Submission to the Victorian Government on its proposed duty of candour law:

Strengthening quality and safety in health care delivery

8 April 2021

Thorne Harbour Health

Thorne Harbour Health is one of Australia's largest community-controlled health service providers for people living with HIV, and the lesbian, gay, bisexual, trans and gender diverse, intersex, queer, and other diverse (LGBTIQ+) communities. Thorne Harbour Health primarily services Victoria and South Australia, but also leads national projects. Thorne Harbour Health works to protect and promote the health and human rights of LGBTIQ+ people and all people living with HIV.

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1. Introduction

A cluster of perinatal deaths in 2013 and 2014 in Victoria initiated the *Targeting Zero* report into minimising avoidable patient harm. The report recommended a duty of candour – a statutory obligation for hospitals and certain health services to admit when a serious harm was caused to a patient, offer an apology, and detail the actions taken to minimise the event from occurring in the future. An Expert Working Group was convened to provide advice on the legislative reforms arising from the *Targeting Zero* report, and the Group's findings, along with the government's response, were published in December 2020.

As the state's largest community-controlled LGBTIQ+ and HIV health service, Thorne Harbour Health welcomes the opportunity to contribute to Safer Care Victoria's consultation into the proposed statutory duty of candour.

This submission discusses balancing the interests of the relevant stakeholders to be covered by the proposed Victorian duty of candour legislation and guidelines, and considers the broader approach to policy development and implementation, drawing on international lessons learned in the development of duty of candour legislation and guidelines overseas.

2. Summary of recommendations

1. Acknowledge the continuum of care required during the apology process; it is not a one-off interaction.
2. Tailor the apology process in a way that is culturally sensitive and maintains trust with the patient and family.
3. Incorporate open disclosure and duty of candour knowledge into the early and ongoing education of health care professionals.
4. Comprehensively support health care professionals while fulfilling duty of candour requirements.
5. Learn from the experiences and attitudes of health care professionals overseas that have undergone a duty of candour process, so that Victoria does not repeat similar mistakes.
6. Ensure sufficient and ongoing training, education and support for health care organisations seeking to enact cultural change.
7. Reform apology laws in step with New South Wales and Queensland, but ensure the apology is admissible in court as evidence.
8. Collaborate with international jurisdictions in policy design that have implemented similar laws and learn from their mistakes.
9. In the early stages of implementation, work closely with one hospital or department to develop a case-study as an educational and capacity building tool.

3. Balancing stakeholders interests

In the past 20 years, open and compassionate disclosure of medical errors has become increasingly foregrounded as critical to promoting patient care, safety and professional learning.[1] At this early stage in government consultation, most concerns regarding the proposed legislation and guidelines involve balancing the interests of three groups of stakeholders: 1) the patient and family, 2) health care organisations, and 3) health care practitioners and colleagues.[2]

3.1. Patients and families

From the perspective of patients and families, a trade-off could be perceived as occurring, in which their legal rights are being diminished for a greater benefit to public safety. Namely, improved transparency in the communication of medical errors would encourage professional learning and promote future patient safety, but potentially limit a patient and their family's ability for legal recourse.

For example, the Expert Working Group proposed that incident reporting not be admissible in court as evidence, nor subject to Freedom of Information requests, so as to create an environment in which frank discussion of medical errors can occur. The patient's rights could be further diminished should their right to declare a medical harm not be provided for in legislation. In order to compensate for this decreased power to seek legal redress, the patient and family will require comprehensive and culturally tailored support throughout the apology process.

A patient's expectations in an apology can be formed in the lead up to the disclosure, as well as throughout the follow up support after the disclosure is made.[3] Furthermore, an apology is often only perceived as sincere when an admission of fault is explicitly made.[4] This time-sensitive continuum of care throughout the disclosure process can make it difficult to maintain trust and meet a patient's expectations. Therefore, health care organisations need to have the will and skills to tailor each disclosure event to the specific and unique needs of the patient and family. This includes, for example, an understanding of the unique and diverse experiences of individuals from LGBTIQ+ communities, who have and can experience adverse interactions with health care professionals whose cultural competency remains poor.[5]

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[1] Harrison, Reema et al, 'Enacting Open Disclosure in the UK National Health Service: A Qualitative Exploration' (2017) 23(4) *Journal of Evaluation in Clinical Practice* 713; Wu, Albert W et al, 'Disclosure of Adverse Events in the United States and Canada: An Update, and a Proposed Framework for Improvement' (2013) 2(3) *Journal of Public Health Research* 186

[2] Holmes, Alice et al, 'The Potential for Inadvertent Adverse Consequences of Open Disclosure in Australia: When Good Intentions Cause Further Harm' (2019) 59(4) *Medicine, Science and the Law* 265

[3] Iedema, Rick et al, 'Patients' and Family Members' Experiences of Open Disclosure Following Adverse Events' (2008) 20(6) *International Journal for Quality in Health Care* 421

[4] Mazor, Kathleen M et al, 'Health Plan Members' Views about Disclosure of Medical Errors' (2004) 140(6) *Annals of Internal Medicine* 409

[5] Malik, Saba et al, 'In Our Own Words: A Qualitative Exploration of Complex Patient-Provider Interactions in an LGBTQ Population' (2019) 2(2) *Canadian Journal of Bioethics* 83; Bonvicini, Kathleen A, 'LGBT Healthcare Disparities: What Progress Have We Made?' (2017) 100(12) *Patient Education and Counseling* 2357

Recommendation 1

Acknowledge the continuum of care required during the apology process; it is not a one-off interaction.

Recommendation 2

Tailor the apology process in a way that is culturally sensitive and maintains trust with the patient and family.

3.2. Health care professionals and colleagues

The majority of the peer-reviewed research into duty of candour legislation and open disclosure has focused on the perspective of health care professionals.[6] Research conducted in the UK after the introduction of their duty of candour legislation found that perceiving open disclosure as a moral and professional duty is one of the greatest enablers of open disclosure.[7] Therefore, integrating open disclosure into the earliest stages of a health professionals' education and incorporating it into ongoing professional development will be critical.

Gathering insights from international jurisdictions will be important for the effective implementation of duty of candour laws in Victoria. For example, many health professionals in England, where a duty of candour has existed for six years, can perceive open disclosure as a "blame-allocation device",[8] where initiatives intended for learning and improvement can become or are perceived to be performance management tools. This is made even more challenging in the high-stress and fast-paced environment of a hospital, in which changing institutionalised routines and norms is difficult.

Overseas examples of open disclosure efforts suggest that health professionals may be concerned about aggravating the patient's harm, especially if the disclosure is not done well or they are unfamiliar with the process.[9] Support is therefore needed for health professionals as the duty of candour is implemented.

[6] Busetti, Federico et al, 'Policies and Practice in the Disclosure of Medical Error: Insights from Leading Countries to Address the Issue in Italy' (2021) 61(1) *Medicine, Science and the Law* 88
[7] Harrison, Reema et al, 'Enacting Open Disclosure in the UK National Health Service: A Qualitative Exploration' (2017) 23(4) *Journal of Evaluation in Clinical Practice* 713
[8] Martin, Graham Paul, Sarah Chew and Mary Dixon-Woods, 'Senior Stakeholder Views on Policies to Foster a Culture of Openness in the English National Health Service: A Qualitative Interview Study' (2019) 112(4) *Journal of the Royal Society of Medicine* 153
[9] Kaldjian, Lauris Christopher, 'Communication about Medical Errors' (2020) *Patient Education and Counseling*

Recommendation 3

Incorporate open disclosure and duty of candour into the early and ongoing education of health care professionals.

Recommendation 4

Comprehensive support is needed for health care professionals while fulfilling duty of candour requirements.

Recommendation 5

Learn from the experiences and attitudes of health care professionals overseas that have undergone a duty of candour process, so that Victoria does not repeat similar mistakes.

3.3. Health care organisations

The health care organisations affected by the proposed legislation will be tasked with integrating the duty of candour legislation and guidelines into day-to-day operations. Barriers to implementation can occur on personal, institutional and societal levels.[10] These can include the fear of litigation or uncertainty over medico-legal implications, organisational resistance to change, a lack of policy clarity, and a lack of training or education.[11]

Monitoring and sanctions will also be an important consideration in the implementation of duty of candour legislation. There have been some high profile and recent cases of fines given to hospital trusts in England for not appropriately disclosing when an adverse medical event occurred.[12] While the Expert Working Group recommended not introducing a punitive approach to breaches, citing that sanctions would decrease disclosure, a lack of consequences for not disclosing could also decrease disclosure, as there would be no disincentive for failing to disclose. If this is coupled with the patient having no legislative provision to declare a medical harm the problem of lack of disclosure will only be compounded.

[10] Perez, Bianca et al, 'Understanding the Barriers to Physician Error Reporting and Disclosure: A Systemic Approach to a Systemic Problem' (2014) 10(1) *Journal of Patient Safety* 45
[11] Harrison, Reema et al, 'Open Disclosure of Adverse Events: Exploring the Implications of Service and Policy Structures on Practice' (2019) 12 *Risk Management and Healthcare Policy* 5
[12] Dyer, Clare, 'Plymouth Trust Is First to Be Fined for Breaching Duty of Candour Rules' (2020) 370 *BMJ m3737* <http://www.bmj.com/content/370/bmj.m3737.abstract>

While the Australian Open Disclosure Framework was adopted in 2013, open disclosure rates remain as low as 18% for those over 45 years old who experience an adverse event.[13] This is partly attributable to the non-mandatory enforcement of the framework.[14] The statutory duty of candour seeks to increase the disclosure rate, however, addressing barriers to disclosure and ensuring a sufficient network of training, education and support that is tailored to the heterogeneous nature of health care organisations will be critical for successful policy uptake. The importance of health care organisations is expanded upon in the following section.

Both the Victorian Ombudsman in 2017[15] and the Government's *Access to Justice* review in 2016[16] recommended reforms to apology laws in Victoria. Currently, an apology is defined as "an expression of sorrow, regret or sympathy but does not include a clear acknowledgment of fault."[17] An apology is protected from an admission of liability where death or injury has occurred.[18] Reforms to apology laws in the *Wrongs Act* Vic (1958) are seen as necessary because ascribing liability has created uncertainty over whether or when an apology can be made, especially from insurers and public servants. It is believed that this uncertainty is hindering efforts towards genuine conflict resolution.

The duty of candour Expert Working Group similarly recommended that apology laws should not constitute an admission of fault, which matches similar legislative changes in NSW and Queensland. The Victorian Ombudsman's report in 2017 found that such reforms have been "without apparent problems."[19] The Expert Working Group argued that efforts towards transparency with a duty of candour would be undermined if legislative clarity is not provided in this respect. However, to balance the interests of the patient and the health care provider, the Expert Working Group recommended that the apology should still be admissible as evidence in court, without conferring liability or fault. Given the proposed significant increase in protections for health care providers through the inadmissibility of incident investigations and protections from applications for freedom of information, while it should not ipso facto be an admission of liability, an apology should be admissible as evidence in court.

Recommendation 6

Ensure sufficient and ongoing training, education and support for health care organisations seeking to enact cultural change.

[13] Iedema, Rick et al, 'Patients' and Family Members' Experiences of Open Disclosure Following Adverse Events' (2008) 20(6) *International Journal for Quality in Health Care* 421
[14] Op cit. 2
[15] Victorian Ombudsman, *Apologies* (Report, 2017) <https://assets.ombudsman.vic.gov.au/assets/Best-Practice-Guides/Apologies.pdf?mtime=20191217142411>
[16] Government of Victoria Department of Justice and Regulation, *Access To Justice Review* (Report, 2016) <https://s3.ap-southeast-2.amazonaws.com/hdp.au.prod.app.vic-engage.files/9814/8601/7130/Access_to_Justice_Review_-_Summary_and_recommendations.PDF>
[17] *Wrongs Act* 1958 (Vic) Part IIC
[18] Ibid 14J
[19] Op. cit. 15, 13

Recommendation 7

Reform apology laws in step with NSW and Queensland, but ensure the apology is admissible in court as evidence.

4. Policy design and implementation

While the government's processes of policy development through the *Targeting Zero* report, the Expert Working Group, and now community consultation are critically important, there are two inherent assumptions: First, that striking the correct balance of interests will create a policy environment in which stakeholders will want to implement or maximise efforts towards open disclosure and transparency; Second, that the current top-down approach (namely creating a policy framework through legislation and guidelines and hospitals implementing them) will lead to improved patient care, safety and professional learning.

In challenging the first assumption, a duty of candour came into force in late 2014 in England that similarly sought to balance stakeholders' interests. Six years on, while there is a general consensus that this has been a positive move,[20] there have also been numerous criticisms, from a lack of enforcement and monitoring to the process becoming a 'box-ticking' exercise for some hospitals.[21] The Victorian Government is now in a position to learn from the policy mistakes of England's duty of candour process. Therefore, collaborations should be sought such that knowledge transfer can occur to ensure the same mistakes are not repeated in Victoria.

In challenging the second assumption, an important case study of successful improvements to patient safety is the Virginia Mason Institute.[22] The hospital has significantly decreased insurance premiums and encouraged an organisational culture of transparency and openness to improve patient outcomes by ensuring:

- staff feel safe reporting a patient safety event without punitive consequences;
- every reported incident is given equal importance in investigation;
- staff are supported throughout the reporting incident;
- leadership and management are actively involved;
- staff take ownership in constant improvements to the disclosure process; and
- individuals and teams are recognised for modelling desired behaviours.

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[20] Martin, Graham Paul, Sarah Chew and Mary Dixon-Woods, 'Senior Stakeholder Views on Policies to Foster a Culture of Openness in the English National Health Service: A Qualitative Interview Study' (2019) 112(4) *Journal of the Royal Society of Medicine* 153

[21] Peter Walsh, 'The Duty of Candour – where are we now?', Professional Standards Authority (Blog, 2020) <https://www.professionalstandards.org.uk/news-and-blog/blog/detail/blog/2020/01/30/the-duty-of-candour-where-are-we-now>

[22] Virginia Mason Institute, Case Study | Embedding a System to Protect Patient Safety, (Website, 2018) <https://www.virginiamasoninstitute.org/resource/embedding-a-system-to-protect-patient-safety/>; Nelson-Peterson, Dana L and Carol J Leppa, 'Creating an Environment for Caring Using Lean Principles of the Virginia Mason Production System' (2007) 37(6) JONA: *The Journal of Nursing Administration* 287

This is an example of one hospital enacting cultural change through all levels of staff and management in order to prioritise patient safety. If a duty of candour is legislated in Victoria, each hospital will have a different approach in their implementation, which could lead to significant uncertainty and variability.

In the early stages of this policy implementation, a similar case study approach could be taken, in which Safer Care Victoria works closely with one hospital or a department of a hospital to develop their duty of candour procedures. This would better inform and build experiential awareness and capacity within both the hospital and Safer Care Victoria, to have an on-the-ground understanding of how the legislation and guidelines can be implemented. It would also result in a case-study other hospitals and Safer Care Victoria can refer to as an educational tool.

Directing resources intensively to one hospital or department, rather than broadly across the health sector, would be a slower but more thorough process. While this is still a top-down approach, a case-study that builds capacity in stakeholders would be a helpful tool for the significant cultural change required in successfully implementing the duty of candour across the health sector.

Recommendation 8

Collaborate with international jurisdictions in policy design that have implemented similar laws and learn from their mistakes.

Recommendation 9

In the early stages of implementation, work closely with one hospital or department to develop a case-study as an educational and capacity building tool.

5. Conclusion

Thorne Harbour Health supports the Victorian Government's move to introduce a statutory duty of candour. Open disclosure and the proposed duty of candour legislation seek to improve a system that has, for too long, hidden medical errors and limited learning. In seeking to redesign this system, a comprehensive and tailored understanding of patients' expectations throughout the disclosure process will be critical, with support both before and after the event. Additionally, training, education and support of health care professionals and organisations will be fundamental to translating policy into practice that recognises the heterogeneity of the health sector and encourages stakeholders to want to genuinely institute cultural change.