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| A statutory duty of candour  Report to the Minister for Health  Expert Working Group to advise on legislative reforms arising from *Targeting Zero* |
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| Department of Health |
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# Foreword

Patients and consumers have a fundamental right to a full explanation and an apology when something goes wrong in their health care. This right is as important as the well-recognised right to be fully informed when giving consent to a medical procedure.

It is the hallmark of a great healthcare system that mistakes are acknowledged, that patients are informed of harm, that appropriate redress and remedies are provided and that lessons are learned to prevent repetition.

We know that Australia has one of the best open disclosure frameworks in the world and a good record of compliance, although research tells us there are some gaps in knowledge as to how this can best be implemented; and with whom responsibility ultimately lies for compliance.

We also know that not receiving a full explanation of what went wrong, a genuine apology and an assurance that steps are being taken to avoid recurrence, are among the key drivers for complaints to the health complaints commissioners or even civil proceedings.

We acknowledge that a statutory duty of candour will not, alone, address all of the concerns of consumers and ensure safety and quality in health care. It is an important part of system reform and legal measures already underway.

However, a statutory duty elevates the importance of open disclosure to all involved in health care, and most particularly to boards and managers of health services.

When the Expert Working Group began its consultation on how aspects of open disclosure for incidents of harm could be enshrined in legislation, we realised this was only part of what we needed to consider.

Through the written submissions in response to the consultation paper and our many conversations with consumers and stakeholders, we realised there was a great deal more reform required to make a statutory duty work, and work well. For example, we found strong support for the right of consumers to a written description of what occurred in a language they understood. There was support for contemporising Victoria’s apology laws in the healthcare context to enable genuine and frank apologies, even if this includes admissions of fault.

Confirming what *Targeting Zero* told us about the paucity and quality of information shared with healthcare consumers in the Victorian health system – we found a reticence on the part of health services to document their reflections and learnings about significant errors in health care following investigations into such incidents. This reticence, we were told, arises from fear that these documents will be used as evidence against the service or its clinicians in medico-legal action.

Again we turned to other Australian jurisdictions that had reformed the law to see how they had tackled this problem and to see how we could provide some statutory protections – balancing rights of consumers to take legal action with the benefits to the Victorian community of better and safer health services informed by learning from mistakes. We realised we needed to recommend a safe way for health service clinicians – new and experienced – to work together and analyse medical errors, hypothesise on what did, or could have, gone wrong in relation to significant incidents, and frankly record their learnings to share and inform improvements in safety and quality assurance.

I think we have struck the right balance.

I would like to thank the Parliamentary Secretary, Gabrielle Williams MP, for her participation in the work of the Expert Working Group and the stakeholders who took time out of their busy lives to share their lived experience of open disclosure, learnings from significant health incidents and ideas about how to ameliorate the terrible situation of serious medical harm through a heartfelt apology, a thorough explanation of what went wrong and a capacity to contribute to learnings to improve the quality and safety of health care for all Victorians.

I am grateful for the significant contribution made by each member of the Expert Working Group and for the great work of the Department of Health and Human Services officers, particularly Kathy Ettershank, Alison Morris and Lucia Clarke of the Health and Wellbeing Division.



Michael Gorton AM

Chair

Expert Working Group

# Executive summary

Background

Victorians should have confidence in the safety and quality of our health system and – in the unfortunate event that harm does occur – have a right to an apology, an explanation of what happened and why, and to be informed of lessons learnt and efforts made to ensure it never happens again.

The Expert Working Group was asked to consider the implementation of a statutory duty of candour in Victoria in response to Recommendation 5.3 made in *Targeting Zero: supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care*, the report of the Review of Hospital Safety and Quality Assurance in Victoria led by Dr Stephen Duckett.

*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.

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 seriously wrong with their care. It is not proposed that a statutory duty of candour replace current obligations to practice open disclosure. Rather, it will establish a complementary legal obligation to support improved compliance in a defined set of circumstances. Consultation confirmed the view that a statutory duty of candour would strengthen the commitment to the practice of open disclosure; clarify when open disclosure must occur, how and who is responsible; and clarify medico-legal consequences and protections in order to encourage and support full and effective disclosure and engagement with consumers.

Although open disclosure is a longstanding, well accepted practice in Victorian health care, it does not always occur. It 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. Consultation feedback validated that there are perceived barriers to good open disclosure practice, such as fear of medico-legal consequences.

A statutory duty of candour will not exist in isolation but, as well as sitting alongside existing open disclosure requirements, will operate alongside a range of related statutory and regulatory requirements placed on health service providers and implemented or oversighted by a number of Commonwealth and state agencies with potentially overlapping responsibilities. The duty will complement existing incident response and reporting requirements.

Furthermore, the statutory duty of candour, as proposed to be legislated, will not cover all issues for, and experiences of, patients and consumers, and will not be the only avenue for consumers to seek information and redress.

Scope of the duty

The Expert Working Group recommends the application of the statutory duty of candour to hospitals (public and private), public health services, multi-purpose services and day procedure centres regulated under the *Health Services Act 1988*, Ambulance Services and the Victorian Institute of Forensic Mental Health. Other entities, such as residential aged care facilities or community health centres are not recommended for inclusion but potentially may become within scope over time.

It is recommended the statutory obligation should be placed at an organisational level only in recognition that responsibility to create an organisational culture of safety and of recognising and valuing the patient experience is a board responsibility. This will also enable the organisation to drive accountability for delivery of the practice and actions that should occur as part of a candour response in an environment where health care often occurs in a system of multiple providers, players and processes.

The involvement of individual practitioners is critical in making the statutory duty of candour successful. Therefore, it will be important that individual practitioners are appropriately trained and supported and systems ensure that individuals are able to play their part, including through policies and procedures, conditions of employment and contracts of engagement.

Trigger for the duty to apply

Clarity and certainty in any statutory obligation is paramount. If legislative provisions are open to interpretation or judgement, the practice of open disclosure could be hampered or defensive medicine resorted to. It is recommended that the statutory duty apply to significant harm, with ongoing open disclosure obligations to continue to apply for other incidents. The current *Victorian health incident management policy[[1]](#footnote-1)* categories of Incident Severity Rating 1 and 2 – well understood by providers – are proposed as the threshold for the statutory duty of candour to apply.

It is recommended that ‘harm’ should be understood to include both physical and psychological harm. Near misses and other incidents that do not result in significant harm, however, are not recommended for inclusion as they – more appropriately – form the basis of a systemic review of processes or professional competency alone.

The Expert Working Group supports the concept of a ‘consumer right to declare’ where they have been harmed and recognises that there will be circumstances when service providers are unaware that harm has been suffered. Where the self-reported harm is of a level that would trigger the statutory duty of candour as recommended, the duty should apply just as it would if the harm had been identified by the provider. The non-inclusion of a specific consumer declared harm category in a statutory duty of candour does not mean that it should be overlooked. Consumer declared harm has a place in the professional obligations of open disclosure and the broader open disclosure framework.

It is not intended that the statutory duty apply retrospectively. While there may be an ethical imperative that harm identified prior to commencement of the legislative provisions be disclosed, the obligation for candour should arise in relation to harm that is identified after the introduction of the relevant legislative provisions, regardless of when that harm itself occurred.

Components of the duty of candour

To meet the objectives of providing certainty and supporting good practice, while at the same time avoiding unnecessary inflexibility, it is recommended that the provisions to be included in legislation to introduce the statutory duty of candour be high level and minimal in nature. These provisions will be supported by more flexible Victorian candour and open disclosure guidelines (which will be a subordinate instrument) to provide information on how the duty should be discharged and how services might implement its requirements. It is also recommended that there be further consultation undertaken with stakeholders to inform the content of the guidelines. The existing Australian Open Disclosure Framework will continue to provide useful contextual information.

Under the proposed new statutory duty it will be required that consumers be provided with: (a) a factual description of what occurred, in language understandable to the consumer; (b) an apology; and (c) an explanation of the steps being taken to manage the event and prevent recurrence.

Supports and protections

#### Apology laws

There is a recognised need to support those working in the healthcare system. Being involved in an incident of patient harm can have profound impacts on practitioners. Not only can they be personally traumatised, some may be dissuaded from disclosing such events for fear of personal and/or professional consequences.

While there is evidence that effective apologies can assist to resolve disputes or complaints earlier and more effectively, there is a perception that a statutory duty of candour will increase risk of medico-legal proceedings. Unless this perception is addressed, the benefits of the statutory duty could be seriously undermined – resulting in poor quality conversations perceived as insincere by patients; or a lack of compliance with the duty.

There is significant confusion about Victoria’s existing apology laws. Currently under the *Wrongs Act 1958*, an apology does not constitute an admission of fault but the term ‘apology’ is limited. In a number of other Australian jurisdictions admissions of fault or liability are defined as part of the apology and are therefore protected.

The Expert Working Group recommends strengthening the Victorian apology laws in line with other jurisdictions so that patients cannot rely on an admission of fault in subsequent legal proceedings. Factual explanations of what has occurred, which will be required to be provided to consumers under the duty, however, will not be protected and can be used as evidence in any legal proceedings. It is further recommended that information provided about any changes or improvements made subsequent to an incident not be admissible as an admission of fault or liability but still be admissible in court proceedings.

These changes will not remove any causes of action open to consumers. It is noted that reforms similar to those recommended by the Expert Working Group have been recommended following the 2016 Access to Justice Review and a 2017 review of apologies by the Victorian Ombudsman, as a means of improving resolution of complaints and disputes.

For clarity, the reforms recommended should sit alongside the duty of candour in the relevant health legislation.

#### Incident reporting to inform quality improvement

Submissions received by the Expert Working Group indicated that protections for incident review for serious incidents (such as root cause analyses) could have a significant positive impact on the success of the statutory duty of candour and related training and cultural development initiatives. The Expert Working Group heard that protections are likely to reduce concern about medico-legal risk, and thereby facilitate more robust discussion and analysis during incident reviews, which in turn will lead to more effective quality and safety improvements. In contrast, others argued that such protections are inconsistent with the transparency and culture change that are objectives of the duty of candour.

By their nature, incident review processes such as root cause analyses and in-depth case reviews are valuable quality and safety improvement processes, conducted in relation to serious incidents. They involve sometimes speculative, and invaluable, discussion about factors that may have contributed to the incident and/or related harm. The Expert Working Group is convinced that the nature of the discussions is such that if their details were relied upon as evidence in civil legal proceedings, inappropriate or perverse outcomes may result.

It is recommended that concurrent with the introduction of the statutory duty of candour, the Minister introduce statutory protections for incident review processes conducted in relation to specified serious incidents, along the lines of those in place in New South Wales and Queensland. Careful consideration will need to be given to ensuring that the proposed protections are not implemented in a way that prevents disclosure for certain oversight and regulation for quality and safety purposes, such as to Safer Care Victoria or the Australian Health Practitioner Regulation Agency.

#### Qualified privilege

In considering the legal protections for individuals and entities that should accompany the statutory duty of candour, the Expert Working Group became aware of significant confusion amongst both individual healthcare practitioners and healthcare organisations as to when the qualified privilege afforded to ‘quality assurance committees’ declared under section 139 of the Health Services Act does and does not apply. Accordingly, it is also recommended that the qualified privilege protections be reviewed.

#### Impact of the protections proposed in this section on the rights of consumers

The Expert Working Group heard some concerns that the introduction of the recommended protections may be contrary to the consumer-focused transparency that is an objective of open disclosure or could restrict consumer rights to pursue litigation or other redress. In addressing such concerns, the Expert Working Group stresses that the aims of the protections are: to improve the quality of the information and apology provided to consumers and to make more ‘just’ the cultures of organisations that are providing health services.

There is evidence that protections for incident review processes will lead to more robust discussion, a better understanding of what occurred in a particular case and more comprehensive and effective recommendations for improvements. Following from this, they aim to support the rights of consumers to request and access better informed information about what occurred in the course of their care. In addition to this, protecting admissions of liability or fault in an apology context provides for a fuller expression of regret, compassion and sympathy for the harm a consumer has experienced.

Monitoring, remedies and sanctions

#### Monitoring

The Expert Working Group considered a range of potential options for monitoring compliance with the statutory duty of candour and identifying breaches and formed the view that there is value in routine reporting and providing for sanctions for serious breaches to drive culture change and enhance accountability. It is proposed that established mechanisms for reporting data on incidents should be used to collect information on whether a duty of candour process has been commenced and/or completed. Existing auditing processes can then be applied to those datasets, to monitor compliance with the duty of candour.

Complaints to the health complaints commissioners (the Health Complaints Commissioner and the Mental Health Complaints Commissioner) or the Australian Health Practitioner Regulation Agency may be the way that breaches of the duty are most readily identified. The Expert Working Group recommends that it should be the Department of Health and Human Services that takes any necessary action in response to breaches of the duty. There should, therefore, be identified within the department an area to which the commissioners can report failures to comply and to which others (for example, clinicians and other staff) can directly advise of compliance issues.

#### Responding to breaches

The Expert Working Group concluded that a punitive approach to failures to make disclosures under the statutory duty may be counterproductive and result in increased secrecy and defensiveness rather than encouraging good practice and culture change. Rather, where one off or less significant failures are identified, the department should work with organisations to assist them to improve practice.

Where breaches do occur, the health complaints commissioners are best placed to ensure that patients receive the information they are entitled to. The commissioners have at their disposal a suite of powers to obtain information and support both parties to a dispute to participate in processes designed to facilitate resolution.

Nonetheless, where persistent serious breaches of the duty are found to be occurring, it will be important that the department is able to take appropriate action. The Expert Working Group does not support the introduction of financial penalties and recommends the strong powers already contained in the Health Services Act (and where relevant the *Ambulance Services Act 1986* and the *Mental Health Act 2014*) be used to require improvements and, where necessary, sanction services.

Support for success

The Expert Working Group was mindful that simply introducing a legislative provision for a statutory duty of candour without supporting change will inevitably fail. What is needed is a change of culture and it is not possible to legislate culture or mandate empathy or compassion. While a statutory duty can focus attention at the highest level and ensure that appropriate effort and commitment to change is made, success will also require a range of non-legislative actions.

#### Culture change

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. In hospitals with a positive culture, there is a powerful organisational commitment and investment in safety. It is recommended that health services subject to the statutory duty of candour and the proposed candour and open disclosure guidelines should also take action to tackle bullying, harassment and undermining, and investigate any instances where a member of staff may have obstructed another in exercising the statutory duty of candour or open disclosure.

The Expert Working Group received many suggestions as to how to make the reform a success. It is envisaged that the proposed candour and open disclosure guidelines will provide a clear and user-friendly basis for understanding the requirements of the statutory duty of candour and guidance about how it is to be applied. It is also recommended that health services develop bespoke policies based on those developed by the department in consultation with stakeholders.

#### Training and support

A core requirement is training and information. Particular issues raised by stakeholders included the challenge of providing and engaging relevant training to all medical staff across diverse approaches to health service provision, including those in private practice, contractors, rotating junior doctors, fractional appointment and visiting medical officers. It is understood that Safer Care Victoria is currently undertaking work to explore how some of the gaps in open disclosure training can best be addressed and how foundational skills training in this area can be delivered to clinical staff.

Training and awareness raising should be available for clinicians, consumers, consumer advocates and other relevant bodies so they can participate in candour or open disclosure conversations effectively. It is recognised that consumers may need training, information, advice and/or support not only about the open disclosure processes itself, but also to ensure they have sufficient understanding about their care and the health service system that delivers this care.

In conclusion, the Expert Working Group hopes that elevating certain key elements of open disclosure to a legal obligation, and providing additional information provision requirements and certain protections, will lead to more consistent, comprehensive and widespread candour and open disclosure practice. The benefits of this 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 within health services where open communication is valued throughout the life of a care relationship.

# Recommendations

1. It is recommended that the department partners with Safer Care Victoria to monitor the impact and any unintended consequences of the proposed statutory duty of candour and report to the Minister on the first three years of operation of the new duty.
2. It is recommended that the Minister seeks to amend the Health Services Act to establish a new statutory duty of candour applicable to the following entities defined in the Act:

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

1. It is recommended that:

* the Minister seeks to amend the Ambulance Services Act to establish a new statutory duty of candour applicable to ambulance services
* the Minister for Mental Health seeks to amend the Mental Health Act to establish a new statutory duty of candour applicable to the Victorian Institute of Forensic Mental Health.

1. It is recommended that Safer Care Victoria be asked to lead work to develop a model for open disclosure appropriate to residential care services, community health and other appropriate settings.
2. It is recommended that the Minister considers consulting relevant stakeholders about the possibility of extending the statutory duty of candour to include other types of health service organisations as part of the planned forthcoming review of the Health Services Act.
3. It is recommended that the statutory duty of candour apply to incidents that meet the criteria of Incident Severity Rating 1 or 2 as defined in the *Victorian health incident management policy* regardless of whether the harm is physical or psychological and if it is identified by a health service, an individual clinician, a consumer, their family or carer.
4. It is recommended that consumers and their families/carers should be supported to report instances of harm and that services should have in place systems to respond to such reports.
5. It is recommended that the statutory duty of candour apply to any instance of harm that meets the criteria set out in Recommendation 6, which occurs after the commencement of the relevant legislative provisions, or is identified after commencement regardless of when the harm occurred.
6. It is recommended that amendments proposed to the Health Services Act, the Ambulance Services Act and Mental Health Act (Recommendations 2 and 3) link to new Victorian candour and open disclosure guidelines to be developed as a subordinate legislative instrument.
7. It is recommended that the department work with stakeholders (including health services, consumers and major insurers in the public and private sectors) in developing the proposed Victorian candour and open disclosure guidelines and materials to support implementation.
8. It is recommended that the Minister considers releasing draft Victorian candour and open disclosure guidelines (as proposed at Recommendation 9) at the time of introducing relevant legislation to the Parliament.
9. It is recommended that the proposed model for the duty of candour includes a statutory obligation on services to disclose information to consumers. This obligation will include a requirement that a written factual explanation of what occurred be made available to the consumer and that this will not be protected from admissibility as evidence in legal proceedings.
10. It is recommended that the relevant legislation (Health Services Act, Ambulance Services Act and Mental Health Act) be amended so that, for the purposes of any civil proceeding against the health service or any individual who was involved in providing care to the consumer:

* an apology – being an expression of sympathy, regret or compassion – will not constitute an admission of fault and will not be relevant to any determination of fault or liability in the proceeding, even if the statement of sympathy, regret or compassion may admit or imply an admission of fault
* a description of improvements that has been, or will be, made to prevent similar harm in the future does not constitute an admission of fault.

1. It is recommended that concurrent with the introduction of the statutory duty of candour, the Minister introduces statutory protections for incident review processes conducted in relation to specified serious incidents, along the lines of those in place in New South Wales and Queensland.
2. It is recommended that the Minister instructs the department to:

* carefully consider the issues raised above (and in Appendix E); and the interaction between the proposed protections and any other planned reforms, arising from *Targeting Zero*, that relate to the ways in which information is shared between entities and oversight bodies
* in legislating this protection, give careful consideration to ensure the protections do not compromise the oversight and regulation of quality and safety by the department, Safer Care Victoria or the Victorian Agency for Health Information.

1. It is recommended that the Minister tasks the Expert Working Group to work with Safer Care Victoria to review qualified privilege protections. The outcomes of this review could inform the planned review of the Health Services Act.
2. It is recommended that the department require that health services routinely report on the statutory duty of candour.
3. It is recommended that the department work with the Health Complaints Commissioner and the Mental Health Complaints Commissioner to:

* identify any necessary amendments to the *Health Complaints Act 2016* and the Mental Health Act to enable the commissioners to receive complaints about failures of services to comply with the statutory duty of candour
* ensure the Health Complaints Commissioner and Mental Health Complaints Commissioner are resourced to enable them to respond to complaints related to a failure to comply with the statutory duty
* identify any necessary amendments to the Health Complaints Act and the Mental Health Act to allow the commissioners to advise the Minister or the department of breaches of the duty**.**

1. It is recommended that consideration be given to amendments that may be required to the Health Services Act, the Ambulance Services Act or the Mental Health Act to provide that repeated and/or serious breaches of the statutory duty of candour be grounds for existing sanctions available under those Acts.
2. It is recommended that consideration be given to amendments that may be required to the Health Services Act to allow for providers to be named if there are repeated and/or serious breaches of the statutory duty of candour.
3. It is recommended that all health service providers subject to the statutory duty of candour and the candour and open disclosure guidelines should have internal policies and procedures to support a culture of openness and transparency, and processes to ensure that staff and contractors follows them.
4. All health service providers subject to the statutory duty of candour and the candour and open disclosure guidelines should also take action to tackle bullying, harassment and undermining, and investigate any instances where a member of staff may have obstructed another in participating in or contributing to statutory duty of candour or open disclosure processes.
5. The department should work with key stakeholders, the Victorian Managed Insurance Authority, the Australian Commission on Safety and Quality in Health Care and Safer Care Victoria to develop model policies and procedures that can be adopted, and adapted, to be fit for purpose for the different organisations that will be subject to the statutory duty of candour and the candour and open disclosure guidelines.
6. It is recommended that the department provide Safer Care Victoria with de-identified summaries of the issues and suggestions raised in submissions to the Expert Working Group to inform Safer Care Victoria’s work on training to improve open disclosure practice; and that Safer Care Victoria include in its work:

* a focus on how such training can be delivered in the private sector
* consideration of the training and support needs of consumers and consumer advocacy groups.

1. It is recommended that the department consider how training to board directors can incorporate training about their obligations in relation to the statutory duty of candour and how this might inform board directors’ understanding of their broader clinical governance role.
2. It is recommended that the Minister liaises with the Minister for Mental Health to facilitate further consultation with the Mental Health Complaints Commissioner, the mental health sector and consumer advocates to identify the particular training, materials and support that may be required by mental health service providers and/or consumer advocacy organisations to:

* ensure that the statutory duty of candour can be appropriately implemented by mental health services
* improve the practice of open disclosure within mental health services.

1. It is recommended that the Minister tasks the department to:

* consider ways to streamline the avenues for consumers to raise concerns about their care (including considering the opportunities to introduce a ‘one door in’ approach for complaints and notifications)
* support the various entities involved in these processes to better align their responsibilities.

# Introduction

This report has been prepared by an Expert Working Group appointed by the Minister for Health to provide advice on legislative reforms arising from *Targeting Zero: Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care*, the report of the Review of Hospital Safety and Quality Assurance in Victoria led by Dr Stephen Duckett (*Targeting Zero)*.

The Expert Working Group was asked to consider the implementation of a statutory duty of candour in Victoria in response to Recommendation 5.3 made in *Targeting Zero* (p. 201):

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.

In undertaking this work, and in providing advice to the Minister, the Expert Working Group has been mindful of the context in which this recommendation was made. The review was commissioned by the Minister for Health in 2015 following the discovery of a cluster of tragically avoidable perinatal deaths at Djerriwarrh Health Services.

*Targeting Zero* provided a detailed and extensive analysis of quality and safety supports and oversight across the Victorian hospital system. It made 179 recommendations aimed at delivering better protections and improved outcomes for patients. *Targeting Zero* 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.

A key finding of the review was that the events at Djerriwarrh occurred in the context of catastrophic failures in clinical governance at all levels of the organisation. Importantly, the review found that the conditions that led to these failings were not unique to Djerriwarrh and that there was a need to elevate safety and quality across the hospital system as a whole.

Recommendation 5.3 was one of a suite of recommendations aimed at improving the flow of information in the health system to ensure deficiencies in care are identified and focus attention on opportunities for improvement. It recognised that the faith of the community in the hospital system had been significantly affected by the events at Djerriwarrh, resulting in a need to rebuild trust through strengthened accountability to patients and greater transparency about hospital safety and quality.

This recommendation was also made in the context of strong observations about the influence of organisational culture and the need to establish ‘just cultures’[[2]](#footnote-2) within the health service environment.

Culture is particularly important in hospitals.… Cultures of blame lead staff to conceal poor outcomes and so allow system weaknesses to incubate and fester. Culture can be the difference between a staff member concealing error in fear of punitive consequences, ignoring it in the knowledge that reporting will achieve nothing, or bringing it to the attention of managers without hesitation.

*Targeting Zero, p. 203*

## Expert Working Group

The Expert Working Group was appointed in September 2017 to provide advice on legislative reforms arising from *Targeting Zero*. Members of the Expert Working Group are:

* Mr Michael Gorton (AM) (Chair), Partner, Russell Kennedy; Chair, Board of Alfred Health; Member, Board of Ambulance Victoria; Chair, Australian Health Practitioner Regulation Agency
* Ms Sophy Athan, Chair, Board of Health Issues Centre; Member, 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; Member, Board of Ambulance Victoria
  + Ms Karen Cusack, Health Complaints Commissioner.

The Expert Working Group is grateful for the support received from Ms Gabrielle Williams MP, Parliamentary Secretary for Health and Parliamentary Secretary for Carers and Volunteers, while undertaking this work.

Implementation of a statutory duty of candour has been the first matter considered by the Expert Working Group. At the request of the Minister, this report includes findings from research and consultation on this issue and makes recommendations about the appropriate statutory model for the introduction of a duty of candour as well as advice about:

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

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

The Expert Working Group was assisted by officers of the Department of Health and Human Services in undertaking the consultation process that informed this report.

## Public consultation

To guide the public consultation, the Expert Working Group released a consultation paper on 2 November 2017.[[3]](#footnote-3) In particular, the consultation paper sought guidance from stakeholders in relation to:

* *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?

The paper was distributed broadly to:

* key providers of health services (such as chief executive officers, directors of medical services, directors of nursing, quality and safety managers and board chairs) within both public and private health service organisations
* consumer, carer, provider and specialist representative organisations
* unions, professional associations and colleges
* medical defence and plaintiff law firms
* major insurers
* national health practitioner registration boards
* primary healthcare networks
* relevant commissioners and ombudsmen
  + key representatives of the department and the newly established entities – Safer Care Victoria and the Victorian Agency for Health Information.

Stakeholders were invited to respond to the questions raised in the consultation paper by early December 2017. Although the timeframe available for submissions to be made was short, the Expert Working Group was impressed by the level of interest and the considered responses received. A total of 61 written submissions were received from 18 individuals and 43 organisations. Organisational respondents included health service providers, regulators, unions and professional associations, insurers, legal firms, ombudsmen/commissioners and peak bodies representing providers and consumers. Of the organisations that made submissions, nine cover metropolitan areas, seven cover rural or regional areas and the remaining 26 have a statewide focus. A full list of organisations that made submissions is included in Appendix A.

Members of the Expert Working Group also liaised directly with a number of stakeholders over the consultation period including:

* attending 11 existing meetings of public and private sector health service provider representatives
* attending a meeting of the Targeting Zero Implementation Oversight Steering Committee
* leading a consultation session with the Victorian Clinical Council
* convening meetings with legal and insurer representatives and commissioner and statutory entity representatives
* working with the Health Issues Centre to ensure the consultation paper reached a broad range of consumer representatives, consumers and carers, and to convene a consumer representative consultation
* working with the Victorian Healthcare Association to convene a health service provider forum
  + engaging with a number of key stakeholders to encourage them to make submissions and address particular issues or concerns.

## Other information considered

In addition to the matters raised by stakeholders, the Expert Working Group has considered a range of relevant literature, reports and the approaches taken in other comparable jurisdictions. The Expert Working Group has also drawn on the varied expertise and experience of its members in coming to its conclusions.

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## Note

Throughout this paper we have used quotes and examples drawn from particular submissions or consultation activities. We have attributed the source of this information (unless it is drawn from the submission of an individual member of the public) in order to provide the Minister with context to assist in understanding the nature of the assertions made.

If the Minister elects to make this report public, the Expert Working Group is of the view that these quotes or examples should either be de-identified or the respondents be given the opportunity to consent or not consent to their submission being identified in the report.

# Context

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

The concept of a statutory duty of candour needs to be understood within the context of the broader concept of open disclosure. This proposed legal obligation is distinct from ongoing obligations to implement open disclosure that arise from government policy for public health entities, 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.

## Open disclosure in practice – the case for a statutory duty of candour

The case for a statutory duty of candour was set out in the consultation paper in terms of the benefits of, and barriers to, effective open disclosure practice. Consultation feedback generally validated this perspective, with many stakeholders reiterating the benefits of good open disclosure practice and confirming the barriers to effective practice that were outlined in the consultation paper.

As the consultation paper noted, the benefits of open disclosure, when done well, include the capacity to improve healing and outcomes for the harmed consumer and support the maintenance of ongoing consumer–practitioner relationships. Apologies and explanations can have a neutralising effect on harmed individuals seeking redress through the courts or external complaint schemes.[[4]](#footnote-4) Open and honest communication with consumers and their families following healthcare incidents is consistent with the shift that has occurred over recent years to more patient-centred and patient-focused approaches to healthcare provision. Perhaps most importantly, when patients are harmed they have a right to know what has happened and why. Offering honesty, openness and compassion in the face of harm suffered as a result of health care is simply the right thing to do.[[5]](#footnote-5)

In our experience, a big driver for people contacting lawyers and making complaints is the lack of explanation and the need to know. While there has been an increase in open disclosure being practised, it is by no means comprehensive. Strengthening open disclosure through the proposed duty of candour will assist and will have a positive effect on the therapeutic relationship and protect against the breakdown of trust.

*Maurice Blackburn Lawyers*

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.[[6]](#footnote-6) Hospitals offering the highest quality of service require robust systems for open disclosure, and cultures that support disclosure of failures 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. Such developments also reflect the direction being advocated in emerging literature, such as the recent Grattan Institute report *All complications should count*.[[7]](#footnote-7)

The shift toward patient centredness furthers, rather than competes with, clinical objectives. When data about patients’ likely outcomes is made public, clinicians evaluate the benefits and risks of care more accurately. When patients are more engaged in shared decision making, they gain a more accurate appreciation of the risks involved, and become more comfortable with the decisions made and more satisfied with their care. They also suffer fewer adverse events.

*All complications should count, p. 11*

By elevating responsibility for candour to a board level obligation, the recommendation intended that a statutory duty of candour would improve the practice of open disclosure across health services and would support the necessary cultural change.

Open communication and a genuine apology can be a powerful remedy when a person has a legitimate grievance. It demonstrates that an authority acts with integrity and treats the public with courtesy and respect. It can also help resolve complaints and disputes sooner, although this is not always guaranteed.

*Victorian Ombudsman*

Although open disclosure is a longstanding, well accepted practice in Victorian health care, it does not always occur. It 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.

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, p. 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. As the consultation paper noted, there is evidence to suggest that there is a gap between ‘disclosable’ and ‘disclosed’ events,[[8]](#footnote-8) and that often the practice of disclosure does not meet consumer expectations.[[9]](#footnote-9)

Consultation feedback validated our understanding of the barriers to good open disclosure practice. As set out in the consultation paper, for instance, a fear of medico-legal consequences poses a barrier, despite evidence that harmed consumers may be less likely to pursue action through the courts or complaints bodies.

The evidence obtained by the *Apologies* enquiry is consistent with many of the observations in the consultation paper – that open disclosure does not always occur in practice; that it often does not meet consumer expectations; that organisational cultures do not always support open disclosure; and that confusion and fear of legal consequences is a barrier to good practice.

*Victorian Ombudsman*

Submissions from many respondents reinforced the consultation paper’s proposition that a statutory duty of candour would strengthen commitment to the practice of open disclosure; clarify when open disclosure must occur, how and who is responsible; and clarify medico-legal consequences and protections.

## System context

### The statutory duty and open disclosure

In considering how a statutory duty of candour might operate in Victoria, the Expert Working Group is cognisant that any new legislative obligation will not exist in isolation. It will sit within the existing context of open disclosure requirements, and will operate alongside a range of related statutory and regulatory requirements placed on health service providers, and implemented or oversighted by a number of Commonwealth and state agencies with potentially overlapping responsibilities.

The statutory duty will exist as part of a broader field of communication with consumers that encompasses all elements of open disclosure. It will be at the core of a framework for disclosure, as Figure 1 illustrates. 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 itself is part of a broader person-centred and just culture, which encourages and supports open and honest communication and transparency.

The Expert Working Group has considered how the proposed statutory duty will sit alongside the existing well-regarded Australian Open Disclosure Framework,[[10]](#footnote-10) and open disclosure as mandated in the National Safety and Quality Health Service Standards (Standard 1). This standard is subject to accreditation required for registration for private hospitals and day procedure centres, and under service agreements for public hospitals and health services.

It is worth noting that a professional duty to be honest with consumers also exists in most codes of conduct for health practitioners registered by the Australian Health Practitioner Regulation Agency (AHPRA).[[11]](#footnote-11) Under the *Health Complaints Act 2016*, general health service providers[[12]](#footnote-12) are required to comply with a code of conduct. This code of conduct includes a requirement for disclosing adverse events to clients.

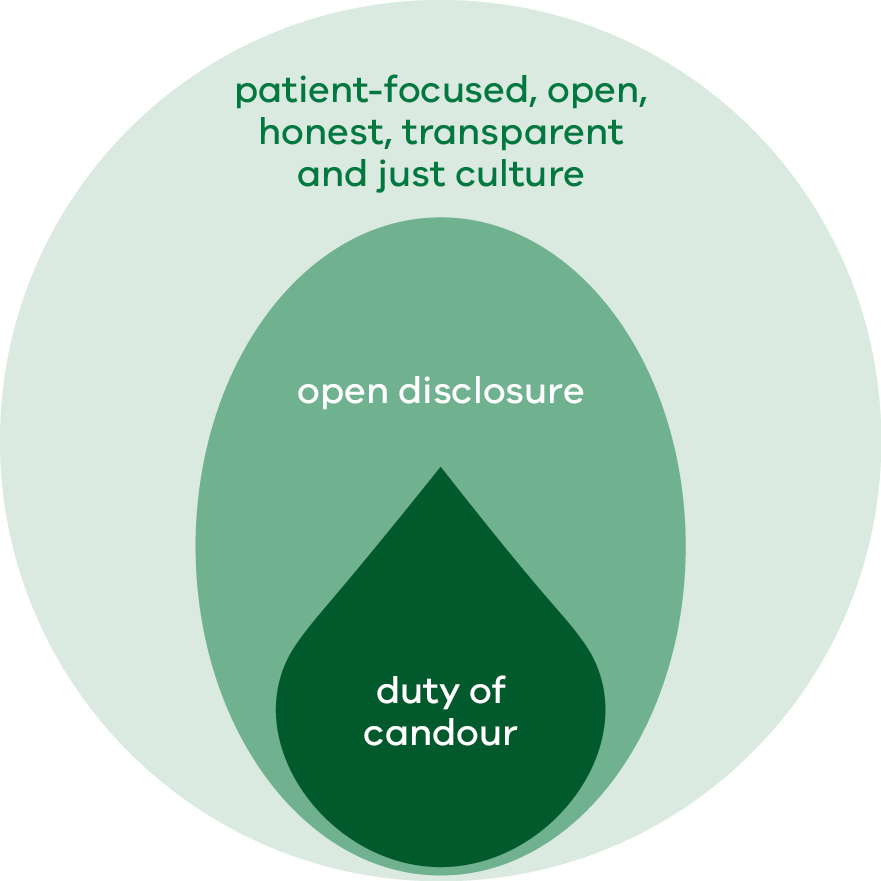


Figure 1. The statutory duty of candour within a broader framework for open, honest communication

### Existing incident response and reporting requirements

The statutory duty will also operate alongside existing incident response and reporting requirements.

Public hospitals in Victoria report monthly to the department on de-identified data on clinical incidents.[[13]](#footnote-13) Incident management and response by public hospitals is guided by the *Victorian health incident management policy* issued by the department. The policy requires an incident investigation, with the type and level of investigation being determined by the incident severity rating allocated to the incident.

Sentinel events are reported to Safer Care Victoria.[[14]](#footnote-14) Safer Care Victoria has a role in reviewing and providing feedback on the root cause analysis (RCA) reports that are produced by health services in response to sentinel events, and on risk reduction action plans arising from these reviews.[[15]](#footnote-15) Legislative amendments were passed in 2017 to introduce stronger reporting requirements for registered private hospitals and day procedure centres. Regulations to support a new obligation to report to the Secretary on particular matters are currently subject to consultation. It is anticipated that this may include a requirement to report on sentient events. The new legislative provisions will also include a requirement for the proprietor of a private sector service to notify the Secretary of any serious risk to patient health or safety in relation to health services provided at the hospital or day procedure centre.[[16]](#footnote-16)

### The broader healthcare quality and safety context

The broader healthcare quality and safety environment in which the statutory duty of candour will operate is a complex, multifaceted one with many bodies often playing multiple roles. A variety of agencies spanning the public and private sectors at the state and Commonwealth levels interact at various points with health service providers. Their roles are often multiple, and can include standard and policy setting, accreditation, monitoring and review, regulation and discipline, funding and commissioning, responding to quality and safety risks, complaint resolution, advocacy and representation, clinical leadership, education and training, and information dissemination for quality and safety improvement. Figure 2 indicates some of the key agencies that operate in the environment in which the statutory duty of candour will sit.

Of particular relevance to this work are:

* the role of Safer Care Victoria in leading quality and safety improvement in health care. Safer Care Victoria oversees and supports health service providers to provide safe and high-quality care. Staffed and led by clinicians and researchers, Safer Care Victoria’s work is significant in seeking to eliminate avoidable harm and strengthen quality of care within health services
* the work of the Australian Commission on Safety and Quality in Health Care in setting standards and the role of accreditation agencies
* the roles of the Health Complaints Commissioner under the Health Complaints Act and the Mental Health Complaints Commissioner under the *Mental Health Act 2014,* to receive, resolve and investigate complaints about health and mental health services

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*The diagram conveys visually the description in ‘The broader healthcare quality and safety context’ section. 

The duty of candour is depicted as occurring in relation to a healthcare incident that occurs in the context of a pre-existing relationship between a consumer (and potentially their family and carer) and a health service provider.  The diagram suggests that outcomes at the level of the individual (consumer) impact outcomes at the level of the health system, and that conversely health system outcomes shape outcomes for individuals. 

The diagram also depicts the duty of candour as at the ‘pointy end’ of open disclosure. Open disclosure is conveyed as one of a spectrum of activities that are both driven by consumers and requirements placed on health service providers. These activities are displayed (in order of decreasing drive by consumers) as: litigation; complaint resolution; information provision; open disclosure; openness and honesty; prompt disclosure; and incident management, review and response. 

For each of these activities/requirements, the source of the requirement is given as: litigation – common law; complaint resolution – complaint handing standards; information provision – information and privacy legislation, Victorian Charter of Human Rights and Responsibilities; open disclosure – Australian Open Disclosure Framework, National Safety and Quality Health Service Standards (Standard 1), insurance policies; openness and honesty – professional codes for professions registered under National Law, insurance policies; prompt disclosure – code of conduct for professions not registered under National Law, insurance policies; and incident management, review and response – service agreements, registration requirements, statute.

For each of these activities/requirements, examples of relevant key bodies are given as: litigation – courts and tribunals; complaint resolution – Health Complaints Commissioner, Mental Health Complaints Commissioner; information provision – Health Complaints Commissioner, Victorian Information Commissioner, Victorian Equal Opportunities and Human Rights Commission; open disclosure – Safer Care Victoria, Department of Health and Human Services, Australian Commission on Safety and Quality in Health Care, accreditation agencies, insurers; openness and honesty – Australian Health Practitioner Regulation Agency, national boards, insurers; prompt disclosure – Health Complaints Commissioner, insurers; and incident management, review and response – Department of Health and Human Services, Safer Care Victoria, Chief Psychiatrist, Coroner’s Court.*

Figure 2. The statutory duty of candour within the broader context surrounding a healthcare incident

* requirements under the Health Complaints Act for health services to comply with minimum complaint handling standards
* the regulatory role of AHPRA and National Boards in registering health practitioners, managing notifications (complaints) about practitioners and taking disciplinary action to protect the public when required. AHPRA may use data obtained through notifications made under the *Health Practitioner Regulation National Law (Victoria) Act 2009*, or through the registration process, for the purposes of determining whether a practitioner poses a risk to the public. If a complaint is made about an individual practitioner by a member of the public, AHPRA will investigate and present their findings to the National Board for consideration
  + regimes supporting access to personal information including the *Freedom of Information Act 1982*, the *Health Records Act 2001*, and the *Information Privacy Act 2000*.

Accordingly, whilst a statutory duty of candour will elevate obligations for disclosure to consumers, it does not stand alone and supports and is supported by other significant obligations and protections which already exist in the health system. To the extent that the statutory duty of candour, as legislated, may not cover all issues for, and experiences of, patients and consumers, it will not be the only avenue for consumers to seek information and redress.

Appendix B includes further information about the broader context of quality and safety statutory and regulatory requirements in which the statutory duty of candour will exist.

## Principles

Before consultation commenced, the Expert Working Group identified six core principles to be observed in making recommendations about the introduction of a statutory duty of candour. These were:

1. health service consumers, their families and carers must be supported to be active partners in their care
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
3. healthcare workers should be recognised for their efforts and commitment and supported to share their knowledge and learnings
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
5. a statutory duty of candour must sit within a wider commitment to safety, learning and improvement
6. unintended adverse consequences and administrative burden associated with implementation of the statutory duty of candour should be minimised.

Through the course of the consultation – reflecting both the context in which this work has been carried out, and acknowledging the feedback from stakeholders – the Expert Working Group has identified a further set of core requirements that have been observed in framing recommendations in this report. That is, the statutory duty of candour must be implemented in a way that:

* ensures patient safety is paramount
* does not result in an erosion of rights
* addresses harm and supports the resolution of issues for patients
* encourages and supports the cooperation of health services and clinicians
* ensures appropriate protections are in place to protect the health and wellbeing of all involved
  + enables learnings from incidents and facilitates system improvement.

# Legislating for candour

In reaching the recommendations described in the sections to follow, the Expert Working Group sought to ensure that the statutory duty of candour would not undermine the benefits of the existing open disclosure framework. As outlined above, open disclosure is a well-established part of health care in Australia, and in some places is done very well. However, the consultation has confirmed the expectation that the practice, understanding and awareness of open disclosure across the state are highly variable.

The anticipated value of the statutory duty of candour is to elevate the importance of disclosure, to raise awareness and ensure that there is a stronger organisational focus on compliance. It will mean that responsibility for ensuring stronger policies and processes sits with the highest level of organisational governance. It will become an issue of statutory compliance, requiring review and oversight by boards of health services as part of their governance obligations. It raises this duty from a ‘management issue’ to a ‘board issue’.

The introduction of a statutory duty of candour is an opportunity to centralise and modernise the existing obligation and further embed 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. This is a sentiment reflected in the majority of submissions.

Open Disclosure (OD) as enshrined in the Australian Open Disclosure Framework (AODF) is designed to foster a ‘safe just and ethical’ culture and ‘to foster effective communication’. Patients who have had an adverse outcome should be entitled to open communication in relation to that outcome, irrespective of sector.

*Victorian Managed Insurance Authority*

In elevating certain key elements of open disclosure to a legal obligation, it is hoped that the profile of open disclosure will be raised, leading to more consistent 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 within health services where open communication is valued throughout the life of a care relationship.

Alfred Health agrees with this position and in our (admittedly pragmatic) view, the *instrumental* benefit of a statutory duty of candour is to ensure that health practitioners feel safe in acknowledging and reporting that something has gone wrong. The *ultimate* benefit of a statutory duty of candour lies in preventing similar events from happening again. Unless open disclosure achieves these actual benefits, it risks being an exercise in bureaucracy and image control.

*Alfred Health*

While there was general support for the introduction of a statutory duty of candour (although with some reservation about how it would be framed and implemented), many stakeholders stressed that without related broader reforms, the statutory duty alone would at best achieve little; and at worst would risk undermining gains achieved since open disclosure was first introduced to Australia.

The imposition of a statutory duty could have the effect of reducing the therapeutic effect of apologies. Patients may view the apology as a legal ‘tick’ rather than as a genuine act of transparency and regret. If patients form an impression that an apology is given merely to satisfy the strict legal requirements of the statutory duty, then the power of the apology is undermined.

*Monash Health*

The Expert Working Group agrees that this new legislative requirement must be but one part of a broader system of reform and any requirements must be clearly positioned within the broader context already described in the *System context* section above.

Establishing simple policy and practice advice that positions statutory duty of candour in the continuum of open communication, shared decision making, informed consent, participation in treatment and care planning, and open disclosure when things do not go as planned, will mitigate against the risk of the statutory obligation becoming solely a regulatory compliance activity.

*Safer Care Victoria*

Although the Expert Working Group strongly believes that the recommendations in this report implemented in their entirety will ensure that the statutory duty delivers the benefits envisaged by *Targeting Zero*, it also recognises that there have been significant concerns raised by some stakeholders (a little under a fifth of respondents indicated that they did not support the introduction of a statutory duty).

There is ample evidence that mandatory requirements merely create organisational tension points and reinforce cultural intransigence. Without an accompanying culture change strategy, there is a prospect that legislation could lead to greater opacity as a response to the threat of punitive sanctions.

*Health Issues Centre*

The Expert Working Group therefore believes that monitoring of the impact of the duty will be critical to ensure that reforms achieve their intended aims.

**Recommendation 1**

It is recommended that the department partners with Safer Care Victoria to monitor the impact and any unintended consequences of the proposed statutory duty of candour and report to the Minister on the first three years of operation of the new duty.

# Establishing the parameters of the statutory duty

## Scope of the duty

### Hospital services

The Expert Working Group found general support for the application of the statutory duty of candour to hospital and health service organisations 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.

There was also general support for inclusion of private hospitals and day procedure centres within the scope of the statutory duty, although we heard submissions that there may be practical and legal difficulties in applying a legislated duty of candour in the private sector.

Privately operated hospitals and health providers should be included in scope as well as registered community health centres, ambulance services, state funded residential care and primary health services.

*IPC Health*

The APHA also wishes to emphasise that there are particular practical and legal difficulties in applying a legislated duty of candour in the private sector. It is inherent to the nature of private hospital services that the private hospital is but one amongst a number of independent entities involved in the provision of care. Most medical services are provided by credentialed medical officers (CMOs) which are neither employees nor contractors of the hospital; rather they are independent service providers. Multiple independent clinicians and health service providers commonly work together to care for each patient.

*Australian Private Hospitals Association*

The Expert Working Group has, however, formed the view that these difficulties could be overcome and that inclusion of these organisations is consistent with the *Targeting Zero* (p. 23) assertion that ‘all members of the public should be confident of receiving safe care, regardless of their condition and regardless of whether they are being treated in a big, small, public, forensic or private health service’. It is also consistent with recent legislative reforms introduced through the *Health Legislation Amendment (Quality and Safety) Act 2017*, which, in part, sought to better align the regulatory requirements of different health and hospital services across the public and private sectors.

A legal obligation for open and honest communication should apply regardless of the sector in which clinical services are being provided.

*Professional association A*

**Recommendation 2**

It is recommended that the Minister seeks to amend the Health Services Act to establish a new statutory duty of candour applicable to the following entities defined in the Act:

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

### Ambulance services and the Victorian Institute of Forensic Mental Health

A significant number of respondents (12) argued that the statutory duty of candour should be applied to ambulance services as well as hospital services. The inclusion of Ambulance Victoria is consistent with the move towards the professionalisation of paramedicine, through the recent establishment of the National Paramedicine Board and inclusion of paramedic registration under the Health Practitioner Regulation National Law (Victoria) Act, and was strongly supported by Ambulance Victoria.

We are committed to providing effective open disclosure in accordance with the national Framework and are supportive of initiatives to strengthen processes to improve disclosure practise, such as is being considered through this paper. We are undertaking actions to strengthen our own open disclosure processes; to improve the transparency, effectiveness of practise and the personal experience of the disclosure for patients, carers and the families who are involved.

*Ambulance Victoria*

To ensure excellence in patient care, the principle of transparency should apply to all participants in the chain of care which may begin with paramedic service providers and practitioners. It’s not something that applies only to hospitals. As provided for in the UK (under the CQC), this governance requirement for transparency might form part of a national system of quality assurance and accreditation for paramedic (ambulance) service providers in Australia. Greater transparency and sharing of data also may help to drive best practice.

*Adj Assoc Prof Ray Bange*

The inclusion of private hospitals, day procedure centres and Ambulance Victoria reflects the view that these services are places where risk and harm does occur and where an appropriate level of apology is warranted. This approach presents as an opportunity to drive practice improvement in areas where communication is critical but there are weaker regulatory processes; it also creates consistent quality and safety requirements for Victorian health services irrespective of whether they are delivered publicly or privately. Ambulance Victoria is included because it is a health service in terms of risk, clinical care and policy and quality and safety performance.

SCV has concerns that if not all of these health services are included, it will create a two tier system for clinicians and consumers and will mitigate against driving a just health system culture.

*Safer Care Victoria*

The Expert Working Group is of the view that extending the duty to include Ambulance Services would be beneficial and consistent with the amendments made through the Health Legislation Amendment (Quality and Safety) Act which sought to align quality and safety obligations for Ambulance Services with those of hospital services regulated through the Health Services Act.

Given the Health Legislation (Quality and Safety) Act also made amendments to the Mental Health Act to align the quality and safety governance responsibilities of the Victorian Institute of Forensic Mental Health, it is proposed, for consistency’s sake, that this health service also be included in the first tranche of services to be covered by the new statutory duty.

All of the designated mental health services prescribed in the Mental Health Regulations 2014 are within this scope except for the Victorian Institute of Forensic Mental Health (VIFMH) which is established by section 328 of the *Mental Health Act 2014* (MHA). The duty should also apply to VIFMH.

*Mental Health Complaints Commissioner*

**Recommendation 3**

It is recommended that:

* the Minister seeks to amend the *Ambulance Services Act 1986* to establish a new statutory duty of candour applicable to ambulance services
* the Minister for Mental Health seeks to amend the Mental Health Act to establish a new statutory duty of candour applicable to the Victorian Institute of Forensic Mental Health.

### Mental health services

Under the proposal above, mental health services will be in scope as they are either provided under the Mental Health Act in public health services or in the private hospital system. The Expert Working Group believes this is appropriate but wishes to acknowledge the significant particular complexities of the issues that arise from a duty of candour in the mental health context.

A number of submissions articulated these complexities, which are addressed where relevant throughout the report.

### Other healthcare organisations

A smaller number of respondents proposed that the duty be applied to other healthcare organisations regulated under the Health Services Act, including residential care services and community health and/or other health sector providers including primary health or dental services.

Duty to be universal. To include Community Health Centres and any other healthcare provider that is regulated by the National Safety and Quality Health Service (NSQHS) Standards as well as private primary health providers (i.e. large GP practices).

*Community health centre*

Aged care services, registered community health centres and state-funded residential care services should be in scope for the statutory duty of candour. Health care is provided in these services in teams, with a similar potential for errors arising from systems issues (organisational processes) as the hospital services above.

*Professional association A*

We strongly agree that there should be open and honest communication between providers in each of these service types and the individuals they care for, and that there would be significant safety and quality benefits arising from improved disclosure. However, we also agree with the observations made by Safer Care Victoria, that, at least for community health services, there is ‘foundational work required to implement a model of open disclosure which is appropriate to their scope and practice of clinical care’ and that therefore it would be premature to extend the statutory duty of candour to this broader set of services at this time.

There would be value in working with these services to improve approaches to open disclosure, and to potentially work towards extending the statutory duty to other types of service over time, once the legislation has been embedded and when existing processes are more mature. As suggested by one respondent ‘whether it applies or not, having legislation relevant to health services will still “send a signal” to other providers’.

**Recommendation 4**

It is recommended that Safer Care Victoria be asked to lead work to develop a model for open disclosure appropriate to residential care services, community health and other appropriate settings.

**Recommendation 5**

It is recommended that the Minister considers consulting relevant stakeholders about the possibility of extending the statutory duty of candour to include other types of health service organisations as part of the planned forthcoming review of the Health Services Act.

### Individual healthcare providers

The Expert Working Group notes that a minority of submissions (16) supported the application of the statutory duty to *individuals* as well as organisational healthcare providers. In considering the arguments made for inclusion of individuals, it became apparent that (for many respondents), their support for that approach stemmed from: (a) the importance they placed on individual practitioners being aware of their obligations and participating in discussions with patients; or (b) a belief that organisations may find the duty difficult to implement and enforce unless there was a corresponding statutory obligation on individuals. There were also concerns raised that individuals working in private consulting rooms would not be subject to a duty if it is only applied at an organisational level.

A similar number of respondents (18) argued against the inclusion of individuals within the scope of the duty. It was noted that doing so could be contrary to the stated aims of developing more open, honest and blame-free cultures, and that an individual approach does not align with modern health care which is generally delivered by teams of professionals.

The statutory duty must not apply to individual clinicians and practitioners but rather to the organisations that manage and oversee the delivery of the care services. [This organisation] recognises that doctors will often be relied on to discharge such a duty on behalf of hospitals and organisations.

*Professional association B*

ANMF believe that all health services operating in Victoria should be required to meet the statutory duty of candour, and believe it should be extended to include more than those defined under the Health Services Act. The statutory obligation should be kept with the organisation rather than the individual as we believe this will ensure identification of a central lead who can ensure education, reporting and processes are managed in a standard way and can ensure that corrective actions can be implemented as necessary.

*Australian Nursing and Midwifery Federation Victorian Branch*

All Registered Health Professionals have professional and ethical obligations to be open and honest with patients/clients when things go wrong. In the private sector, there is a direct therapeutic relationship with individual practitioners with whom the statutory duty should rest. In the public hospital sector insurance, legal, administrative, compliance and monitoring complexities mean the statutory obligation should rest with the hospital rather than an individual.

*Victorian Managed Insurance Authority*

The statutory duty should not apply to individual practitioners. In our view, applying the duty to practitioners, if accompanied by penalties and AHPRA notifications for non­compliance, will reinforce a blame culture and will not lead to cultural change.

*Avant Mutual Group*

ADAVB therefore urges the Government not to add unnecessary duplicative regulation, which could confuse health practitioners about their obligations, and interfere with existing regulatory processes.

*Australian Dental Association Victorian Branch*

Organisation-wide accountability is much more likely to foster consistency of practice and greater cultural change where required. Organisational accountability also better reflects contemporary models of healthcare delivery, which focus on the role of the team rather than individual practitioners.

*Alfred Health*

In VARTA’s experience when adverse incidents occur, there is usually more than one person involved. Incidents commonly occur in the laboratory through human error and can involve the loss of gametes or embryos. [When incidents are clinical eg women experiencing severe ovarian hyperstimulation syndrome, policies and clinical governance will be important. Even if one person makes a mistake, systemic corrective actions are usually identified. Individuals are counselled and the entity takes responsibility for the adverse incident. It makes sense for the entity to take responsibility for a statutory duty of candour if the ART sector is to be captured within the health sector affected by legislative candour requirements.]

*Louise Johnson, CEO, Victorian Assisted Reproductive Treatment Authority (personal submission)*

The Law Institute of Victoria cited two opposing views from its members:

In support of the proposal that individuals owe a statutory duty of candour are the following contentions:

if an error is made by an individual who does not work within an organisation where there are board members or other persons who owe the statutory duty of candour, there will be no statutory duty of candour owed by that individual. For example, a surgeon who makes an error in private rooms or after hours in failing to respond to a medical emergency where there is no overseeing corporation or body that owes the statutory duty of candour; and

if the statutory obligation of candour does not apply to individuals and an individual does not disclose an error that has caused harm to a consumer to any relevant healthcare provider (such as a hospital or day procedure facility), the error will go undisclosed without penalty. Codes of Conduct for any particular health professionals do not have the effect of legislation.

*Law Institute of Victoria*

However, the Law Institute of Victoria also noted:

Against the proposal that individuals owe a statutory duty of candour is the contention that within large health organisations, it would be burdensome if every individual who became aware of harm caused by error owed the obligation of disclosure. This concern would be addressed by an individual’s statutory duty of candour being able to be satisfied by the organisation in or with which an individual works fulfilling the requirements of the statutory duty of candour.

*Law Institute of Victoria*

In England, where the concept for the *Targeting Zero* recommendation originated, a distinction is drawn between a *statutory* and a *professional* duty of candour. Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014establishes the statutory duty of candour in England. Regulation 20 applies to organisations as opposed to individual members of staff. It requires the provider to ensure that its entire staff, regardless of seniority or permanency, understand the organisation’s responsibility to be open and transparent in their communication with relevant persons in relation to a notifiable safety incident. It requires the provider to understand their own role, and to put policy and processes in place to ensure they are supported to deliver it. Individual members of staff who are professionally registered are separately subject to the professional duty of candour, which is overseen by the professional regulatory bodies.[[17]](#footnote-17)

At an individual level, open disclosure is an essential clinical skill and should be taught, supported, expected and monitored as such, rather than enforced through legislation.

*Public hospital A*

An additional consideration is that a clinician involved in an adverse event may not, in a hospital setting, be best placed or sufficiently senior to conduct or lead the disclosure/candour process. Further, it is conceivable that more than one hospital or healthcare provider may be involved in the relevant adverse event. Such a situation could create insurance, legal, administrative, compliance and monitoring complexities best managed through hospital protocols and clinical governance controls.

Having considered the advice from stakeholders as well as the context in which the statutory duty will apply, we are convinced that the statutory obligation for candour should be placed at an organisational level only. Healthcare delivery occurs in a system of multiple providers, players and processes, and interventions are frequently delivered by teams of practitioners. We agree with the view expressed by Safer Care Victoria in its submission that placing regulatory obligations on the organisation enables the organisation to drive accountability for delivery of the practice and actions that should occur as part of a candour response. Moreover, it supports the board to fulfil its responsibility in creating an organisational culture of safety that recognises and values the perspective and experience that consumers can bring.

The Expert Working Group has noted in its interactions with a number of stakeholders that there remains inconsistent understanding at a board level about the clinical governance role of boards. Indeed, *Targeting Zero* found that 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.[[18]](#footnote-18)

Just as *Targeting Zero* pointed to the fundamental need for boards to broaden their understanding of governance to quality and safety matters, it is hoped that the introduction of a statutory duty – with a clear responsibility imposed on boards – may have an additional benefit of broadening and improving the organisational leadership role of boards more generally.

The Expert Working Group has formed the view that any concerns about a failure on the part of a relevant clinician to take part in the open disclosure process, where appropriate, are best addressed through accreditation or internal disciplinary processes. Most individual practitioners will be subject to codes of practice that require open and honest discussion with patients and, under the Health Complaints Act, general health service providers (that is, those not required to be registered under the Health Practitioner Regulation National Law (Victoria) Act) are required to comply with a code of conduct that includes a requirement for disclosing adverse events to clients. The Expert Working Group sees this as the parallel obligation to the UK’s Regulation 20 Professional Duty of Candour.

Much of what is proposed in this set of legislative reforms is already adequately covered by current open disclosure requirements and multiple professional codes of conducts across the medical professions. Acknowledging that the recommendation for this change arose from significant organisational failures the focus of this legislation should be on improving transparency and disclosure requirements at the senior organisational level.

*Royal Australian College of Surgeons*

The involvement of individual practitioners will, of course, be critical in making the statutory duty of candour successful. Therefore, it will be important that individual practitioners are appropriately trained and supported and that organisations have systems in place to ensure that individuals are able to play their part. Later recommendations are aimed at addressing these needs.

In recommending that a statutory duty of candour should be imposed on the hospital responsible for providing the services to which the relevant incident relates, we have given careful consideration to whether a hospital will be in a reasonable position to access and communicate the necessary information to comply with the duty of candour, given there may be a range of individuals and third parties involved in providing the relevant services. We have also noted that there may be particular complexities for private providers operating within public hospitals or private facilities. Nonetheless, we have determined that this approach is reasonable. Details of these considerations are outlined in Appendix C.

It must be acknowledged that private contractors engaged in public hospitals pose a specific challenge. Similarly, doctors working at private hospitals are contracted to provide their services and may work on an ad-hoc basis at several different private hospitals around Victoria.

*Professional association B*

## Trigger for the duty to apply

### Types and seriousness of harm

The Expert Working Group received numerous submissions stressing the importance of clarity and certainty in any statutory obligation.

Given the duty is intended to facilitate prompt action, “harm” should be limited to harm which manifests itself before discharge from hospital, thus excluding mental health and other conditions which are not apparent until later. “Harm” should also be limited to something which is objectively manifest, and it should not be able simply to be declared by the patient. Legislatively requiring candour in respect of a phenomenon which is not objectively apparent leaves a great degree of uncertainty as to obligations.

Harm to mental health should be excluded from the definition of harm altogether, given that a diagnosis of such will not be possible in the short term.

*Public hospital B*

Whilst reporting of more minor incidents should be promoted (where appropriate) within organisations’ quality systems, enforcing a statutory obligation to disclose such incidents may be overly burdensome for some healthcare providers to implement and may cause unnecessary distress to consumers and/or their families/ carers.

On that basis, it seems appropriate that the statutory duty of candour should only apply to those incidents that result in Severe/Death or Moderate harm.

…

[Psychological harm] would also be a need for independent expert assessment of harm.

*Public hospital C*

Care needs to be given to avoid any statutory duty effectively encompassing all types of incidents and harms covered by existing open disclosure processes. This would then create a broad statutory duty of open disclosure, with enormous burden and administrative challenges.

*MIGA*

For this initiative to be successful ANMF believe there must be clear and measured markers for defining harm. With no such definitions this could result in health services spending enormous amounts of time on issues of a minor nature, health professionals stressed and anxious and consumers confused and not satisfied.

*Australian Nursing and Midwifery Federation Victorian Branch*

Consistent with the open disclosure framework and Victoria’s health incident management policy, the Expert Working Group considers that ‘harm’ should be understood to include both physical and psychological harm. While some stakeholders expressed concern about how psychological harm would be assessed, the majority of those who expressed an opinion agreed that it is appropriate to acknowledge and respond to serious psychological harm in the same way as serious physical harm; and that doing so is consistent with the principles of patient-centred care.

[This organisation] submits that the statutory duty of candour should not apply to psychological harm that is not the primary diagnosis resulting from an adverse event.

As the onus is on the health service to identify ‘threshold’ events and disclose them, [this organisation] is unclear about how a definition can be given to psychological harm – which can be subjective and is harder to categorically define than biomedical or physical harm – in such a way that a fair balance of consumer access to restitution and board accountability is struck.

*Specialist representative organisation*

Peter Mac practices patient-centred care and is cognisant of the psychosocial dimension of individual health. The threshold level of any institutional duty of candour should be aligned with current personal injury schemes or civil liability legislation.

*Peter MacCallum Cancer Institute*

As the [Australian Open Disclosure Framework] points out, there is no universal definition of ‘adverse event’. The AODF currently uses the WHO definition of harm which includes psychological harm. Whether a patient has clinically suffered psychological harm requires psychological or psychiatric assessment. Whilst a matter for psychiatric input, clinical psychological harm may be difficult to assess and diagnose within the window in which [open disclosure] should take place.

*Victorian Managed Insurance Authority*

Dentists are not trained in diagnosis outside of the definition of dentistry, and as such it would not be appropriate to undertake a diagnosis of any psychological state – or change of that state – of a patient. To do so would be crossing professional boundaries. If the appropriate diagnosis was made by a practitioner trained in that field subsequent to an incident, then this circumstance may apply.

*Australian Dental Association Victorian Branch*

[This organisation] believes that the statutory duty of candour should apply to psychological harm. We believe it should apply to both:

* prolonged psychological harm – psychological harm which a consumer has experienced for a 28-day period
* severe acute psychological harm, e.g. suicide, deliberate self-harm, psychosis.

*Professional association A*

Many of the harms that occur in mental health settings are directly or indirectly related to compulsory treatment. While compulsory treatment is lawful under the Mental Health Act in defined circumstances, it nevertheless results in multiple breaches of human rights under the Victorian Charter of Human Rights and Responsibilities, and under the UN Convention on the Rights of Persons with Disabilities. Causing harm to a person at the same time as breaching that person’s human rights and dignities can create particularly complex psychological distress and suffering.

VMIAC strongly urges that psychological harm be included in the scope for the statutory duty of candour, particularly in the context of mental health services.

*Victorian Mental Illness Awareness Council*

Respondents were concerned that if legislative provisions were open to interpretation or judgement, the effect could be to either reduce the practice of open disclosure or encourage the use of defensive medicine. Stakeholder views on the types and levels of harm that should ‘trigger’ the statutory duty varied greatly.

[This organisation] submits that objectivity and clarity are necessary features…

…

In this context, consideration should be given to setting the threshold for triggering the statutory duty intentionally high, for example for ISR1 and ISR2 incidents (and their non-VHIMS equivalents).

A high threshold trigger of the statutory duty will not detract from existing open disclosure policies, but it will give clarity to boards, executives and employees about when the statutory duty is triggered.

The use of VHIMS (and when rolled out, VHIMS2) provides a standardised framework for categorising incident severity, reporting requirements and guidance on how health services must assess, understand and respond to clinical incidents.

*Specialist representative organisation*

While there was some support for a very broad definition of harm, on balance we have determined that the statutory duty should apply to *significant* harm, with ongoing open disclosure obligations to continue to apply for other incidents.

The current Victorian Health Incident Management System categories of Incident Severity Rating (ISR) 1 and 2 are proposed as the threshold for the statutory duty of candour to apply. These thresholds are well understood by providers and as such the need for services to implement new assessment systems or to assess individual incidents against more than one set of categories will be avoided.[[19]](#footnote-19)

Beyond ISR 1 and 2 events, the existing [Australian Open Disclosure Framework] provides useful guidance in relation to when the statutory duty should apply. If the statutory duty is to extend beyond ISR 1 and ISR 2 events, consideration should be given to encapsulating this in Principles or Regulations or Guidelines to guide the implementation of the Act. Given the potential consequences of non-compliance, the framework for identifying triggers should not allow for uncertainty.

*Victorian Managed Insurance Authority*

Using the current VHIMS ISR as a basis for determining a threshold for a duty of candour could support consistency and could aid implementation, if adequately supported by additional coding guidance.

*Public hospital A*

The inclusion of mild harm as a trigger for the duty of candour obligation warrants careful consideration, particularly in those situations where the patient is unaware that an incident has occurred. In addition to being administratively burdensome, adopting a broad approach to a harm/ incident threshold may erode public confidence in the health system over time. Furthermore, a patient who is unaware that an incident has occurred may be upset or traumatised if apprised of such information.

*Australian and New Zealand College of Anaesthetists*

### Near misses not recommended for inclusion in scope of duty

There is a strong rationale for health services to discuss ‘near misses’ with consumers – complications and/or incidents that could have – but did not – result in harm. A dialogue between provider and patient allows for the complete picture of an event to be established. While honest communication with a consumer about any harm they may have experienced is important, another key aim of the statutory duty of candour is to ensure that services are able to learn from mistakes. Understanding how near misses occurred, and how they were avoided, offers an opportunity to make quality and safety improvements before harm occurs.

However, there was very limited support from stakeholders for inclusion of near misses in the scope of the legislated duty and significant concerns raised about the possible detrimental impacts of doing so. These include – an unreasonable administrative burden on services; difficulties in defining and categorising near misses; and the risk of undermining consumer confidence in the health system.

A near miss is not an adverse outcome, or an incident which results in any harm, and as such should not be included. Medical (and dental) treatment is subject to biological variations, and as such a practitioner should modify or change treatment in response to any circumstances that may arise during treatment.

…Complications of treatment are also expected in a percentage of cases. These should not trigger the Statutory Duty of Candour.

*Australian Dental Association Victorian Branch*

In considering the inclusion of near miss situations, we do not believe these should be included as there are already mechanisms for reporting these events. The purpose of near miss events reporting is to correct, where possible, the circumstances which created the near miss in the first place. The fact that the event did not occur would result in no harm occurring anyway.

*Australian Nursing and Midwifery Federation Victorian Branch*

Open reporting of near misses serves to improve institutional learning and quality improvement. Unintended negative consequences of including near misses and no harm events in a statutory duty of candour framework may include:

* reduced reporting of near misses;
* increased administrative burden; and
* reduced public confidence in the quality of the healthcare system.

It is also important that legislation makes clear that potential treatment side effects (even if rare) are excluded in definitions of ‘harm’.

*Australian and New Zealand College of Anaesthetists*

Whilst recognising near misses should form part of an effective clinical governance system and enable health services to learn from mistakes *and* near mistakes, it would be difficult to encapsulate this concept in the statutory duty. That does not mean that the concept of recognising near misses should be overlooked or not form part of the clinical governance armoury of an effective health service. Rather than be within the scope of the duty of candour, it has been argued in submissions, near misses and other incidents that do not result in significant harm should – more appropriately – form the basis of a systemic review of processes or professional competency alone. It is noted that the *Victorian health incident management policy* provides that all incidents, irrespective of their ISR rating, require review to assess the level of investigation required.

On balance, the Expert Working Group has decided that the value of including near misses within the scope of the statutory duty is outweighed by the risks and disadvantages. Accordingly, it is not recommended. Nonetheless, as argued by Safer Care Victoria, this does not mean that such incidents should not be discussed as part of normal practitioner/client communication, nor does it mean that such events should not be thoroughly investigated to identify learnings, including, where relevant, discussion with patients or their families who may be able to add to understandings of what happened and how it can be avoided in the future.

SCV proposes that the disclosure and apology for near misses and/or complications of treatment that result in no harm and/or no lasting harm should be conducted under open disclosure and good practitioner patient/communication. This in line with the principle that regulated practice should be in areas of greatest harm and impact. This should not diminish the importance of communicating to patients and learning from these events.

*Safer Care Victoria*

### Consumer declared harm

The prospect of a ‘consumer right to declare harm’ as a trigger for the application of the statutory duty of candour was raised in the consultation paper and generated significant interest and discussion amongst stakeholders. Twenty-three respondents expressly supported this idea in some form.

Consumers are often aware of errors, oversights, sentinel events and harms that either do not come to the attention of staff, or which the staff involved will not identify as harmful, or will not proactively disclose or admit to others. Academic research has consistently shown that consumers can and do identify a swathe of medical errors, near misses and harms that are not detected or recorded by other means.

*Jen Morris, Healthcare Consumer Advocate*

We are strongly supportive of a consumer declared harm triggering the duty. Where a patient or their family raises concerns, it is vital that they be taken seriously. To maximise the opportunity for continuing trust, the statutory duty of candour should be discharged. To not do so would have a deleterious impact on patients and families who raise concerns and will undermine faith in the provision of health services.

*Maurice Blackburn Lawyers*

We agree that, if a consumer experiences harm that has not been identified by a health service, there should be scope and opportunity for the consumer to bring it to the health service’s attention and – following a review of the admission in question – to commence an open disclosure process.

The Australian Open Disclosure Framework raises the concept of ‘patient perception or report of harm’ and acknowledges that ‘the patient’s view on whether harm has been suffered may differ from the clinician’s or health service organisation’s view’. In this context, it is appropriate that ‘consumer declared harm’ continues to facilitate an open disclosure, when appropriate.

There is already a provision in the Open Disclosure Framework for consumer declared harm to be acknowledged and responded to. If the Statutory Duty of Candour is to be introduced, processes to address consumer declared harm should be consistent with that of the Open Disclosure Framework.

*Australian Dental Association Victorian Branch*

It was pointed out in submissions, however, that it is unclear how a statutory duty and its accompanying legal accountability for health service directors can be applied fairly in these instances, particularly if the health service and its employees did not intentionally fail to disclose harm and implement an open disclosure.

There was also concern that unless tightly defined, a ‘consumer right to declare’ could result in a significant administrative burden for services and could duplicate existing avenues for consumers to raise concerns, such as through hospital complaints processes or via complaint to the Health Complaints Commissioner or Mental Health Complaints Commissioner or via notification to AHPRA.

[This organisation] does not agree that consumer declared harm should trigger the statutory duty, however, [this organisation] strongly supports maintaining the existing options available to consumers to declare that harm has occurred, and if appropriate, have the health service in question implement an open disclosure process.

*Specialist representative organisation*

This should not be contained in legislation.… Including consumer declared harm in legislation is likely to create a burden of investigations for claims that are either vexatious or misunderstood by the patient. There is already an appropriate outlet through the Australian Health Practitioner Regulation Agency (AHPRA) for consumers to make a complaint if they feel they have not received appropriate treatment from a medical professional.

*Royal Australasian College of Surgeons*

Careful consideration would need to be given to what falls within the scope of ‘consumer declared harm’. Conceivably a patient, family member or carer may raise concerns in the following circumstances:

* An unanticipated clinical adverse event may be identified.
* An anticipated complication of a procedure in relation to which consent may or may not have been given.
* An adverse event as a result of natural disease progression.
* Patient, family or carer perception of harm where no clinical harm or error is identified.

It is difficult to see how a Duty of Open Disclosure or Candour which assumes an explanation of potential consequences, and the steps being taken to manage and prevent recurrence of an adverse event, could apply if there is no identified clinical adverse event or error.

*Victorian Managed Insurance Authority*

On balance, the Expert Working Group supports the right for consumers to declare that they have been harmed and recognises that there will be circumstances in which service providers are unaware that harm has been suffered. It is good practice for health services to have in place avenues for consumers to make this declaration and be supported to do so, and for services to have systems to deal with issues raised by consumers.

Where the self-reported harm is of a level that would trigger the statutory duty of candour as recommended (incidents that meet the threshold for ISR 1 and 2), the duty should apply just as it would if the harm had been identified by the provider.

The Expert Working Group has formed the view that some advocacy in submissions for consumer declared harm was intended to draw attention to the fact that open disclosure in some instances is not performed well, or at all. The open disclosure framework provides for consumers to initiate the process. We heard many times of consumers frustrated by a lack of compliance with the open disclosure process. Others expressed frustration that they did not receive an acceptable explanation to the issues they raised; they were not taken seriously or they were not listened to. This, in many cases, leads them down the path of making a complaint to the organisation, or to a health complaints commissioner[[20]](#footnote-20) or AHPRA – processes which may well have been avoided had an open disclosure process been properly followed.

Not including a specific consumer declared harm category in a statutory duty of candour does not mean that it should be overlooked. Consumer declared harm has a place in the professional obligations of open disclosure and the broader open disclosure framework.

The recognition of ‘consumer declared harm’ in respect of open disclosure and duty of candour is a key principle of person-centred care.

*Public hospital A*

### Applying the statutory duty in mental health services

While one professional association was supportive of a reasonably narrowly defined application of the duty (similar to that proposed in Recommendation 6), the Victorian Mental Health Advocacy Centre argued that the duty of candour should apply very broadly to a range of healthcare services provided to consumers in mental health settings.

The Victorian Mental Illness Awareness Council also advocated a broad application of the statutory duty of candour: including in respect of a range of serious risks of harm common to prescribed neuroleptic medications and the experience of mental health consumers who are harmed while subject to compulsory treatment under the Mental Health Act as this can result in layering further psychological harm along with the indignity of being compulsorily forced to take the medications that caused the physical injury or disability.

There is currently no transparent process for monitoring the compliance of clinical mental health services with the practice of open disclosure, however anecdotal evidence gathered through VMIAC’s work with consumers and the sector would suggest that open disclosure in this sector is relatively rare and inconsistent.

It is critical that any adoption of a statutory duty of candour includes consumers of clinical mental health services. This group of people are amongst the most disadvantaged, distressed, isolated and traumatised Victorians – and is likely to be one of the consumer groups most likely to benefit from this potential new legal obligation.

*…*

VMIAC welcomes the acknowledgement in the consultation paper that ‘consumers and clinicians may conceptualise harm differently’ (p11). We advise that this is frequently the case within mental health services, particularly, but not only, in relation to psychological harm, and in relation to disability resulting from medication adverse events. Further, harm that results from compulsory treatment can be contested between consumers and clinicians.

*Victorian Mental Illness Awareness Council*

This complex issue was also addressed by the Mental Health Complaints Commissioner.

It is more complicated where there is psychological harm due to the person’s experience of compulsory treatment or a restrictive practice, or where the patient declares psychological harm as a result. Pursuant to the MHA, statutory criteria must be met before compulsory treatment and restrictive practices are lawful. It is not uncommon for people subject to compulsory treatment and restrictive practices to describe psychological harm as a consequence of these practices…. Having regard to this statutory regime, the application of a statutory duty of candour to any psychological harm that may be caused by the use of these compulsory powers would therefore appear to warrant particular consideration and the identification of scenarios as to how a statutory duty of candour would apply.

*Mental Health Complaints Commissioner*

The Expert Working Group maintains the view that the application of the duty should be consistent with ISR 1 and 2 incidents and that treatment side effects that are experienced by consumers, at times in an involuntary context, do not warrant application of the duty when they are conventional and appropriate treatments in accordance with recognised medical treatment for mental health conditions.

It should be noted, however, that the Mental Health Complaints Commissioner herself has some concerns as to how the triggers might apply to mental health incidents.

One of our key concerns about existing arrangements is that the ISR rating system that applies to public health services does not appropriately reflect the gravity of some incidents and does not provide adequate safeguards for consumers (for example, an alleged ‘staff on consumer’ physical assault is unlikely to be rated as an ISR 1).

*Mental Health Complaints Commissioner*

Several submissions also highlighted that the public mental health system in Victoria has an additional layer of oversight and regulation through the Chief Psychiatrist and a specialist complaints body – the Mental Health Complaints Commissioner.

In recognition of these particular issues, the Expert Working Group has, later in this report, considered particular additional supports that might be considered for the mental health sector (see *Support for success*).

### 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.

The Expert Working Group cannot stress strongly enough that 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 to set 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 potentially creating additional administrative burden, such an increase could diminish public faith in health service organisations by creating a perception that services are unsafe or errors are too commonplace.

As was pointed out in *Targeting Zero*, and evidenced in the submissions to the consultation paper, open disclosure is not always done well, if done at all. All this points to the need for significant training in relation to both existing open disclosure processes and the proposed statutory obligation. We believe understanding and practice of both will be enhanced by the suggested process of consulting and developing the proposed Victorian candour and open disclosure guidelines (see Recommendation 9); and through ensuring that appropriate training and support accompanies the introduction of the new obligation.

**Recommendation 6**

It is recommended that the statutory duty of candour apply to incidents that meet the criteria of ISR 1 or 2 as defined in the *Victorian health incident management policy* regardless of whether the harm is physical or psychological and if it is identified by a health service, an individual clinician, a consumer, their family or carer.

**Recommendation 7**

It is recommended that consumers and their families/carers should be supported to report instances of harm and that services should have in place systems to respond to such reports.

### Recency of incidents

In most cases, the occurrence of harm will be known almost immediately or become clear in a relatively short period of time. However, as the tragic events at Djerriwarrh Health Service showed, there will be times 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 was proposed in the consultation paper, and supported in submissions, 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.

**Recommendation 8**

It is recommended that the statutory duty of candour apply to any instance of harm that meets the criteria set out in Recommendation 6, which occurs after the commencement of the relevant legislative provisions, or is identified after commencement regardless of when the harm occurred.

# Approach to legislating – striking the right balance

In addition to seeking clarity about the triggers for the statutory duty to apply, respondents were concerned that the statutory duty should not be overly prescriptive. The Expert Working Group heard many examples of instances where it might be inappropriate for providers to be compelled to disclose information to consumers in a particular manner or at a particular time, or where requirements for a particular approach could be detrimental to a patient or impact negatively on an ongoing care relationship.

Modern health services are by their nature multi-disciplinary and involve many thousands of employees – including doctors, nurses, allied health practitioners and a range of non-clinical staff – interacting with consumers across a range of settings.

In this context, it is essential that the proposed duty of candour strikes a fair balance between prescribing clear roles, responsibilities and boundaries for the threshold triggers of a mandated open disclosure process, and allowing sufficient flexibility so that health services are able to respond to individual incidents of harm with confidence and in a manner that meets the needs of all parties, including consumers, employees and the health service’s board of directors.

*Specialist representative organisation*

[This organisation] reiterates the need to be able to defer timely communication when the mental health of consumers is not conducive to participating in open disclosure (and conversations required under the statutory duty).

*Professional association A*

If the statutory duty is implemented as a governance responsibility for Boards and executives it should not contain detail about operational matters or specify elements of the open disclosure process.

*Avant Mutual Group*

It is also clear that there is a range of complexities that may arise in particular circumstances, for example, the question of when other parties – such as family members, carers, guardians, and nominated persons – should be included in a statutory duty of candour. Similarly, issues may arise in relation to how family conflict or differing preferences among the significant others who have a legal relationship to the affected person should be responded to.

The Expert Working Group has heard that the practice of open disclosure is highly variable. Safer Care Victoria has reported clinician feedback that there is a need for a more succinct and accessible policy framework to support practice.

SCV proposes that operational and best practice requirements to inform statutory requirement could sit within a policy that is recognised by regulations. This allows for more responsive enhancements to systems and processes that support effective appropriate duty of candour.

*Safer Care Victoria*

To meet the objectives of providing certainty and supporting good practice, while at the same time avoiding unnecessary inflexibility, we have formed the view that the provisions to be included in the legislation to introduce the statutory duty of candour should be high level and minimal in nature. It is proposed that this high level legislative ‘hook’ be supported by new Victorian candour and open disclosure guidelines (which will be a subordinate instrument). These guidelines will provide information on how the duty should be discharged and how services might implement its requirements. They will provide examples and case scenarios as guidance where it may not be appropriate to provide regulatory rules but where there is significant interest in clearer guidance about how to grapple with complex or emerging issues. Detail of the proposed content of these guidelines is included in Appendix D.

It is hoped that such guidelines might mitigate against the concern amongst clinicians and health service executives that the statutory duty of candour may become a legislative compliance activity, rather than a mechanism that tackles the failure to systematically implement open disclosure in a consistent way.

The existing Australian Open Disclosure Framework will continue to provide useful contextual information.

**Recommendation 9**

It is recommended that amendments proposed to the Health Services Act, the Ambulance Services Act and Mental Health Act (Recommendations 2 and 3) link to new Victorian candour and open disclosure guidelines to be developed as a subordinate legislative instrument.

# Elements of the proposed statutory duty

Respondents proposed a number of requirements that could be mandated as part of the statutory duty of candour. Generally these aligned with the elements of the recommended open disclosure conversation outlined in the Australian Open Disclosure Framework, and include:

1. a factual explanation of what happened, in language understandable to the patient
2. an apology or expression of regret, which should include the words ‘I am sorry’ or ‘we are sorry’
3. an opportunity for the patient, their family and carers to relate their experience
4. discussions of the potential consequences of the adverse event
5. the proposed remedial steps to be taken, if applicable
6. an explanation of the steps being taken to investigate and manage the event and prevent recurrence.[[21]](#footnote-21)

It is important to note that open disclosure is not a one-way provision of information; but rather a discussion between two parties and an exchange of information that may take place in several meetings over a period of time. Information should avoid jargon and be in language understandable to the patient, including translation to the patient’s preferred language if required.

The Statutory requirements should be outlined by guidelines/policies endorsed by the Minister and contain a certification that:

* Disclosure was made in person and when not possible for a written letter to the affected individuals inviting them to a follow up conversation.
* Disclosure to involve the affected clinician to give them the opportunity to participate and either the most senior clinician responsible or the most senior person who is trained in open disclosure processes to lead the disclosure.
* The Organisation ensures staff meet minimum levels of competency for open disclosure, ensuring frequency of training and support.
* Written communication to include matters covered in the conversation, details of enquiries to be undertaken, results of further enquiries and an apology (based on the Open Disclosure Framework).
* Disclosure to occur as soon as reasonably practicable after the responsible person becomes aware of the incident (timeliness of disclosure and action).

*Community health centre*

It was also repeatedly suggested that there should be some documentation requirements to support the implementation of the duty. For example, a written record of the disclosure contained in the consumer’s medical record or in applicable incident reports. It was also proposed that there should be a requirement for consideration of quality and safety improvement learnings that may be gained through investigation of the incident.

It was also proposed that it may be beneficial that providers are required to provide information about consumers’ rights, for example, that a complaint could be made to the Health Complaints Commissioner, or a notification to AHPRA and/or any legal redress.

Ideally, the duty of candour should be discharged in the course of a face to face conversation.…

We certainly agree that those conducting the necessary candour conversation be appropriately skilled and supported.…

… Often it will be vital for the practitioner involved and responsible for the patient’s care to be part of the conversation but in some cases it would not be appropriate.

… for some patients having the practitioner present and prepared to confront the issues and explain what went wrong can be important.…

It should be open to patients to bring with them a family member or other support person to be present in the conversations.

Requirements for documentation should include an entry being made in the patient record and records of any review or enquiry undertaken.

In addition, written communication should be provided to the patient setting out the matters covered in the conversation together with the apology.

… depending on the circumstances, an appropriately conducted duty of candour conversation may take some time. Therefore, it may not be reasonable to impose a timeframe. However, it would be desirable to have an outer timeframe by which the duty is discharged of four months.

*Maurice Blackburn lawyers*

The Expert Working Group also considers that matters such as timeliness of disclosure and how the disclosure should be delivered, might be usefully described in the suggested candour and open disclosure guidelines.

However, it is acknowledged that the timing of the consultation period for this report was short and that there may be value in additional consultation to seek stakeholder views about specific aspects of the policy. The proposed framework of a high level legislative provision that would trigger the statutory obligation, supported by a policy offering significant detail about what is involved in the candour obligation (as well as by general open disclosure more broadly) offers the opportunity to undertake this further consultation and potentially to release an ‘exposure draft’ of the proposed Victorian candour and open disclosure guidelinesat the time of introducing legislation.

**Recommendation 10**

It is recommended that the department work with stakeholders (including health services, consumers and major insurers in the public and private sectors) in developing the proposed Victorian candour and open disclosure guidelines and materials to support implementation.

**Recommendation 11**

It is recommended that the Minister considers releasing draft Victorian candour and open disclosure guidelines (as proposed at Recommendation 9) at the time of introducing relevant legislation to the Parliament.

# Support and protection for individuals working in the healthcare system

As was acknowledged in the consultation paper, being involved in an incident of patient harm can have profound impacts on practitioners. Not only can they be personally traumatised, as secondary victims in the event, some practitioners may be dissuaded from disclosing such events for fear of personal and/or professional consequences.

The Expert Working Group was reminded during the consultation that there may also be consequences for a person involved in reporting an incident to a patient or family member, even when they were not involved in the incident itself.

A clear theme of the submissions received was the need to ensure that there is adequate support and protections available to those working in the healthcare system.

The statutory duty of candour proposed above will require that information be provided to the consumer during a face-to-face discussion and in a written summary statement, including:

* a factual description of what occurred, in language understandable to the consumer
* an apology
  + an explanation of the steps being taken to manage the event and prevent recurrence.

These proposed components, considered necessary for meaningful engagement between clinicians and consumers, are based on:

* the views expressed in submissions
* the need for the candour conversation to be as effective as possible and thereby include an apology or expression of regret, including a thorough explanation of what went wrong and if relevant, an admission of liability
  + the right of consumers to the facts of the incident should they wish to pursue an avenue such as the complaints commissioners or the courts.

However, there is concern that the possibility of this information being used in medico-legal or other proceedings against a clinician or service may compromise the transparency of that discussion and thereby undermine the benefits of the candour process.

Uncertainty surrounding the medico-legal aspects of [open disclosure] and the Statutory Duty of Candour is recognised both within the [Australian Open Disclosure Framework] and the Consultation Paper as a key barrier.

Sufficient and clear legal protections around investigations into adverse events and [open disclosure] may be a significant enabler to ensure full and frank candour in both the investigation and disclosure process.

*Victorian Managed Insurance Authority*

As no other jurisdiction has introduced a statutory duty of candour as is proposed for Victoria, there is no retrospective data to assess how likely it is that it will increase the likelihood or incidence of medico-legal litigation.

There is evidence that effective apologies can assist to resolve disputes or complaints earlier and more effectively.[[22]](#footnote-22) This suggests that introduction of the statutory duty of candour may reduce litigation, to the extent that litigation is a result of ongoing dissatisfaction on the part of the consumer, as the duty will be designed to encourage and improve open disclosure processes, including the provision of effective apologies.

These findings are consistent with the experience of the Health Complaints Commissioner, and others involved in the Expert Working Group and consulted by the Expert Working Group, who noted anecdotally that an early and well managed open disclosure process is often effective at resolving a complaint or dispute.

Conversely, there is some evidence to suggest that candour processes may lead to consumers being more informed about possible deficiencies in the care that was provided to them, and therefore more able to pursue legal action when they would not have done so had they remained ignorant of their basis for doing so.[[23]](#footnote-23)

Irrespective of any new statutory requirements, information about what occurred during the course of treatment is currently available to the consumer in a number of ways.[[24]](#footnote-24) This suggests that limited access to evidence may not be a major barrier to litigation currently, which would indicate that any increase in access to that information will not necessarily lead to a substantial increase in litigation.

Regardless of whether the expectation that a statutory duty of candour will increase medico-legal risk is justified or not, the Expert Working Group acknowledges that the perception is real and that the perception, unless addressed, could seriously undermine the desired benefits of the statutory duty. As outlined in the consultation paper, a 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, and can contribute to organisational cultures that do not support or promote candour.[[25]](#footnote-25)

Unless there are changes to the available protections, it is likely that these effects will continue under a statutory duty of candour, resulting in poor quality conversations which are unsatisfactory to, or perceived as insincere by, patients; or a lack of compliance with the duty.

The Expert Working Group is also well aware that additional protections for those working in the health sector may be perceived as potentially in some way eroding the rights of patients. In coming to the findings and recommendations presented in this section, we have been mindful of these perceptions and have sought to understand and articulate the likely impacts of each proposed course of action. (The specific anticipated impacts on patient rights of the protections recommended below are discussed towards the end of this section.)

## Apology laws

Currently under the *Wrongs Act 1958*, an apology does not constitute an admission of fault but the term ‘apology’ does not include a statement that is a clear admission of fault. Further, the legislation specifies that its protection of the apology does not impact the admissibility into evidence of a statement about a fact that is in issue or that might tend to establish a fact at issue. As outlined in the consultation paper, this differs from the approach taken in a number of other Australian jurisdictions. New South Wales, the Australian Capital Territory and Queensland all 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.

Feedback obtained through submissions and consultation sessions indicate that there is significant confusion about Victoria’s existing apology laws and that many practitioners hold serious concerns that incorrectly worded apologies will leave them open to medico-legal consequences. Some respondents argued that it would be unfair to impose a statutory obligation that would potentially result in increased litigation without providing enhanced protections. Some suggested that this could result in an unintended increase in the practice of defensive medicine.

Alfred Health notes, and respectfully agrees with, the Consultation Paper’s analysis of Victoria’s apology laws. Given the limited definition of an apology, these laws provide little practical protection for organisations or individuals engaging in open disclosure. This is because it is impossible in a frank conversation to express regret, without explaining precisely what one is regretting. Our view is that the broader features of apology laws that apply in some States … would be desirable in Victoria.

*Alfred Health*

We support the working group reviewing legislation in other states with regard to the apology laws so that these can be strengthened and again clearly articulated so that individuals and health services do not feel impediments in undertaken open disclosure.

*Public hospital D*

Others argued that compliance with the statutory duty would be compromised, or the quality of the disclosure conversation negatively impacted, if practitioners were concerned about avoiding liability rather than engaging openly with the patient.

Doctors are deeply concerned, that if not worded correctly, an apology or expression of regret could be interpreted as an admission of fault, either systemic (at the organisational level) or individual. Some of the challenges associated with adherence to the proposed statutory obligation are in part a reflection of the tension between informing patients and the perceived risk that disclosure could give rise to a potential (implied) liability.

*Professional association B*

The *Apologies* report identified two consequences [of the limitations in the Wrongs Act]. Firstly, research shows that people may not accept an apology as genuine unless it includes an admission of fault or responsibility. Where a full apology is made it can reduce the likelihood of litigation.

Secondly, it means authorities need to refer to common law principles to work out whether an apology might cause legal problems. Several authorities said that they would like guidance about when an apology might give rise to liability. The report observed that it is not surprising that staff can be reluctant to apologise in the face of such legal uncertainty.

*Victorian Ombudsman*

There was strong support from stakeholders for strengthening Victoria’s apology laws (in line with those in place, for example, in New South Wales) with 37 submissions received specifically identifying this as a necessary change to accompany the introduction of the statutory duty of candour.

Conversely, a few stakeholders argued that any strengthening of the apology laws would have a detrimental impact on consumers seeking recourse through legal action in response to a medical error.

I am not supportive of further amending the Wrongs Act 1958 to address the barriers issue. It could risk removing a person’s right to sue in the case where there has been negligence. Removal of barriers to apologising could be addressed by other means, such as education and culture change.

*Commission for Children and Young People*

The apology law as set out in Section 14J of the Wrongs Act ensures that an apology is not taken to constitute an admission of liability for death or injury or an admission of unprofessional conduct or incompetence or carelessness etc. This protection should continue. There should not be an extension of this protection to statements around fault or liability. Should there be an acknowledgement of fault or an admission of liability in the course of an open disclosure conversation or as part of a candour conversation, it should be possible for this to be relied upon in subsequent legal proceedings.

*Maurice Blackburn Lawyers*

We have grave concerns, however, regarding the possibility of changes to the Wrongs Act (1958) to indemnify admissions of liability. Initial legal advice obtained suggests that this could compromise the right to legal redress and would therefore effectively diminish consumer rights by exempting evidence needed for successful litigation.

*Health Issues Centre*

The tension between these two positions is well illustrated by the statements below, both from the submission made by the Law Institute of Victoria.

One view is that there is an unfair inconsistency between apologising for, and disclosing to a consumer, an error that was made that has caused harm while at the same time considering it to be appropriate to statutorily prevent a consumer from relying on such disclosure in litigation.…

The opposing view is that, if a consumer were not statutorily prevented from relying on the disclosure in litigation, the principle of open disclosure will be undermined. This is likely to occur because practitioners will not candidly discuss individual cases for fear of litigation and/or professional censure.

*Law Institute of Victoria*

In coming to a position on this matter the Expert Working Group weighed up the concerns raised in these submissions.

Strengthening the Victorian apology laws in line with other jurisdictions such as New South Wales will mean that patients cannot rely on an admission of fault in subsequent legal proceedings. Factual explanations of what has occurred, which will be required to be provided under the duty, will not be protected and can be used as evidence in any legal proceedings. It should also be noted that consumers also have access to information about what occurred during the course of their treatment in a number of other ways. Changes to the apology laws will not restrict the use of this information in any medico-legal claim. It is, however, true that establishing an argument for liability may be more difficult or costly than if an admission of fault could be relied on in legal proceedings.

In coming to a recommendation regarding apology laws, it is necessary to strike a balance between the value to consumers of being able to rely on an admission of fault made during a disclosure conversation against the value of more candid conversations (and therefore more information being made available to consumers) and more full apologies that would be expected to arise from strengthened apology laws.

Given the potential advantages of strengthened apology laws described above and the weight of feedback received in submissions, the Expert Working Group considers that Victoria’s apology laws should be contemporised and broadened and that (to improve clarity and aid understanding) the protections should be included in the same legislation that sets out the duty of candour.

The proposed model (as set out in the recommendations below) would:

* *not* restrict the use in legal proceedings of factual statements about what has occurred
* mean that saying sorry would not constitute an admission of fault and would not be relevant to court determinations; even if the apology was worded in a manner that implied fault. This would allow practitioners to be more frank and empathetic in the delivery of an apology
* mean that information provided about any changes or improvements made subsequent to an incident could not be taken as an admission of fault or liability. This information would, however, still be admissible in court proceedings.

**Recommendation 12**

It is recommended that the proposed model for the duty of candour includes a statutory obligation on services to disclose information to consumers. This obligation will include a requirement that a written factual explanation of what occurred be made available to the consumer and that this will not be protected from admissibility as evidence in legal proceedings.

**Recommendation 13**

It is recommended that the relevant legislation (Health Services Act, Ambulance Services Act and Mental Health Act) be amended so that, for the purposes of any civil proceeding against the health service or any individual who was involved in providing care to the consumer:

* an apology – being an expression of sympathy, regret or compassion – will not constitute an admission of fault and will not be relevant to any determination of fault or liability in the proceeding, even if the statement of sympathy, regret or compassion may admit or imply an admission of fault
* a description of improvements that has been, or will be, made to prevent similar harm in the future does not constitute an admission of fault.

It should be noted that reforms to Victoria’s apology laws have also been the subject of two reports over recent years. Reforms were recommended by the Victorian Ombudsman in April 2017[[26]](#footnote-26) and the Victorian Government’s Access to Justice Review in 2016.[[27]](#footnote-27) In its response to the Access to Justice Review, the government committed to considering an amendment to the provisions in the Wrongs Act. To date, no amendments have been progressed.

We are of the view that the Minister should consider liaising with the Attorney General in relation to any new protections for apologies and ensure that the proposed changes are consistent with any planned whole-of-government response to address these issues. Nonetheless, the Expert Working Group considers that there is value in including apology protection provisions alongside legislative provisions for the duty of candour, to address concerns about confusion of the protections and their relationship to the duty of candour.[[28]](#footnote-28)

## Incident reporting to inform quality improvement

Incident management and response by public hospitals are guided by the *Victorian health incident management policy* issued by the department. This requires an incident investigation (the type and level of investigation is determined by the ISR rating allocated to the incident).

An RCA process is conducted in relation to each ISR 1 incident. An in-depth case review (IDCR) (a detailed and thorough investigation that is similar to the RCA but less resource intensive) is to be conducted in relation to ISR 2 events.

Submissions received by the Expert Working Group have indicated that protections for incident review processes conducted in relation to serious incidents could significantly impact the implementation of a statutory duty of candour and related training and cultural development initiatives in a positive way.

There may be merit in including statutory protections for e.g. Root Cause Analysis findings/documents and case investigation documents as their purpose is to find contributory factors for the purpose of learning and improving. If there is a fear that these documents will be used against practitioners in legal proceedings it may result in the processes not being fully open and robust in its deliberations. This would however need to be balanced with the rights of consumers to have a full understanding of what occurred.

*Ambulance Victoria*

In our view, the relationship between open disclosure and incident investigation, including root cause analysis, needs to be considered holistically. The entire process, including open disclosure, incident investigation and root cause analysis, should attract qualified privilege. This will reassure practitioners that they are not exposing themselves to liability and will encourage a just culture where lessons are learned from adverse events.

*Avant Mutual Group*

Such protections would be consistent with the approaches taken in New South Wales and Queensland with each of these states having statutory protections for the clinical investigations of serious incidents, when conducted in accordance with the relevant legislation.

In the consultation sessions, there was strong anecdotal feedback that such protections are likely to reduce concern about medico-legal risk, and thereby facilitate more robust discussion and analysis during incident reviews, which in turn will lead to more effective quality and safety improvements. That argument was reflected in the written submission by the Victorian Managed Insurance Authority and in discussions with the Victorian Managed Insurance Authority and Safer Care Victoria.

These investigations are a core component of clinical incident management designed to identify and eliminate or mitigate problems with the health services systems or processes and improve quality and safety and patient outcomes. The effectiveness of RCAs, IDCRs and ultimately the veracity of [open disclosure] depends on the willingness of participants to freely supply information and opinions.

Victoria unlike other Australian States, does not have statutory protections around the provision or admissibility of RCAs and IDCRs in legal proceedings. Further the involvement of external experts as recommended by Safer Care Victoria lessens any ability to rely on Public Interest Immunity exemptions.

Statutory protection over RCAs and IDCRs removes the fear of adverse legal ramifications, discourages ‘defensive medicine’ and is therefore likely to support full and frank disclosure and improve the [open disclosure] process.

*Victorian Managed Insurance Authority*

In contrast others argued that such protections are inconsistent with the transparency and culture change that are objectives of the duty of candour.

There is an inconsistency between withholding information based on qualified privilege and the public interest and a requirement for open disclosure and a duty of candour. We are familiar with the concerns that if the findings of quality assurance committees were made public, even if just to the patient involved, future inquiries and reviews will be in jeopardy as practitioners involved in the care will be reluctant to provide free and frank accounts and cooperate with the inquiry. However, this raises the issue of cultural change which is necessary for a properly administered open disclosure framework and statutory duty of candour.

*Maurice Blackburn Lawyers*

By their nature, incident review processes such as RCA and IDCR are valuable quality and safety improvement processes, conducted in relation to serious incidents. They involve sometimes speculative discussion about factors that may have contributed to the incident and/or related harm. It has been argued, convincingly, that the nature of that discussion is such that if details of the discussion were relied upon as evidence in civil legal proceedings, inappropriate or perverse outcomes may result.

It is proposed to establish protections in relation to incident review processes (such as RCA), when they are conducted in respect of specified – serious – incidents,[[29]](#footnote-29) with protections to provide:

* confidentiality obligations on the individuals involved in the incident review
* that information obtained and judgements made and opinions expressed during the formal process and documents created during the formal process are not admissible as evidence in medico-legal proceedings
  + exemptions from disclosure requirements under freedom of information and privacy legislation.

It is noted that these protections would apply to a smaller range of incidents that the proposed duty of candour. That is, the protections will apply in relation to incident reviews that are conducted in relation to specified serious incidents and the incidents specified are unlikely to cover all incidents classified as an ISR 1 or 2.

**Recommendation 14**

It is recommended that concurrent with the introduction of the statutory duty of candour, the Minister introduces statutory protections for incident review processes conducted in relation to specified serious incidents, along the lines of those in place in New South Wales and Queensland.

Careful consideration will need to be given to the ways in which the content and outcomes from the protected incident review process can be disclosed, communicated or otherwise used (notwithstanding the protections). In particular we stress the importance of ensuring that the proposed protections are not implemented in a way that compromises the oversight and regulation of quality and safety by the department or other entities. Details of some of the issues that should be considered in drafting the relevant provisions are outlined in Appendix E.

**Recommendation 15**

It is recommended that the Minister instructs the department to:

* carefully consider the issues raised above (and in Appendix E); and the interaction between the proposed protections and any other planned reforms, arising from *Targeting Zero*, that relate to the ways in which information is shared between entities and oversight bodies
* in legislating this protection, give careful consideration to ensure the protections do not compromise the oversight and regulation of quality and safety by the department, Safer Care Victoria or the Victorian Agency for Health Information.

## Qualified privilege (quality assurance committees)

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 considering the legal protections for individuals and entities that should accompany the statutory duty of candour, the Expert Working Group has also become aware that there is significant confusion amongst both individual health practitioners and healthcare organisations as to when the qualified privilege afforded to ‘quality assurance committees’ declared under section 139 of the Health Services Act does and does not apply.

From feedback received during consultation sessions and comments in written submissions, it appears there may be benefit in clarifying – for the sector – the application of Victoria’s current regime of qualified privilege and how it impacts on open disclosure obligations.

We would urge a review of the qualified privilege bestowed by operation of Section 139 of the *Health Services Act 1988* (Vic) and the reliance on section 30(1) of the *Freedom of Information Act 1982* by health services not to disclose Victorian Health Incident Management System reports and root cause analysis reports on the basis that to do so would be against the public interest.

In our experience, there is no consistency as to when such reports will be provided to patients and when not. They are sometimes disclosed on request or only later in the course of a Coronial Inquiry or when proceedings are pursued under discovery. In many instances they are not disclosed at all.

*Maurice Blackburn Lawyers*

[This organisation] agrees with the analysis in the paper that there is a lack of clarity regarding qualified privilege and its interaction with open disclosure processes.

Health services require clarity regarding the extent to which information and documentation requested during an open disclosure process must be shared, and the extent to which it can be protected.

*Specialist representative organisation*

This [relationship between qualified privilege and open disclosure] should be clarified in the legislation and Qualified Privilege under section 139 should be reviewed for its relevance.

*The Royal Children's Hospital Melbourne*

Many services operate without these protections and, even amongst those with designated approved quality assurance bodies, the approach taken to the release of information varies significantly. It also appears that the protections offered by section 139 are sometimes used (mistakenly or unjustifiably) as a rationale to withhold information from processes instigated by the Health Complaints or Mental Health Complaints Commissioners.

The MHCC supports the underlying policy for the qualified privilege in s 139 of the HSA but we believe it is being relied on by services in some cases where it does not apply and that there is a need to review the provision.

The experience of the MHCC is that services regularly claim s 139 privilege applies to documents so as to prevent disclosure of information contained in those documents to the MHCC.[[30]](#footnote-30)

*Mental Health Complaints Commissioner*

The Expert Working Group notes that all Australian jurisdictions have some model of qualified privilege attaching to a declared quality assurance committee. This includes those jurisdictions, such as New South Wales and Queensland, which have introduced protections for serious incident investigation processes.

Given the complexity of this issue, the inconsistencies reported by respondents to this consultation and the extent of confusion, it would seem appropriate that the existing Victorian approach be reviewed – taking into account recent developments and any protections that are ultimately put in place alongside the statutory duty of candour.

(Note we do not consider that the protections recommended above in relation to incident reviews need be deferred until after the section 139 provisions are reviewed. The strength of feedback received about the need for protections in relation to these serious incident review processes to accompany the introduction of the statutory duty of candour, and the existence in other jurisdictions of quality assurance committees alongside protected processes for incident reviews, suggests that the proposals for protections for incident review processes should proceed at the same time as the legislative provisions for the statutory duty of candour are introduced.)

**Recommendation 16**

It is recommended that the Minister tasks the Expert Working Group to work with Safer Care Victoria to review qualified privilege protections. The outcomes of this review could inform the planned review of the Health Services Act.

## The *Targeting Zero* link to a no fault insurance scheme

This issue of a ‘No Fault Liability Scheme’ for hospital injuries, as exists in New Zealand, is outside the terms of consideration for the Expert Working Group. This issue arose, however, in a number of submissions and is worthy of comment.[[31]](#footnote-31)

Indeed, the discussion about medico-legal litigation in *Targeting Zero* is in relation to the recommendation for a no fault insurance scheme (not the recommendation for a statutory duty of candour – although the two recommendations sit side by side). In support of the recommendation for a no fault scheme, *Targeting Zero* argued that a reduction in litigation and litigation risk that would allow an increased focus on prevention and improvement.

Recommendation 5.6 of *Targeting Zero* is that ‘government refer the issue of the feasibility of extending no-fault medical insurance to all healthcare injuries not covered by the National Injury Insurance Scheme (NIIS) to the Legal and Social Issues Committee of the Legislative Council for investigation’. *Better Safer Care* (the government’s response to *Targeting Zero)* included a commitment to ‘examine the option of extending no-fault medical insurance for healthcare injuries – similar to compensation schemes for injuries in the workplace and from motor vehicles’.

Bendigo Health believes that it may be time to consider Tort law reform generally with the introduction of the Duty of Candour. The New Zealand system applicable to health care harm would in our view be an excellent model to consider as New Zealand’s ‘no fault’ system truly encourages health care providers to be open and honest with their patients.

*Bendigo Health*

It is suggested that at the heart of this lies blame. If clinicians are going to be legally obliged to accept blame it needs to be able to be done without the fear of retribution. For example, in New Zealand the duty of candour also exempts clinicians from liability. Those supporting the statutory duty of candour proposal should, using their same principles, support clinician indemnity in order to permit full and open disclosure.

*Australian Orthopaedic Association Victorian Branch*

There is a range of complexities and uncertainties in relation to the recommendation regarding no-fault medical insurance. The recommendation is predicated on a number of assumptions about the impact of the National Disability Insurance Scheme (NDIS) and the coverage of a National Injury Insurance Scheme which are as yet untested given the very recent roll out of this huge and ambitious scheme. It is not yet known the extent to which people who sustain a medical treatment injury will receive support through the NDIS.

However, since the release of *Targeting Zero*, the Council of Australian Governments (COAG) has met to discuss the issue of a National Injury Insurance Scheme. At the June 2017 COAG meeting, leaders agreed with treasurers’ advice not to proceed with a medical treatment stream of National Injury Insurance Scheme at this time. Leaders asked treasurers to review the cost implications of this decision in the context of the Productivity Commission Review of NDIS Costs. Treasurers were also tasked, in consultation with the Disability Reform Council, to provide advice on a general accident stream of the National Injury Insurance Scheme for the first COAG meeting of 2018.[[32]](#footnote-32)

## Impact of the protections proposed in this section on the rights of consumers

As noted above, the Expert Working Group is conscious that the introduction of the protections discussed in this section may be perceived as contrary to the consumer-focused transparency that is an objective of open disclosure. There may be concerns that the protections could restrict consumer rights to pursue litigation or other avenues of redress in relation to the adverse outcomes they have experienced.

The protections are aimed at improving the quality of the information and apology provided to consumers and making more ‘just’ the cultures of organisations that are providing health services. They are therefore aimed at protecting and supporting the rights of consumers to request and access information about what occurred in the course of their care.

There is evidence that the protections for incident review processes will lead to more robust discussion, a better understanding of what occurred in a particular case, and more comprehensive and effective recommendations for improvements.

When I compare to jurisdictions that do not have statutory protection for an RCA, those jurisdictions can be more reluctant to gather staff statements on the basis that they could be accessed in a civil claim, staff may be more reluctant to participate or if they participate will limit strictly to a factual explanation and not address criticisms or areas of improvement, and as the report is not protected there is often more consideration to the implications of certain causation statements and recommendations that may result in a weaker document. Therefore, when balancing the benefits to safety as against the restrictions that arise from implementing the privileges and protections, I consider that safety has been significantly enhanced by introduction of the statutory RCA scheme.

*Shane Evans, Partner, Minter Ellison Lawyers*[[33]](#footnote-33)

The protections for apologies are designed to allow a fulsome expression of regret, compassion and sympathy for the harm a consumer has experienced. There is evidence that this can lead to earlier and more effective resolution of their concerns. This was discussed in the 2017 report on Apologies by the Victorian Ombudsman and the 2016 Access to Justice Review. On this basis both those reports recommended amendments to the Victorian apology laws to increase the protections in order to facilitate more full apologies.

There is evidence that consumers who take action in relation to their healthcare experience are often motivated by a desire to obtain information; an acknowledgement of their negative experience; and an explanation of what steps will be taken to prevent a recurrence.[[34]](#footnote-34)

In facilitating these things, it is intended that the protections in this section will benefit consumers and support their right to transparent and just engagement with the organisation that provided their care.

There may be concern that consumers will be restricted in seeking legal redress for harm they have experienced because information from the candour process and the incident review process will not be admissible as evidence in a civil claim. It is not intended that the protections will restrict consumer rights to access factual information about the care that was provided to them. It is proposed that the *factual information* provided during a candour process – provided in writing under the requirements of the proposed duty – will be available for use in a civil claim. Indeed, the requirement to provide that factual statement in writing, along with the improved incident review process, may mean the consumer is more informed about what occurred and therefore more able to identify and pursue possible avenues of redress in relation to the care they received.

The details of the protections will need to be carefully designed to ensure that the intended balance is struck. Education, training and communications resources for both clinical personnel and consumers, about the impact of the protections, will be an important aspect of introducing the proposed duty.

# Monitoring, remedies and sanctions

## Monitoring compliance

The Expert Working Group considered a range of potential options for monitoring compliance with the statutory duty of candour and identifying breaches.

Consequences would be limited to a requirement to demonstrate clear action to improve performance undertaken. An approach that focusses on nurturing problem solving and corrective action, would promote a climate that encourages good practice.

*Public hospital C*

Many submissions expressed concern about monitoring and compliance mechanisms and saw these as contrary to the desire to enhance open and honest communication. We have, however, formed the view that there is value in monitoring, reporting and providing for sanctions for serious breaches to drive culture change and enhance accountability.

The introduction of active monitoring by a separate entity could introduce additional reporting requirements, and require a framework for data collection and analysis, as well as funding to support and sustain the process.

*Australian Dental Association Victorian Branch*

Nonetheless, the benefits of active monitoring must be weighed against costs and administrative burden and it may be more appropriate to have in place mechanisms to require routine reporting (for example, in annual reports) of the number of duty of candour disclosures made, and to identify breaches and respond when they are found.

Currently, public sector hospitals report clinical incident data to the department monthly. This includes information about the ISR rating allocated to an incident. Legislative amendments were passed in 2017 to introduce stronger reporting requirements for private sector services (registered private hospitals and day procedure centres). This includes an obligation to report to the Secretary as set out in regulations. The regulations are being developed currently in consultation with stakeholders. It is proposed that these established mechanisms for reporting data on incidents should be used to collect information on whether a duty of candour process has been commenced and/or completed. Existing auditing processes could then be applied to those datasets, to monitor compliance with the duty of candour. For example, there could be a check that all adverse and sentinel events have been reviewed and open disclosure and/or a candour conversation (if the elements are present) have taken place.

Identification of non-compliance should be made by requiring details about an open disclosure following a threshold adverse event to be included in the relevant incident review or root cause analysis.

*Specialist representative organisation*

The Expert Working Group also considered options for which agency or agencies might take a role in identifying breaches of the duty. Based on submissions, a number of options were considered: Safer Care Victoria, the complaints commissioners (Health Complaints Commissioner and Mental Health Complaints Commissioner), or the department.

There are a number of ways in which a breach of the duty of candour might come to light through these agencies:

* the matter is raised with the department, Safer Care Victoria or AHPRA
* a consumer may be aware of a breach and complain directly to the department, the Minister or a complaints commissioner about the failure of a provider to comply with the duty
  + a complaint to one of the complaints commissioners may reveal, during resolution or investigation, that a mandated disclosure was not made.

If there is a clear relationship between open disclosure and subsequent medicolegal litigation then education would be enough to promote this principle.

Having consequences or sanctions legislated is too rigid, and the definitions as to who needs to apologise and for what are too broad to be practically outlined in legislation. If people breach these requirements they would be reportable to the AHPRA or leave themselves open to litigation, both of which are sufficient to promote compliance with the legislation.

*Royal Australasian College of Surgeons*

It seems that there are many authorities to which health services are currently accountable; another authority would potentially add to the confusing suite of accountabilities.

*Colac Area Health*

While Safer Care Victoria will clearly have an important role to play in supporting the introduction of the statutory duty of candour, the entity does not currently have a regulatory compliance role, and introducing such a role in relation to the duty of candour may impact on clinician and consumer perceptions about the entity and its primary purpose.

Whether the names of the organisations are publically identified (outside of the concerned individuals/consumers) must be carefully weighed up as it is imperative that public trust in health services must not be undermined – and this would be particularly the case in regional and rural areas where choice is limited. Whatever is determined, the ANMF’s position is that individual practitioners must not be identified as they are subject to a different process.

*Australian Nursing and Midwifery Federation Victorian Branch*

While there was general agreement that complaints to the complaints commissioner or AHPRA may be the way that breaches of the duty are most readily identified, there was a view put that it would not be sufficient to rely on complaints or notifications and that there should be an active auditing for a special body or the complaints commissioners.

The identification process can include:

1. Where there has been a finding of unprofessional conduct or misconduct as a result of a notification to AHPRA;
2. A Court verdict that injury has occurred as a result of a breach of the duty of care owed;
3. The conduct has come to light through another avenue; for example, public awareness through a media report as unsatisfactory;
4. Findings of a coronial inquiry that the death was caused or contributed to by healthcare going wrong.

Non-compliance should be brought to the attention of the Department of Health and Human Services.

*Maurice Blackburn Lawyers*

Although the complaints commissioners may be the first to become aware of breaches of the duty, *Targeting* Zero was clear that the department should take a more active role in oversight and stewardship of the health system and the Expert Working Group believes that it should be the department that takes any necessary action in response to breaches of the duty. There should, therefore, be identified within the department an area to which the complaints commissioners can report failures to comply and to which others (for example, clinicians and other staff) can directly advise of compliance issues.

**Recommendation 17**

It is recommended that the department require that health services routinely report on the statutory duty of candour.

**Recommendation 18**

It is recommended that the department work with the Health Complaints Commissioner and the Mental Health Complaints Commissioner to:

* identify any necessary amendments to the Health Complaints Act and the Mental Health Act to enable the commissioners to receive complaints about failures of services to comply with the statutory duty of candour
* ensure the Health Complaints Commissioner and Mental Health Complaints Commissioner are resourced to enable them to respond to complaints related to a failure to comply with the statutory duty
* identify any necessary amendments to the Health Complaints Act and the Mental Health Act to allow the commissioners to advise the Minister or the department of breaches of the duty.

## Responding to breaches

In general, the Expert Working Group is of the view that a punitive approach to failures to make disclosures required under the statutory duty may be counter-productive and result in increased secrecy and defensiveness rather than encouraging good practice and culture change. Rather, where one off or less significant failures are identified, the department should work with organisations to assist them to improve practice.

The imposition of financial penalties would take away funds that could otherwise be used on patient care, and this may be particularly harmful in the case of small (e.g. rural) health care providers. The costs are not only those associated with the penalty itself (and we note that the penalty might be capped by legislation); they are also associated with conducting litigation, including litigation which appeals a primary finding against or in favour of the hospital.

*Monash Health*

Where breaches do occur, the most important remedy will be to ensure that patients receive the information they are entitled to. We are of the view that the Health Complaints Commissioner and the Mental Health Complaints Commissioner are best placed to ensure this occurs. The commissioners have at their disposal a suite of powers to obtain information and support both parties in a dispute to participate in processes designed to facilitate resolution. We have therefore formed the view that the role of the commissioners will be critical in obtaining the information that consumers need and have a right to.

Nonetheless, where persistent serious breaches of the duty are found to be occurring, it will be important that the department is able to take appropriate action.

Critical for consumer credibility is that there are consequences for breaches of statutory duty of candour.

*Safer Care Victoria*

The Expert Working Group does not support the introduction of financial penalties. Rather, it proposes that the strong powers already contained in the Health Services Act be used to require improvements and, where required, sanction services.

These powers include:

* the capacity for both the Minister and the Secretary to issue directions to services. These provisions (or amended provisions) could be used to address failings in relation to the statutory duty of candour (for example, as suggested in the consultation paper, to ensure that a service implements compulsory education or undertakes a case review to identify and remedy any failings)
* for more significant or repeated breaches in public sector services 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
  + for significant or repeated breaches in the case of private sector hospitals and day procedure centres non-compliance with a statutory duty of candour may be a matter to be considered at the time decisions are being made about registration, and might, in serious circumstances, lead to a decision to place conditions on, or deny registration or renewal of registration, of a service.

The Expert Working Group also proposes that for persistent and/or serious breaches of the duty within services that have not responded to other actions it may be appropriate for the Minister to have a capacity to publicly name the service.

The legislative reforms we recommend will enable the proposed action to be taken.

In cases where important information has been withheld without justification, intentionally obfuscated or hidden, there may be scope to consider specific sanctions for health services.

The [consultation] paper correctly notes that the Minister for Health and the Secretary of the Department of Health and Human Services are already vested with broad powers to issue directions, appoint delegates to the board and censure organisations. [This organisation] suggests that these powers are significant and offer a meaningful incentive for health services to ensure they are compliant with the statutory duty.

*Specialist representative organisation*

The MHCC could also have a key compliance role in relation to designated mental health services. We suggest that consideration be given to amending the legislative framework of the MHCC to empower the MHCC to:

* receive an undertaking from a service to take remedial action pursuant to s 243(4)(e) MHA in the event of a breach of the statutory duty of candour
* issue a compliance notice pursuant to s 260 for a breach of the statutory duty of candour.

*Mental Health Complaints Commissioner*

It may also be the case that a particular registered health practitioner does not comply with the requirements to be open and honest set out in their professional Code of Conduct. This is likely to be behaviour that is also inconsistent with the statutory duty or open disclosure. In such cases, there may well be grounds for a notification to AHPRA and action by the relevant National Board. In serious cases, the actions of the practitioner may amount to unprofessional conduct or in the very worst case scenario, professional misconduct.

**Recommendation 19**

It is recommended that consideration be given to amendments that may be required to the Health Services Act, the Ambulance Services Act or the Mental Health Act to provide that repeated and/or serious breaches of the statutory duty of candour be grounds for existing sanctions available under those Acts.

**Recommendation 20**

It is recommended that consideration be given to amendments that may be required to the Health Services Act to allow for providers to be named if there are repeated and/or serious breaches of the statutory duty of candour.

# Support for success

Throughout its deliberations, the Expert Working Group has been mindful that simply introducing a legislative provision for a statutory duty of candour without supporting change will inevitably fail.

What is being sought is a change of culture and it is not possible to legislate culture or mandate empathy or compassion. While a statutory duty can focus attention at the highest level and ensure that appropriate effort and commitment to change is made, success will also require a range of non-legislative actions.

Safer Care Victoria (SCV) often provides advice to health services regarding the appropriate classification of incidents and the preferred response. This role should continue, as it allows a greater degree of consistency to be applied across the health system.

*Specialist representative organisation*

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

*Building a culture of candour,[[35]](#footnote-35) p. 2*

Submissions were full of suggestions as to how to make the reform a success.

* Sound engagement with all across the system.
* Relating the statutory duty of candour introduction back to the essential intent of *Targeting Zero* – that “…transparency and candour in care must be system-wide.”
* Ensuring staff are supported and the intent is to promote an open supportive environment for all.
* Timely advice is offered to Boards and Chief Executives on events and trends state-wide and at service level to aid internal processes.
* Establish a more effective incident management system that encourages staff engagement and reporting. The current system is clumsy and far too time consuming for clinicians to engage with. The system is more designed for state-wide analysis rather than being a quality tool for health services.

*Colac Area Health*

The most important factors [to ensure success] are as follows:

* Addressing concerns around medicolegal implications
* Resourcing training and support
* Clarifying and embedding key language and phrases
* Developing consistent resources centrally to minimise variability and effort
* Avoiding inconsistency
* Identifying mechanisms to embed and maintain a culture of openness (i.e. the requirement to comply with a “duty of candour” is not the same as working in a “culture of candour”, which is really what is trying to be achieved)
* Linking the requirements of this with broader activity related to optimal clinical communication (e.g. informed consent and other clinical communication) – often new programs are implemented without linking to other related pieces of work creating a fragmented approach – it would be ideal if this could be avoided
* Clarifying the role of different disciplines.

*Public hospital E*

The most important factors to ensure the statute achieves its aims are a strong patient safety culture (including reporting culture) and clear lines of accountability and responsibility.

*The Royal Children's Hospital Melbourne*

ANZCA believes that key considerations to ensure a statutory duty of candour achieves its intended aims include:

* setting realistic and practical reporting thresholds (ANZCA does not support near-misses or no- harm events triggering a duty of candour obligation);
* ensuring that any additional administrative and documentary burden is minimised;
* providing adequate training materials and resources for training of staff;
* supporting organisations to implement and embed appropriate processes (particularly in smaller facilities); and
* ensuring that duty of candour responsibilities are not delegated to junior or untrained staff.

*Australian and New Zealand College of Anaesthetists*

[This organisation] considers that a subordinate instrument (guidelines) be developed to support the regulation and that the Department take the lead in its development. The current evidence around Open Disclosure points to inadequate training and knowledge, leading to level of confusion in the implementation of the standard. A document that provides both guidelines and examples will assist the individual health professionals and health service organisations meet the statutory requirements. Such a document, developed in consultation with key stakeholders, will provide clarity and assist in a successful implementation of the requirement.

*Professional association C*

## The importance of culture

As the Parliamentary Secretary for Health said in the Foreword to the consultation paper:

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.

*A statutory duty of candour: consultation paper, p. vi*

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 reporting culture is essential in an open disclosure framework. It is important that a legal framework does not inhibit the reporting culture.

*Dental Health Services Victoria*

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

Culture is particularly important in hospitals.… Cultures of blame lead staff to conceal poor outcomes and so allow system weaknesses to incubate and fester. Culture can be the difference between a staff member concealing error in fear of punitive consequences, ignoring it in the knowledge that reporting will achieve nothing, or bringing it to the attention of managers without hesitation.…

… Approaches to care go beyond mere compliance with protocols, with staff vigilant about emergent risks to safety and invested in continuous improvement of care.

*Targeting Zero, p. 203*

*Targeting Zero* alludes to the risk suggested that increased public reporting can lead to hospitals avoiding patients who are risky, difficult to manage or at high likelihood of readmission, while also reducing screening that can identify hospital-acquired diagnoses in patients before they are discharged, and shifting the focus of quality and safety improvement to documentation. However, the report recommends the department counter this ‘head on’.

The best way to do this is to support hospitals to develop just cultures. Hospitals with ‘just cultures’ (as opposed to cultures of blame) balance appropriate accountability for blameworthy events with an understanding that, in many cases, human errors are the consequence of system failures.

*Targeting Zero, pp. 201–202*

We agree that resistant culture in services and lack of skills and knowledge are key barriers to open disclosure. Our experience of dealing with complaints about adverse events is that open disclosure is commonly not undertaken or that it takes place only after the person has made a complaint to the MHCC.

*Mental Health Complaints Commissioner*

Hospital cultures also make a difference to how members of staff approach their jobs. In hospitals with a positive ‘safety culture’, there is a powerful organisational commitment to and investment in safety. Many submissions referred to the importance of culture change to the success of a statutory duty of candour and open disclosure.

There is also the question of what is valued in health care or, more accurately, on whose values resource allocation decisions are based. Patients expect clinical care with humanity, especially when things go wrong. If it is accepted that the purpose of a healthcare service is to serve its patients, then resources should be allocated to improve the necessary skills and to manage post-harm care consistent with patient preferences.

*Open Disclosure Standard: review report,[[36]](#footnote-36) p. 102*

It is envisaged that the proposed candour and open disclosure guidelines will provide a clear and user-friendly basis for understanding the requirements of the statutory duty of candour and guidance about how it is to be applied.

The key barrier to open disclosure in health services is the resistant culture rather than a lack of education about open disclosure or unreasonable administrative burden. The resistant culture is likely to relate to a fear of litigation and personal professional consequences regarding employment, promotion and standing. Amongst health professionals in training, entry into and progression within specialist medical and nursing and other training programs may be negatively impacted by open disclosure and statutory duty of candour requirements. The possible professional consequences for an individual health practitioner are not a valid reason for non-disclosure. However, such consequences may be a significant barrier to compliance with disclosure requirements. This issue requires addressing if the intended aims of the statutory duty of candour are to be achieved.

*Law Institute of Victoria*

**Recommendation 21**

It is recommended that all health service providers subject to the statutory duty of candour and the candour and open disclosure guidelines should have internal policies and procedures to support a culture of openness and transparency, and processes to ensure that staff and contractors follows them.

**Recommendation 22**

All health service providers subject to the statutory duty of candour and the candour and open disclosure guidelines should also take action to tackle bullying, harassment and undermining, and investigate any instances where a member of staff may have obstructed another in participating in or contributing to statutory duty of candour or open disclosure processes.

**Recommendation 23**

The department should work with key stakeholders, the Victorian Managed Insurance Authority, the Australian Commission on Safety and Quality in Health Care and Safer Care Victoria to develop model policies and procedures that can be adopted, and adapted, to be fit for purpose for the different organisations that will be subject to the statutory duty of candour and the candour and open disclosure guidelines.

## Training and support

A core requirement for effective implementation of a statutory duty and the desired culture change is training and information. A number of submissions made very specific and detailed recommendations about how training could best be designed and delivered. Particular issues raised include the challenge of providing and engaging relevant training to all medical staff across a health service, including those in private practice, contractors, rotating junior doctors, fractional appointment and visiting medical officers. This may be particularly acute for doctors working in private hospitals who may work on an ad hoc basis at several different private hospitals across the state.

It is understood that Safer Care Victoria is currently undertaking work to explore how some of the gaps in open disclosure training can best be addressed and how foundational skills training in this area can be delivered to clinical staff. The Expert Working Group is of the view that this work should sit within a broader context of support for improved patient–practitioner communication more generally.

Face to face experiential learning: skill based content enhanced by scenario based role play learning is reportedly highly beneficial in increasing confidence and competence of clinicians practising open disclosure. Many clinicians still report that they have not yet had access to training where they can develop these skills in a supportive learning environment. SCV is currently exploring how to address some of these gaps and deliver foundational open disclosure skill training probably focussing on our rural and regional health services.

*Safer Care Victoria*

Epworth HealthCare recommends training be provided via multiple modalities and by providers specifically audited to do so to ensure that [all health professionals or health service organisations particularly those that] operate in regional or rural areas are able to access education and training easily, effectively and in a cost-effective manner.

*Epworth HealthCare*

Doctors must be supported to understand how their own professional obligation of open disclosure interacts with a statutory duty of candour and the differences between them. Organisations must have clear policies and procedures about open disclosure and the statutory duty of candour, which should be consistent with existing clinical governance frameworks, quality and safety policies, professional indemnity requirements and employment obligations.

The Department of Health and Human Services must provide resources and assist organisations to meet any new statutory obligations.

*Professional association B*

While the consultation paper states that the introduction of a statutory duty of candour presents an opportunity to further embed the principles of open disclosure across the health system, it should also be acknowledged that in reality there is likely to be some confusion between the two. Clear communication and education as to the role of a duty of candour within a broader open disclosure framework will be required.

An additional issue will be to ensure that statutory duty of candour obligations are not delegated to junior doctors. Having said this, junior staff must be included in the process for learning purposes.

*Australian and New Zealand College of Anaesthetists*

Training:

* Will be critical to support the introduction of a duty of candour.
* 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.

*Dental Health Services Victoria*

Submissions also suggested training and awareness raising should not only be for clinicians but also for consumers, consumer advocates and other bodies who may have a role that intersects with the functions delivered to support an effective statutory duty of candour. In order to participate in candour or open disclosure conversations effectively, consumers may need training, information, advice and/or support not only about the open disclosure processes itself but also to ensure they have sufficient understanding about their care and the health services system that delivers this care.

It is essential that people from culturally and linguistically diverse communities and those who may experience difficulties communicating verbally and/or physically are not disadvantaged from participating in an open disclosure, or from declaring harm. [This organisation] recommends that access to interpreters and/or translation services be stipulated in subordinate instruments and that if, as could be the case, demand for those services increases as a result of the introduction of the statutory duty, that the Victorian Government positively adjusts funding for translation and interpreter services.

*Specialist representative organisation*

**Recommendation 24**

It is recommended that the department provide Safer Care Victoria with de-identified summaries of the issues and suggestions raised in submissions to the Expert Working Group to inform Safer Care Victoria’s work on training to improve open disclosure practice; and that Safer Care Victoria include in its work:

* a focus on how such training can be delivered in the private sector
* consideration of the training and support needs of consumers and consumer advocacy groups.

It is also clear that training will be required for board directors to understand their role and obligation in relation to the statutory duty of candour.

**Recommendation 25**

It is recommended that the department consider how training to board directors can incorporate training about their obligations in relation to the statutory duty of candour and how this might inform board directors’ understanding of their broader clinical governance role.

The Expert Working Group is mindful that simply focusing on the disclosure conversation in isolation would artificially separate communication after harm has occurred from all the other communication that must occur between clinician and consumer. Open disclosure exists as part of a continuum of communication that starts at the first meeting and encompasses a range of important opportunities to share information and build the therapeutic relationship. It includes advice about diagnosis, information about treatment options, informed consent for treatment and discharge advice. Any conversations required to explain unexpected harm will be simpler and more readily accepted where the foundations of the clinician–consumer relationship are already strong and where risks and possible outcomes have been explained and understood.

## Mental health services

As noted in relation to the scope of the duty, the Expert Working Group wishes to acknowledge the significant complexities of these issues for provision of mental health care. The particular issues facing the mental health system feature throughout *Targeting Zero*.

Like all patients, mental health patients are at risk of harm during the course of treatment in healthcare settings. However, they are also at risk of an additional range of safety incidents that are uniquely or strongly associated with mental health settings. These include self-harm and suicide, assault (including sexual violence) from other patients, (which … is very rare for general patients) along with trauma or physical harm arising from seclusion and restraint. Further, mental health patients may have lower capacity for self-advocacy and so be less able to protect themselves from harm.

*Targeting Zero, p. 133*

The Expert Working Group also acknowledges that nature of mental health treatment may require particular consideration as to how and when disclosure conversations should occur. It will be important that the introduction of the duty allows sufficient flexibility and is accompanied by appropriate guidance and materials to allow services to respond to these considerations.

It is particularly critical that open disclosure is undertaken routinely and effectively in public mental health services having regard to the vulnerability of consumers, and the human rights affected by compulsory treatment and detention, and the risks of closed environments.

*Mental Health Complaints Commissioner*

We recommend that the Victorian Government develop guidance material, including scenarios, to illustrate when the statutory duty would apply. The guidance should include cases where the consumer lacks capacity and cases where consent to share information has been withheld.

*Professional association A*

**Recommendation 26**

It is recommended that the Minister liaises with the Minister for Mental Health to facilitate further consultation with the Mental Health Complaints Commissioner, the mental health sector and consumer advocates to identify the particular training, materials and support that may be required by mental health service providers and/or consumer advocacy organisations to:

* ensure that the statutory duty of candour can be appropriately implemented by mental health services
* improve the practice of open disclosure within mental health services.

# The statutory duty in a broader landscape

As outlined earlier in this report and detailed in Appendix B, the statutory duty of candour will sit alongside a range of quality and safety related statutory and regulatory requirements. The Expert Working Group has heard from numerous stakeholders that the range of these requirements is not well understood and that the various players in the landscape are not well coordinated.

There is evidence that consumers find the range of pathways to raise concerns confusing and some concern was raised that the implementation of a statutory duty of candour could add to this confusion.

Consumers also point out that the current labyrinth of options for complaint and redress will become even more confusing as an additional avenue becomes available and they find themselves referred from one channel to another.

It is difficult even now for consumers to understand where to process a complaint (at the health service? The Commission? AHPRA?) without the added complexity of an additional pathway.

*Health Issues Centre*

The Statutory duty of candour should wherever possible link to other Standards such as Child Safety, Work Health and Safety (link to facility and equipment, workforce), Health and Child Wellbeing Legislation Amendment.

*Community health centre*

Better alignment of the efforts of the various relevant bodies with specific quality and safety functions such as AHPRA, the complaints commissioners, professional colleges, the Victorian Agency for Health Information, the Victorian Managed Insurance Authority and the department would assist in alleviating this existing confusion and support effective implementation of the statutory duty.

Other enablers for implementation include alignment of efforts by other bodies with specific quality and safety functions such as AHPRA, the Complaints Commissioners, professional colleges, [the Victorian Agency for Health Information], and [the Victorian Managed Insurance Authority]. These bodies may: identify when harm has occurred requiring statutory duty of candour, foster a shift from defensive communication, promote good practice in delivering an apology, promote the value of system review and learning, promote patient rights and redress processes.

*Safer Care Victoria*

The recommendations made in *Targeting Zero* for legislative reform to support better information sharing and those additional changes specifically recommended in this report will assist with this alignment. However, the Expert Working Group is of the opinion that more needs to be done to better support consumers to navigate the complex system and that there would be value in considering options for a ‘one door in’ approach to complaints and notifications about health services.

**Recommendation 27**

It is recommended that the Minister tasks the department to:

* consider ways to streamline the avenues for consumers to raise concerns about their care (including considering the opportunities to introduce a ‘one door in’ approach for complaints and notifications)
* support the various entities involved in these processes to better align their responsibilities.

# Appendices

**Appendix A** Submissions received

**Appendix B** Context: quality and safety statutory and regulatory requirements

**Appendix C** Implications of recommending an organisational obligation for candour for individuals and other third parties involved in incidents

**Appendix D** Draft content for proposed candour and open disclosure guidelines

**Appendix E** Further considerations regarding the protection of incident review processes

## Appendix A – Submissions received

The Expert Working Group received submissions from 18 individuals and 43 organisations.

Organisational submissions were received from:

* Alfred Health
* Ambulance Victoria
* Austin Health
* Australian and New Zealand College of Anaesthetists
* Australian Dental Association Victorian Branch
* Australian Medical Association Victoria
* Australian Nursing and Midwifery Federation Victorian Branch
* Australian Orthopaedic Association Victorian Branch
* Australian Private Hospitals Association
* Avant Mutual Group
* Ballarat Health Services
* Barwon Health
* Bendigo Health
* Colac Area Health
* Commission for Children and Young People
* Connect Health and Community
* Council of Presidents of Medical Colleges
* Day Hospitals Australia
* Dental Health Services Victoria
* East Grampians Health Service
* Epworth HealthCare
* Goulburn Valley Health
* Health Issues Centre
* IPC Health
* Law Institute of Victoria
* Mansfield District Hospital
* Maurice Blackburn Lawyers
* Melbourne Health
* Mental Health Complaints Commissioner
* MIGA
* Monash Health
* Peter MacCallum Cancer Institute
* Royal Australasian College of Medical Administrators
* Royal Australasian College of Surgeons
* Royal Australian and New Zealand College of Psychiatrists Victorian Branch
* Royal Children’s Hospital Melbourne
* Safer Care Victoria
* South West Healthcare
* St Vincent’s Hospital Melbourne
* Victorian Healthcare Association
* Victorian Managed Insurance Authority
* Victorian Mental Illness Awareness Council
* Victorian Ombudsman

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## Appendix B – Context: quality and safety statutory and regulatory requirements

There is a range of bodies that operate in the health service quality and safety field, often with overlapping roles, functions and responsibilities. These can broadly be broken down into the following four categories:

* standard and policy setting
* monitoring, review and recommendations
* regulation and discipline
  + complaint handling.

Many organisations perform multiple roles.

### Standard and policy setting

The **Department of Health and Human Services** (the department) is the key system leader in the Victorian hospital system in the context of standard and policy setting and, through a set of statutory powers, provides oversight of a range of health entities, including private and public hospitals, day procedure centres and ambulance services. The department assists the Minister with public sector hospital board appointments, which take place in accordance with legislated requirements. It is also responsible for the registration and oversight of private hospitals (including day procedure centres).

The department issues guidelines and policies and sets minimum requirements for Victorian public sector hospitals via statements of priorities, and for Victorian private hospitals and day procedure centres through the registration framework.[[37]](#footnote-37) The department is responsible for progressing any proposals for legislative reform to establish or amend statutory standards and requirements in the *Health Services Act 1988*, *Mental Health Act 2014*, *Ambulance Services Act 1986* and *Health Complaints Act 2016* as well as others. The department also sets standards and requirements in prevention and control, and has other regulatory functions.

The **Australian Commission on Safety and Quality in Health Care** sets the National Safety and Quality Health Service Standards, against which all Victorian hospitals and day procedure centres are required to be assessed and accredited.

The **Australian Health Practitioner Regulation Agency** (**AHPRA**) works in partnership with National Boards for fifteen registered health professions. National Boards set standards and codes of conduct for each profession under the *Health Practitioner Regulation National Law (Victoria) Act 2009* (the **National Law**). A professional duty to be honest with consumers exists in each of the codes of conduct for health practitioners registered by AHPRA. National Boards also set requirements for entry to the professions, such as qualifications and competencies and requirements for ongoing continuing professional development. AHPRA investigates notifications about unprofessional conduct, unsatisfactory professional performance and about impairment where this is placing the public at risk. The relevant National Board will refer serious matters to the Victorian Civil and Administrative Tribunal where the risk to public may warrant restriction of a practitioner’s registration.

One of the functions of **professional colleges** is to set requirements for membership and play a role under the National Law in relation to granting specialist qualifications required for specialist registration.

The **Health Complaints Commissioner** provides complaint resolution processes for health service complaints. The Health Complaints Commissioner also issues complaint handling standards for health service providers under the Health Complaints Act. TheHealth Complaints Act includes a statutory code of conduct for unregistered health service providers and provides the Commissioner with powers to investigate and make recommendations.

The **Chief Psychiatrist** issues practice notes and guidelines about the quality and safety of services provided by mental health service providers, under the Mental Health Act. The Chief Psychiatrist can make recommendations for mental health service providers and can issue guidelines in relation to quality and safety of the mental health services they provide.

Other organisations that set standards and/or issue policies include the **Victorian Pharmacy Authority**, **Commonwealth Department of Health**, **Therapeutic Goods Administration** and **Reproductive Technology Accreditation Committee**.

### Monitoring, review and recommendations

The **department** monitors the performance of regulated public and private sector health service entities, using information collected directly from hospitals, under legislative mechanisms and through conditions of funding. This monitoring is done for the purposes of performance monitoring, performance management, funding/commissioning, regulation and service/system design. Those activities are also informed by information and analysis obtained from other organisations, such as Safer Care Victoria, the Victorian Agency for Health Information, AHPRA, the Victorian Managed Insurance Authority, and complaints commissioners.

The department has periodic and ad hoc performance discussions with hospitals (both public and private) and day procedure centres in relation to quality and safety matters.

In response to an identified quality and safety deficiency or concern, the department may initiate an increased level of performance monitoring and/or a range of other regulatory responses under applicable legislation.

**Safer Care Victoria** uses information collected directly from hospitals, and information obtained from the department. This monitoring is done for the purposes of providing clinical leadership and advice to hospitals and to the department about quality and safety risks and opportunities for improvement, and best practice in quality and safety. The information from Safer Care Victoria also informs the department’s performance monitoring, performance management, funding/commissioning and regulation. Safer Care Victoria’s monitoring and clinical leadership also take into account information and analysis obtained from third parties such as AHPRA, the Victorian Agency for Health Information, the Victorian Managed Insurance Authority, complaints commissioners, consumers, clinical networks, consultative councils and the Victorian Clinical Council.

Safer Care Victoria conducts reviews in response to incident reports received from hospitals pursuant to the department’s requirements, or information received through other mechanisms, including from third parties such as AHPRA or consumers. These reviews are for the purposes of identifying and assessing quality and safety risk, identifying opportunities for improvement, overseeing and supporting incident response, remediation and improvements and providing advice to the hospital and the department about those matters and any related systemic quality and safety issues at the hospital or across the hospital system. Safer Care Victoria may provide advice to a hospital about remediation or improvement actions that should be taken to address identified risk.

**AHPRA** conducts reviews in response to notifications received about individual practitioners and presents information about individual practitioners to the National Board who registered the individual if there are concerns that the practitioner might not be practicing appropriately and safely. The National Law provides for information sharing between AHPRA, health complaints entities and regulators like the department.

**Consultative Councils** such as the Consultative Council on Obstetric and Paediatric Mortality and Morbidity (CCOPMM) use data reported directly by hospitals under the *Public Health and Wellbeing Act* *2008*, and some **professional colleges**, such as the Royal Australian College of Surgeons,[[38]](#footnote-38) use data reported directly by hospitals. These reviews inform feedback to the clinicians and hospital involved, and development of best practice guidance. Aggregate reports are produced and published, which inform broader monitoring activity and research. Legislation passed by Parliament in October 2017 will require CCOPMM to report to the department (Safer Care Victoria) on individual cases where CCOPMM considers harm occurred that was likely preventable.

The **Health Complaints Commissioner** uses information obtained through complaints made under the Health Complaints Act in relation to a broad range of health service providers. This is for the purposes of ‘research in respect of complaint handling and matters relevant to the improvement of the quality of health service systems,’ and the commissioner’s other functions under the Act. The commissioner also conducts reviews of information obtained in the course of dealing with a complaint or conducting an investigation. These reviews are for the purpose of identifying persistent or recurrent issues related to the provision of a health service. The commissioner may provide advice based on the results of a review to a health service provider regarding the provision of a health service.

The **Victorian Agency for Health Information** monitors and reports on public and private hospitals and health services. The agency analyses and shares information, to produce regular reports to monitor safety and performance for the department, Safer Care Victoria and hospital boards. These reports are used by the recipients to identify quality and safety risks and inform improvement activities.

The **Mental Health Complaints Commissioner** monitors information obtained through complaints made under the Mental Health Act, in relation to mental health service providers. This is for the purposes of the commissioner’s functions under this Act, which include to identify, analyse and review quality, safety and other issues arising out of the complaints and to make recommendations for improving the provision of mental health services.

The **Chief Psychiatrist** monitors quality and safety in relation to public mental health services, using information collected from hospitals under the Mental Health Act. They also conduct investigations and reviews under this Act. These reviews are for the purposes of identifying and assessing quality and safety risk, identifying opportunities for improvement, overseeing and supporting incident response, remediation and improvements, and providing advice to mental health service providers and the Secretary of the department about those matters and any related systemic quality and safety issues. The reviews may also inform advice and guidance material issued to mental health service providers generally.

The **Victorian Managed Insurance Authority** provides insurance and risk advice to theVictorian Government. The authority conducts reviews in the course of responding to insurance claims, for the purposes of assessing the claim and making payments in response to the claim under the applicable policy.

The **Chief Health Officer**, **Victorian Assisted Reproductive Treatment Authority** and **Victorian Pharmacy Authority** also have quality and safety monitoring roles.

The **Independent Broad-Based Anti-Corruption Commission**, **Coroner’s Court**, **Victorian Assisted Reproductive Treatment Authority**, **individual health service providers** and the **Commonwealth Department of Health** review incidents or episodes of care.

The **Coroner’s Court** makes findings about the cause of a sudden and unexpected death and recommendations about how similar deaths could be avoided.

### Regulation and discipline

The **Minister for Health** and the **department**, in accordance with the Health Services Act,can impose a range of consequences on regulated agencies for non-compliance or poor performance. The departmentmay take regulatory action in response to an identified quality and safety deficiency or concern. Regulatory mechanisms, through powers of the Minister or Secretary, include increasing performance monitoring or performance management; commissioning an audit, recommending appointment of board delegates, amalgamation or closure of public sector providers; and placing conditions upon or revoking the registration of a private sector provider. Legislative amendments passed in October 2017 will ensure that such actions can be initiated on the basis of failures in relation to quality and safety.

**National Boards** can take urgent interim action to restrict or suspend a practitioner’s registration whilst AHPRA conducts an investigation, if the National Board determines there is a serious risk to the health or safety of the public. At the conclusion of an investigation where the issues are serious, National Boards can refer a practitioner to a Victorian Civil and Administrative Tribunal hearing. The tribunal may restrict or cancel the practitioner’s registration.

The **Health Complaints Commissioner** can issue orders prohibiting an unregistered health service provider from providing services, or impose conditions on the provision of services, and can also issue public warning statements under certain circumstances.

The **Mental Health Tribunal** hears and determines a number of matters and applications in regard to mental health services. For example, matters in relation to whether a treatment order should be made, or matters in relation to applications involving the transfer of the treatment of a compulsory patient to another designated mental health service.

The **County Court of Victoria**, **Supreme Court of Victoria**, **Victorian Civil and Administrative Tribunal** and **Commonwealth Department of Health** also play important roles in determining and reviewing disciplinary outcomes.

### Complaint handling

**Health service providers** must have their own complaint handling procedures consistent with the requirements of the Health Complaints Act. Larger hospitals and health service providers often have consumer liaison officers to assist patients and their families to raise concerns about their treatment or experience. Smaller organisations typically receive complaints or feedback through their senior management team. If consumers are unhappy with the response received from the healthcare professional or organisation involved, they are encouraged to lodge their complaint with the relevant independent regulatory body or authority. This could include the Health Complaints Commissioner, Mental Health Complaints Commissioner, AHPRA, Victorian Ombudsman, Disability Services Commissioner or Private Health Insurance Ombudsman.

The **Health Complaints Commissioner**,under the Health Complaints Act, conducts complaint resolution processes in response to complaints made about a wide range of health services. The commissioner determines how the matter will be dealt with. This may include an informal resolution process, a more formal process that may involve confidential conciliation, or an investigation. Complaints can be made by any person who received or sought a health service, the carer of such a person, or anyone who perceives the health service provider to have acted unreasonably when a person received or sought the health service.

The **Mental Health Complaints Commissioner** accepts, assesses, manages and investigates complaints relating to public mental health services and endeavours to resolve complaints in a timely manner using formal and informal dispute resolution as appropriate. A person may make a complaint to the commissioner if the person is a consumer, is acting at the request of a consumer or satisfies the commissioner that he or she has a genuine interest in the wellbeing of a consumer. Complaints can only be made to the commissioner in relation to a matter arising out of the provision of mental health services or failure to provide mental health services by a public mental health service provider. The commissioner has powers to investigate and issue compliance notices.

**AHPRA** deals with notifications made about practitioners by members of the public. These must be in relation to a practitioner’s behaviour placing the public at risk, a practitioner practising their profession in an unsafe way, or a practitioner’s ability to make safe judgements about their patients possibly being impaired due to their health. At the end of the assessment process, AHPRA presents its findings to the relevant National Board for consideration in relation to the conduct, competence or health (impairment) of the practitioner subject to a notification.

## Appendix C – Implications of recommending an organisational obligation for candour for individuals and other third parties involved in incidents

### Hospital staff

The Expert Working Group has recommended that responsibility for the statutory duty rest with boards of public and private health service entities within the proposed scope (see Recommendations 2, 3 and 6).

In relation to the employees of these services, we believe the position is reasonably straightforward. Employees are governed by their contracts of engagement and formal policies, guidelines and protocols of their employer. As well as training and education in the duty of candour and open disclosure, this may include requirements for credentialing. Furthermore, organisations are, generally, vicariously liable for the acts of their employees and agents (so long as they are generally acting within the scope of their duties e.g. not necessarily for criminal matters).

Contractors, for example, visiting medical officers, are regarded as agents of the hospital. Notwithstanding the status of the patient, such as a private patient in the public system, we are of the view that the legal obligation on the board with respect to the duty of candour should be identical – how the organisation operationalises this might be covered in guidelines, and in the case of visiting medical officers for instance, in the letter of engagement addressing the issue of private practice.

In relation to private sector organisations, the Expert Working Group recognises that the relationship between medical practitioners and the organisation is based on accreditation and medical by-laws rather than employment or service contract. In our view, the board of private health service organisations carries the same duty of candour obligations as the board of a public health service organisation. It is up to the board to give effect to the requirement of the legislation using the engagement instruments that are in place. For employees, the process will be similar to the public healthcare setting. For visiting doctors and other health practitioners accredited to practice at a health service, the terms of accreditation and the associated medical (clinical) by-laws should be amended to give effect to the duty of candour obligations of the board. For contracted services, particularly those involving direct patient contact, contracts should reflect and give effect to the board’s duty of candour obligations. (See Appendix D for draft content for proposed candour and open disclosure guidelines.)

The Expert Working Group recognises that clinicians employed or engaged by private health service organisations bear responsibility for their own insurance costs. There may be concern that costs could be impacted if clinicians are obliged by conditions of engagement with the health service to comply with candour obligations. However, clinicians are already subject to professional obligations to undertake open disclosure and provide explanations to patients. In this regard we also note there is a range of protections discussed in this paper, designed to address concerns about any increase in medico-legal risk associated with candour processes.

### Other contractors engaged by private or public sector hospitals

Consultation feedback confirmed it is reasonable to expect that the entity on which the duty of candour is imposed has a contractual basis for ensuring that its contractors provide information to it to so it can comply with its duty of candour obligations.

Accordingly, such contractual arrangements should allow for the provision of necessary information if the candour process could otherwise be compromised (for example, if the relevant service had been provided, in whole or in part, by a contractor who was neither required nor willing to participate in a candour process). It would be a very undesirable result if the explanation provided to the patient was incomplete due to non-participation by a key member of the care team.

To enable boards to comply with the statutory duty, this should apply in relation to contractors who have information relevant to the services provided to a patient – be they agency staff, visiting specialists or other services that are outsourced (for example, private pathology laboratories or private contractors providing non-emergency patient transport).

We anticipate this may require health service boards to review their terms of engagement, and if appropriate, accreditation and medical/clinical by-laws, to reflect and give effect to compliance with the obligations on the board. (Further consultation and analysis to ensure that such an obligation is couched in feasible and reasonable terms may be usefully undertaken in the development of the Victorian candour and open disclosure guidelines proposed at Recommendation 9 and outlined in Appendix D.)

## Appendix D – Draft content for proposed candour and open disclosure guidelines

The proposed candour and open disclosure guidelines will be developed as a subordinate legislative instrument, referenced in legislative provisions introducing the statutory duty of candour. Although the guidelines will be subject to consultation, it is anticipated that they will set out the minimum requirements for compliance with the statutory duty of candour and open disclosure obligations, as well as guidance and information to support best practice.

Matters to be covered will likely include:

* the **underpinning principles** and the anticipated benefits of candour and open disclosure
* a simple description of the **service settings in scope** for the statutory duty of candour and the scope of broader open disclosure obligations
* an accessible and easily understood description of **when the statutory duty of candour will apply** and when open disclosure should be undertaken (for incidents that may not reach the thresholds established for the statutory duty of candour, but which otherwise warrant an open disclosure process)
* mandatory requirements for discharging the statutory duty of candour, including that consumers (or family members/carers) be:
* provided with a *written factual explanation* of what occurred, in language that is understandable by the consumer (including that the explanation must be translated into the consumer’s preferred language if required)
* provided with an *apology* (including the words ‘I am/we are sorry’) as early as possible
* given an opportunity to relate their experience
* advised of *potential consequences* of the incident that gave rise to the conversation and development of a plan to ensure they receive appropriate treatment
* offered appropriate practical and emotional support
* given an explanation of the steps being taken to *investigate and manage the event* and *any improvements* that have been or will be made to prevent similar harm in the future
  + - offered an opportunity for *further dialogue*
* **documentation and reporting requirements** to demonstrate compliance with the statutory duty of candour
* **roles and responsibilities** in relation to the statutory duty of candour – including the responsibilities of boards, service management, clinicians, other hospital employees, the Department of Health and Human Services, relevant entities and consumers and their families.
  + **organisational requirements –** including minimum conditions that will be necessary to ensure compliance with mandatory requirements (this may include, for example, the employment/contractor arrangements necessary to ensure compliance, the processes and systems necessary [including processes for consumers to raise concerns themselves] and minimum capability training for personnel).

The document may also set out:

* **information about the statutory duty in context** – including an explanation of how the statutory duty relates to the existing (and ongoing) requirements for open disclosure, and how the statutory duty and open disclosure fit within a broader regulatory and quality and safety improvement environment
* **non-mandatory best practice approaches,** for example, the timeframe in which disclosure should generally occur (and discussion of factors that may necessitate different timeframes), deciding who should participate in the disclosure conversations, guidance about developing local candour and open disclosure policies and procedures
* **guidance about legal context** for the exercise of the statutory duty of candour and open disclosure (including explanation of the statutory protections for apologies and clinical review processes and privacy and confidentiality requirements and links to the Charter for Human Rights and Responsibilities)
* **guidance about support requirements** – inclusive of the consideration of supports that may be required by the consumer and/or their family/carer and staff or professionals involved in an incident
* **guidance about risk management** – inclusive of the potential risks to the hospital/health service, the consumer and/or their family/carer and staff or professionals involved in an incident
* **detailed advice** about key steps, decision points and processes (including relationships to requirements for case review and investigation), including examples of scripts and scenarios (or references to these)
* **guidance and supports for developing a just and open culture** (including references to existing policies and procedures)
* **considerations in relation to specific cases** – for example disclosures involving multiple consumers; disclosures regarding events that occurred across multiple services or paediatric cases; disclosures regarding events that have been identified through other review processes (for example look backs)
* **particular considerations in relation to mental health services**
* **governance and process requirements to support organisational learning and system improvements** from review of candour and open disclosure events
* **links to relevant documents and information sources, training resources (e.g. Victorian Managed Insurance Authority website etc.)**.

## Appendix E – Further considerations regarding the protection of incident review processes

It has been argued that disseminating learnings and/or recommendations from incident review processes such as root cause analysis can be valuable for quality and safety improvement purposes, including to those involved in the relevant case (although Safer Care Victoria has noted that it may be appropriate to provide only relevant information to those parties. For example, the information provided to an individual clinician who was involved in the case may not include the same information that is provided to another clinician who was involved in the case).

It has also been noted by Safer Care Victoria that it would be undesirable if the protections applying to specified – serious – categories of incident had an unintended impact on decisions by hospitals about how incidents are classified. It has been suggested that there should be a mechanism for a decision that an incident does not in fact meet the threshold for a protected incident review process. There is such a mechanism in the Queensland legislation. For example, there could be a requirement that, in relation to certain kinds of incidents, the health service must consult with Safer Care Victoria about its categorisation before proceeding with the incident review.

It will be necessary to ensure that protections for incident reviews do not restrict oversight and regulation of quality and safety, service delivery and professional conduct. In this regard the Queensland legislation provides an example of a series of authorisations for information that arises from the protected incident review to be provided to various relevant bodies. It will be necessary to strike a balance so that the prospect of information being provided to oversight and regulatory bodies does not undermine the intended benefits of the protections by constraining discussion during the protected incident review process.

In this regard, quality and safety reviews and discussions conducted by Safer Care Victoria must be considered carefully, as these are a key source of information for the Department of Health and Human Services in relation to all is functions – including performance monitoring, performance management and regulation. In designing protections for incident review processes, and any framework for Safer Care Victoria’s review activities, it is necessary to ensure that Safer Care Victoria has access to information as required – including information that may relate to a protected incident review process – and that the outcomes of Safer Care Victoria’s reviews are available to the department as necessary.

It will also be necessary to consider how and when a statutory incident review team may notify certain parties if they consider the incident to involve professional misconduct, unsatisfactory professional conduct, unsatisfactory professional performance or an impairment, to ensure there is clarity for services and practitioners. For example, in New South Wales there is provision for this to be communicated to the health service organisation that employed or engaged the relevant practitioner. In Queensland the statutory incident review is stopped if the Ombudsman is notified of those matters, or if the statutory incident review team believes that the incident involves deliberate abuse or a criminal act.

Finally, it will be necessary to consider whether the statutory incident review provisions should include personal protections for those conducting or participating in a statutory incident review process. For example, in Queensland and New South Wales members of statutory incident review teams are protected from liability for things done in good faith as part of their role as team member, specific privilege in relation to claims of defamation, and entitlements to be indemnified for costs incurred in defending themselves from liability against which those provisions protect them. In Queensland there are also protections for those who provide information to a statutory incident review team, so they are not exposed to disciplinary action or a defamation claim in relation to their provision of information to the team.

1. In August 2019, Safer Care Victoria released the Adverse Patient Safety Events Policy, which replaces the former Victorian health incident management policy issued by the department <https://www.bettersafercare.vic.gov.au/reports-and-publications/policy-adverse-patient-safety-events> [↑](#footnote-ref-1)
2. ‘[Just culture](http://vhimsedu.health.vic.gov.au/opendisclosure/help/glossary.php#just)’ 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. [Victorian Government Health Information 2010, ‘VHIMS education: glossary’, State](http://vhimsedu.health.vic.gov.au/help/glossary.php) Government of Victoria, viewed 12 February 2018, <<http://vhimsedu.health.vic.gov.au/help/glossary.php>>. [↑](#footnote-ref-2)
3. Expert Working Group 2017, *A statutory duty of candour: consultation paper*, State Government of Victoria, Melbourne, viewed 12 February 2018, <<https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/better-safer-care/statutory-duty-of-candour>>. [↑](#footnote-ref-3)
4. The absence of an apology or explanation is one of the key motivators for legal action and for escalating complaints to the Health Complaints Commissioner. In addition, there is some evidence from the United States that while apologies can have a neutralising effect, in other circumstances apologies may alert a patient to malpractice and thereby prompt litigation. See, for example, McMichael, BJ 2017, ‘The failure of ‘sorry’: an empirical evaluation of apology laws, health care, and medical malpractice’, *Lewis & Clark Law Review* (forthcoming), posted 21 August 2017, viewed 12 February 2018, <<http://dx.doi.org/10.2139/ssrn.3020352>>. [↑](#footnote-ref-4)
5. Bismark, M & Paterson, R 2005, ‘“Doing the right thing” after an adverse event’, *The New Zealand Medical Journal (Online)*, vol. 188, no. 1219, viewed 12 February 2018, <<https://www.researchgate.net/publication/7688496_%27Doing_the_right_thing%27_after_an_adverse_event>>. [↑](#footnote-ref-5)
6. Trask, S 2013, ‘Will a duty of candour provoke a culture change in the NHS?’ *The Guardian* 19 November 2013, viewed 12 February 23018, <<https://www.theguardian.com/healthcare-network/2013/nov/18/duty-of-candour-nhs-culture-change>>. [↑](#footnote-ref-6)
7. Duckett, S & Jorm, C 2018, *All complications should count: using our data to make hospitals safer*, Grattan Institute, viewed 12 February 2018, <<https://grattan.edu.au/report/all-complications-should-count-using-our-data-to-make-hospitals-safer/>>. [↑](#footnote-ref-7)
8. Australian Commission on Safety and Quality in Health Care 2012, *Open Disclosure Standard: review report*, Commonwealth of Australia, viewed 12 February 2018, <<https://www.safetyandquality.gov.au/publications/open-disclosure-standard-review-report/>>. [↑](#footnote-ref-8)
9. Mazora, K; Greene, S et al. 2013, ‘More than words: patients’ views on apology and disclosure when things go wrong in cancer care’, *Patient Education and Counselling,* vol. 90, no. 3, pp. 341–346. This is further highlighted in the evidence for the key motivations behind medico-legal action and complaints to the Victorian Health Complaints Commissioner (formerly the Health Services Commissioner) – see data contained in annual reports at <<https://hcc.vic.gov.au/resources/reports>>. [↑](#footnote-ref-9)
10. Developed by the Australian Commission on Safety and Quality in Health Care. [↑](#footnote-ref-10)
11. For example, the Medical Board of Australia’s *Good medical practice: a code of conduct for doctors in Australia* (p. 10) includes:

    3.10 Adverse events

    When adverse events occur, you have a responsibility to be open and honest in your communication with your patient, to review what has occurred and to report appropriately. When something goes wrong you should seek advice from your colleagues and from your medical indemnity insurer.

    Good medical practice involves:

    3.10.1 Recognising what has happened.

    3.10.2 Acting immediately to rectify the problem, if possible, including seeking any necessary help and advice.

    3.10.3 Explaining to the patient as promptly and fully as possible what has happened and the anticipated short-term and long-term consequences.

    3.10.4 Acknowledging any patient distress and providing appropriate support.

    3.10.5 Complying with any relevant policies, procedures and reporting requirements.

    3.10.6 Reviewing adverse events and implementing changes to reduce the risk of recurrence.

    3.10.7 Reporting adverse events to the relevant authority, as necessary.

    3.10.8 Ensuring patients have access to information about the processes for making a complaint (for example, through the relevant healthcare complaints commission or medical board).

    Medical Board of Australia 2014, *Good medical practice: a code of conduct for doctors in Australia*, viewed 12 February 2018, <<http://www.medicalboard.gov.au/Codes-Guidelines-Policies.aspx>>. [↑](#footnote-ref-11)
12. That is, those not required to be registered under the *Health Practitioner Regulation National Law (Victoria) Act 2009.* [↑](#footnote-ref-12)
13. A clinical incident is an event or circumstance that could have, or did, lead to unintended and/or unnecessary harm to a person receiving care. Since 2017, Victorian public health services are required to provide incident data to the Victorian Agency for Health Information quarterly. [↑](#footnote-ref-13)
14. For this purpose the definition of ‘sentinel event’ reflects the eight nationally defined categories of sentinel event, and also includes a ninth category of ‘other catastrophic’ event, being one with an Incident Severity Rating (ISR) of 1. [↑](#footnote-ref-14)
15. An RCA process is conducted in relation to each sentinel event, with a de-identified RCA report provided to Safer Care Victoria. The report is then reviewed by Safer Care Victoria and feedback provided to the hospital. A risk reduction action plan is provided to Safer Care Victoria three months after the RCA report, setting out the progress on implementing the recommendations that arose from the sentinel event incident response process. [↑](#footnote-ref-15)
16. These amendments will come into operation on 1 July 2018 unless Governor in Council proclaims an earlier commencement date. [↑](#footnote-ref-16)
17. Care Quality Commission 2015, ‘Regulation 20: duty of candour – information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare’, viewed 12 February 2018, <<https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour#legislation-links>>. [↑](#footnote-ref-17)
18. *Targeting Zero* (p. 200) cites a 2014 study by Marie Bismark et al. that was ‘based on a survey of 322 board members from 85 public health services, and semi-structured interviews with 35 board members and senior executives from 13 public health services in Victoria’. [↑](#footnote-ref-18)
19. The ISR methodology was developed to provide a more consistent classification of incident severity and was created following analysis of methodologies used both nationally and internationally. The ISR rating scale is a four-point scale (1 – severe/death, 2 – moderate, 3 – mild, 4 – no harm/near miss) that is derived from three related areas: degree of impact/harm, level of care required, and treatment required. Once these areas have been addressed by the user, an algorithm determines the ISR rating. [↑](#footnote-ref-19)
20. Health Services Commissioner 2013, *Study of people lodging complaints with the Victorian Health Services Commissioner: final report*. [↑](#footnote-ref-20)
21. Under the National Health Service system in the United Kingdom, to meet the requirements of Regulation 20 a registered provider has to:

    make sure it acts in an open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on a regulated activity

    tell the relevant person, in person, as soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, and provide support to them in relation to the incident, including when giving the notification

    provide an account of the incident which, to the best of the provider’s knowledge, is true of all the facts the body knows about the incident as at the date of the notification

    advise the relevant person what further enquiries the provider believes are appropriate

    offer an apology

    follow up the apology by giving the same information in writing, and providing an update on the enquiries.

    keep a written record of all communication with the relevant person.

    Care Quality Commission 2015, ‘Regulation 20: duty of candour – information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare’, pp. 9–10, viewed 12 February 2018, <<https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour#legislation-links>>. [↑](#footnote-ref-21)
22. The context for the recommendation for a statutory duty of candour in *Targeting Zero* is a focus on the importance of transparency and accountability to patients. The report argues for the importance of responding effectively to consumer issues, not only because of the increased opportunity for learnings to improve quality and safety but also as a means of reducing the number of complaints that proceed to litigation (which in turn allows for a greater focus on prevention and quality improvement). See pages 215–216 of *Targeting Zero*, as well as Chapter 5 generally, which focuses on transparency and accountability to patients.

    In her 2017 report *Apologies*, the Victorian Ombudsman cited expert studies suggesting that apologies can help resolve disputes sooner. See, for example, (as cited in that report) Robbennolt, J 2003, ‘Apologies and legal settlement: an empirical examination’, *Michigan Law Review*, vol. 102, no. 3; and Allan A 2007, ‘Apology in civil law: a psycho-legal perspective’, *Psychology, Psychiatry and the Law*, vol. 14, no. 1.

    Similarly, theAccess to Justice Review report (p. 209) cites research that indicates that there is ‘some evidence to suggest that apologies can be a very meaningful means of redress and can reduce the desire to litigate’. Vines, P ‘Apologising to avoid liability: cynical civility or practical morality?’, *Sydney Law Review*, vol. 27, no. 3; cited by Department of Justice and Regulation 2016, *Access to Justice Review: volume 1 report and recommendations*; State Government of Victoria, Melbourne. [↑](#footnote-ref-22)
23. It should be noted, however, that the same research indicates that overall merit-less malpractice claims are likely to be reduced by effective disclosure and apology processes, and overall there may be a reduction in the frequency and size of malpractice claims. [↑](#footnote-ref-23)
24. Patients have a right to access their medical records, including under the Health Records Act. In addition, health service organisations are required to implement open disclosure as part of the National Safety and Quality Health Service Standards. This involves establishing processes consistent with the Australian Open Disclosure Framework. One element of this is ‘open and timely communication’, including that the consumer should be provided with information about what happened, in an honest and open manner at all times. Australian Commission on Safety and Quality in Health Care 2014, *Australian* *Open Disclosure Framework*, Commonwealth of Australia, viewed 12 February 2018, <<https://www.safetyandquality.gov.au/publications/australian-open-disclosure-framework/>>. [↑](#footnote-ref-24)
25. Australian Commission on Safety and Quality in Health Care 2012, *Open Disclosure Standard: review report*, Commonwealth of Australia, viewed 12 February 2018, <<https://www.safetyandquality.gov.au/publications/open-disclosure-standard-review-report/>>. [↑](#footnote-ref-25)
26. Victorian Ombudsman 2017, *Apologies*, viewed 12 February 2018, <<https://www.ombudsman.vic.gov.au/Publications/Parliamentary-Reports/Apologies>>. [↑](#footnote-ref-26)
27. Department of Justice and Regulation 2016, *Access to Justice Review: volume 1 report and recommendations*; State Government of Victoria, Melbourne. [↑](#footnote-ref-27)
28. As per Recommendations 2 and 3, this would include the Health Services Act, the Ambulance Services Act and Mental Health Act (to apply to the Victorian Institute of Forensic Mental Health). [↑](#footnote-ref-28)
29. For example, in New South Wales a legislative (and therefore protected) RCA must be conducted in relation to a ‘reportable incident’ as defined in the NSW *Health incident management policy* and may be conducted if the chief executive officer of the relevant health services organisation is of the opinion that the incident may be the result of a serious systemic problem that justifies the appointment a statutory RCA team. In Queensland the RCA protections apply in relation to an RCA conducted under the statute in relation to a ‘reportable event’ as defined in the regulations. Those definitions are closely aligned with the nationally defined list of sentinel events. [↑](#footnote-ref-29)
30. The MHCC has advised that since its submission in 2017 it has observed a change in practice whereby more services have cooperated with the MHCC by providing internal review documents on a confidential basis and services have been less likely to rely on the s 139 privilege. [↑](#footnote-ref-30)
31. New Zealand established a no-fault compensation insurance scheme for patients harmed as a result of medical errors. In 2005 the so-called ‘no-fault’ compensation reforms waived the requirement for medical error and extended eligibility to all treatment injuries regardless of error or injury rarity and severity. 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. [↑](#footnote-ref-31)
32. Council of Australian Governments 2017, ‘COAG meeting communiqué, 9 June 2017’, viewed 12 February 2018, <<https://www.coag.gov.au/meeting-outcomes/coag-meeting-communique-9-june-2017>>. [↑](#footnote-ref-32)
33. Mr Evans states ‘I am a legal practitioner and I have assisted clients in the health sector with respect to clinical incident management, system reviews and open disclosure for over 20 years, as well as managing subsequent civil compensation claims and coronial inquests. During this time I have seen the introduction of statutory RCAs in New South Wales (approximately 13 years ago) and Queensland (approximately 10 years ago).’ [↑](#footnote-ref-33)
34. This was noted in the Access to Justice Review in the context of its recommendation in relation to the apology laws. [↑](#footnote-ref-34)
35. Dalton, D & Williams, N 2014, *Building a culture of candour: a review of the threshold for the duty of candour and of the incentives for care organisations to be candid*, viewed 12 February 2018, <<https://qi.elft.nhs.uk/resource/building-a-culture-of-candour/>>. [↑](#footnote-ref-35)
36. Australian Commission on Safety and Quality in Health Care 2012, *Open Disclosure Standard: review report*, Commonwealth of Australia, viewed 12 February 2018, <<https://www.safetyandquality.gov.au/publications/open-disclosure-standard-review-report/>>. [↑](#footnote-ref-36)
37. These form a condition of an organisation’s licence. [↑](#footnote-ref-37)
38. This body is responsible for the Victorian Audit of Surgical Morbidity and Mortality. [↑](#footnote-ref-38)