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A Victorian statutory duty of candour

VHA submission

1 December 2017

The Victorian Healthcare Association (VHA) welcomes the opportunity to provide feedback to the Victorian Government's consultation paper (the paper) on the introduction of a statutory duty of candour to health services.

The VHA notes that while the responses offered in this submission have been developed and informed by direct input from the VHA's members, this submission should not be seen to override any submission made by our individual member organisations, whose specific concerns and considerations may differ from those that have been highlighted here.

The VHA invited its members to participate in this consultation, and held direct meetings with and received written submissions from 11 hospitals and community health services, ranging from specialist and tertiary health services in metropolitan Melbourne to metropolitan and rural community health services, and rural public hospitals.

The VHA agrees to this submission being made available publicly.

1. Introduction

The publication of *Targeting Zero - Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care, Report of the Review of Hospital Quality and Safety Assurance in Victoria* marked a significant point in the evolution of the Victorian health system. The events that triggered the review of hospital safety and quality assurance were tragic and the final report offers a roadmap that restructures the roles, responsibilities and mechanisms that provide oversight to clinical governance, incident management and response.

A key theme in Targeting Zero was the need to move towards a system that is defined by openness, a focus on continuous quality improvement and one that elevates that experience and the needs of its consumers.

Identifying and responding to incidents of harm that occur during the provision of healthcare is an essential component of a system that is consumer focused, and is strongly supported by the VHA and its members.

Currently, health services are mandated to have in place an open disclosure policy, both as a requirement of accreditation under the Australian Commission on Safety and Quality in Health Care's (ACSQHC) National Safety and Quality Health Service (NSQHS) Standards, and as part of their funding and service agreement with the Department of Health and Human Services (the department). These requirements provide for a clear responsibility to undertake and implement open disclosure; however the VHA notes that the requirement for implementing an open disclosure policy alone does not necessarily provide sufficient clarity and guidance about precisely when open disclosure should be undertaken.

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.

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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.

2. Response to consultation questions

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

The VHA submits that the statutory duty of candour should apply to health services described in schedules 1-5 of the Health Services Act 1988 (the Act), as recommended in Targeting Zero.

There are potential complications to a broader application outside of health service settings, the first being the lack of a consistently applied incident reporting framework across other agencies. Public hospitals and registered community health services, for example, deliver a broad range of government-funded services, including acute and sub-acute health services, but increasingly with a focus on social and community services. Many of the social and community services are governed by the Client Incident Management System (CIMS), which while playing a similar role to the health-focused Victorian Health Incident Management System (VHIMS), is fundamentally different in its categorisation of incidents and the prescribed response and reporting framework that accompanies them.

A further complicating factor in applying the statutory duty in a community health service setting is the use of VHIMS and CIMS being defined largely along programmatic lines, rather than an organisational delineation. For example, an integrated health service with a substantial acute and sub-acute service mix will categorise and report incidents through VHIMS, while their community health service's alcohol and other drug service would categorise and report through CIMS.

The points above would need to be clarified and understood before any legislative amendments are drafted and community health services and other non-hospital organisations are included.

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

The VHA notes that there are advantages in expanding the application of the duty of candour to other health and community services, including the community sector, ambulance services, registered community health services, residential aged care facilities and general practitioners. Doing so would ensure there is a consistent understanding and application of both open disclosure and the statutory duty across all key service providers of the Victorian health system and, importantly, it would ensure consistency for consumers accessing these services.

However, and as noted at 2.1, there are potential complications to a broader application outside of health service settings, including the lack of a consistently applied incident reporting framework across other agencies. Also, clarity relating to community health services broader role within the health system must first be clearly defined and consideration given to the cost of implementing these changes in such a setting.

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

The VHA submits that the statutory obligation should only apply to organisations, not individuals.

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While employees as agents of the health service will undertake the *act* of open disclosure and apology to a harmed individual, it is important that it is on behalf of the health service and in a way that is consistent with that health service's policies and procedures.

The VHA believes that applying the statutory duty of candour to individuals would not improve the *act* of open disclosure. Additionally, it would create confusion about which individual in a multi-disciplinary team would be responsible for complying with the statutory obligation and, most importantly, undermines the principle of a consistent and comparable regime applied across all in-scope health services.

If the obligation was to fall on individuals, there is a risk that it could act as a disincentive to practitioners who are concerned about the medico-legal risks.

Applying the obligation to organisations would allow sufficient flexibility for a health service's executive, legal counsel and clinical leaders to assess each incident and ensure that the act of open disclosure is undertaken by the appropriate employees and in doing so, meet the needs of the consumer who has been impacted.

Furthermore, while existing open disclosure policies and the proposed statutory duty of candour have at their core the intent to improve communication and transparency with consumers, health services have a duty of care towards their employees.

For example, following an incident involving a medical intern that meets the threshold for the statutory duty, the VHA suggests that placing the obligation on that intern is inappropriate and would not serve the best interests of either the consumer, the employee, or the health service. Rather than drafting legislation that would mandate that a junior employee be obliged to undertake an open disclosure, the VHA suggests that it would be more appropriate for the health service to determine which member of staff is best placed to participate, to ensure the consumer's needs are met.

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

The VHA submits that objectivity and clarity are necessary features of an open disclosure framework, namely that the decision-making process of the health service's employees is unambiguous when determining incidents of harm and the approach to open disclosure.

Existing open disclosure policies and procedures should not necessarily be changed by the introduction of a statutory duty; a culture of candour and honest communication should be a foundation of a health service's interactions with its consumers.

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.

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.

If the statutory duty of candour is applied to a broader set of organisations, particularly those that use CIMS or currently do not have a standardised incident reporting framework, in-depth consultation should be

undertaken to ensure the thresholds are equivalent with the aim of generating consistency between organisations and not placing some at an unfair disadvantage.

Should the statutory duty apply to a broader set of organisations than those recommended in Targeting Zero, an issue that would require close focus from the Victorian Government relates to which agency would adopt the centralised role that SCV currently undertakes for hospitals.

It may be possible to broaden SCV's scope to include oversight of community sector providers; the VHA notes that this would represent a substantial extension of SCV's role and would need consultation with in-scope organisations, the community sector and SCV.

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

The VHA 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, the VHA 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.

A key component of health services' approach to open disclosure is ensuring that the adverse event in question is assessed and understood, and ascertaining whether the health service and its employees were liable for the harm that has occurred.

When identifying adverse events that result in harm to a consumer, it is essential that the health service can identify what caused the harm, whether it was preventable and what steps will be taken to ensure it is not repeated.

These factors are core components of providing safe, consumer-centred and appropriate health services and building and maintaining a culture that fosters continuous improvement in the quality and safety of the care and health services that hospitals provide.

When considering applying the statutory duty of candour to instances of psychological harm, the VHA cautions that it can be unclear if the care received in a health service is responsible for the resultant psychological harm.

According to the Victorian Auditor-General's Office, the average length of stay in large Victorian public hospitals between 2011-12 and 2013-14 was 3.6 days, with variations based largely on casemix and complexity of consumers.[1] This is a relatively short period of time within which to fairly attribute responsibility for psychological harm done to a consumer, particularly in cases of consumer declared harm brought to the health service's attention after the separation in question has concluded.

The VHA notes that there may be subsequent instances of psychological harm that result from adverse events and it is important that they are acknowledged and managed, including via providing access to counseling and mental health services, when appropriate. This extends to an acceptance that open disclosure processes may be an appropriate means of informing consumers of harm, however this should remain part of the broader open disclosure framework and not within the threshold of the statutory duty.

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[1] Victorian Auditor-General's Office, *Hospital Performance: Length of Stay,* February 2016. https://www.audit.vic.gov.au/sites/default/files/20160210-Length-of-Stay.pdf

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2.6.1. Should the statutory duty of candour apply to near misses and/or complications of treatment that result in no harm and/or no lasting harm?

The VHA submits that the statutory duty should not apply to near misses and/or complications of treatment that result in no harm and/or no lasting harm. As noted, clarity and consistency is needed when framing the statutory duty of candour if the Victorian Government is to ensure that principle six (*unintended adverse consequences and administrative burden associated with implementation of the statutory duty of candour should be minimised*) is upheld.

In addition, the current trigger for undertaking open disclosure is appropriate, namely that the actions of the health service resulted in an adverse event that caused harm to a consumer.

Broadening this to include 'near misses and/or complication of treatment that result in no harm and/or no lasting harm' would add to the administrative burden without clearly improving the experience and wellbeing of the consumer.

If during the analysis of a recorded incident, a health service determines that due to complications experienced by the consumer, an open disclosure process should be undertaken, they should continue to be empowered to do so.

However, given the range of circumstances to which 'near misses' or 'complication of treatment resulting in no harm and/or no lasting harm' could reasonably apply, the VHA recommends that these circumstances remain covered by the existing open disclosure framework, rather than it being mandated under the statutory duty.

2.6.2. Should it apply where the wrong treatment was given or non-evidence-based treatment was given if there is no harm as a result?

It is preferable that the thresholds for triggering the statutory duty are clear, replicable and easily understood. Additionally, the key criteria should be that a consumer has experienced preventable harm.

The VHA is aware of some treatments that have had their therapeutic benefit questioned, for example the use of therapeutic ultrasound to treat musculoskeletal injuries, pain and soft tissue lesions[2] and arthroscopic debridement for osteoarthritis of the knee.[3]

While these treatments may not have a robust evidence basis, if their use results in no harm to the consumer, it is unclear what benefit would be gained if it were to be considered a trigger to initiating an open disclosure under the statutory duty.

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

A statutory duty of candour should not have the unintended consequence of reducing the ability of a consumer to declare that harm has occurred.

However, the intent of open disclosure is to ensure health services and their employees commit to maintaining a culture of transparency, where incidents and errors are discussed with consumers or, in some cases, brought to their attention.

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[2] Robertson V., Baker K., *A Review of Therapeutic Ultrasound: Effectiveness Studies*, Physical Therapy, Volume 81, Issue 7, 1 July 2001, Pages 1339–1350, https://doi.org/10.1093/ptj/81.7.1339

[3] Duckett, S., Breadon, P., Romanes, D., Fennessy, P., Nolan, J., *Questionable care: Stopping ineffective treatments*, Grattan Institute, 2015, https://grattan.edu.au/wp-content/uploads/2015/08/828-Questionable-Care2.pdf

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In this context, it is not clear as to how 'consumer declared harm' should trigger a statutory duty of candour, particularly if the threshold for triggering the duty is set at a level where objective measures of harm are clear.

It is entirely appropriate that consumers, family members and/or carers be empowered to approach a health service or other statutory body to raise concerns about the care they have received, or the outcome of their stay in hospital. But these processes should be separate to a health service undertaking an open disclosure process with a patient who has been harmed during care.

Prima facie, 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 VHA notes that 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.

It is unclear, however, 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.

Therefore, the VHA does not agree that consumer declared harm should trigger the statutory duty, however, the VHA 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.

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

The VHA submits that each clinical incident and occurrence of harm is different and as such requires a tailored response. Prescribing in statute how an open disclosure process should be undertaken will be inherently unwieldy and may result in a mandated process that is not appropriate for each circumstance in which it is required.

The suggestion that mandatory requirements could be set out in a subordinate instrument is a more appropriate approach, as it will allow the requirements to be adjusted with more flexibility compared to those set in statute.

In terms of the core elements that are included as a requirement of open disclosure, the VHA again notes the need for consistency and clarity. Hospitals and community health services are currently accredited against the NSQHS standards and the Australian Open Disclosure Framework, which serves as an appropriate benchmark for determining what elements should be required. It is appropriate that this Framework continues to form the basis of the Victorian approach to open disclosure.

It is preferable that senior employees are involved in the open disclosure process, where appropriate. The VHA understands that consumers may seek the opportunity to engage directly with the employees involved in their care, even if these employees are relatively junior. As noted, health services take seriously their duty of care to all employees, and in many cases may decide that people directly involved in a challenging or traumatic incident are not best-placed to manage an open disclosure process.

As such, the VHA does not support stipulating which people should be involved in an open disclosure, either in legislation or subordinate instruments. There may, however, be scope to suggest that the people who manage the process are appropriately trained to do so.

The VHA offers caution about stipulating the types of documentation required in this process. There may be instances when sharing information with a consumer may breach the privacy of another person or health

service employee. This risk can be managed on a case by case basis, but it should be left to the discretion of the health service.

England's Care Quality Commission's regulations are appropriate in that the documentation is focused on relevant information, specifically related to the events that cause the patient harm, any enquiries undertaken and their results, details of conversations between the health service and the consumer, and an apology.

Regarding the timeliness of open disclosure, the VHA supports an approach that promotes meaningful and mutually beneficial open disclosure. This may mean that a consumer is notified immediately after an incident has occurred; in other instances, it may be practical for the health service to gather relevant information to ensure any and all questions can be answered accurately.

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

The VHA and its members seek clarity around the interactions and roles of other entities that may receive notifications of 'consumer declared harm', and how a health service would be expected to respond. For example, complaints about care, including allegations of harm, are made to the department, SCV, the Health Complaints Commission, local members of parliament, health services, and the media. It is unclear how complaints or notifications made through 'alternative' channels will be assessed, and the degree to which health services will be held accountable.

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. The VHA 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.

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

Generally speaking, the VHA believes that the barriers and enablers identified in the paper are accurate.

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

The VHA suggests that clarity regarding the threshold triggers of the statutory duty is an essential factor, particularly if the threshold is set at a higher level than has been canvassed in the paper.

Training for board directors, executives and employees of health services is needed to ensure they understand what their responsibilities are regarding the act of candour in all interactions with consumers, and how this relates to the proposed statutory duty.

The intended aim of open disclosure and the proposed statutory duty must be broader than simply a means of improving communication between consumers and health services.

Transformational improvement to the quality and safety of the Victorian health system should continue to be a goal to which open disclosure contributes. To ensure its success, the Victorian Government must commit resources so that health services can appropriately respond to any additional administrative requirements that result from the statutory duty and, importantly, ensure that a centralised analysis and reporting of systemic risks that led to harm or near misses is undertaken.

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2.12. How can the necessary training best be delivered?

The VHA recommends that following legislative change, a single source of information, resources and tools that informs both health services and consumers must be readily available via the department website.

It will not be practicable for the department to offer in-depth training to all employees of public hospitals, however there will be a need for key leaders at board and executive level to have a clear understanding of both the role of open disclosure and its interaction with the proposed statutory duty. This responsibility, and the cost of delivering the training, must not fall on individual health services and should be fully supported by the Victorian Government.

The VHA notes that the governance structures in health services differ, so it is not appropriate to prescribe which employees or board sub-committee chairs should attend training.

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

The support requirements identified in the paper are brief but appropriate.

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

Yes. The VHA's members have consistently reported that the existing apology laws are too vague and do not offer sufficient protection to allow a more useful conversation between a health service and a consumer during an open disclosure process.

Due to the limited definition of an apology, Victoria's apology laws offer little practical protection for organisations and individuals engaging in open disclosure.

The VHA suggests that the approach taken in other Australian jurisdictions, where expressions of regret carry greater protection, would be an appropriate model on which to base reforms to our existing apology laws.

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

The VHA submits that including statutory protections for open disclosure alongside the statutory duty of candour would remove a barrier for health professionals in undertaking open disclosure.

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

The VHA 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.

2.17. Are other statutory protections required?

The VHA does not have suggestions of additional protections at this time.

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

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.

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The VHA notes that compliance or otherwise with the statutory duty can only be practically identified if there are sufficiently clear definitions and thresholds about which events trigger the statutory duty and, therefore, accountability expectations.

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

The VHA holds significant concerns about proposals to introduce sanctions – either for individuals or organisations – in instances of routine (i.e. non-malicious or unintentional) breaches of the statutory duty.

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 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. The VHA suggests that these powers are significant and offer a meaningful incentive for health services to ensure they are compliant with the statutory duty.

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

Documentation requirements need to be set out clearly to allow health services to assess their current processes and determine, what, if any, changes are needed.

In terms of mandating process requirements, again, the VHA cautions against setting these in statute. Health services need to be able to determine whether final feedback after an open disclosure process has concluded is best undertaken via a face-to-face meeting, by correspondence or both.

About the VHA

The VHA is the not-for-profit peak body supporting Victoria's public health and community services to deliver high quality care. We represent public sector health services, hospitals, registered community health services, multi-purpose services, and bush nursing services.

Further information

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