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MIPS supports healthcare practitioners in openly disclosing adverse or unexpected healthcare outcomes. This process is fundamental to both patients and clinicians. It can assist practitioners in mitigating the risk of being the subject of legal and/or regulatory action in the aftermath of an adverse clinical event.

Watch this video to learn more about open disclosure from a medico-legal perspective.

The role of informed consent in mitigating negative outcomes from an adverse event

With the exception of emergency interventions, healthcare practitioners are bound to discuss the risks associated a clinical intervention, prior to the procedure taking place. During this informed consent conversation, the likelihood of complications and the degree of certainty regarding a therapeutic outcome will be outlined. Well-articulated informed consent conversations should ensure the consent given by the patient is valid at law⁴. Thus, the following three criteria must be met:

- The patient must have **capacity** to make clinical treatment decisions.
- The consent must be free and voluntary.
- The consent must cover the act to be performed.

Legislation all Australian states recognise patients' right to autonomy and the duty on healthcare professionals to warn a patient about the material risks inherent in any clinical intervention. Accordingly:

"A risk is considered material if, in the circumstances of the particular case, a reasonable person in the position of the patient, if warned of the risk, would be likely to attach significance to it, or if a healthcare practitioner is, or should reasonably be, aware that the particular patient, if warned of the risk, would be likely to attach significance to it"

Therefore, when assessing how to inform a patient of a particular risk, there are three questions that will require consideration⁵:

- Would a reasonable person, in the position of the patient, be likely to attach significance to a specific risk?
- Are you aware, or should you be reasonably aware, that this particular patient would be likely to attach significance to that risk?
- Do you think the patient might change their mind if informed of the risk?

Informed consent discussions should include written acknowledgement from the patient that they have weighted the pros and cons of the intervention and have made an informed decision to proceed forward. Ensuring the informed consent process is carried out adequately, taking into consideration the views and needs of the patient, can go a significant way to mitigating the psychological and emotional affects that any future adverse event may have on a patient and their family.

Open disclosure legislation

Legislation in Australia allows healthcare practitioners to acknowledge with adverse outcomes, without an admission of liability. This is achieved by:

- expressing regret or apologising for an adverse outcome;
- expressing sorrow or sympathy;
- reducing fees; or
- waiving fees entirely

In Australian jurisdictions, there is some protection for all professionals, not just doctors. For example, in NSW it is provided in Section 69 of the Civil Liability Act 2002 (NSW):

An apology made by or on behalf of a person in connection with any matter alleged to have been caused by the person:

- does not constitute an express or implied admission of fault or liability by the person in connection with that matter, and
- is not relevant to the determination of fault or liability in connection with a matter.

Evidence of an apology made by or on behalf of a person in connection with any matter alleged to have been caused by the person is not admissible in any civil proceedings as evidence of the fault or liability of the person in connection with that matter.

In Queensland, there is some similarity in The Civil Liability Act 2003 (QLD) where an apology which is an "expression of sympathy or regret, or of a general sense of benevolence or compassion, whether or not it admits or implies an admission of fault", may be made without risk that it will be tendered in Court as evidence of fault or liability.

Medical and dental care, especially procedures or prescriptions, carry risks that a

practitioner should make a patient aware of beforehand. If one of those risks eventuates, it's wouldn't be considered malpractice, it's simply a known risk for which a patient should have provided their informed consent to accept. Saying sorry in these instances is simply a caring and dutiful way to treat your patients.

Saying sorry may also help you as a doctor to move on from an incident and feel better about your own conduct.

As a rule, we feel that saying the word 'sorry' carries the most weight compared to 'l apologise' or expressing 'deep regret'. Additionally, try to use the personal pronoun "I" as this carries more weight than apologizing for the medical team or hospital, that is saying "we're sorry" or "our apologies". If you're a little lost for words, here's some of the ways we think you can say sorry:

- "I'm sorry we didn't get the outcome for which we were both hoping."
- "I apologise. It's not what I expected to happen."
- "I really regret what's happened. I'm sorry."
- "It's not what we expected or planned for. I hope you can accept my apology."

Apology and/or expressions of regret are key components of open disclosure, but also the most sensitive. 'Saying sorry' requires great care. The exact wording and phrasing of an apology (or expression of regret) will vary in each case. The following points should be considered.

- The words 'I am sorry' or 'we are sorry' should be included. It is preferred that, wherever possible, people directly involved in the adverse event also provide the apology or expression of regret.
- Sincerity is the key element for success. The effectiveness of an apology or expression of regret hinges on the way it is delivered, including the tone of voice, as well as non-verbal communication such as body language, gestures and facial expressions. These skills are often not innate and may need to be practised. Training and education in open disclosure should address this.

Challenges and potential solutions

While open disclosure offers promise to all stakeholders involved, there are challenges at each stage of the process. healthcare organisations and individiual practitioners should be aware of the potential pitfalls at each stage of the process and prepare contingency plans to prevent each from happening wherever possible. The following diagram highlights some of these challenges.

Diagram 1: Challenges at each stage of the open disclosure process. Image developed and modified from Holmes (2019)².

Your MIPS Indemnity Insurance Policy

Even though an apology may be appropriate, there are certain things you should not do in handling a complaint. This is set out in MIPS Members' Indemnity Insurance Policy

27. Consent to settlement

27.1 You must:

a. not admit liability for a claim; and

b. not agree to settle a claim; unless you have our prior written consent.

27.2 We will not admit liability for, or settle, any claim against you without your prior consent.

27.3 If you refuse to consent to us making a settlement offer which we have recommended in respect of a claim, our liability in respect to that claim is limited to the amount of our recommended offer plus defence costs incurred to the date we recommended making the offer to you.

You must contact MIPS in the event of a complaint, and you must not admit liability until this has been agreed with MIPS.

Conclusion

MIPS encourages healthcare practitioners to be transparent, empathetic and responsive to patients' needs following an adverse event. Engaging in an open disclosure dialogue is a valuable tool to resolve patients concerns, mitigate future legal and/or regulatory action and to foster high quality healthcare outcomes.

As highlighted in this summary, there are several challenges to its successful implementation and roll out. MIPS members must contact MIPS in the event of a complaint, and you must not admit liability until this has been agreed with MIPS. Should members have any queries related to these issues they are advised to contact MIPS for advice on 1800 061 113.

Complete assessment questions!

References

¹Australian Commission on Safety and Quality in Health Care (ACSQHC). Australian Open Disclosure Framework.

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

Canberra, Australia.

²Holmes, Bugeja, L., Ranson, D., Griffths, D., & Ibrahim, J. E. (2019). The potential for inadvertent adverse consequences of open disclosure in Australia: when good intentions cause further harm. Medicine, Science and the Law, 59(4), 265–274. https://doi.org/10.1177/0025802419872049

³ What is Open Disclosure? Clinical Excellence Commission Open Disclosure Handbook – Chapter 3. What is Open Disclosure? (nsw.gov.au)

⁴Medical Law in Queensland, Barry Nilsson Lawyers (2021). Course material, module 2 notes.

⁵Open Disclosure Position Paper, Royal Australasian College of Surgeons (2015).



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