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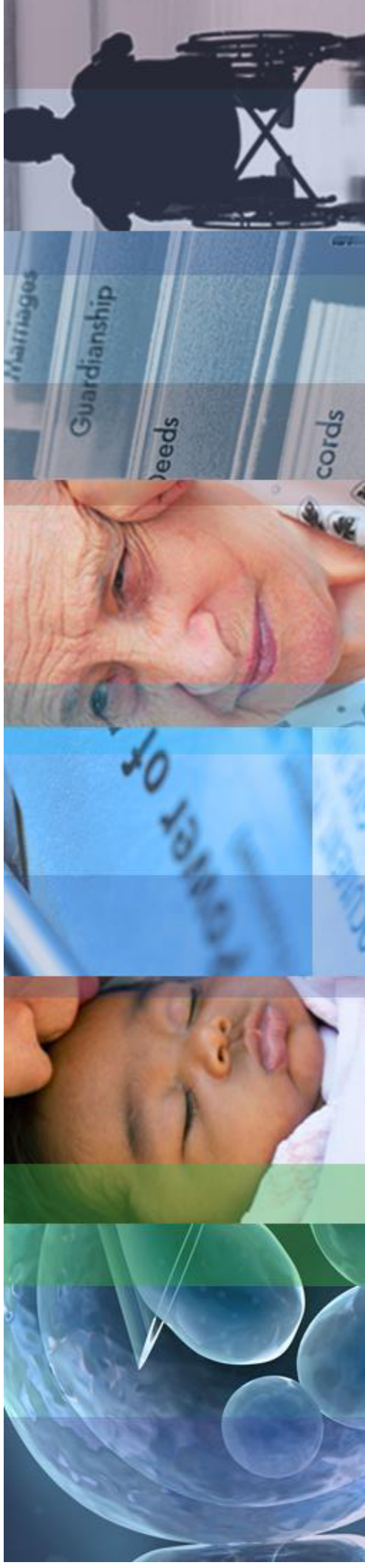
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Open disclosure and statutory duty of candour

Associate Professor Tina Cockburn
Australian Centre for Health Law Research

1. Disclosure of adverse events
 - ethics, policy and guidelines
2. Barriers and enablers for open disclosure
 - apology protections
3. Clinician failure to disclose adverse
 - disciplinary consequences and civil liability
4. Statutory duty of candour
 - UK experience and proposed legislation in Victoria





Open disclosure

Open disclosure is an open discussion with a patient about an *incident(s)* that resulted in *harm* to that patient while they were receiving health care.

Australian Commission on Safety and Quality in Health Care (2013), Australian Open Disclosure Framework. ACSQHC, Sydney

<http://www.safetyandquality.gov.au/wp-content/uploads/2013/03/Australian-Open-Disclosure-Framework-Feb-2014.pdf>



Adverse events

- **Adverse event:** means an *incident* in which *harm* resulted to a person receiving health care.
 - (used interchangeably with *harmful incident*)
- **Harm:** ‘[i]mpairment of structure or function of the body and/or any deleterious effect arising therefrom, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological.’
 - ACSQHC Open Disclosure Framework (2013)

- For patient safety terminology – see: William Runciman, Peter Hibbert, Richard Thomson, Tjerk Van Der Schaaf, Heather Sherman and Pierre Lewalle “Towards an international Classification for Patient Safety: Key terms and concepts” *International Journal for Quality in Health Care* 2009; Volume 21, Number 1: pp. 18–26



Adverse events happen

- Medical treatment is inherently risky and complex
- Adverse events occur in approx 10.6% of admissions (QAHCS 1995)
- 50-80% of adverse events may be preventable
- Not all adverse events involve negligence
- Adverse events mostly due to system error



Why disclose adverse events?

- Patient expectations
- Duty of candour
- Good clinical practice
- Health systems and individual service provision quality improvement
- Organisational and individual risk management benefits

“Open disclosure is a patient right, is anchored in professional ethics, considered good clinical practice, and is part of the care continuum.”

ACSQHC Open Disclosure Framework (2013) page 11



Dr Lucian Leape on disclosure and apologies in health care
<https://www.youtube.com/watch?v=bJLsh9VTLml>

Disclosure of adverse events: Ethics, Policy and Guidelines

•

Australian Open
Disclosure Framework
Better communication,
a better way to care



Duty of candour

“Honest, effective and open communication is the foundation of the relationship between clinicians and patients. Telling the truth is always the right thing to do. Concealing the truth is wrong.”

Barron and Kuczewski (2003)





Australian Medical Council

Good Medical Practice: A Code of Conduct for Doctors in Australia (2020)

4.11 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 professional indemnity insurer. Good medical practice involves:

4.11.1 Recognising what has happened.

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

4.11.3 Explaining to the patient as promptly and fully as possible in accordance with open disclosure policies, what has happened and the anticipated short-term and long-term consequences.

4.11.4 Acknowledging any patient distress and providing appropriate support.

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

National Safety and Quality Health Service (NSQHS) Standards for Accreditation

Clinical Governance Standard



Clinical Governance, which describes the clinical governance, and safety and quality systems that are required to maintain and improve the reliability, safety and quality of health care, and improve health outcomes for patients.

Patient safety and quality systems

Safety and quality systems are integrated with governance processes to enable organisations to actively manage and improve the safety and quality of health care for patients.

Incident management systems and open disclosure

1.12 The health service organisation:

- a. Uses an open disclosure program that is consistent with the Australian Open Disclosure Framework⁶
- b. Monitors and acts to improve the effectiveness of open disclosure processes





Open Disclosure: Elements

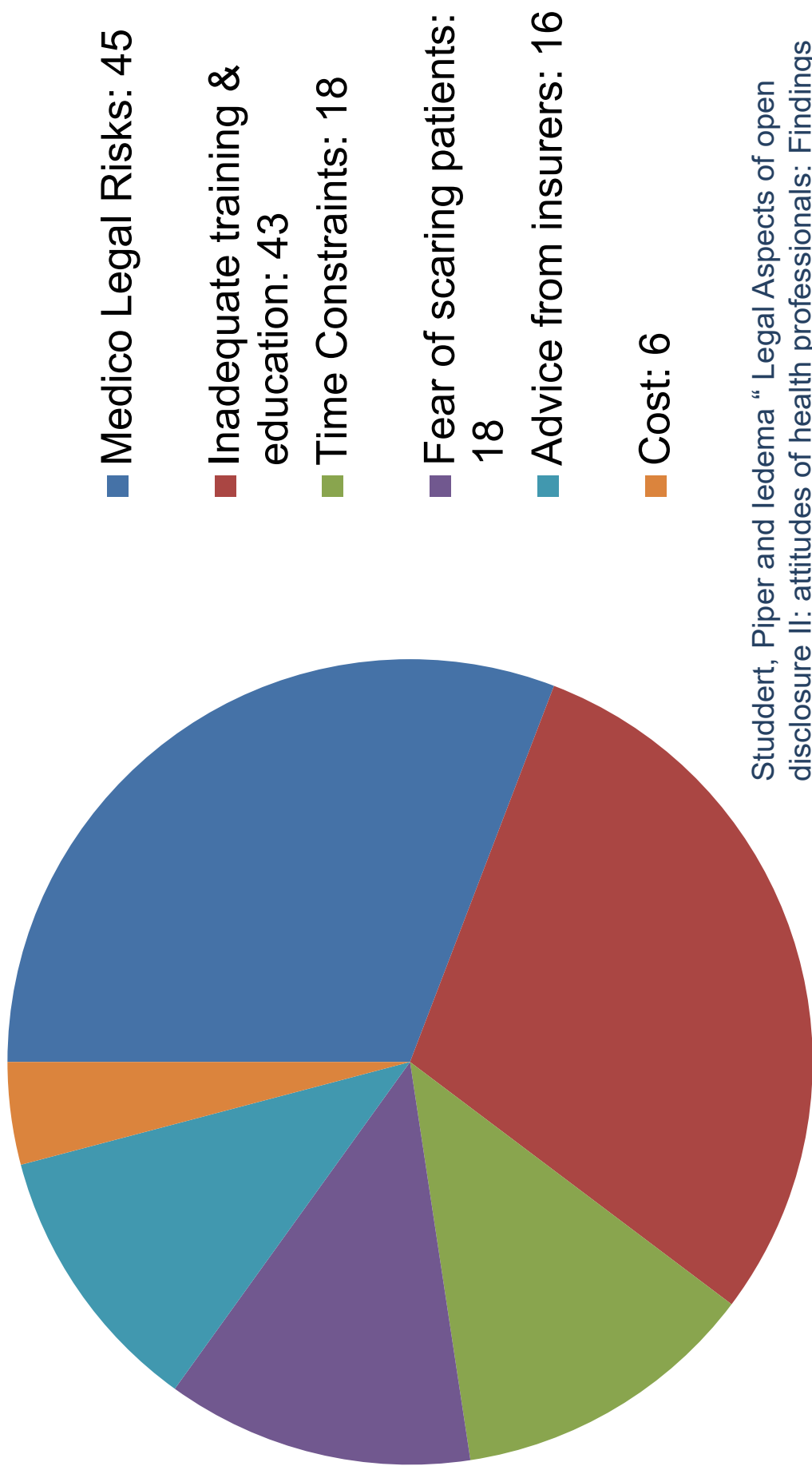
- an apology or expression of regret (including the word sorry)
- a factual explanation of what happened
- an opportunity for the patient to relate their experience
- an explanation of the steps being taken to manage the event and prevent recurrence.

– ACSQHC Open Disclosure Framework (2013)

Barriers to open disclosure: the incident disclosure gap



Barriers to open disclosure



Studdert, Piper and Iredema "Legal Aspects of open disclosure II: attitudes of health professionals: Findings from a national study" *MJA* 2010

Lowering the barriers to Open Disclosure

- Education & Information
- Leadership
- Promotion of benefits
- Realistic representation of risks

Source: Luke Slawomirski, Australian Commission on Safety and Quality in Health Care, “Review of the Open Disclosure Standard”, paper delivered at IIR Medicolegal Congress, Sydney, February 2013.)

> **Fostering ‘just cultures’** (not cultures of blame)

Health service organisations should create an environment in which all staff are:

- encouraged and able to recognise and report adverse events
- prepared through training and education to participate in open disclosure
- supported through the open disclosure processes

Australian Open Disclosure Framework Principles and Processes: 5. Supporting, and meeting the needs and expectations of those providing health care

Apologies



Apology of sympathy

- “I am sorry that this happened to you”
 - does not admit liability - facts but no conclusions
- *‘I am really sorry you had a reaction to drug X we prescribed you. As we explained when we asked you if you had ever taken it before, unfortunately you are one of the small number of people who react to this medication. We will make sure this allergy is recorded in your medical record and that you are never given this drug in the future. We will write down all its alternative names for you. Please make sure you advise other healthcare providers of this allergy in the future’*

- Example from Open Disclosure Standard Review Report (June 2012)
<https://www.safetyandquality.gov.au/sites/default/files/migrated/Open-Disclosure-Standard-Review-Report-Final-Jun-2012.pdf> p46



Apology of fault

- “I am sorry that I did this to you”
 - admits liability by admitting breach and causation.
- *“The nurse knew your husband, John, was allergic to penicillin, because it is written all over the notes; but she gave him the injection by mistake that caused him to have an anaphylactic reaction, from which he could not be resuscitated. We are very sorry about this incident”.*
 - Example from NSW Guidelines 2005, p11 (now superseded)

Do we need apology protections?

- A powerful barrier to effective implementation of open disclosure is not the law, but apprehensions held by providers regarding medico-legal risks associated with openness around adverse events.
 - Compounded by jurisdictional differences and confusion regarding relevant statutes.
- HOWEVER “... laws that make compassion inadmissible in court or protect truthful expressions of responsibility are unnecessary, they operate on ethically shaky grounds and risk diminishing the value of apologies and fuelling public cynicism towards the medical profession.”
 - Stuart R McLennan and Robert D Truog “Apology laws and open disclosure” *Med J Aust* 2013; 198 (8): 411-412.



***Dovuro Pty Ltd v Wilkins* [2003] HCA 51**

- D distributed canola seed contaminated with weed seed to growers during 1996
- D then issued media release:
 - “we apologise to canola growers and industry personnel. This situation should not have occurred.”
- D also wrote letter to growers referring to:
 - (its) “failing in its duty of care to inform growers of the presence of these weed seeds. We got it wrong in this case...”

Dovuro Pty Ltd v Wilkins (cont...)

HELD: D liable BUT statements in media release and letter could not be a basis for a finding of negligence

- such statements should be “used with caution by a fact finder”
- “consider precisely what it is that is being admitted. ”
- “statement cannot be an admission of law, and it is not useful as an admission of failure to comply with a legal standard of conduct. There is no evidence that the author of the statement knew the legal standard.”

– Gleeson CJ at [25]; see also Kirby J at [173]

Apology Protections

	Apology defn incl fault	Not admission of liability	Not relevant to fault	Not admissible evidence
ACT	X	X	X	X
NSW	X	X	X	X
Tas		X	X	X
WA		X	X	X
Qld	X	X	X	X (AND expression of regret inadmissible)
NT				X (expression of regret not admissible)
Vic		X		
SA	X	X	X	X

Based on Prue Vines "Apologising to Avoid Liability: Cynical Civility or Practical Morality" (2005) 27 *Sydney Law Review* 483 at 490, as amended following subsequent legislative changes. See: Bill Madden, Janine McIlwraith and Ben Madden, *Australian Medical Liability* (Lexis Nexis Butterworths, 4th ed, 2021 forthcoming)

Narrow construction of admission

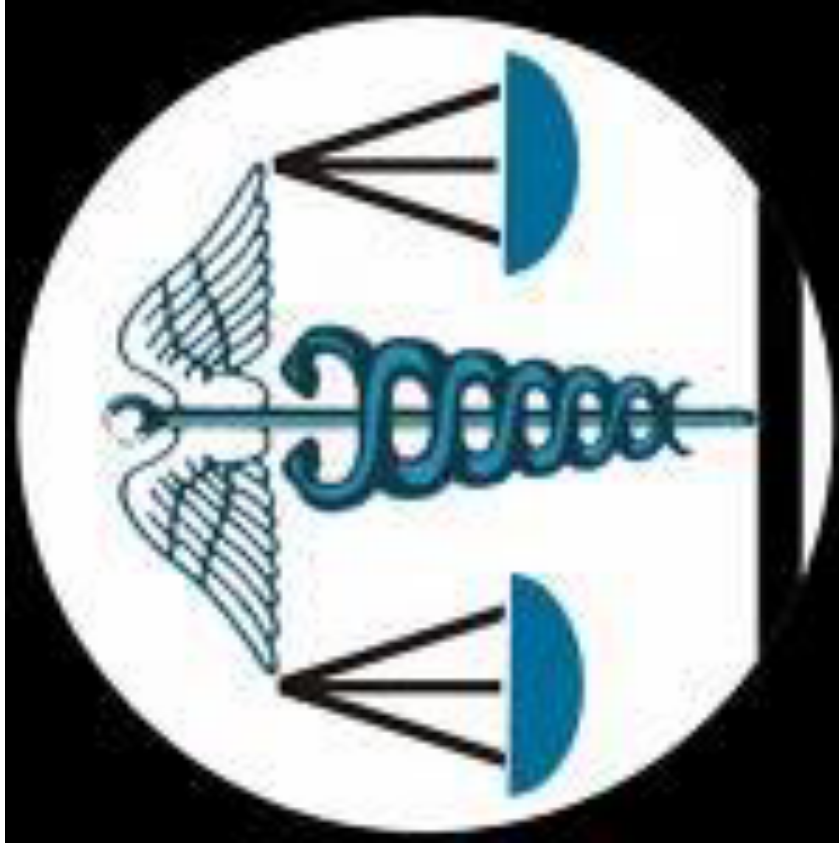
- ***Watson v Meyer* [2012] NSWDC 3**
- P attacked by D's horse while both out riding on P's property
 - negligence claim
- Evidence:
 - I said, "Did she have a fall from her horse?"
 - and he said, "No, it was my fault, my horse."
- Held: All that the defendant was saying was that the plaintiff had not fallen from her horse but had fallen because it was "my fault, my horse". That is not an admission about liability, but a description of the accident. Accordingly, the evidence does not amount to an admission. [244]

Hutchison v Fitzpatrick [2009] ACTSC 43

- the defendant ‘would not have been placing himself at risk by visiting the plaintiff or proffering an apology to him. If solicitors are still advising their clients not to apologise and not to visit or telephone or write to people who might sue them, notwithstanding part 2.3 of the [*Civil Law (Wrongs) Act 2002 (ACT)*], this would be regrettable.’

– Master Harper [32]

Clinician failure to disclose adverse events: Disciplinary action & Civil liability



- “Errors do not necessarily constitute improper, negligent, or unethical behaviour, but failure to disclose them may.”

- Ethics manual, fourth edition: disclosure. Ann Int Med 1998; 7: 576-94

Skidmore v Dartford & Gravesham [2003] UKHL 27

- During keyhole surgery to remove Mrs A's gall bladder, Dr S punctured artery
 - large blood loss
 - conversion to open surgery
 - short period of cardio-pulmonary resuscitation
 - 8 units of blood transfused during operation and 2 more units post operatively.
- Operation eventually completed successfully - full recovery
- Mrs A's husband sought explanation
 - Dr S blamed faulty instrument, suggested blood loss normal (only 2 units) and that Mrs A had not arrested or required resuscitation.
- Held: professional misconduct - Dr S deliberately misled Mrs A & her family



Tasmanian Board of the Medical Board of Australia v D [2014] TASHPT 1

- Pre-operative letters and operation note showed intention to perform surgical procedure at C3/C4 level.
- Post-operative imaging suggested that surgery had been carried out at different level (C2/C3)
- D met with patient on several occasions after surgery and provided advice to other treating doctors > failed to disclose that he had undertake surgery at wrong level of patient's surgical spine: [2] & [4]



Tasmanian Board of the Medical Board of Australia v D (cont...)

- [6] ... such adverse events are always possible in a surgical environment. ... However, the Tribunal is more concerned as to the professional misconduct aspect being the practitioner's failure to disclose the error that had been made. Not only does the failure of the respondent to disclose the error that he had made in a timely manner place the patient's physical and psychological health at risk but it also fell below the basic tenant required of the medical profession to be forthright, open and honest in relation to the performance of professional duties...

Tasmanian Board of the Medical Board of Australia v D (cont...)

- [10] “ ... no indication that the clinical skills and professional skills of D require remedial treatment or because of their unsatisfactory level there is a need to take steps to protect the general public in that regard. ... **There is, however, the more significant aspect of his failure to disclose this error. I accept that there is a need for a sanction that includes both a personal and general deterrent in order to uphold the reputation of the profession and I accept that this is achieved in the form of a period of suspended practice, a fine and an obligation that the respondent pays the costs associated with these proceedings. ... the Tribunal finds that D is guilty of professional misconduct following consideration of his conduct in his post-operative dealings with a patient ... conducted in a deceptive manner.** ”

Duty to provide proper medical treatment and advice

***Breen v Williams* (1994) per Bryson J**

“Informing a patient of what treatment has been given and what has taken place while doing so, whether or not there has been a catastrophe, is **integrally and necessarily part of giving medical treatment** to a person. One cannot stick a needle into a person and walk away wordless, as one would with a horse.”

Duty to provide reasonable aftercare and follow up

Wighton v Arnot [2005] NSWSC 367

- Dr A severed Ms W's right spinal accessory nerve during surgery
- Held: negligent failures to
 - inform patient of suspicion that he severed nerve
 - disclosure to patient's general practitioner may have sufficed
 - confirm he severed nerve by appropriate examination
 - refer patient to appropriate specialist for timely remedial surgery.
- Dr A may not have been held negligent if adverse event had been disclosed (negligent treatment not established)

Therapeutic Privilege?

“ Dr Arnot said that he did not tell the plaintiff ...because of her emotional state and because it was only a possibility that he had severed this nerve, and that possibility he considered to be ‘probably wrong’ because of his examination following surgery.

... I do not find the defendant’s explanation for not telling the plaintiff about the division of the nerve to be an acceptable explanation.”

Wighton v Arnot at [69] (Studdert J)



Do we need a statutory duty of candour in Australia?

“While most accept the moral case for candour, many stop short of supporting a legal duty, instead preferring to leave this as a matter for regulatory codes of conduct. However, given that ethical and policy guidance has largely failed to encourage greater disclosure, it is legitimate to consider a stronger statutory duty which should be taken more seriously.

Quick O “Regulating and legislating safety: the case for candour” *BMJ Qual Saf* 2014; 23:614 – 618

Statutory duty of candour (UK)

- *Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:*
20(1) "A health service body must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity".

Statutory duty of candour:

- to be open and honest with patients/families ('service users')
- when something goes wrong that **appears to have caused or could lead to significant harm in the future** (a notifiable safety incident)
 - Death
 - Severe or moderate harm
 - Prolonged psychological harm
- includes an account of all facts known about the incident, and a timely apology.
- applies to all health and social care organisations registered with the regulator, the Care Quality Commission (CQC) in England.

University Hospitals Plymouth NHS Trust re *Elsie Woodfield*

- UHP NHS Trust did not tell 91 yr old EW's family facts (after endoscopy went wrong and she died in Dec 2017 after a perforated oesophagus at Derriford Hospital, Plymouth) or apologise within a reasonable time
- Although UHP NHS had an incident policy, EW's death not categorised as a serious incident requiring investigation (as her death was a known complication of the procedure) - mistake meant UHP NHS did not follow its process for duty of candour.
- Successful prosecution for breach of statutory duty of candour 23 Sept 2020:
 - UHP NHS fined £1,600 (maximum £2,500 – guilty plea noted)
 - 10,854.43 costs order
 - £120 victim surcharge
 - £12 565 total



UHP NHS Trust re Elsie Woodfield

- District judge Joanna Matson
 - "Not only have [the family] had to come to terms with the tragic death, but their loss has been compounded by the trust's lack of candour. ... That communication was clearly not sufficient."
 - "significant failings in the leadership and governance framework"
 - "My view is that any fine in that range would be insufficient to deal with the extent of harm and distress that was caused to the family, but I am limited by the law."
 - "This offence is a very good example of why these regulatory offences are very important."
 - "I hope that something like this will never happen again."



UHP NHS Trust re Elsie Woodfield

- Elsie Woodfield's daughter Anna Davidson:
 - letter apologising for the incident lacked "remorse".
 - "Our family is very grateful to the CQC for pursuing this prosecution to a successful conclusion. All we have sought from the beginning is openness and honesty from the trust as to what occurred that day. The lack of this has been extremely hurtful and disrespectful and has had a lasting negative emotional impact on us all."
 - "We hope this conviction will underline to other hospitals the critical importance of advising patients and families as soon as it's recognised mistakes have occurred and of apologising unreservedly. This will help others in similar circumstances avoid the unnecessary pain, anxiety and stress we have suffered."

UHP NHS Trust re Elsie Woodfield



- Nigel Acheson, deputy chief inspector of hospitals, CQC
 - “All care providers have a duty to be open and transparent with patients and their loved ones, particularly when something goes wrong, and this case sends a clear message that we will not hesitate to take action when that does not happen.
 - “Sadly, Mrs Woodfield’s family received neither a prompt apology nor full explanation regarding the tragic events that took place prior to her death. UHP NHS Trust was not transparent or open with regards to the surgical error and it did not apologise to Mrs Woodfield’s family in a timely way. Patients and their families are entitled to the truth and a formal written apology as soon as practical after a serious incident and the trust’s failure to fulfil this duty is why the Care Quality Commission took action.”
 - “This is the first time CQC has prosecuted an NHS trust for failure to comply with the regulation concerning duty of candour, and we welcome the outcome of today’s hearing.”

UHP NHS Trust re Elsie Woodfield



- Mr Williams, representing UHP NHS:
 - "This is a threefold apology, the first is for the incident itself, secondly for the breach, and thirdly for the effect it has had on the family.
 - "An offer to meet has been made on numerous occasions, but for reasons, it hasn't taken place. Later on, it wasn't appropriate because of an investigation at that stage. "I would not want there to be the view that the trust has not looked clearly at what has happened."
- UHP NHS executive director of nursing Lenny Byrne:
 - "On behalf of the trust I'd like to wholeheartedly and unreservedly apologise to our patient's family for the issues that bring us to court today."
 - "accepts and acknowledges" the decisions made in court and that "procedural changes that have been made within the trust already have and will continue to prevent issues like this happening again in the future."

A Statutory Duty of Candour in Australia?

- *Targeting Zero* (2016) Rec 5.3
 - That a statutory Duty of Candour be introduced that requires all hospitals to ensure that any person harmed while receiving care is informed of this fact and apologised to by an appropriately trained professional in a manner consistent with the National Open Disclosure Framework.

Stephen Duckett, *Targeting Zero: Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care* (October 2016)



Consultation Paper: Statutory duty of candour (Vic) - issues

- **The Scope of the Duty** – which healthcare providers should be subject of 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?

- Department of Health and Human Services Victoria Consultation: <https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/better-safer-care/statutory-duty-of-candour> (Consultation closed 1 Dec 2017)



Expert Working Group Report: Statutory Duty of Candour recommended

- 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.
- Does not replace current open disclosure obligations – establishes complementary legal obligation to support improved compliance in defined circumstances.
- A statutory duty of candour would:
 - strengthen commitment to open disclosure;
 - clarify when open disclosure must occur, how and who is responsible;
 - clarify medico-legal consequences and protections to encourage and support full and effective disclosure and engagement with consumers.
 - Be high level and supported by the *Victorian candour and open disclosure guidelines* (subordinate legislation).
- Expert Working Group to advise on legislative reforms arising from *Targeting Zero*, A statutory duty of candour - Report to the Minister for Health (August, 2020) <https://www2.health.vic.gov.au/Api/downloadmedia/%7BEB9245FC-76DF-4C7D-99F2-C488BBADE407%7D>

Proposed statutory duty of candour (Vic)

- **Scope of the Duty:**
 - 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 (Rec 2 and 3)
 - residential aged care facilities and community health centres not included but may become within scope (Rec 4)
 - Operate at organisational level only and not to apply to individual clinicians
- **When the Duty Applies**
 - Significant harm: incidents of a high incident severity rating (ISR 1-2)
 - ISR 1 – severe/death
 - ISR 2 – moderate
 - Includes physical and psychological harm but not near misses
 - Includes consumer right to declare (self reported harm)
 - Not intended to apply retrospectively (Rec 6)

Proposed statutory duty of candour (Vic)

- **Requirements of the Duty**
 - specified health services must provide consumers impacted by serious adverse events with
 - Written factual explanation (Rec 12)
 - Apology (Rec 13)
 - Steps to manage the event and improvements to prevent recurrence (Rec 13)
- **Barriers and enablers**
 - Culture change – just culture (not a culture of blame) (Rec 21, 22)
 - Training, information and support – clinicians, consumers, consumer advocates (Rec 23, 24, 25, 26, 27)
 - Candour and open disclosure guidelines to be developed as subordinate legislation (Rec 9, 10, 11)

Proposed statutory duty of candour (Vic)

- **Legal protections**
 - Apology law reform proposed (Rec 13)
 - Protections for root cause analysis proposed and review of qualified privilege laws (Rec 16)
- **Monitoring and compliance**
 - Routine reporting and sanctions for breaches to drive culture change and enhance accountability – report to Dept of Health and Human Services (complaints to HCC or APHRA) (Rec 17,18,19,20)
 - Financial penalties not supported
 - Most important remedy is for patients to receive information sought
 - Persistent/serious breaches – directions for education or case review; censure; deny registration/renewal
 - possibility of publicly naming service
 - Expert Working Group to advise on legislative reforms arising from *Targeting Zero*, A statutory duty of candour - Report to the Minister for Health (August, 2020)

Victorian Government Response: Statutory Duty of Candour



Media Release

The Hon Martin Foley MP
Minister for Health
Minister for Ambulance Services
Minister for Equality



Friday, 11 December 2020

DUTY OF CANDOUR LAW CONSULTATION BEGINS

Safer Care Victoria is launching community consultation on a proposed Australia- first duty of candour law and related proposals aimed at further strengthening the culture of our health services.

The Andrews Labor Government today released the 2018 report from a former Expert Working Group appointed to advise on legislative reforms proposed in *Targeting Zero*, the final report of the Review of Hospital Safety and Quality Assurance in Victoria released in 2016.

The Government has accepted in principle all recommendations made by the report and will undertake further consultation to get the details right.

Under the proposed law, hospitals would have an obligation to apologise to any person seriously harmed while receiving care and explain what went wrong and what action will be taken. Apologies would not be admissible in court. The duty would build on existing requirements under the Australian Open Disclosure Framework.

As part of the most significant reform of our health system in decades, the Labor Government created Safer Care Victoria to overhaul oversight of quality and safety in Victoria's hospitals. We've also required health services to publicly report sentinel events through their annual reports for the first time.



Conclusions

- Ethics, policy and guidelines support open disclosure of adverse events
- Patients expect open and honest communication following adverse events but this does not always happen – questionable whether apology protections necessary and/or helpful
- Clinician failure to disclose adverse events may give rise to disciplinary and civil liability consequences
- Statutory duty of candour legislation and candour and open disclosure guidelines (subordinate legislation) proposed in Victoria – law reform consultation underway

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