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| Subject: | Open Disclosure | Ref. No. | FES-PST-049 |
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BACKGROUND

The Royal Australasian College of Surgeons supports the practice of medical professionals engaging in open disclosure with their patients when procedures do not go to plan. The College endorses the Australian Commission on Safety in Health Care (ACSHC) *National Guidelines for Open Disclosure*¹ and Medical Council of New Zealand (MCNZ) *Disclosure of harm following an adverse event*².

The College aims to provide general guidelines towards the issue, recognising that the policy and legal frameworks in place will vary between Australia and New Zealand and within the individual states of Australia and districts of New Zealand.

'Open Disclosure' can be broadly described as:

- a patient and consumer right
- a core professional requirement and institutional obligation
- a normal part of an episode of care should the unexpected occur, and a critical element of clinical communications
- an attribute of high-quality health service organisations and an important part of healthcare quality improvement³

Open disclosure is a process where surgeons can advise their patients that an adverse event has taken place during or after their surgery. The open disclosure meeting is an opportunity to outline the implications of the adverse event and discuss possible options moving forward. The open disclosure process has a key role in ensuring that relationships between patients, surgeons and health services are underpinned by transparency and trust that is in accord with the College's values.⁴

The open disclosure meeting following an adverse event should primarily be viewed as an informative and supportive measure for the patient and family, where the surgeon can explain what has happened and express regret that it occurred. The open disclosure meeting is not a time for blame to be accepted or insinuated. Importantly, the opportunity for discussion has been shown to be as important as understanding the reasons behind what has transpired.⁵

INFORMED CONSENT

In most surgical scenarios, with the exception of some emergency procedures, the surgeon will openly discuss the risks of the procedure with the patient prior to the operation. The likelihood of complications and the degree of certainty regarding a therapeutic outcome will be outlined during this process. An effective informed consent process should ensure that the patient understands the risks with a procedure.

The law has always recognised that a doctor has a duty to warn a patient of a material risk inherent in any proposed procedure or treatment.

A risk will be 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 the medical doctor is, or should reasonably be, aware that the particular patient, if warned of the risk, would be likely to attach significance to it.

Thus, when considering the need to inform a patient of a particular risk, there will be two separate matters that require consideration:

1. Would a reasonable person, in the position of the patient, be likely to attach significance to the risk? (ie. may change their mind about the treatment)
2. Is the doctor aware, or should the doctor be reasonably aware, that this particular patient would be likely to attach significance to that risk? (ie. may change their mind about the treatment).

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Informed consent should include written acknowledgement from the patient that they have understood the information. This process can go a significant way to reducing the psychological and emotional affects that any adverse event may have on a patient and their family. In the event of an emergency where immediate intervention is necessary it may not be possible to provide complete information or obtain written consent. The College's position paper on Informed Consent outlines this in more depth.⁶

THE OPEN DISCLOSURE PROCESS

An open disclosure meeting should occur in a timely manner. At the open disclosure meeting the most appropriate medical personnel relevant to the patient's care should be present. In most cases the senior surgeon responsible for the patient's care will take the lead in explaining the situation to the patient or family members if the patient cannot participate.⁷ The senior surgeon should clearly outline what has occurred and how it has impacted upon the patient. The discussion should be both informative and empathetic. The patient may be accompanied at the meeting by family members and/or support person/s.

The initial open disclosure discussion should not dwell on who is at fault and the senior surgeon may not be in possession of the full facts, particularly before any formal investigation has taken place. Depending on the nature and consequences of the adverse event surgeons and medical personnel should seek advice from the head of the surgical team and/or hospital administration to discuss what information is known and based on the circumstances, what can be shared with the patient.

The College has concerns over open disclosure processes and meetings that are lengthy and interrogative; as such meetings can be counterproductive to patient welfare. The open disclosure process is not the appropriate place for a formal investigation.⁸

Legislation in Australia now generally allows doctors to deal with adverse outcomes, without there being any admission of liability, by:

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

Such events should also not constitute an admission of professional misconduct, or otherwise expose the doctors to civil liability for carelessness, incompetence, or unsatisfactory performance.

The legislation does vary from State to State, and appropriate advice should be obtained.

In addition to these legislative changes, the Australian Safety and Quality Commission has issued standards or guidelines to assist doctors and hospitals in discussing these issues frankly with patients.

The standards address the following issues:

- openness and timeliness of communication;
- acknowledgment of the adverse event;
- apology or expression of regret;
- recognition of the reasonable expectations of patients;
- support for staff throughout the process;
- processes for risk management and systems improvement;
- governance frameworks to ensure appropriate clinical risk management;
- confidentiality.

Once an adverse event has occurred, it is important that the patient is kept informed, as appropriate. The clinical team should ensure that:

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- they establish the basic clinical and other facts relevant;
- assess the event and the level of response required;
- identify who will take responsibility for advising the patient;
- consider whether additional patient reports are required;
- identify other support and needs;
- ensure that all appropriate staff are sufficiently informed and ensure a consistent response to the patient.

Clearly, as matters develop, patients should be provided with sufficient and up to date information, so that they feel appropriately informed. Recommendations for further remedial care should be made as soon as possible. Follow up is an essential part of the process.

Nonetheless, the process should ensure:

- confidentiality, privacy and professional privilege;
- responses to any negligent or criminal or unsafe acts (if any) including coronial investigations;
- consideration of whether any disclosure might further harm the patient;
- consideration of any other insurance or contractual arrangements.

MEDICO LEGAL IMPLICATIONS

The College recognises that there are inherent differences in the function of health law in Australia and New Zealand. In New Zealand the Accident Compensation Act 1972 gave rise to the 1974 establishment of the Accident Compensation Corporation (ACC) that is still responsible for managing most of the claims made in regards to procedures or against medical practitioners. In Australia each state and territory has its own system and legislative framework relating to medical negligence and compensation and the protection given for open disclosure. The College would welcome a consistent approach to these issues.

Some of the challenges associated with implementing open disclosure processes are in part a reflection of the tension between informing patients and the perceived risk that practitioners feel in admitting an adverse event and any potential liability that may be implied.⁹ Much of the tension and reluctance from surgeons to participate in open disclosure stems from a concern that an apology or expression of regret can be interpreted as an admission of fault or liability.¹⁰

TRAINING IN OPEN DISCLOSURE

The College encourages health services to conduct regular training sessions in open disclosure, so that staff can be confident of what the process entails and the information and phrases that are the most appropriate for use in that forum. The College recommends that all surgeons be aware of their legal obligations and that health services make efforts to provide relevant information to surgeons and patients within their care. The College offers the Care of the Critically Ill Surgical Patient (CCrISP[®]) course which provides training in open disclosure processes.

The College supports ongoing consideration of legislative reforms that provides more consistent protection for surgeons and other staff during the open disclosure process. Such reforms could provide further legal clarity on the issue of liability and help surgeons feel more at ease with the process.¹¹

CONCLUSION

As public expectations of the medical profession continue to rise and as medical science promises more successful procedures and interventions it is vital that patients are fully informed of the inherent and real risks associated with any medical procedure. Open disclosure frameworks provide health services and medical professionals with guidance in conducting open disclosure meetings when

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adverse events occur. The College encourages surgeons to be transparent, factual and empathetic to their patients following an adverse event.

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¹ Australian 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.

² Medical Council of New Zealand, Disclosure of harm following an adverse event. <http://www.mcnz.org.nz/assets/News-and-Publications/Statements/Disclosure-of-harm.pdf>. 2010; Wellington, New Zealand.

³ Australian 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.

⁴ Studdert DM. 'Disclosure of medical injury'. In: Healy J, Dugdale P, editors. Patient safety first: responsive regulation in health care. Sydney: Allen and Unwin, 2009.

⁵ Aaliyah Eaves-Leanos, JD. Open disclosure of Adverse Events: Transparency and Safety in Health Care. *Surgical Clinics of North America*. 2012; **92** (1): 163-77.

⁶ Royal Australasian College of Surgeons, Informed Consent Policy. http://www.surgeons.org/media/312206/2014-08-29_pos_fes-pst-042_informed_consent.pdf. 2014; Melbourne, Australia.

⁷ Medical Council of New Zealand, Disclosure of harm following an adverse event. <http://www.mcnz.org.nz/assets/News-and-Publications/Statements/Disclosure-of-harm.pdf>. 2010; Wellington, New Zealand.

⁸ Western Australian Health Department. Communication and Disclosure: Requirements for Health Professionals Working in Western Australia. <http://www.health.wa.gov.au/CircularsNew/attachments/395.pdf>. 2012; Perth, WA.

⁹ Studdert DM, Piper D, Iedema, R. Legal aspects of Open Disclosure II: Attitudes of health professionals – findings from a national survey. *Med J Aust*, 2010; **193** (6): 351-55.

¹⁰ Finlay A, Stewart C, Parker M. Open disclosure: Ethical, professional and legal obligations and the way forward for regulation. *Med J Aust*. 2013; **198** (8): 445-48.

¹¹ Studdert DM, Richardson MW. Legal aspects of Open Disclosure: A review of Australian Law. *Med J Aust*. 2010; **193** (5): 273-76.

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