A statutory duty of candour

Consultation Paper

Expert Working Group to advise on legislative reforms arising from *Targeting Zero*

October 2017

VICTORIA State Government | Health and Human Services

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Minister's foreword

All Victorians should have confidence in the safety and quality of our health system.

A review of quality and safety across our health system led by Dr Stephen Duckett found that while Victorian hospitals deliver some of the best care in the world, the Department of Health and Human Services needed to do more to adequately oversight quality and safety across our health services.

Dr Duckett's report, *Targeting Zero: Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care* called for changes at government, board and management level to encourage and establish a culture of inquiry and open disclosure and to introduce systems to monitor and improve the safety and quality of health care.

Work is well underway and we are implementing the report's recommendations – with a goal to 'target zero avoidable harm'.

Safer Care Victoria, established in January 2017, is working with consumers and their families, clinicians and health services to improve the quality and safety of care delivered across our health system to drive system-wide improvement in safety and quality.

The Victorian Agency for Health Information, also established in January 2017, will provide boards, managers, clinicians and patients with the information they need to know whether services and care are safe and whether they are providing the outstanding outcomes we expect for all patients.

The Victorian Clinical Council is providing independent and authoritative leadership from clinicians on how to make the system safer and provide better care to all Victorians.

We are improving sector governance by supporting the increased professionalism and upskilling of boards so they are equipped to identify and address issues and drive quality and safety improvements. The Boards Ministerial Advisory Committee provides authoritative advice on board appointments to strengthen local governance and decision making.

Targeting Zero outlined the significant appetite in the hospital sector for greater transparency – and a strong belief that members of the public are entitled to it. To investigate how this can be taken a step further, I announced, when responding to *Targeting Zero*, a public consultation on the adoption of a statutory 'duty of candour' to further support open disclosure. I asked an Expert Working Group, chaired by Michael Gorton, AM, to undertake this consultation and this paper is the first stage in that work, and have asked the Parliamentary Secretary for Health, Gabrielle Williams MP, to work closely with this group as they progress.

I urge you to consider the questions posed in this consultation paper and provide your views to the Expert Working Group to ensure your voices are heard as we implement this next important reform.

The Hon Jill Hennessy MP

Minister for Health

Minister for Ambulance Services

Statement from the Parliamentary Secretary for Health

I am pleased to have been asked by the Minister for Health to work closely with the Expert Working Group appointed to provide advice on legislative reforms arising from *Targeting Zero.* The Expert Working Group comprises representatives of health service providers, health service consumers and clinical experts and is well placed to consult broadly with relevant stakeholders and provide informed recommendations.

Victorians expect that if avoidable harm does occur, those involved are apologised to and given a full explanation, lessons are learnt and every effort is made to ensure it never happens again. Truly excellent hospitals have robust systems for, and cultures that support, disclosure of failure and encourage learning from mistakes. *Targeting Zero* argued that health services should strengthen their practices around open disclosure, alongside moves towards greater transparency about healthcare performance more generally. The recommendation that a statutory duty of candour be introduced was made in the context of fostering just cultures in hospitals and health services to encourage open and honest conversations about opportunities for improvement.

Australia's Open Disclosure Framework is praised internationally. The fundamental purpose of both a statutory duty of candour and the standard practice of open disclosure is to foster an open and honest culture in health services and to improve the quality of care, particularly in terms of safety and person-centeredness.

A statutory duty of candour is seen as a mechanism to drive culture change, particularly for health services who have not fully adopted and embedded a comprehensive approach to openness and transparency as part of a process of continuous improvement and learning.

The Expert Working Group is passionate about this work and committed to hearing your views in relation to this important reform. A Victorian health system rooted in openness, honesty and the general principle of continuous improvement in patient quality and safety is essential.

Gabrielle Williams MP

Parliamentary Secretary for Health

Executive summary

This paper seeks stakeholder views on the introduction of a statutory duty of candour.

A statutory duty of candour is a recommendation of a review led by Dr Stephen Duckett into quality and safety across the Victorian health system.

A statutory duty of candour is a legal obligation to ensure that consumers of healthcare and their families are apologised to, and communicated with, openly and honestly when things have gone wrong in their care.

The term ‘statutory duty of candour’ is used to differentiate the proposed legal obligation from ongoing obligations to implement open disclosure which arise from accreditation requirements, funding conditions and professional codes. The statutory duty of candour will not replace current open disclosure obligations. Rather, it will establish a complementary legal obligation to support improved compliance with open disclosure in a defined set of circumstances.

Effective open disclosure practices have been shown to have a range of benefits at both an individual and a system level.

- Open and honest communication with consumers and their families following health care incidents is consistent with the shift that has occurred over recent years to a more patient centred and patient focussed approach to healthcare provision.
- Open disclosure is associated with better detection and awareness of risk and strengthened trust in health care institutions. Ongoing improvement requires recognition, open discussion and ownership of problems when they occur.

A statutory requirement for candour can be enacted in a range of different ways. Consideration will be given to the extent to which requirements are included in the statute, mandated through reference to existing standards, or articulated in new Victorian policy or guidelines. Views on this are being sought in addition to other critical issues including:

- *The scope of the duty* – which healthcare providers should be subject to the statutory duty?
- *When the duty applies* – what should be the trigger for the statutory duty to apply?
- *Requirements of the duty* – what elements of the process should be legislated?
- *Barriers and enablers* – what is required to ensure that the statutory duty is effective?
- *Legal protections* – are changes to apology laws or other protections required?
- *Monitoring and compliance* – how should breaches of the duty be identified and responded to?

CONSULTATION QUESTIONS

Q1. Do you agree that the statutory duty of candour should apply to the set of health services [regulated by the *Health Services Act 1988*] including private sector organisations?

Q2. Which, if any, other healthcare providers should be in scope for the statutory duty of candour?

Q3. Do you believe the statutory obligation should apply to individuals instead of, or as well as, organisations?

Q4. At what threshold of harm and/or for what type of incidents should the statutory duty of candour apply?

Q5. Should the statutory duty of candour apply to instances of psychological harm as well as physical harm?

Q6. Should the statutory duty of candour apply to near misses and/or complications of treatment that result in no harm and/or no lasting harm? Should it apply where the wrong treatment was given or non-evidence-based treatment was given if there is no harm as a result?

Q7. Do you agree that there should be provision for 'consumer declared harm' as a trigger for the statutory duty of candour to apply?

Q8. Which, if any, of the matters [identified in the paper] should be included within the statutory requirements for the duty of candour?

Q9. Are there other matters that should be included within the statutory requirements or encouraged through other means?

Q10. Do you agree with the key barriers and enablers identified [in the paper]?

Q11. What are the most important factors to ensure the statutory duty of candour achieves its intended aims?

Q12. How can the necessary training best be delivered?

Q13. Do you agree with the support requirements identified [in the paper]? What other actions might be needed?

Q14. Is there a need to strengthen Victoria's apology laws?

Q15. Do you think there is merit in including statutory protections for open disclosure alongside the statutory duty of candour?

Q16. Is there a need to clarify, in legislation or through supporting materials, the relationship between open disclosure and qualified privilege?

Q17. Are other statutory protections required?

Q18. How should failures to comply with a statutory duty of candour be identified?

Q19. What consequences or sanctions should be available in response to identified breaches of the statutory duty of candour?

Q20. Are there other issues, not covered in this paper, that should be addressed or considered as part of the introduction of a statutory duty of candour?

Contents

1. Introduction

Targeting Zero, *the review of hospital safety and quality assurance in Victoria*, was commissioned by the Minister for Health in 2015 following the discovery of a cluster of tragically avoidable perinatal deaths at Djerriwarrh Health Services.

The review provided a detailed and extensive analysis of quality and safety support and oversight across the Victorian hospital system. The review made a total of 179 recommendations, intended to: enhance system leadership; strengthen clinical engagement; ensure better use is made of information and data; improve sector governance; and strengthen departmental oversight.

Among these was a recommendation that a statutory duty of candour be introduced in Victoria.

Recommendation 5.3
That a statutory duty of candour be introduced that requires all hospitals to ensure that any person harmed while receiving care is informed of this fact and apologised to by an appropriately trained professional in a manner consistent with the national Open Disclosure Framework.
Targeting Zero (page 200)

The Victorian Government has accepted in principle all the recommendations of the review. The response to *Targeting Zero – Better, Safer Care - Delivering a world-leading healthcare system* was released in October 2016 and set out how the government is addressing the Review's recommendations.

This response included a commitment to consult on the introduction of a statutory duty of candour where health services must apologise to any person harmed while receiving care, and explain what has gone wrong and what action will be taken.

Victorians deserve to know that should things go wrong, their needs will be dealt with swiftly and transparently, and any lessons learned and shared across the hospital system.
Secretary's Statement – *Better, Safer Care* (2016)

What is a statutory duty of candour?

A statutory duty of candour is a legal obligation to ensure that consumers[1] of healthcare and their families or carers are apologised to, and communicated with, openly and honestly when things have gone wrong in their care. It is a legally enforceable requirement for open disclosure – the practice of frankly discussing, with consumers and their supporters, incidents that have resulted in harm.

A statutory duty of candour will not replace existing open disclosure obligations. Rather it will be an enforceable mechanism for ensuring that open disclosure occurs in defined circumstances.

Expert Working Group

An Expert Working Group, comprising representatives of health service providers, health service users and clinical experts, has been appointed to provide advice to the Minister for Health on legislative reforms arising from *Targeting Zero.*

[1] The term *consumers* is used throughout this paper (unless in a quote or where context dictates the use of an alternative term such as patient) to refer to those who seek and/or receive healthcare. It is intended to include those individuals who might also be referred to as patients, clients, service users or residents.

Members of the Expert Working Group are:

- Mr Michael Gorton (AM) (Chair), Partner, Russell Kennedy; Chair, Alfred Health; Board Member, Ambulance Victoria and Chair, Australian Health Practitioner Regulation Agency
- Ms Sophy Athan, Chair, Board of Health Issues Centre and member of the Victorian Clinical Council
- Dr Michael Walsh, Chief Executive Officer, Cabrini Health
- Ms Jan Child, Chief Executive Officer, Bass Coast Health Service
- Dr John Ballard, Administrator, Djerriwarrh Health Services; Associate Vice-Chancellor (Victoria), Australian Catholic University
- Dr Victoria Atkinson, Group General Manager Clinical Governance/Chief Medical Officer, St Vincent's Hospital; Deputy Chair, Board of Better Care Victoria, Member, Board of Alfred Health
- Dr Joanna Flynn, Chair, Medical Board of Australia; Chair, Board of Eastern Health; Board Member Ambulance Victoria
- Ms Karen Cusack, Health Complaints Commissioner.

The initial matter for consideration by the Expert Working Group will be the implementation of a statutory duty of candour. The Group will make recommendations to the Minister about the appropriate statutory model for introduction of a duty of candour and provide advice on matters including:

- the scope of the duty and thresholds to apply
- the processes, compliance measures and protections to accompany such an obligation; and
- the supports required to implement the statutory change.

In providing this advice, the Expert Working Group will use the *Targeting Zero* recommendation as the starting point for considerations, but will not, however, be bound by the specific wording or parameters of the recommendation.

Purpose of this paper

As part of its work, the Expert Working Group has been asked to consult with the public and consider the views put forward by stakeholders. Its recommendations to the Minister will be informed by this public consultation.

This paper outlines the issues and challenges that need to be considered in introducing a statutory duty and seeks the views of health service users, providers and other interested parties about how a statutory duty of candour for Victoria should be framed and the conditions that will be needed to ensure its success.

This is not a consultation on the merits of open disclosure. Open disclosure is already enshrined in national standards and is generally accepted as rightly part of health care provision in Australia. This is a consultation about a legal framework to support the existing national open disclosure standard and enhance the practice of open disclosure in this state.

> Open disclosure is a patient right, is anchored in professional ethics, considered good clinical practice, and is part of the care continuum
>
> Australian Open Disclosure Framework (2013)

How to make a submission

Submissions in relation to the questions raised in this paper are invited from interested organisations and individuals.

Responses should be emailed to: dutyofcandour@dhhs.vic.gov.au

or can be mailed to:

Expert Working Group - *Targeting Zero* Legislative Reform

C/- Department of Health and Human Services

Level 20

50 Lonsdale Street

MELBOURNE VIC 3000

The closing date for submissions is 1 December 2017

2. Why a statutory duty of candour?

> 'A culture of candour is a culture of safety, and vice versa'
>
> Sir David Dalton and Professor Norman Williams 'Building a culture of candour' (2014)

To understand the context of a statutory duty of candour, it is necessary to first look at the broader concept of 'open disclosure'.

Benefits of open disclosure

Effective open disclosure practices have been shown to have a range of benefits at both an individual and a system level.

Open and honest communication with consumers and their families following health care incidents is consistent with the shift that has occurred over recent years to a more patient centred and patient focussed approach to healthcare provision. When done well, open disclosure has the capacity to improve healing and outcomes for the harmed consumer and support the maintenance of ongoing consumer-practitioner relationships.

There is evidence that apologies can have a neutralising effect on harmed individuals seeking redress through the courts or external complaint schemes.[2] The absence of an apology or explanation is one of the key motivators for legal action[i] and for escalating complaints to the Health Complaints Commissioner.

At a system level, open disclosure is associated with better detection and awareness of risk and strengthened trust in health care institutions. Ongoing improvement requires recognition, open discussion and ownership of problems when they occur[ii].

> 'The ethical case for disclosure is clear: it is about truth telling and respect for persons'
>
> Nancy Berlinger, 'After harm: medical error and the ethics of forgiveness (2005)

Perhaps most importantly, offering honesty, openness and compassion in the face of harm suffered as a result of healthcare is simply the right thing to do[iii].

Current requirements for open disclosure

The benefits of open disclosure have been recognised for some time and open disclosure is a longstanding, well accepted practice in Victorian healthcare.

Australia's Open Disclosure Framework establishes well-regarded national standards. Open disclosure is mandated in the National Safety and Quality Health Service (NSQHS) Standards (Standard 1) and is subject to accreditation. In Victoria, accreditation against these standards is a requirement for registration for private hospitals and day procedure centres, and public hospitals and health services must comply with the standards as a condition of their service agreements[3].

Furthermore, a professional duty to be honest with consumers exists in most health profession codes.

Nonetheless, we know that open disclosure does not always occur, and did not occur at Djerriwarrh Health Services at the time of the tragic preventable perinatal deaths that led to the commissioning of the *Targeting Zero* review.

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[2] There is some evidence from the United States that while this can be the case, in other circumstances apologies may alert a patient to malpractice and thereby prompt litigation. The Failure of "Sorry": An Empirical Evaluation of Apology Laws, Health Care, and Medical Malpractice, Benjamin J. McMichael, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3020352. Posted: 21 Aug 2017

[3] Further information about the Open Disclosure Framework, National Standards and existing open disclosure obligations of Victorian health services is included in Appendix A. A summary of approaches in other jurisdictions in included in Appendix B

‘Unfortunately, hospital cultures do not always support admission of error, let alone disclosure of it to patients. Further, there appears to be weak familiarity with obligations for open disclosure at the board level in Victoria, as highlighted in 2014 research that found that 46 per cent of surveyed board members were 'not familiar' with the national Open Disclosure Standard. ....Appropriate open disclosure practices clearly did not occur at Djerriwarrh.’

Targeting Zero page 200

Submissions to *Targeting Zero* indicated that the presence of the open disclosure standard in itself has not embedded the practice of open disclosure within all services and there is significant room for improvement in the practice of open disclosure in Victoria. There is evidence to suggest that there is a gap between ‘disclosable’ and ‘disclosed’ events[iv], and that often the practice of disclosure does not meet consumer expectations[v].

What is a statutory duty of candour?

Throughout this document the term ‘statutory duty of candour’ has been used to refer to the obligation proposed to be set out in legislation. This reflects the language of the *Targeting Zero* recommendation and the language used in England where a statutory duty of candour was introduced for the NHS in 2014.

The term statutory duty of candour is used to differentiate the proposed legal obligation from ongoing obligations to implement open disclosure which arise from accreditation requirements, funding conditions and professional codes. The statutory duty of candour will not replace current open disclosure obligations. Rather, it will establish a complementary legal obligation to support improved compliance with open disclosure in a defined set of circumstances.

As outlined in the following section, the statutory duty will exist as part of a broader field of communication with consumers that encompasses all elements of open disclosure. As the diagram below illustrates, the statutory duty will be at the core of a framework for disclosure. It will set minimum requirements for when disclosure must occur, and how, and provide a legally enforceable mechanism for ensuring it does. This environment of open disclosure should itself be part of a broader person-centred and just culture which encourages and supports open and honest communication and transparency.

What will a statutory duty of candour achieve?

Strengthened commitment to the practice of open disclosure

The introduction of a statutory duty of candour is an opportunity to centralise and modernise the existing obligation and further embed the commitment to the principles of open disclosure across the health system. It is anticipated that through this, there is an opportunity for an overall improvement in the practice of open disclosure and open, honest communication with consumers and their families more generally.

In elevating requirements for open disclosure to a legal obligation, it is hoped that the profile of open disclosure will be raised, leading to more consistent

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

Sir David Dalton and

Professor Norman Williams

‘Building a culture of candour’ (2014)

and widespread open disclosure practice. The benefits of this will include improved outcomes for consumers, better maintenance of ongoing consumer – practitioner relationships, better detection of risk and learnings from errors, and support for more just cultures[4] [vi] within health services where open communication is valued throughout the life of a care relationship.

Clarity of responsibilities – elevated to Boards of public health services / proprietors of private services

Importantly, as a matter of legislative compliance, responsibility for ensuring that consumers and their families are apologised to, and communicated with openly and honestly when things have gone wrong in their care, will rest with the Board of public services rather than with the management team. (In private sector services that responsibility will rest with the proprietor.)

It is hoped that this will assist in addressing the concerns identified in *Targeting Zero* which found there was weak familiarity with obligations for open disclosure at the Board level.

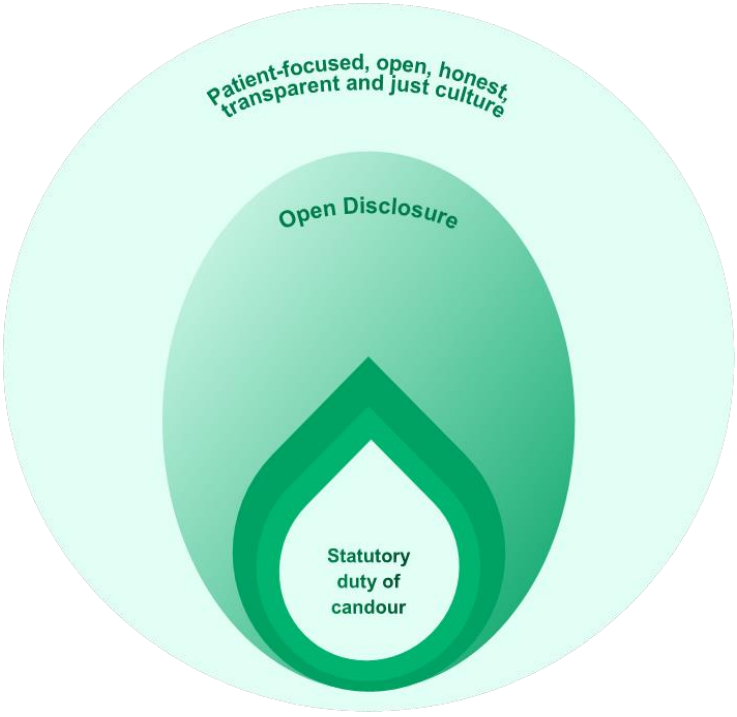
Clarity of requirements – triggers for disclosure

By setting out requirements in statute, the duty of candour will give greater surety for practitioners, service management and Boards about when disclosure must occur and how. There is some anecdotal evidence that practitioners are not always clear about obligations.

This is consistent with the findings of the 2012 *Open Disclosure Standard review* report which found that health care professionals were frequently uncertain about which incidents 'trigger' open disclosure; as well as whether their organisation would support the carrying out of open disclosure in particular circumstances.

Clarity of medico-legal consequences and protections

Despite evidence suggesting that apologies can have a neutralising effect on harmed consumers seeking redress through the courts or complaints bodies (and that the absence of an apology can be a key motivator for action)[vii], a fear of medico-legal consequences is a known barrier to the practice of open disclosure.



It is not intended that a statutory duty encourage the practice of defensive medicine, nor that it lead to an increase in litigation. Rather, the introduction of a statutory duty is an opportunity to ensure that there are sufficient protections for those involved to fulfil their obligations without additional adverse legal ramifications. It is also an opportunity to ensure that practitioners are aware of, and understand, these protections (see section 4.5).

[4] 'Just culture' is a term that refers to a "culture in which frontline personnel feel comfortable disclosing errors - including their own - while maintaining professional accountability". It is a culture that is both fair to staff who make errors and effective in reducing safety risks.

3. Principles

The Expert Working Group has identified six core principles they will seek to observe in recommending a framework for a statutory duty of candour. These principles, which are consistent with the Government's vision for health care as articulated in *Better, Safer Care* and *Health 2040* as well as the *Department of Health and Human Services' Strategic Plan*, are:

Principle 1: Health service consumers, their families and carers must be supported to be active partners in their care

People want to be part of decisions about their care and it is expected that consumers will be provided with information about treatment options to allow them to do so.

In the event of an incident, disclosure of information is critical to enable a consumer to understand their condition and to make informed decisions about future care options.

The further evolution of a patient-centred health care system is central to government and Department of Health and Human Services' stated vision for the health system.

> For individual patients or clients, it [patient-centred care] means putting people and their families at the centre of decisions and seeing them as experts, working alongside professionals to give them greater control over their life and the services they receive.
>
> Department of Health and Human Services' Strategic Plan

Principle 2: Consumers' views and experiences are central to how the health system should be managed, as a measure of performance and as a driver of improvement

It is now accepted that the people with the greatest expertise in our health system are the people who have experience of the services within it, along with their families and loved ones. Enabling opportunities for them to share their experiences and ideas – and learning from these – is critical to understanding performance, addressing areas of risk or inconsistency, fostering patient-centred services and driving improvement.

Principle 3: Healthcare workers should be recognised for their efforts and commitment and supported to share their knowledge and learnings

Victoria's healthcare workers are at the forefront of service delivery and efforts to enhance quality and safety. They are critical to the overall success of the state's health system.

Practitioners want what is best for their patients, and complications are rarely the result of incompetence or malice. It is known that being involved in an incident of patient harm can have profound impacts on practitioners[viii]. There is a body of literature that recognises that, without appropriate supports, practitioners can become the 'second victims' following such incidents. Implementation of the statutory duty of candour should aim to assist healthcare workers to manage these difficult situations when they arise, rather than add to their burden.

> Our health system is only as strong as the people who work in it. Our health workforce is engaged and passionate and should be valued for its contribution, supported and encouraged to embrace new opportunities to deliver the best possible care.
>
> Health 2040: advancing health access and care

Healthcare workers should also be supported to learn from errors and incidents and to use these to build stronger relationships with their patients. They should also be encouraged to share their learnings and drive improvements both in their own practice and at a system level.

Principle 4: A statutory duty of candour should act to drive the development of just cultures within health services and to encourage the routine practice of open disclosure by health professionals

The fundamental purpose of both a statutory duty of candour and the standard practice of open disclosure is to foster an open and honest culture in health services and to improve the quality of care. Our approach to introducing a statutory duty must support the development of just cultures in hospitals and health services and address perceived barriers to open disclosure.

Principle 5: A statutory duty of candour must sit within a wider commitment to safety, learning and improvement

Following the release of *Targeting Zero*, the Minister for Health and the Secretary of the Department of Health and Human Services each made a clear, unequivocal commitment to strengthening their focus on quality and safety and supporting continuous improvement and learning across the system. To achieve this, transparency and a commitment to a culture of improvement needs to be evident at every level of the system. While a statutory duty of candour may contribute to this, it will not, in isolation, achieve it.

> Our vision for quality and safety in Victoria's health system:…
>
> …the world-class care patients receive is supported by a world-class system of quality and safety assurance.
>
> *Better, Safer Care* (2016)

Principle 6: Unintended adverse consequences and administrative burden associated with implementation of the statutory duty of candour should be minimised

In an environment of scarce resources, where the priority should be on delivering high quality and accessible patient care, it is critical that new requirements do not place an unnecessary burden on health services. Any new requirements on services should be fair, administratively efficient and, wherever possible, not lead to a duplication of effort or unintended changes in service delivery.

The statutory duty of candour must not have the effect of encouraging defensive medicine, nor should it take resources away from service delivery. As services are already required to implement open disclosure policies – through accreditation or service agreements – it will be important to ensure that new requirements do not needlessly introduce new administrative tasks without real value.

4. Issues for consideration

4.1 Scope

Targeting Zero recommended that the statutory duty of candour be "applied to hospital boards and executives who are responsible as organisation leaders, to create a culture of candour in which staff feel comfortable and indeed encouraged to disclose errors in care to consumers."

Recommendation 5.3
That a statutory duty of candour be introduced that requires all hospitals to ensure that any person harmed while receiving care is informed of this fact and apologised to…

Targeting Zero (page 200)

In scope organisations

In considering this recommendation, the Expert Working Group understands "all hospitals" to include those hospital services regulated under the *Health Services Act 1988*, including (as defined in that Act):

- public health services
- public hospitals
- multi-purpose services
- denominational hospitals
- privately operated hospitals
- private hospitals and
- day procedure centres

Through registration requirements and service agreement conditions, these are organisations that are currently required to implement open disclosure under the NSQHS Standards.

In contrast, the English statutory duty of candour applies more broadly to all providers of health services including, for example, aged care providers.

In the Victorian context, consideration will also be given to whether there is merit in applying the statutory duty to other services regulated under the *Health Services Act*, such as *registered community health centres,* or to a broader range of healthcare organisations (for example, *ambulance services*, *state funded residential care services* or *primary health services*).

Obligation on individual practitioners

Although the act of being candid – or not – belongs to individual health professionals, the statutory duty of candour proposed by *Targeting Zero* would apply to organisations. Individual health professionals already have professional and ethical obligations to be open and honest with patients when things go wrong[5] [ix]. Nonetheless, consideration might be given to the obligation, if any, under statute that should apply to individuals. In considering this issue, it is worth noting that the evolving nature of health care service provision means that it is no longer an 'individual craft.' Health care is usually delivered by teams of professionals. This might add complexity to the practice of open disclosure and to identifying the

[5] The Medical Board of Australia *Good Medical Practice: A Code of Conduct for Doctors In Australia* states that "when adverse events occur, you [doctors registered to practice medicine in Australia] have a responsibility to be open and honest in your communication with your patient, to review what has occurred and to report appropriately" and references the National Open Disclosure Framework. Similarly, the Nursing and Midwifery Board of Australia *Code of Professional Conduct for nurses in Australia* states that "nurses practise in accordance with wider standards relating to safety and quality in health care and accountability for a safe health system, such as those relating to … formal open disclosure procedures."

responsible party or parties who ought to be personally held to account for providing an explanation and apology to an affected consumer. Furthermore, the application of an individual obligation would do little to address the cultural issues, identified in *Targeting Zero,* which might act to limit the practice of open disclosure.

CONSULTATION QUESTIONS - SCOPE

Q1. Do you agree that the statutory duty of candour should apply to the set of health services described above including private sector organisations?

Q2. Which, if any, other healthcare providers should be in scope for the statutory duty of candour?

Q3. Do you believe the statutory obligation should apply to individuals instead of, or as well as, organisations?

4.2 When should the duty apply?

Types of events / incidents

Targeting Zero did not propose a threshold at which the statutory duty of candour should apply, but did note that "disclosure should occur regardless of whether a complaint has been made or a patient has made enquiries."

Recommendation 5.3

That a statutory duty of candour be introduced that requires all hospitals to ensure that any person harmed while receiving care is informed of this fact and apologised to…

Targeting Zero (page 200)

Types of harm

Like the related terms 'incident' and 'event', there is no single accepted definition of 'harm' in the patient safety field. This can lead to confusion for health professionals and may be unhelpful in discussions with consumers. Clearly any statutory duty requires clear and consistent definitions and should avoid introducing further confusion or, without good reason, propose different terminology.

In Victoria, hospitals and health services are required to report patient safety incidents via the Victorian Health Incident Management System (VHIMS), which uses an Incident Severity Rating scale to define harm based on degree of impact, level of care and treatment required, resulting in ratings of: severe/death; moderate; mild; no harm/near miss. These definitions do not include psychological harm.

The **Open Disclosure Framework** refers to 'adverse events', defined as '*an incident in which a person receiving health care was harmed*'.

It adopts the World Health Organisation definition of harm as:

> *'impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological.'*

The Open Disclosure Framework also makes a distinction between circumstances requiring higher level and lower level responses (see details in Appendix A).

Following extensive consultation in England, it was decided that the duty of candour would apply to all cases of death, severe and moderate harm, including prolonged psychological harm. In introducing the duty, the Care Quality Commission, the National Medical Council and other professional organisations prepared guidance, including scenarios, to illustrate when the duty would apply, There has been some suggestion that even with these materials, there remained some initial uncertainty about definitions and their application[x].

Consumer declared harm

It is known that consumers and clinicians may conceptualise 'harm' differently. The definitions described above are based primarily on a functional medical model of harm, and require the practitioner to identify that harm has occurred. While such definitions are important in providing clarity, they may not encompass all instances where an individual perceives that they have been harmed.

It has been proposed that a statutory duty of candour should also provide for the consumer to identify that harm has occurred. The proposed model is the introduction of a 'consumer right to declare' to match the practitioner's obligation to disclose. That is, a right for a consumer (or their family or carer) to declare that they have been harmed; and an obligation to discuss the events that led to this harm. It is suggested that these declarations, just like practitioner identified harm, would trigger the statutory duty of candour obligations

Avoiding unintended consequences

A final consideration in defining the set of circumstances in which a statutory duty of candour would apply, is the importance of ensuring that any thresholds set do not result in unintended consequences.

Defining thresholds for the statutory duty is not intended to limit an organisation's practice of open disclosure. It is intended that the statutory duty be a trigger for a more mature approach to open disclosure and a greater organisational focus on its practice. The necessity of setting clear triggers for the purpose of legislative certainty should not undermine this aim.

It would also be undesirable to define the statutory duty of candour in a way that dramatically increased the number of disclosure conversations that are required. As well as being potentially administratively burdensome, this could have the effect of diminishing public faith in health service organisations by creating a perception that services are unsafe or errors are too common.

Recency of incidents

In most cases, the occurrence of harm will be known almost immediately. However, as the tragic events at Djerriwarrh Health Service have shown, there will be circumstances when the nature or extent of harm arising from healthcare is not identified until weeks, months or even years after the event.

In establishing a new statutory obligation, it is necessary to clearly define when the obligation arises in relation to events that preceded the legislative change. It is proposed that the obligation for candour arise in relation to any *identification* of harm that occurs *after* the introduction of the relevant legislative provisions, regardless of when that harm itself occurred. For example, an organisation would be obliged to comply with the statutory duty of candour if, after the commencement of the relevant provisions, it uncovers evidence that, some years earlier, a number of individuals received sub-optimal treatment that may have resulted in harm that meets the threshold for the statutory duty.

While there may be an ethical imperative that harm identified prior to commencement of the legislative provisions be disclosed, it is not intended that the statutory duty apply retrospectively to such cases.

CONSULTATION QUESTIONS – WHEN SHOULD THE DUTY APPLY?

Q4. At what threshold of harm and/or for what type of incidents should the statutory duty of candour apply?

Q5. Should the statutory duty of candour apply to instances of psychological harm as well as physical harm?

Q6. Should the statutory duty of candour apply to near misses and/or complications of treatment that result in no harm and/or no lasting harm? Should it apply where the wrong treatment was given or non-evidence-based treatment was given if there is no harm as a result?

Q7. Do you agree that there should be provision for 'consumer declared harm' as a trigger for the statutory duty of candour to apply?

4.3 What should be required by the statutory duty of candour?

Targeting Zero indicated that the statutory duty of candour should require disclosure be undertaken by an appropriately trained professional and that the disclosure should be in a manner consistent with the *Open Disclosure Framework*.

Recommendation 5.3

That a statutory duty of candour be introduced … to ensure that any person harmed while receiving care is informed of this fact and apologised to … in a manner consistent with the national Open Disclosure Framework.

Targeting Zero (page 200)

The Open Disclosure Framework[6] sets out the elements of open disclosure and details components of open disclosure practice including: preparation; engagement in discussions; providing follow-up; and completing and documenting the process.

It is neither possible nor appropriate to stipulate this level of detail in legislation.

There may, however, be some elements of effective open disclosure practice that are of sufficient importance to warrant being mandated as essential for compliance with the statutory duty of candour.

Mandatory requirements can be set out in a range of ways. For example, it may be possible to include the statutory duty in legislation and set out particular requirements in regulations or require that the duty be carried out in accordance with some other subordinate instrument, such as guidelines or a policy endorsed by the Minister.

Under the Open Disclosure Framework, the elements of open disclosure are:

- An apology or expression of regret; (including the word 'sorry');
- a factual explanation of what happened;
- an opportunity for the consumer to relate their experience; and
- an explanation of the steps being taken to manage the event and prevent recurrence.

The Framework emphasises that open disclosure is a discussion and an exchange of information that may take place over several meetings. It is a dialogue between two parties, it is not a legal process and it does not imply that an individual or service has blameworthy facts to disclose.

Possible practice requirements that might be mandated are summarised below.

Elements of the candour conversation

The statutory duty of candour introduced for the NHS in England includes in regulations that the disclosure must:

- provide an account…of all the facts … [known] about the incident as at the date of the notification
- advise … what further enquiries into the incident … are appropriate
- include an apology and
- be recorded in a written record.

Other elements of the discussion that might be considered important are:

- an outline of what remedial action is proposed – both for the individual involved and at a system level and

[6] The Open Disclosure Framework and related supporting materials can be accessed via the Australian Commissioner on Safety and Quality in Health Care website: https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework/

- information about what rights the affected individual might have (for example, to make a complaint to the Health Complaints Commissioner, to notify the Australian Health Practitioner Regulation Agency and/or any legal redress).

How should the disclosure be delivered?

In England, it is required under the statutory duty of candour that the disclosure be made in person. It has been suggested, however, that there may be times when it is impractical, or not desirable, that face-to-face conversations take place, or at least in the first instance. For example, if there is a need to quickly advise a large number of people that a treatment error has occurred. It is possible that under these circumstances it would be preferable to write to affected individuals and, in doing so, offer them a follow up conversation (if appropriate and desired).

Who should be involved in the disclosure?

In England, the Care Quality Commission guidance for the duty of candour regulations states that: "in making a decision about who is most appropriate to provide the notification and/or apology, the provider should consider seniority, relationship to the person using the service, and experience and expertise in the type of notifiable incident that has occurred."

Going further – to mandate that a particular individual undertake the candour conversation – is unlikely to be beneficial.

While generally there is value in the person responsible for the consumer's care conducting the discussions, there may be circumstances in which this is not desirable. The affected person may not wish to discuss the matter with the practitioner, the practitioner may be unprepared to conduct the discussion, or may not believe that the incident requires such a conversation.

The Open Disclosure Framework, states that –

'*where appropriate, open disclosure should be an interprofessional process, and the participants from the health service organisation will vary depending on circumstances'*

and

'it is recommended that clinicians involved in adverse events be given the option to participate in the disclosure…when it is not possible for the most senior clinician responsible for the clinical care of the consumer to be present, an appropriately senior person who is trained in open disclosure processes should lead the disclosure'

It may be more appropriate to ensure that whoever conducts the necessary conversations is appropriately skilled and supported. It might be possible, for example, to require that organisations ensure staff meet minimum levels of competency in relation to open disclosure, that there is appropriate saturation and frequency of training and/or that just-in-time training and support is readily available (see section 4.4).

It might also be beneficial to require that the affected individual has a right to nominate who they would like to have discussions with. It has also been suggested that the consumer should have a right to have a support person present for these conversations.

Requirements for documentation

The Open Disclosure Framework stresses that comprehensive documentation significantly contributes to successful open disclosure. It requires that the disclosure of an adverse event and the facts relevant to it must be properly recorded. Relevant documentation includes patient records, incident reports and records of the thorough review of the adverse event.

The Care Quality Commission (England) regulations in relation to the statutory duty of candour requires that the conversation must be followed with written communication including the matters covered in the conversation, details of any enquiries to be undertaken, the results of any further enquiries into the incident, and an apology.

Timeliness

There is clear evidence that timely communication is beneficial both to ensure that consumers have the information they require to make decisions about further care requirements and to assist with healing. The statutory duty of candour introduced in England requires that the disclosure occurs "as soon as reasonably practicable" after the responsible person becomes aware of the incident.

The Open Disclosure Framework recognises however that "prompt open disclosure may not be indicated in every situation and may need to be deferred in some instances". This may be the case, for example, if the physical or mental health of the consumer is not conducive to participating in open disclosure or if the consumer or their families request deferral.

CONSULTATION QUESTIONS – WHAT SHOULD BE REQUIRED BY THE STATUTORY DUTY OF CANDOUR?

Q8. Which, if any, of the matters outlined above should be included within the statutory requirements for the duty of candour?

Q9. Are there other matters that should be included within the statutory requirements or encouraged through other means?

4.4 What is needed to make the statutory duty of candour effective?

Legislation alone will not be sufficient to achieve the aims of reducing the disclosure 'gap' and, more importantly – improving the quality of open disclosure dialogue. Other changes will also be required. Organisational and cultural factors have a significant impact on the practice of open disclosure[xi].

> No legal duty will ever produce by itself the necessary skill, commitment and support to make a culture of candour a reality for patients.
>
> Sir David Dalton and Professor Norman Williams 'Building a culture of candour' (2014)

What barriers might work against effective implementation of the statutory duty of candour?

Resistant culture in services

Targeting Zero identified a failure of hospital cultures to support open disclosure and recognised that there is weak familiarity with existing obligations. A statutory duty might encourage organisations to pursue cultural change, however, organisation culture change is complex[xii] and a statutory duty alone will not deliver the culture of candour *Targeting Zero* identified as being necessary.

Lack of skills or knowledge

Research cites inadequate training and knowledge as among the key barriers to the practice of open disclosure[xiii]. The 2012 Open Disclosure Standard review report found that health care professionals admitted that they were uncertain about:

- which incidents 'trigger' open disclosure;
- the impact of open disclosure on staff and their organisation's reputation; and
- whether colleagues would support those carrying out open disclosure.

> Professional regulation was just one among many influences on registrants' daily behaviour, judgements and decisions….the regulator is not overtly present in the small ethical decisions of everyday life.
>
> Professional Standards Authority advice to the Secretary of State for Health - *Can professional regulation do more to encourage professionals to be candid when healthcare or social work goes wrong?* (2013)

Unreasonable administrative burden

Practitioners and service providers rightly prioritise patient care. If the requirements of the statutory duty place too high a level of administrative burden on services, and are seen as taking time or resources away from direct service provision, this may impact on compliance.

What will enable good practice?

Clear lines of responsibility and supportive leadership

Introducing a statutory duty will make clear that the responsibility for ensuring that services comply with obligations for candour rests at the Board level.

To ensure that all members of an organisation are aware of, and carry out, their responsibilities, there is a need for strong leadership and clear lines of accountability.

It may be appropriate for services to identify a "responsible person" to take carriage of leading implementation, and ensuring effective compliance with, the statutory duty. This would not diminish the ultimate responsibility of hospital boards and management, but might ensure there is effective day to day leadership and clear lines of reporting and accountability. Having a designated person responsible for a particular obligation can ensure that there is someone within an organisation with a deep knowledge of

regulatory requirements and what regulators expect; and they can coordinate operational responses accordingly.

Cultural change will require the development of an organisational willingness to hear 'bad news' and take action to prevent reoccurrence. Organisations that foster collective reflection on safety issues and concerns and take action to improve safety by applying lessons learnt can help remove the stigma associated with errors and encourage open disclosure.

Clarity about obligations under the statutory duty and how they intersect with other related obligations, such as those set out in professional codes or under accreditation standards, will also be important to effective implementation. A lack of such clarity may result in unintended consequences, such as more narrowly practiced or delayed open disclosure[xiv].

Robust reporting systems

There is likely to be much higher compliance with the statutory duty where service providers can see benefits in terms of learnings and system improvement. Reparative quality improvement action requires strong systems of reporting both within services at Board level and across the health system. There is scope for improvement in the level and accuracy of reporting of patient safety incidents and in the capacity to share and apply lessons learned across the health system.

Training

Comprehensive training will be critical to support the introduction of a statutory duty of candour.

Recommendation 5.3
That a statutory duty of candour be introduced … to ensure that any person harmed while receiving care is informed of this fact and apologised to by an appropriately trained professional...

Targeting Zero (page 200)

Such training would cover the open disclosure process and consumer's rights and expectations. Health professionals also need to be equipped with the necessary communication skills to handle open disclosure conversations and with knowledge about the implications of disclosure[xv]..

There may be significant value in considering how consumers and/or their families might be involved in the design, delivery and evaluation of such training.

Training should not be limited to communication after something has gone wrong. Open disclosure (and a statutory duty of candour) should exist at one end of a spectrum of open communication with consumers which starts when they first present for treatment or assessment, encompasses supportive informed consent and continues throughout their care. The process of apologising and informing a consumer that something has gone wrong is less difficult for all if the consumer has been made aware of, and is prepared for, risks associated with treatment.

Support for staff

In addition to ensuring that effective open disclosure training is available, health service providers have a role in ensuring sufficient professional support is provided to staff to manage their experience of making an error or of being involved in an adverse event. The importance of this support is reflected in a growing body of literature about the distress experienced by health professionals in these situations.[xvi]

Role of the Department of Health and Human Services as system leader

While individual hospitals and health services have a significant role to play in supporting frank and open discussions with consumers, some of the issues identified above will require redress at a system level and will require support and leadership from the Department of Health and Human Services.

CONSULTATION QUESTIONS – WHAT IS NEEDED TO MAKE THE STATUTORY DUTY OF CANDOUR EFFECTIVE?

Q10. Do you agree with the key barriers and enablers identified above?

Q11. What are the most important factors to ensure the statutory duty of candour achieves its intended aims?

Q12. How can the necessary training best be delivered?

Q13. Do you agree with the support requirements identified above? What other actions might be needed?

4.5 Are additional protections are needed?

Apology laws

Concern about medico-legal consequences as a barrier to disclosure practices

Fear of medico-legal consequences and uncertainty about the legal implications of open disclosure are among the main factors in clinicians' reluctance to apologise, and to disclose adverse events in general.[xvii] Confusion about legal protections may also contribute to organisational cultures that do not support or promote candour.

Apology laws in Victoria

Apology laws protect statements of apology or regret made after incidents from subsequent use in certain legal settings.[xviii]

In Victoria the relevant legislation is the *Wrongs Act (Vic) 1958* which says that an apology is not an admission of fault or liability and an admission of fault or liability is not protected. This means that saying sorry doesn't increase the risk of medico-legal consequences (being sued) but other aspects of an open disclosure conversation (for example, explaining what happened in a way that admits fault) may.

In the recent *Apologies* review, the Victorian Ombudsman recommended that –

the Victorian Government consider amending Part IIC of the Wrongs Act 1958 (Vic) to:

a. prevent apologies being used as an admission of liability or evidence in all types of civil proceedings

b. expand the definition of apology to include apologies that involve an acknowledgement of responsibility or fault.

The Victorian Government's *Access to Justice Review* (2016) contained a similar recommendation seeking amendments to the *Wrongs Act* to broaden the protection given to apologies so they are not admissible as evidence of fault or liability.

Wrongs Act (Vic) 1958
s14I Definitions
In this Part —
apology means an expression of sorrow, regret or sympathy but does not include a clear acknowledgment of fault;

s14J Apology not admission of liability
(1) In a civil proceeding where the death or injury of a person is in issue or is relevant to an issue of fact or law, an apology does not constitute—
(a) an admission of liability for the death or injury; or
(b) an admission of unprofessional conduct, carelessness, incompetence or unsatisfactory professional performance, however expressed, for the purposes of any Act regulating the practice or conduct of a profession or occupation.
(2) Subsection (1) applies whether the apology—
(a) is made orally or in writing; or
(b) is made before or after the civil proceeding was in contemplation or commenced.
(3) Nothing in this section affects the admissibility of a statement with respect to a fact in issue or tending to establish a fact in issue.

Apology laws in other jurisdictions

New South Wales, the Australian Capital Territory and Queensland, each have more recent apology laws. Unlike in Victoria, in these jurisdictions admissions of fault or liability are defined as part of the apology and are therefore protected.

Comparison of the features of apology laws in Australian jurisdictions

State or territory	Apology defined to expressly exclude any admission of fault or liability	Apology not an admission of fault or liability on the part of the person making it	Apology not relevant to a determination of fault or liability	Evidence of apology inadmissible in civil proceedings as evidence of fault or liability
Victoria	**Yes**	**Yes**	**No**	**No**
NSW	No	Yes	Yes	Yes
Queensland	Yes	No*	No*	Yes
South Australia	No	Yes	No	No
Western Australia	Yes	Yes	Yes	Yes
Tasmania	Yes	Yes	Yes	Yes
Northern Territory	Yes	No*	No*	Yes
ACT	No	Yes	Yes	Yes

**Not expressly stated but implicit from the nature and purpose of related sections*
See Appendix 2 for more details

International approach

The approach in other international jurisdictions varies significantly.

- Approaches taken in the US differ across different states. 33 states have enacted what can be described as partial apology laws – that is, protection of statements of sympathy, condolence, and apology – that do not protect statements admitting fault, error, or negligence. Five states have put in place more comprehensive apology laws which cover both the apology and statements of fault or liability
- Canadian apology laws in each jurisdiction cover the full apology, including admission of fault or mistake and go further to protect apologies in proceedings before a tribunal, an arbitrator and any other person who is acting in a judicial or quasi-judicial capacity. In most cases it also expressly covers issues of limitation of actions and insurance policies
- The UK Compensation Act 2006 states that “An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty”
- NZ has addressed concerns of medico legal consequences of apology and disclosure differently. NZ has introduced a no-fault insurance scheme which replaces malpractice insurance with a government fund for payout to affected patients.

It has been argued that the placement of statutory protections alongside a statutory duty may act to alleviate doubt about what may or may not be admissible in subsequent legal proceedings.

Qualified privilege

Qualified privilege is a legal doctrine that protects certain documents and communications from demands to disclose them in legal proceedings. To encourage the free flow of information, some information produced as part of activities aimed at improving the quality of health care is protected. In Victoria, like a number of other Australian jurisdictions, qualified privilege is anchored in “quality assurance committees” (under s139 of the Health Services Act).

While the quality assurance work of a committee declared under s139 is essentially separate to open disclosure, the two are related. There is evidence that there is some uncertainty within the sector about:

- the extent to which the existence of qualified privilege might prohibit or impact on the release of information to consumers through the open disclosure process if the information is also relevant to a quality assurance committee's work and
- the extent to which the qualified privilege protections provided to quality assurance committee information extends to the same information if it is disclosed as part of the open disclosure conversation.

Analysis suggests that the link between qualified privilege law and open disclosure is weak. The law does not present a significant barrier to the provision of information to consumers nor offer significant protection over information provided as part of an open disclosure conversation[xix]. Nonetheless, the reported uncertainty may indicate a need for greater clarity in the statute; or at least robust educational materials addressing this issue when a statutory duty of candour is introduced.

CONSULTATION QUESTIONS – ARE ADDITIONAL PROTECTIONS NEEDED?

Q14. Is there a need to strengthen Victoria's apology laws?

Q15. Do you think there is merit in including statutory protections for open disclosure alongside the statutory duty of candour?

Q16. Is there a need to clarify, in legislation or through supporting materials, the relationship between open disclosure and qualified privilege?

Q17. Are other statutory protections required?

4.6 Identifying and responding to failures to comply with the statutory duty of candour

The purpose of a statutory duty of candour is to improve practice in services and to promote honest, open and just cultures.

To have meaning, the duty requires a capacity to identify good practice and to identify when there are instances of non-compliance. At a basic level, the response to breaches of the duty should be to consult, educate and reinforce the positive messages about why candour is important. There may be times, however, when there are serious or repetitive breaches that require more significant action. A range of sanctions could be available for use in these circumstances.

Monitoring compliance / identifying breaches

Compliance with the statutory duty of candour in England is monitored by the independent healthcare regulator, the Care Quality Commission.

Monitoring and reporting on compliance

There is a range of bodies in Victoria that might play a role in monitoring and reporting on compliance with a statutory duty in Victoria, for example, Safer Care Victoria, the Department of Health and Human Services, or the Health Complaints Commissioner. However, there may also be limitations to the role these entities could appropriately play. Safer Care Victoria's main function is as an improvement body and not a regulator and the Health Complaints Commissioner does not currently have an active auditing role.

Identifying breaches

Non-compliance might come to the attention of relevant agencies without the necessity for an active monitoring or auditing function. For example, instances of breach of the statutory duty may come to light through existing mechanism for assessing services against National Standards, through complaints about failures to appropriately practice open disclosure made to the Health Complaints Commissioner or through notifications to the Australian Health Practitioner Regulation Agency.

It will be important to ensure that there are no barriers to such agencies sharing information when they become aware of failures to comply with the duty.

Responding to failures to comply

Where non-compliance is identified, it is necessary to have clear systems in place to respond.

In the first instance, it will be important to have processes in place to ensure that any affected consumer and/or their family is advised about the incident if they are not yet aware of the issue.

Secondly, it may be appropriate that some form of sanction be applied. Sanctions for non-compliance with a statutory duty of candour must be proportionate and must support the principle of encouraging open disclosure.

The maximum penalty for breaching the statutory duty of candour in England is £2,500, however the Care Quality Commission has stated that it expects to use its powers mainly to confirm or encourage good practice through its inspections and ratings.

Non-penalty sanctions should also be considered. The types of sanctions required will depend on how the duty is framed, in particular who is responsible under the law for compliance – the organisation or individual practitioners.

Sanctions that could apply to individual practitioners

Aside from penalty fines, sanctions relevant to individual practitioners would relate to their professional registration and standing. Non-compliance with the statutory duty might be grounds for a notification to the Australian Health Practitioner Regulation Agency and the National Boards and may result in regulatory sanctions.

Sanctions that could apply to organisations

At an organizational level, the availability of appropriate sanctions will assist in ensuring that the issue of candour is given sufficient weight at the Board and/or management level of hospitals and health services.

Again, in addition (or as an alternative) to a penalty fine, non-compliance with a Victorian statutory duty of candour, a range of other sanctions might also be considered for organisations.

Complaints Commissioners

Failure to comply with a statutory duty could be grounds for a complaint or referral to the Health Complaints Commissioner (or where relevant, the Mental Health Complaints Commissioner) for investigation. An identified breach might also be reported to the Minister or Department of Health and Human Services for action.

Action under the Health Services Act

The *Health Services Act* contains a number of provisions that allow the Secretary of the Department of Health and Human Services and/or the Minister for Health to take necessary action in response to issues of concern. In introducing a statutory duty of candour, amendments to the Act could be made so that a failure to comply with the duty becomes grounds for action. For example –

- both the Minister and the Secretary have powers, under specified circumstances, to *issue directions* to services. It may be possible for these powers (or powers under amended provisions) to be used to address failings in relation to the statutory duty of candour (for example to ensure that a service implements compulsory education or undertakes a case review to identify and remedy any failings).
- significant breaches of the duty might be grounds for the *appointment of a delegate* to the board of public health services, public hospitals and multi purposes services or for exercise of the Minister's powers to censure a service.
- in the case of *private sector hospitals and day procedure centres*, the Health Services Act allows for a range of matters to be taken into consideration when decisions are being made about *service registration and renewal*. Non-compliance with a statutory duty of candour may be identified as an additional matter that may be considered at these times, and may, in serious circumstances, lead to a decision to place conditions on or deny registration or renewal of registration, of the service.

CONSULTATION QUESTIONS – IDENTIFYING AND RESPONDING TO FAILURES TO COMPLY

Q18. How should failures to comply with a statutory duty of candour be identified?

Q19. What consequences or sanctions should be available in response to identified breaches of the statutory duty of candour?

4.7 Other

This paper outlines the issues for consideration that have been identified by the Expert Working Group as requiring resolution before a proposal can be put to the Minister.

The Expert Working Group would also like to hear of other issues identified by stakeholders or additional proposals about how the aims of a statutory duty of candour might best be realised.

CONSULTATION QUESTIONS – OTHER

Q20. Are there other issues, not covered in this paper, that should be addressed or considered as part of the introduction of a statutory duty of candour?

Appendices

Appendix A – current Victorian requirements for open disclosure

Appendix B – approach to candour and open disclosure in selected other jurisdictions

Appendix A – relevant current requirements in Victoria

Although there is, as yet, no legislative requirement for candour or open disclosure in Victoria (or any other Australian jurisdiction), there are a number of obligations on health services and health professionals that are relevant to the matters raised in this paper.

Open Disclosure and accreditation

Health service organisations are required to implement open disclosure as part of the *National Safety and Quality Health Service Standards*.

The National Safety and Quality Health Service (NSQHS) Standards (second edition) have recently been endorsed by Health Ministers and will be launched in November 2017. Assessment against this edition will commence from 1 January 2019. Under these Standards (Standard 1: Governance for Safety and Quality in Healthcare Organisations), there will be a requirement that a health organisation – "uses an open disclosure program that is consistent with the Australian Open Disclosure Framework" and "monitors and takes action to improve the effectiveness of open disclosure processes"[7]. This builds on criteria under the first edition of the NSQHS which required health organisations to have in place an open disclosure program consistent with the national open disclosure standard and that the clinical workforce be trained in open disclosure processes.

Victorian public health services must comply with conditions specified in their service agreement (Policy and Funding Plan) with the Department of Health and Human Services. The service agreement requires that health services comply with the NSQHS Standards and suggests that all services should develop their own open disclosure process in accordance with the Australian Open Disclosure Framework.

Private hospitals and day procedure centres are not bound by the service agreements of the Department, however, accreditation is a condition of registration for private services and is required under the Private Health Insurance Act 2007 (Cth) in order to access private health insurance rebates. When the *Health Legislation Amendment (Quality and Safety) Act 2017* comes into effect, there will be a new capacity for the Secretary to approve an accreditation scheme (for example accreditation against the NSQHS) and it will be an offence for the proprietor of a private hospital or day procedure centre to fail, without reasonable excuse, to comply with the requirements of an applicable approved scheme.

The Open Disclosure Framework

The Australian Open Disclosure Framework 2014, developed by the Commission on Safety and Quality in Health Care (ACSQHC), provides a basis for assessment against the standards and includes comprehensive guidance to health service organisations and clinicians. It provides a nationally consistent basis for open disclosure in Australian health care across all settings and sectors[8].

The framework establishes key principles for open disclosure:

- **Open and timely communication** - a patient is to be provided with information about what happened in an open and honest manner at all times, which may involve the provision of ongoing information.

[7] More information is available from: https://www.safetyandquality.gov.au/our-work/assessment-to-the-nsqhs-standards/nsqhs-standards-second-edition/

[8] More information is available from: https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework/

- **Acknowledgment** - health services are to acknowledge when an adverse event has occurred as soon as practicable, and to initiate the open disclosure process.
- **Apology or expression of regret** - a patient is to receive an apology or expression of regret for any harm that resulted from an adverse event as early as possible.
- **Recognition of reasonable expectations** - a patient may reasonably expect to be fully informed of the facts surrounding an adverse event and its consequences, treated with empathy, respect and consideration and provided with support in a manner appropriate to the patient's needs.
- **Staff support** - health services are to create an environment in which all staff are able and encouraged to recognise and report adverse events, and are supported through the open disclosure process.
- **Integrated risk management and systems improvement** - investigation of adverse events and outcomes are to be conducted through processes that integrate a focus on risk management and on improving systems of care and reviewing their effectiveness.
- **Good governance** - a system of accountability must be in place (through the health service's chief executive officer or governing body) to implement clinical risk and quality improvement processes that prevent the recurrence of adverse events, and to ensure changes are reviewed for their effectiveness.
- **Confidentiality** - health services are to develop policies and procedures with full consideration of consumer and staff privacy and confidentiality, and in compliance with relevant law, including Commonwealth and state or territory privacy and health records legislation.

The framework also describes key considerations and core aspects of the open disclosure process.

As outlined in the table below, the appropriate responses described in the Open Disclosure Framework vary according to the severity of the incident, with lower level responses (which may be limited to an acknowledgement and explanation) required for less serious incidents and higher-level responses required for more significant occurrences. Higher-level responses involve a longer process with ongoing dialogue and follow up.

Appendix A Table 1: Responses under the Open Disclosure Framework

Incident type	Criteria
Lower-level response	1. Near misses and no-harm incidents 2. No permanent injury 3. No increased level of care (e.g. transfer to operating theatre or intensive care unit) required 4. No, or minor, psychological or emotional distress
Higher-level response	1. Death or major permanent loss of function 2. Permanent or considerable lessening of body function 3. Significant escalation of are or major change in clinical management (e.g. admission to hospital, surgical intervention, a higher level of care, or transfer to intensive care unit) 4. Major psychological or emotional distress 5. At the request of the patient

Victorian Heath Incident Management policy

Under service agreements (Policy and Funding Plan) with the Department of Health and Human Services, public hospitals and health services must comply with the *Victorian Health Incident Management Policy* (the incident management policy).

The incident management policy instructs health services on establishing an incident management review process consistent with their clinical governance policy, and with the national quality and safety standards of the Australian Commission on Safety and Quality in Health Care. The policy provides information to assist health services, agencies and their staff to identify, manage and review incidents as they occur across the health care environment. The policy and guide considers incident management roles and responsibilities; the incident management process; and the incident severity rating (ISR).

The incident management policy places an obligation on health service CEOs to "ensure the principles of open disclosure are observed when interacting with patients and their families or carers when an incident occurs and that these principles guide the overall management of the incident". It further requires that "all clinical ISR 1 and 2 events[9] are to be managed by the open disclosure process", and that "the initial disclosure to the patient, client or resident or their support person must occur within 24 hours of the incident, or as soon as is practicable, by the health care professional responsible for the care of the patient or their approved delegate"[10].

Professional obligations

A professional duty to be open and honest in communication with patients when an adverse event occurs exists in the Codes of Conduct for each of the 14 professions regulated under the Health Practitioner Regulation National Law (in the case of the Psychology Board of Australia, this is framed as a general obligation to "act with probity and honesty in their conduct"). Most of these codes also note that "Good practice in relation to risk management involves – being aware of the principles of open disclosure and a non-punitive approach to incident management"[11].

Victorian Charter of Human Rights & Responsibilities

The Victorian Parliament passed the *Victorian Charter of Human Rights and Responsibilities 2006* (Vic) to protect human rights and ensure that government departments and public bodies observe these rights when making decisions and developing policy. The Act, which came into effect in July 2007, contains 20 civil and political rights.

At the time - and specifically in relation to open disclosure - the Charter was interpreted to include a new legal obligation (previously an ethical one) for public entities (including public health services) to discuss adverse events with affected patients. Section 15 of the legislation refers to the right to freedom of expression that includes the right to receive information and is relevant to the open disclosure process. This right can only be qualified by the express limitations set out in section 7 of the Act ("such reasonable limits as can be demonstrably justified in a free and democratic society based on human dignity, equality and freedom, and taking into account all relevant factors....").

It has since been argued - more broadly and not specifically in relation to open disclosure - that while the right to freedom of expression also incorporates a right to freedom of information; the right to receive information is not absolute, and may be subject to objective, proportionate and reasonable limitations. In particular, information may be withheld for any of the reasons listed in section 15(3) 'to respect the rights

[9] ISR refers to the Incident Severity Rating which is based on the actual and potential impact to those involved in the incident, and the actual and potential impact to the organisation; with ISR1 being severe/death; 2. Moderate, 3. Mild; and 4. No harm/near miss. The impact to the people involved is automatically derived from three related questions, these are: 1. degree of impact 2. level of care 3. treatment required.

[10] More information is available from https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/clinical-risk-management/health-incident-policy

[11] Codes of Conduct can be viewed via the Australian Health Practitioner Regulation Agency Website: www.ahpra.gov.au

and reputation of other persons' or 'for the protection of national security, public order, public health or public morality'. (see for example, XYZ v Victoria Police [2010] VCAT 255).

All health professionals working in public health services should be aware of the implications of this legislation.

Appendix B – approach to candour and open disclosure in selected other jurisdictions

The following tables provide an overview of approaches to candour, open disclosure and apology law protections in selected Australian and International jurisdictions.

Appendix B Table 1: Open disclosure in selected Australian jurisdictions

Jurisdiction	WA
Open disclosure	**The WA Open Disclosure Policy 2009 (amended 2012)**
Features	Patients in public health services must be informed of the probable or definite occurrence of a clinical incident that has resulted in, or is expected to result in, harm to the patient, including the following: • A defined Sentinel Event that is reportable to the Director, Office of Safety and Quality in Healthcare. • A clinical incident that has or is expected to have a significant clinical effect on the patient and that is perceptible to either the patient or the health care team. • A clinical incident that necessitates a change in the patient's care. • A clinical incident with a known risk of serious future health consequences, even if the likelihood of that risk is extremely small. • A clinical incident that requires hospital/health service staff to provide treatment or undertake a procedure without the patient's consent. Patients have a fundamental right to be informed about all aspects of their treatment. Private hospitals may wish to use the Policy as a basis for developing their own Open Disclosure Policy/Procedure.
Definition of harm	*Clinical incident* – an event or circumstance resulting from health care which could have, or did, lead to unintended harm to a person, loss or damage, and/or a complaint. In the context of this definition, a 'person' includes a patient, client or visitor. Clinical incidents include: • *near misses* – incidents that may have, but did not cause harm • *adverse events* – an incident in which harm resulted to a person. *Harm* includes death, disease, injury, suffering and/or disability.
With whom duty lies	All *hospitals/health services* must also ensure that the endorsed Open Disclosure Process is integrated with their overall clinical risk management systems. Hospitals/health services will therefore ensure that: • integrated risk management and quality improvement processes are in place • systems are in place to identify, manage and investigate clinical incidents • designated key staff participate in and have responsibility for patient safety, quality improvement and risk management • sentinel events are reported to the Director, Office of Safety and Quality in Healthcare within seven working days of the incident occurring, and the sentinel event final report submitted to the Office of Safety and Quality in Healthcare within forty five (45) working days of initial notification • training and support is provided to relevant staff in communication skills, the Open Disclosure Process, investigation and grading of clinical incidents and risk management • the WA Open Disclosure Policy is actively promoted and disseminated to all staff. • WA hospitals/health services must consult with insurer (or private insurers where relevant), the Legal and Legislative Services Directorate of the Department of Health or the State Solicitor's Office or their private insurers, to ensure that: o the implementation of an Open Disclosure Policy will not be in breach of legislation, their insurance policy or self-insurance cover document o appropriate open disclosure policies and protocols are developed and implemented to meet the needs of hospitals/health services, their legal representatives and their insurers o all legal and insurance requirements are fully met.

Jurisdiction	NSW
Open disclosure	**Open Disclosure Policy PD 2014_028 (2 Sept 2014)**
Features	Sets out the minimum requirements for implementing open disclosure within NSW Health facilities and services, describes when open disclosure is required, defines the two stages of the open disclosure process - clinician disclosure and, where indicated, formal open disclosure, outlines key steps, and outlines the roles and responsibilities for NSW Health staff in relation to open disclosure. The mandatory requirements for Health Services in the implementation of the open disclosure policy following a patient safety incident in NSW are as follows: • Acknowledgement of a patient safety incident to the patient and/or their support person(s), as soon as possible, generally within 24 hours of the incident. This includes recognising the significance of the incident to the patient. • Truthful, clear and timely communication on an ongoing basis as required. • Providing an apology to the patient and/or their support person(s) as early as possible, including the words “I am sorry” or “we are sorry”. • Providing care and support to patients and/or their support person(s) which is responsive to their needs and expectations, for as long as is required. • Providing support to those providing health care which is responsive to their needs and expectations. • An integrated approach to improving patient safety, in which open disclosure is linked with clinical and corporate governance, incident reporting, risk management, complaints management and quality improvement policies and processes. This includes evaluation of the process by patients and their support person(s) and staff, accountability for learning from patient safety incidents and evidence of systems improvement.
Definition of harm	Impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological. (World Health Organization The International Classification of Patient Safety, WHO, Geneva, 2009)
With whom duty lies	Health Services Boards, Clinical Councils and staff are responsible for: • Actively committing to open disclosure for all patient safety incidents, to create and support an environment where the focus is on patient-based care • Enabling timely open disclosure through actively promoting a just and fair culture that ensures all staff in the Health Service are supported and encouraged to identify and report when a patient safety incident has occurred • Building a positive culture by learning from all patient safety incidents. Chief Executives are responsible for: • Leading and overseeing the implementation of the NSW Health Open Disclosure Policy • Ensuring that systems and processes are in place for all staff in the Health Service to identify and report when a patient safety incident has occurred, so that open disclosure can be initiated • Ensuring that all clinical staff (and other staff as deemed necessary for their role) access and complete role-relevant open disclosure education and training • Allocating responsibilities and resources to maintain effective open disclosure processes • Ensuring the availability of effective clinician support services • Ensuring the availability of trained Open Disclosure Advisors to support formal open disclosure.

Jurisdiction	South Australia
Open disclosure	**Patient incident management and open disclosure - Policy Directive July 2016**
Features	After a patient incident, two separate but linked and related processes are initiated: • *open disclosure* - that will assist the patient and carers in their recovery from the incident, and guide the health workforce and health service organisations in supporting patients who have experienced harm • *incident reporting*, investigation, analysis and action to change practices - these benefit staff, the health service and the patient through improvement of safety and quality of services. The linking of open disclosure and incident management is essential to ensure that: • patients and family/carer can contribute to the investigation, and are informed of the recommendations arising and actions taken or planned to prevent recurrence and improve safety and quality of the service • health service organisations learn from the investigation of incidents and from the patient and family/carer perspectives.
Definition of harm	A *patient incident* is any event or circumstance which could have (near miss) or did lead to unintended and/or unnecessary psychological or physical harm to a patient, that occurs during an episode of health care. • *incident (*patient *incident*) means: any event or circumstance which could have (near miss) or did lead to unintended and/or unnecessary psychological or physical harm to a consumer/patient that occurs during an episode of health care. Incident types are harmful incident, cluster incident, near miss, no harm incident and adverse incidents • *cluster* incident means a type of adverse incident where there is a group or series of harmful incidents that are the result of one systemic error or issue, and that involves a systems failure or multiple systems failure that does or has the potential to place more than five patients directly at risk *open disclosure* means: a process of providing an open, consistent approach to communicating with consumers/patients and their carer/support persons after an incident. The level of open disclosure process required will depend on the outcome and circumstances of the incident: Level 1 that is, more serious incidents or significant patient or family/carer concern; or Level 2 that is, less serious incidents
With whom duty lies	All SA Health employees or persons who provide health services on behalf of SA Health will comply with this policy directive. The health service organisation must have a patient incident management and investigation system that: • supports staff, patients and family/carer to recognise and report patient incidents, and use the patient incident management module of the SLS to document the investigation and analysis of incidents and open disclosure processes in an accurate and timely manner • initiates and provides open and timely communication, that is, an appropriate open disclosure response, with the patient, and carers where appropriate, after a patient incident, and that this includes an acknowledgement of the incident, an expression of regret and provision of ongoing information as required • ensures that staff have the skills and knowledge required for their roles and are supported after distressing incidents • involves staff and patients and family/carer in the investigation and analysis of patient incidents when appropriate; provides timely feedback from the analysis of patient incidents to the governing body, staff and consumer groups; and ensures that recommendations for quality improvement are implemented and monitored • recommends that risks identified during the analysis of patient incidents are included into the local risk management system • meets statutory and other requirements for: reporting or notification to external organisations and bodies of incidents involving patients; and investigation, analysis, documentation and protection of information gained during these processes.

Appendix B Table 2: Apology Laws in Australia

Jurisdiction	Relevant Act	Definition of apology (highlights added)	Admissibility / effect on liability
ACT	*Civil Law (Wrongs) Act 2002* (s14)	An oral or written expression of sympathy or regret, or of a general sense of benevolence or compassion, in relation to an incident, **whether or not the expression admits or implies fault or liability in relation to the incident**.	An apology made by or on behalf of a person in relation to an incident claimed to have been caused by the person— (a) **is not (and must not be taken to be) an express or implied admission of fault or liability** by the person in relation to the incident; and (b) is **not relevant to deciding fault or liability** in relation to the incident. **Evidence of an apology** made by or on behalf of a person in relation to an incident claimed to have been caused by the person is **not admissible in any civil proceeding as evidence of the fault or liability of the person in relation to the incident.**
New South Wales	*Civil Liability Act 2002* (s69)	An expression of sympathy or regret, or of a general sense of benevolence or compassion, in connection with any matter **whether or not the apology admits or implies an admission of fault in connection with the matter**.	An apology made by or on behalf of a person in connection with any matter alleged to have been caused by the person: (a) **does not constitute an express or implied admission of fault or liability** by the person in connection with that matter, and (b**) is not relevant to the determination of fault or liability** in connection with that matter. (2) Evidence of an apology made by or on behalf of a person in connection with any matter alleged to have been caused by the person is **not admissible in any civil proceedings as evidence of the fault or liability of the person in connection with that matter.**
Northern Territory	*Personal Injuries (Liabilities & Damages) Act 2003* (s12 and s13)	An expression of regret is an oral or written statement by a person: (a) that expresses regret for an incident that is alleged to have caused a personal injury; and (b**) that does not contain an acknowledgement of fault by that person.**	**An expression of regret** about a personal injury made at any time before the commencement of a proceeding in respect of that injury **is not admissible as evidence in that proceeding**.
Queensland	*Civil Liability Act 2003* (s71 and s72)	An **expression of regret** made by an individual in relation to an incident alleged to give rise to an action for damages is any **oral or written statement** expressing **regret for the incident to the extent that it does not contain an admission of liability** on the part of the individual or someone else. **An apology** is an expression of sympathy or regret, or of a general sense of benevolence or compassion, in connection with any matter, **whether or not it admits or implies an admission of fault in relation to the matter.**	**An expression of regret** made by an individual in relation to an incident alleged to give rise to an action for damages at any time before a civil proceeding is started in a court in relation to the incident **is not admissible in the proceeding**. **An apology** made by or on behalf of a person in relation to any matter alleged to have been caused by the person— (a**) does not constitute an express or implied admission of fault or liability** by the person in relation to the matter; and (b) is **not relevant to the determination of fault or liability** in relation to matter. (2) **Evidence of an apology made by a person is not admissible in any civil proceeding as evidence of the fault or liability** of the person in relation to the matter.

South Australia	*Civil Liability Act 1936* (s75)	An expression of sympathy or regret, or of a general sense of benevolence or compassion, in connection with any matter, **whether or not the apology admits or implies an admission of fault in connection with the matter.**	An apology made by or on behalf of a person in connection with any matter alleged to have been caused by the person— (a) **does not constitute an express or implied admission of fault or liability** by the person in connection with that matter; and (b) is **not relevant to the determination of fault** or **liability** in connection with that matter. Evidence of an apology made by or on behalf of a person in connection with any matter alleged to have been caused by the person is **not admissible in any civil proceedings as evidence of the fault or liability** of the person in connection with that matter.
Tasmania	*Civil Liability Act 2002* (s7)	An expression of sympathy or regret, or of a general sense of benevolence or compassion, in connection with any matter, **which does not contain an admission of fault in connection with the matter.**	An apology made by or on behalf of a person in connection with any matter alleged to have been caused by the fault of the person – (a) **does not constitute an express or implied admission of fault or liability** by the person in connection with that matter; and (b) is **not relevant to the determination of fault or liability** in connection with that matter. Evidence of an apology made by or on behalf of a person in connection with any matter alleged to have been caused by the fault of the person is **not admissible in any civil proceedings as evidence of the fault or liability** of the person in connection with that matter.
Victoria	*Wrongs Act 1958* (s14I and s14J)	An expression of sorrow, regret or sympathy but **does not include a clear acknowledgment of fault** In a civil proceeding where the death or injury of a person is in issue or is relevant to an issue of fact or law, an **apology does not constitute—** **(a) an admission of liability** for the death or injury; or (b) **an admission of unprofessional conduct, carelessness, incompetence or unsatisfactory professional performance**, however expressed, for the purposes of any Act regulating the practice or conduct of a profession or occupation.	**Nothing in this section affects the admissibility of a statement with respect to a fact in issue or tending to establish a fact in issue**.
Western Australia	*Civil Liability Act 2002* (s5AF and s5AH)	An expression of sorrow, regret or sympathy by a person that does **not contain an acknowledgment of fault by that person**.	(1) An apology made by or on behalf of a person in connection with any incident giving rise to a claim for damages — (a) **does not constitute an express or implied admission of fault or liability** by the person in connection with that incident; and (b) is **not relevant to the determination of fault** or liability in connection with that incident. (2) Evidence of an apology made by or on behalf of a person in connection with any incident alleged to have been caused by the person is **not admissible in any civil proceeding as evidence of the fault or liability** of the person in connection with that incident.

Appendix B Table 3: Some examples of international statutory and policy provisions

Jurisdiction	United Kingdom
Statutory duty	**Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014**
Features	The aim of this regulation is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology. Providers must promote a culture that encourages candour, openness and honesty at all levels. This should be an integral part of a culture of safety that supports organisational and personal learning. There should also be a commitment to being open and transparent at board level, or its equivalent such as a governing body.
Definition of harm	The duty applies to all cases of 'significant harm' defined as: • death (where related to an instance of harm rather than the natural course of illness) • severe and moderate harm • prolonged psychological harm.

With whom duty lies	"Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity." (Reg 20)
	• Providers are expected to carry out the following actions to be compliant with the new duty as soon as reasonably practicable after becoming aware that a notifiable patient safety incident has occurred, the health service body must:
	  ○ Notify the relevant person that an incident has occurred
	  ○ Provide reasonable support to the relevant person in relation to the incident, including when notifying them. This notification must:
	  ▪ Be given in person by one or more representatives of the health service body
	  ▪ Provide an account which is true of all the facts to the best of the health service body's knowledge about the incident at the time of the notification
	  ▪ Advise the relevant person what further enquiries into the incident the health service body believes are appropriate
	  ▪ Include an apology and
	  ▪ Be recorded in a written record which is kept securely by the health service body.
	• The initial notification must then be followed by a written notification. This must contain:
	  ○ All of the information given at the notification meeting
	  ○ Details of any enquiries into the incident
	  ○ The results of any further enquiries into the incident or an update on those enquiries and
	  ○ An apology.
	• The health service body must keep a copy of all correspondence with the relevant person
	• The results of any investigation (e.g. root cause analysis) must be provided to the relevant person in a timely way.

Penalty	The penalty for breaching the statutory duty is a maximum of £2,500.
Apology laws	Section 2 of the Compensation Act 2006 applies to England and Wales but not to Scotland. It provides: *An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty.* The Apology (Scotland) Act 2016 provides that in legal proceedings, an apology made (outside the proceedings) in connection with any matter— is not admissible as evidence of anything relevant to the determination of liability in connection with that matter, and cannot be used in any other way to the prejudice of the person by or on behalf of whom the apology was made.
Protections	The NHS Litigation Authority has made it clear that it will never withhold indemnity insurance on the basis that an apology has been made.

Jurisdiction	Canada
Open disclosure	**Canadian Patient Safety Institute Disclosure Guidelines 2008 (revised 2011)**
Features	The guidelines are intended to encourage and support healthcare providers, interdisciplinary teams, organisations and regulatory authorities in developing and implementing disclosure policies, practices and training methods. The guidelines are used widely in all Canadian provinces and territories to develop their own policies. Disclosure training is increasingly taught in medical schools and residency training.
Definition of harm	Harm is defined as impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, disability or death. Open Disclosure applies following any harm including from a 'patient safety incident' which includes: • *Harmful incident* – A patient safety incident that resulted in harm to the patient (replaces 'adverse event' and 'sentinel event' • *No harm incident* – A patient safety incident which reached a patient but no discernible harm resulted • *Near miss* – A patient safety incident that did not reach the patient. Replaces 'close call'
With whom duty lies	Disclosure of adverse events is considered an ethical and professional obligation of health professionals in Canada.
Duty of candour	Although specific legislation does not exist in every jurisdiction, disclosure may be seen as a legal duty in all of the provinces and territories
Apology laws	Canadian apology statutes protect apologies. Example: The Apology Act in Ontario, Canada, defines an apology as: An expression of sympathy or regret, a statement that a person is sorry or any other words or actions indicating contrition or commiseration. Whether or not the words or actions admit fault or liability or imply an admission of fault or liability in connection with the matter to which the words or actions relate."
Protections	Apology defined to include fault: British Columbia (2006), Saskatchewan (2006). The British Columbia statute, for example, states that an apology does not void or impair any insurance coverage.

Jurisdiction	New Zealand
Open disclosure	**Right 6 of the Code of Health and Disability Services Consumers' Rights** gives all consumers the right to be fully informed (ie, to receive the information that a reasonable consumer in his or her situation would expect to receive).
Features	The Health and Disability Commissioner guidance states what open disclosure should include: • A consumer should be informed about any adverse event, ie, when the consumer has suffered any unintended harm while receiving health care or disability services. • An error that affected the consumer's care but does not appear to have caused harm may also need to be disclosed to the consumer. Notification of an error may be relevant to future care decisions — whether or not to go ahead with the same procedure on another occasion. The effects of an error may not be immediately apparent. • A disclosure should include acknowledgement of the incident, an explanation of what happened, how it happened, why it happened and, where appropriate, what actions have been taken to prevent it happening again. (In some situations specific actions will need to be taken straight away, whereas in other situations where the explanation is still unfolding, the actions that need to be taken may take longer to identify.) • A disclosure should include a sincere apology. This is the provider's opportunity to say, —We are sorry this happened to you.‖ It is not about allocating blame for the event's occurrence, but acknowledging the seriousness of an adverse event and the distress that it causes. Apologies can bring considerable comfort to the consumer and have the potential to assist with healing and resolution. • In some situations, an apology may be critical to the consumer's decision about whether to lay a formal complaint and pursue the matter further. • The consumer should be given contact details and information about the local health and disability consumer advocate as well as options for making a complaint (Disability Services Consumers' Rights and Standards).
Duty of Candour	New Zealand does not have a statutory duty of candour. New Zealand relies on agreed open disclosure standards and guidelines that are based on the Code of Health and Disability Services Consumers' Rights and Standards.
Apology laws	New Zealand does not have apology laws
Protections	New Zealand has established a no-fault compensation insurance scheme for patients who were harmed as a result of medical errors. In 2005 the so-called 'no-fault' compensation reforms waived the prior anomaly of medical error and extended eligibility to all treatment injuries regardless of error or injury rarity and severity. The 2005 changes gave New Zealand's scheme some of the most liberal eligibility criteria in the world, and brought the compensation of medical injury into line with the overall 'no-fault' scheme. The changes also shifted the focus of the scheme away from identifying error (or fault) to providing assistance with treatment and rehabilitation. Under New Zealand's regulatory system, in contrast to malpractice systems, compensation is determined according to *outcome* and may be awarded irrespective of fault or negligence, while doctors are judged (under the Health and Disability Commissioner patient complaints system) according to *process* of care and may be held to account irrespective of injury.
Responsibility	The individual provider with overall responsibility for the consumer's care should usually disclose the incident. Where this provider is not the provider with overall responsibility, both providers should be in attendance. In some cases, particularly where significant harm has resulted, it may be appropriate for senior management to attend with the individual providers involved.

Jurisdiction	USA
Open disclosure	**Several jurisdictions in the United States have legislated for the professional/ethical obligation to disclose medical error** Both the American Medical Association Code of Medical Ethics and the American College of Physicians require physicians to "report an accident, injury or bad result stemming from his or her treatment."
Features	• Disclosure of errors and adverse events is now endorsed by a broad array of organizations. Since 2001, the Joint Commission has required disclosure of unanticipated outcomes of care. In 2006, the National Quality Forum endorsed full disclosure of "serious unanticipated outcomes" as one of its 30 "safe practices" for health care. The disclosure safe practice includes standards for practitioners regarding the key components of disclosure. It also calls for health care organizations to create an environment conducive to disclosure by integrating risk management and patient safety activities and providing training and support for physicians. • Ten states mandate disclosure of unanticipated outcomes to patients, and more than two-thirds of states have adopted laws that preclude some or all information contained in a practitioner's apology from being used in a malpractice lawsuit. • The National Quality Forum originally defined 27 health care "never events"—patient safety events that pose serious harm to patients, but should be considered preventable—in 2002. The 2011 update now consists of 29 events, organized into surgical events (e.g., wrong-site surgery), device events (e.g., air embolism), care management events (e.g., death or disability due to medication errors), patient protection events (e.g., patient suicide), environmental events (e.g., fires), radiologic events, and criminal events. One notable addition to the original list is that serious harm associated with failure to properly follow up on test results is now considered a never event. Since the development and dissemination of this list, many states have mandated that health care facilities report all instances of these events. When such an event occurs, many institutions mandate performance of a root cause analysis
Duty of Candor	The candor process is an approach that health care institutions and practitioners can use to respond in a timely, thorough, and just way to unexpected patient harm events. A candor event is defined as an event that involves unexpected harm (physical, emotional, or financial) to a patient. These events trigger the candor process even when a cause for the event is not yet known.
Apology laws and protections	• A majority of states have enacted laws to encourage expressions of sympathy without the statement of condolence being misconstrued as an admission of liability. • Massachusetts was the first state to enact an apology law, in 1986; Over 30 other states have enacted laws that prohibit a physician's apology as admissible evidence in a legal proceeding. • Most apology laws apply to statements and gestures of benevolence made to either a patient or that patient's family in the wake of an unanticipated outcome. Although some states do not have apology laws in place, others currently have legislation pending. • Some state laws do not say that the expression must be related to the discomfort, pain, suffering, injury, or death of the patient. In addition, in some jurisdictions, apologies made orally or written are covered. Also, some state apology laws do not specifically mention to whom the apology may be given, which can leave the application of the law open for interpretation in a given situation. For example, some states with apology laws do not specifically mention the admissibility of expressions of sympathy to a family member, friend, or representative of the patient. • Maine's apology law specifically covers "a domestic partner relationship with an alleged victim." • Some apology laws apply to the patient, the patient's family, or a friend of the patient, while others apology cover an apology made to any person who has a family-type relationship with the patient.

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