for the individual concerned, we believe that any decision to depart from normal expectations of disclosure needs to be considered thoroughly and based on clear evidence. Professionals and organisations should be sceptical of paternalist arguments of this kind, even if they are on occasion justified. Organisations have an important role to play in providing leadership and the right messages to individuals to ensure that this sort of argument is used sparingly rather than becoming a default attitude.

Re-interpretation of situation or seeing in an excessively clinical way

50. Failure to be candid is often seen as an ethical failure, but it can also be a failure of perception. People and organisations have a remarkable ability to not see what is right in front of their eyes. In relation to harm, we have already seen how patients and service users can have a different view of harm to the clinicians and organisations treating them. We have also seen some of the inherent complexities of definitions and thresholds. It is relatively easy for this to enable a redescription of harm in less serious terms or to dismiss the idea of harm as irrelevant.

51. While this sort of failure of perception tends to happen at an individual level, it is supported and facilitated by the development of a kind of 'groupthink' at team and organisational levels. Systematic and widespread failures to 'see' harm are not a perceptual failure, but an ethical one, as there is a responsibility on organisations and on leaders to put in place the right support and processes to ensure that harm can be clearly seen when it happens. In this context, the application of clear definitions of harm and reporting requirements can be extremely useful as a basis for avoiding a drift away from good practice.

52. We do, however, understand that recognition of a patient safety incident that leads to harm is not necessarily straightforward. Indeed, the majority of harm that occurs is not a simple case of one error leading to obvious identifiable harm. Most harm is a consequence of multiple instances of sub-optimal care that are not necessarily obvious to those involved in the delivery of care. It is therefore vital that the enforcement of the duty of candour is, as we have said, proportionate, and is sensitive to the realities of healthcare.

Conclusion: meeting the challenges

53. The challenges we have outlined are formidable. With determination and hard work they can and should be met. While we have spent much of this chapter on detailed consideration of definitions and thresholds, as is appropriate given the focus of the review, the challenges to developing a culture of candour are just as likely to stem from organisational and individual inhibitors, which are a mix of genuine issues, semi-articulated folk wisdom and sometimes misplaced or outdated assumptions. This further illustrates the need for a 'hearts and minds' approach to candour, rooted in staff and service user engagement.

Chapter 3: Incentivising candour

1. In addition to the question of thresholds, we were also asked to look at how the NHS Litigation Authority (NHS LA) might incentivise candour by seeking reimbursement of compensation costs in relation to cases where a Trust has not been open with patients their family and carers about a patient safety incident which turns into a claim.

2. In the course of our review, we heard from the NHS Litigation Authority itself and a number of other organisations on this question.

3. The NHS Litigation Authority will continue to support the NHS by encouraging apologies and explanations when things go wrong and will never withdraw indemnity cover on the basis that an organisation says sorry.

4. Well-designed incentives can have a powerful effect on the behaviour of organisations. They need not have a financial impact to work well. In our view, incentives that focus on reputation are more likely to be effective. This point has been important for us in considering how the proposal that the NHS Litigation Authority be given the discretion to reduce or remove indemnity cover in cases where a Trust has not been candid with patients or their families could be made to work.

5. We support the public reporting of any failure to be candid. The CQC should determine how to give public prominence to a breach of the duty.

6. We support a proportionate regulatory response to breaches of the duty of candour which would have impact on the reputation of the organisation and its leadership. We would expect that the leadership of an organisation who either wilfully disregard the duty or are found to be in serial breach should have a higher regulatory response - and that this should include consideration of restricting Board members from holding future Board level appointments in organisations registered with the CQC.

7. We have set out our understanding of the potential advantages and disadvantages of seeking reimbursement of compensation costs below.

Advantages and disadvantages

8. There are a number of potential benefits to the use of reimbursement:

- It will provide, in a small number of cases, an incentive for NHS organisations to ensure they support candour for patients, and to ensure a culture of candour is spread throughout the organisation, complementary to the contractual duty and the CQC fundamental standard;

- The power of publicity in relation to cases where the NHS LA reports a failure to be candid, where the media attach importance to reporting financial sanctions on organisations.

5. There are, however, also a number of potential disadvantages:

    - Claims are a very small percentage of reported incidents (less than 1%), and there will be a significant delay between the incident and reimbursement being applied to a resolved claim;[13]

    - It would apply only to NHS LA members and not to all organisations registered with the CQC. The NHS indemnity schemes are voluntary and organisations can choose commercial insurance, and reimbursement would not apply to them;

    - If reimbursement is linked to damages payable for negligence it would not apply in instances where there was an absence of candour but no negligence[14]. Where it did apply, reimbursement will reflect the patient and their injuries, and therefore vary considerably; and

    - Reimbursement may apply to incidents which have already been investigated by CQC and/or regulatory action taken, and where a contractual fine may have been levied by commissioners, resulting in duplication.

Conclusion

6. Our advice is that the Government should explore further through consultation how to make the reimbursement mechanisms, and other potential measures, work well. In this event, we would urge them to consider how to secure the advantages and to address and to mitigate the disadvantages we have identified.

7. We believe that more could and should be done to align organisations with a national level interest in ensuring candour. In this context it is worth recalling that there are existing mechanisms available for incentivising candour financially: the

[13] Claims generally arise up to two years, sometimes more, after the incident and take on average 1.25 years to resolve.
[14] Currently the NHS LA resolves approximately 50% of the claims it receives without paying damages

contractual duty of candour and the CQC's powers to levy a fine for a breach of the organisational duty of candour offer two means of providing a financial consequence for a failure of candour. While it would clearly be wrong for these powers to be used excessively, there is a case for their use in a more co-ordinated way.

8. We also believe that the NHS LA could play an important role in supporting such measures, as it will on occasion hold intelligence about a failure of candour that could and should be made available to both the CQC and to commissioners. The NHS LA could, upon receipt of a claim, ask for the organisation concerned to provide evidence in the form of certification confirming that the organisation is satisfied that it has discharged its duty of candour or for the letter of apology and explanation provided to the patient at the time of the incident. In the event such certification/letter of explanation cannot be produced, the NHS LA could then alert the CQC which could investigate under its regulatory role.

9. In short, we believe that co-operation and sharing of intelligence as part of an integrated, robust and proportionate regulatory response to failures of candour offers an important way forward, and further incentives should be designed within the framework of existing measures in a way that serves to reinforce the overall regulatory framework for candour. The various options, including but not limited to reimbursement, should be explored in consultation.

10. It was also put to us during our evidence sessions that it would be appropriate for patients or family members who had been victims of a failure to be candid as set out in the statutory duty to be eligible for a personal remedy (likely to be in the form of relatively small amounts of compensation). While we recognise that this might act as an incentive to change behaviour, we do not agree that it would be a wise course of action. We believe it would be likely to provoke a great deal of extra litigation and move the focus of organisations and professionals away from safety and learning. This, ultimately, would not be in the best interests of patients. We are strongly of the view that the duty of candour should not include eligibility for a personal remedy.

11. We are therefore recommending the following:

Recommendation 3: The focus of any sanctions on organisations found to be in breach of the duty should have impact on the provider's reputation. The various options for involving the NHS Litigation Authority, including but not limited to reimbursement, should be explored in consultation. National organisations (including the NHS Litigation Authority, the Care Quality Commission and NHS England) should set out how they will:

- **Share intelligence about breaches of the duty of candour;**

- **Incentivise candid behaviour by organisations through co-ordinated action, including commentary within published reports on the findings for individual care organisations;**
- **Ensure proportionate enforcement action is taken by commissioners and the Care Quality Commission in the event of breach; and**
- **levy any financial sanctions on organisations who fail to be candid.**

In consulting on incentives relating to reimbursement of litigation costs, the Government should take account of the advantages and disadvantages outlined in this report, and work to ensure that future incentives form part of a coherent framework. These measures should be subject to an appraisal of how they have affected the behaviour of decision-makers in provider organisations.

Conclusion

Candour – here to stay

1. We began this report by emphasising that candour should be seen as part of a wider set of changes away from paternalism and towards a much more open culture. We believe that the duty of candour can act as a catalyst for change in our care services where each and every organisation acts in a way which gains and keeps the trust of the people it serves.

2. We again wish to emphasise that our views accord with those expressed by the Berwick Report: *A promise to learn. A commitment to act.* We recognise that system and human errors can happen in the complexity of health and care services. What is important is how an organisation acts when these are discovered; that staff are supported to provide an honest account of what happened and that the organisation takes every step possible to reverse the harm and prevent a recurrence. It is our clear view that patients and their families respect organisations that tell the truth and learn from their errors.

3. This report provides the opportunity to state, in the strongest possible terms, that the most significant consequence of the duty of candour is the extent to which organisations create and support the systems and cultural conditions by which mistakes and errors enable learning and support a process of continuous improvement.

4. Our examination of the threshold question has led us to the firm conclusion that 'moderate' harm should be included within the duty and a new composite harm definition of 'significant' should be used, as this is most likely to be understood by service users. It would also have the benefit of simplifying issues of classification by organisations and their staff.

5. On incentives, we have reached the view that reputation is a crucial lever in this context. This conviction, coupled with an examination of the pros and cons of the use of reimbursement by the NHS LA, has led us to conclude that there should be a consultation to explore options for involving the NHS Litigation Authority. The options should include but not be confined to reimbursement. We also recommend that national organisations set out how they will work together to co-ordinate their response and to focus that on the powers that commissioners and the CQC already have to penalise failures of candour.

6. We have ended this process with an even stronger conviction that supporting staff to be open and honest with people at all times, including when things go

wrong, is absolutely essential. This is both the right thing to do, and hugely important for reinforcing a trusting relationship between the public and the organisations that care for them.

Annex A

Terms of reference and Letter of invitation

Duty of candour – review of the threshold, and proposals to adjust NHS LA contributions according to how candid a Trust has been

Introduction

- Following the Government's response to the Mid Staffs Public Inquiry on 19th November 2013, Professor Norman Williams, President of the Royal College of Surgeons, and David Dalton, Chief Executive of Salford Royal Hospital, have been asked by the Secretary of State for Health to lead a review on two proposals to enhance candour in the NHS.

Purpose

- **'The Department will seek advice from experts on how to improve the reporting of patient safety incidents, including whether or not the threshold for the statutory duty of candour should include moderate harm'** (response to recommendation 181)**.**
- The NHS Litigation Authority will develop proposals about **whether 'Trusts should reimburse a proportion or all of the NHS LA's compensation costs when they have not been open about a patient safety incident'** (response to recommendation 181) and report back to the review.

Method

The group's work will focus largely on the threshold for the duty of candour. It will hold evidence sessions from key parties to shape its views. Details of those invited will be published in due course.

The letter of invitation sets out the working method and key questions the review team wish to pursue.

Professor Williams and David Dalton will be supported on the review group by:

- Dr Matt Fogarty (Head of Patient Safety Team, NHS England)
- Catherine Dixon (Chief Executive, NHS Litigation Authority Chief Executive (NHSLA))
- Helen Vernon (Director of Claims, NHS LA)
- Dr Suzette Woodward (Director for Safety, Learning and People, NHS LA)
- Ben Masterson (Deputy Director, NHS LA Sponsor Team, Department of Health)
- Jo Revill (Director of Strategic Communications, RCS England)
- Secretariat (William Vineall and Jason Yiannikkou, Department of Health)

This review does not cover candour issues in social care. The Department of Health will set up a working party covering social care issues.

Department of Health **December 2013**

Review Invitation

13 December 2013

Duty of candour – review of threshold

In the recent response to the Mid Staffordshire Public Inquiry, the Secretary of State has invited David Dalton, Chief Executive of Salford Royal NHS Foundation Trust, and I to review the threshold for the new statutory duty of candour, and whether it should be set at the level of death and serious injury or death, serious injury and moderate harm. We are working to a tight timescale, and have decided that to shape our views we need evidence sessions with key players in the field of candour and patient safety.

We would like you to attend a session with the review team during January or February at the Royal College of Surgeons so we can hear your views on the issue. A couple of organisations will be invited together to each session to ensure we have a good round table discussion on the key issues. You will be contacted to agree a suitable date. If you have papers you want the review team to read, please could you e-mail them the week beforehand to mailbox: candourthresholdreview@dh.gsi.gov.uk. We plan to put your papers on the Royal College of Surgeons website after your evidence session.

The key issues we would like you to address in your evidence session is:

- What is your overall view on where the duty of candour threshold should be set – death or serious injury, or death, serious injury and moderate harm? Please give reasons for your view.

In particular, we would welcome your views on:

  - should the new duty of candour use the definitions that apply to the reporting of patient safety incidents in the existing National Reporting

and Learning System (NRLS), and the existing contractual duty of candour?

- The Government response to the Mid Staffordshire Public Inquiry 'Hard Truths' said that 'The professional regulators will develop new guidance to make it clear professionals' responsibility to report 'near misses' for errors that could have led to death or serious injury, as well as actual harm, at the earliest available opportunity and will review their professional codes of conduct to bring them into line with this guidance'. What is your view on how incident reporting by an individual professional would be made to work best alongside the new statutory duty of candour on organisations?

- what is your view on how the duty on the organisation to report an incident, which resulted in death or serious injury/moderate harm to a patient/family, may take account of incidents which have not been reported by a staff member or were not known at the time and were subsequently discovered to have occurred?

- how do you make a duty of candour work in primary care, eg for a single-handed practitioner?

- do you have any views on the proposal that the NHS Litigation Authority should adjust its contribution according to how candid a Trust has been, and require a contribution to the claim from the Trust?

Yours sincerely

Norman S Williams

President

Royal College of Surgeons

David Dalton

Chief Executive

Salford Royal NHS Foundation Trust

Annex B

List of witnesses and their organisations

- Jeremy Taylor, Chief Executive, National Voices
- David Behan, Chief Executive, Care Quality Commission
- Katherine Rake, Chief Executive, Healthwatch England
- Saffron Cordery, Director of Policy & Strategy, Foundation Trust Network and Christine Baldwinson, Chair of Foundation Trust Network company secretaries network
- Peter Walsh, Chief Executive, Action against Medical Accidents
- Liz McNulty, Patients Association
- Jackie Smith, Chief Executive, Nursing and Midwifery Council
- Harry Cayton, Chief Executive, Professional Standards Authority
- Niall Dickson, Chief Executive, General Medical Council
- Michael Devlin, Head of Advisory Services, Medical Defence Union
- Simon Dinnick, General Counsel, Medical and Dental Defence Union of Scotland
- Dr Jim Rodger, Head of Professional Services, Medical and Dental Defence Union of Scotland
- Prof Karen Yeung, Kings College London
- Dr Mark Porter, Chair of Council, British Medical Association
- Dr Maureen Baker, Chair of the Royal College of General Practitioners
- Dr Peter Carter, General Secretary, Royal College of Nursing
- Chris Cox, Director of Legal Services, Royal College of Nursing
- Robert Francis QC
- Mary Dixon-Woods, University of Leicester
- Prof Sue Bailey, Academy of Medical Royal Colleges
- Dr Stephanie Bown, Director of Policy and Communications, Medical Protection Society
- Dr Liliane Field, Medicolegal Adviser, Medical Protection Society

Written submissions to the review and additional evidence we have found helpful

- *Candour, disclosure and openness,* Professional Standards Authority; see http://www.rcseng.ac.uk/policy/documents/duty-of-candour-psa-research-paper.
- *Foundation Trust Network Submission;* see http://www.rcseng.ac.uk/policy/documents/duty-of-candour-foundation-trust-network-submission.
- *Action against Medical Accidents briefing;* see http://www.rcseng.ac.uk/policy/documents/duty-of-candour-avma-briefing.

- *Healthwatch England submission;* see http://www.rcseng.ac.uk/policy/documents/duty-of-candour-letter-from-healthwatch
- *Care Quality Commission Submission;* see http://www.rcseng.ac.uk/policy/documents/20140125ResponsetoDutyofCandourEvidenceSession.pdf
- *Medical Protection Society Briefing;* see http://www.rcseng.ac.uk/policy/documents/mps-duty-of-candour-review
- *Medical Defence Union Submission;* see http://www.rcseng.ac.uk/policy/duty-of-candour-review
- *Health Foundation Briefing.*
- *NHS Confederation Briefing.*
- *Australian Open Disclosure Framework,* Australian Commission on Safety and Quality in Healthcare; see http://www.rcseng.ac.uk/policy/documents/austrailian-open-disclosure-framework.

- Dr Oliver Quick – pre-publication version of 'Regulating and Legislating Safety: the Case for Candour', *British Medical Journal Quality and Safety* (forthcoming).