Overview
The aim of Surgical Update is to provide MDA National surgeon Members with a “snapshot” of the key medico-legal issues in surgical practice today. Surgical Update is designed to assist in minimising your medico-legal risk with a focus on perennial and emerging medico-legal issues.

This edition discusses:
• what our data shows as the main causes of surgical claims and complaints
• practical tips on how to obtain informed consent
• emerging medico-legal risks in surgical practice.

Please contact our Medico-legal Advisory Service about any specific cases or concerns on 1800 011 255 or advice@mdanational.com.au.

We welcome your feedback on any specific issues you’d like covered in future editions by emailing us at specialtyupdates@mdanational.com.au.

The Causes of Surgical Claims and Complaints

Although a large proportion of the causes of claims and complaints relating to surgeons arise from procedural complications, questions with regard to consent comprise a significant number of calls from our surgeon Members.

Chart 1. Causes of claims involving surgeons

This medico-legal risk is attributed to a variety of factors including:
• unrealistic patient expectations
• inadequate pre-operative assessment
• departure from established processes and standards for obtaining informed consent.

Knowing which clinical risks surgeons should disclose and discuss with patients before treatment is an issue that we encounter regularly.

We have found that the common reasons surgeons give for non-disclosure include:
• the risk was too rare to warrant discussion
• the risk was too obvious
• the specific risk was covered by a more general risk that was discussed.

The following are some of the common questions we receive from surgeons about consent, and the general advice we provide.
Q1: I have received a complaint from a patient who alleges she was not warned of the post-operative scarring and appearance of her breasts following a breast reduction. Although it is my usual practice to discuss with the patient these risks, I unfortunately did not document this in my records - is that likely to be an issue for me?

Ensure your patient understands the nature of the proposed treatment and its benefits and risks. An entry should always be made in the medical records about the consent process. This should include at the very least:

- general and specific risks relating to the patient
- discussion about the alternative treatments available
- any specific questions asked by the patient and details of the answers
- details of any written material provided to the patient.

The more complex or the more elective the proposed intervention, the more time should be spent (if practicable) with the patient to ensure they fully understand the proposed treatment, its benefits and risks and more detail should be included in the medical records.

Q2: Is providing the patient with a standard printed brochure enough without having a full discussion about the risks involved in a proposed procedure?

Written information is an excellent means of stimulating discussion and can reinforce the consent procedure and discussion with the patient. However, written information should not be used as a substitute for a full and frank discussion. Where a patient is intended to return for a second consultation, written information provided at the first consultation could be a useful tool for the doctor to confirm that the patient has read and understood the information and has no further questions.

Surgeons have an obligation to ensure their written information is up to date and to expressly point out any risks material to the patient which may elevate their level of risk beyond that referred to in the written information. Unique characteristics of particular patients may also dictate the breadth and depth of discussion about certain risks.

Ensure that a note is made in the medical records that written information, including the version, has been provided to the patient.

Q3: An 80 year old woman with a fractured hip requires a hip replacement. A referral from the GP indicated the patient had dementia. Although the patient refused treatment - which I considered to be in her best interests - I do not feel that she fully understands, or has the cognitive ability, to appreciate what was proposed. How should I proceed with this patient?

Competence to consent is a common query that we receive.

Before proceeding, assess whether a patient has capacity to consent to treatment. With the exception of life-threatening emergencies, you cannot proceed without consent from either the patient or appropriate substitute decision maker.

By law, an adult patient is presumed to be capable of consenting to treatment.¹ Capacity is present if the patient has the ability to comprehend and retain information and weigh that information in the balance to arrive at a choice.²

Deciding whether or not a patient is competent also depends on the nature and complexity of the intervention proposed.

If competent, the patient has the right to refuse treatment on any grounds and can withdraw consent at any time and practitioners are generally obliged to respect the wishes of a competent person who has the capacity to consent. Also ensure you have detailed documentation of all the steps taken to establish whether the patient is capable of consenting to or refusing treatment.

In circumstances where an adult patient does not have the capacity to consent, there is specific guardianship legislation enacted in each state or territory that provides for valid substitute consent. If you have concerns about whether a patient lacks capacity to consent, contact MDA National or seek assistance from the relevant Guardianship Tribunal or Court in your state or territory.

Practitioners are able to provide "emergency" care in the absence of consent to preserve a patient’s life or health, where it is impractical to obtain consent.

1 Re MB [1997] 2 FCR 514
2 Re C (Adult; Refusal of Medical Treatment) [1994] 1 WLR 290
Consent

The following cases highlight the requirement that consent must be obtained for a further procedure unless it is deemed medically and immediately necessary, and not just convenient.

There are a number of essential elements for consent to be valid:

1. You must obtain consent from either a person or a body legally capable of giving consent.
2. Consent must be given voluntarily and not under duress.
3. Consent should cover the act to be performed.
4. Consent should involve a discussion of the material risks of the procedure or treatment i.e. consent must be informed.

The absence of the first three elements could transform the treatment into a potential assault (which includes battery and trespass). The absence of the fourth element gives rise to a potential action in negligence for failure to warn of potential risks of treatment.

Although the third element consent should cover the act to be performed may seem obvious, this area still generates concern. We have received queries from surgeons which have led to a potential claim or complaint including:

- Performing another procedure considered to be beneficial, but not immediately necessary, in addition to the procedure consented for (this is illustrated in the case study Candutti v ACT Health & Community Care [2003] ACTSC 95).
- Due to the anatomy of the patient, an alternate mode of performing the procedure to that discussed with the patient, was considered more appropriate and adopted.

For example:

- Where consent is obtained for laparoscopic surgery but is converted to open surgery for various issues of access, as opposed to an emergency. Consent should include possibility of performing the surgery by different approach.
- Where a patient undergoes a gastric bypass but during the procedure the surgeon discovers that the small bowel has numerous adhesions and as such is not mobile, and as a result the procedure is changed to a gastric sleeve. The doctor should discuss with the patient (prior to the surgery) the fact that he/she many need to change the procedure following an internal assessment.

We would advise surgeons to firstly consider whether they can be satisfied that in the course of obtaining consent for the specific procedure, they have also obtained the patient's consent to cover the further proposed operative measures. This should involve a review of the documentation and any recollection you may have of the consent process. (See suggested tips referred to later in this article for obtaining consent pre-operatively.)

If consent has not been obtained with respect to the further operative measures:

- If practical, consider discussing and obtaining the patient's consent at that stage (this will obviously not apply to patients who are already under a general anaesthetic).
- If impractical to obtain the patient's consent at that stage, consider whether the further procedure is clinically and immediately necessary, rather than just convenient. If it is not clinically and immediately necessary, our advice would be not to proceed until you have obtained the patient's further consent.

These principles are further highlighted in the following case studies.

**Candutti v ACT Health & Community Care [2003] ACTSC 95**

In this case, the patient was admitted to hospital for a laparoscopic tubal ligation. The patient alleged:

- that she was subjected to a laparotomy with a tubal ligation (a far more invasive procedure) without her consent, leaving her with an abdominal scar, continual abdominal cramps and pain
- she consented to a laparotomy only in the event of an emergency during surgery.

The hospital asserted that the patient had consented to the laparotomy in the event that the laparoscopic procedure was unable to be performed.

The Court heard evidence that during the procedure, the patient's abdomen was not able to be inflated with gas, which prevented a laparoscopic procedure from being performed. The patient succeeded in her claim that the defendant was liable for trespass and was awarded damages. The Court held the hospital did not have the patient's consent to the laparotomy and there was no life-threatening emergency which justified it.

This case highlights that in trespass cases, causation does not need to be established. This is in contrast to cases alleging a failure to warn of material risks, where in order for a claimant to succeed, they need to establish causation (that is, show that they would have acted differently had they been warned).
You must obtain consent from either a person or a body legally capable of giving consent.

There are circumstances where consent has been taken to extend to treatment that is deemed to be medically and immediately necessary and not just convenient. Discussed below are two contrasting cases exploring this issue.

**Murray v McMurchy [1949] 2 DLR 422**

In this case, a patient was admitted for and consented to undergo a caesarean section. During the procedure, the doctor discovered that the patient had a number of fibroid tumours in her uterus, which would have made it hazardous for her to have another pregnancy and - although it wasn’t immediately necessary - the doctor performed a ligation of her fallopian tubes.

The Court held that the doctor was liable for damages because there was no evidence that the fibroids were, at the time of the procedure, dangerous to the patient’s life or health. The Court held that it would not have been unreasonable in the circumstances to postpone the sterilisation until after consent had been obtained, in spite of the convenience of doing it at that stage.

The Court also held that as the harm was avoidable and not imminent, consent provided by the patient was not taken to extend to the tubal ligation. This led to a finding of battery against the doctor.

**Marshall v Curry [1933] 3 DLR 260**

In this case, a surgeon, in the course of a hernia operation under general anaesthetic, discovered that his patient had a diseased testicle. The surgeon removed the testicle during the procedure.

The Court held that the surgeon was justified in removing the testicle without obtaining specific consent, because the testicle could have become gangrenous and constituted a threat to the patient’s life. Proceeding without consent was found to be justifiable as it was “necessary to save the life or preserve the health of the patient”.

*A risk is material if a reasonable person in the patient’s position, if warned of the risk, would be likely to attach significance to it; or if the medical practitioner is or should reasonably be aware that the particular patient, if warned would be likely to attach significance to it.¹*

¹ Rogers v Whitaker (1992) 175 CLR 479

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**Practical Tips**

- Ensure your patient has capacity to consent and if in doubt, seek guidance.
- Ensure you have consent for the act intended and for future circumstances which may be considered “medically necessary” to avoid any ambiguity that consent extends to a further operative measure. Ensure that you have covered this possibility through discussions with the patient and by making references to this in a consent form. Your defence, if required, will be strengthened if there is a written record (either in your medical records or consent form) that provides for alternative operative measures, as may be deemed necessary by you during the course of the operation consented to by the patient.
- A lot of cases turn on what was said and when. Timely and thorough documentation can provide excellent evidence of a particular discussion taking place. Accordingly, document the steps taken to obtain consent and detail any written information provided.
- Ensure you have obtained informed consent. Informed consent involves a discussion of any recognised risks, any risks the patient would consider relevant, any alternative procedures and the effects on the patient of not having the procedure. The provision of educational materials is a very useful means for supplementing that discussion. The level of detail involved may vary depending on the complexity of the proposed treatment.
- Obtain financial consent prior to providing treatment regarding potential costs for the medical treatment, including associated fees of other medical providers and potential rebates for the service. Consent should be acknowledged by the patient in writing.
- When using procedure specific consent forms, ensure there is provision to incorporate the nature, benefits and risks specific to the patient, the alternatives to and the consequences of not having that procedure.

In addition, we suggest you regularly review your own consent policies and procedures in order to minimise your exposure to complaints and possible litigation.
Emerging Medico-legal Risks

• Metal on Metal (MoM) prostheses for hip and knee procedures
• Transvaginal Mesh Implants
• Poly Implant Prosthese (PIP) product recall

MoM

A number of MoM products have been withdrawn from the Australian market. DePuy / Johnson & Johnson voluntarily recalled the Acetabular Cup Hip Replacement and the De Puy ASR Hip Implant from sale in Australia in December 2009. The devices have been found to have a 12-13% failure rate within five years. Additional concerns raised also include possible cobalt and chromium toxicity.

DePuy / Johnson & Johnson also voluntarily recalled the LCS component and the recall was TGA approved on 24 July 2009. DePuy / Johnson & Johnson issued a Hazard Alert on 29 July 2009 which referred to the identification of a slightly increased, but still low, revision rate associated with the LCS Duofix Femoral Component.

The MITCH TRH (‘the System’) is a metal-on-metal hip replacement system comprising two components (the MITCH TRH modular head or resurfacing head; and the MITCH TRH acetabular cup). The System can be used in different combinations with various orthopaedic components from other manufacturers, for either hip resurfacing arthroplasty or total hip replacement.

On 14 April 2012, the TGA issued a notice advising that the MITCH TRH modular head had been cancelled from the Australian Register of Therapeutic Goods and could no longer be used in Australia. The notice identified, from data sourced from Australia’s National Joint Replacement Registry, that when used in total hip replacement in combination with the Accolade (and several other) femoral stems, the System had a higher rate of revision surgery than average for total conventional hip replacements.

The System raises many of the same issues associated with the other products withdrawn. There certainly appears to be increasing awareness of complication rates associated with these products in the regulatory and industry environment. We suggest you periodically review the following websites to remain informed of new developments and recommendations:

• DePuy – depuy.com/aurecallguide
• Therapeutic Goods Administration – tga.gov.au
• Australian Orthopaedic Association – aoa.org.au.

Transvaginal Mesh Implants

The US Food and Drug Administration division (FDA) of the Department of Health & Human Services has been closely monitoring the complications associated with transvaginal placement of surgical mesh in the repair of pelvic organ prolapse (POP) and stress urinary incontinence (SUI) since 2008.

On 20 October 2008, the FDA issued a public health notification indicating that the complications (including but not limited to erosion through the vaginal epithelium, infection, pain, urinary problems and recurrence of prolapse and/or incontinence) associated with transvaginal placement of surgical mesh in the repair of POP and SUI, were serious but rare. At that stage, the FDA recommended physicians:

• obtain specialised training for each mesh placement technique and be aware of its risks
• be vigilant for potential adverse events from the mesh
• inform their patients that implantation of surgical mesh was permanent and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complications
• provide their patients with a written copy of the patient labelling from the surgical mesh manufacturer (if available).

On 13 July 2011, the FDA issued a further public health notification, advising that the use of surgical mesh for transvaginal repair of POP was an area of “continuing serious concern” and the serious complications previously identified in the 2008 notification were no longer rare, although had not been linked to a single brand of mesh.

The concerns expressed in respect of the use of vaginal mesh devices to repair SUI are somewhat more generalised, however the FDA has advised that it continues to evaluate these effects.

Last year it was reported that the Ethicon Unit of the Johnson & Johnson Group of Companies planned to phase out the supply and sales of certain vaginal mesh devices, namely certain Gynecare products, including those marketed under the names: TVT Secur, Prosima Pelvic Floor Repair System, Prolift Pelvic Floor Repair System and Prolift +M Pelvic Floor Repair System.

Johnson & Johnson indicated its plan was not a product recall and it continued to have confidence in the safety and efficacy of the devices. It indicated that the decision to discontinue the supply of the devices was based on the commercial viability in light of changing market dynamics.

We are not aware of any relevant notification from the Australian Therapeutic Goods Administration. While there has not been any explicit prohibition regarding the use of vaginal mesh devices in the repair of POP or SUI, we recommend careful consideration of the FDA’s notifications and recommendations to healthcare providers and regular reviews of the following websites:

• Therapeutic Goods Administration – tga.gov.au
• US Department of Health & Human Services Food and Drug Administration – fda.gov
• Royal Australian and New Zealand College of Obstetricians and Gynaecologists – ranzcg.edu.au.

Poly Implant Prosthese Implants

Patients with Poly Implant Prosthese (PIP) breast implants continue to be worried about the implications of having the implants and what harm they may cause.

The summary of testing has revealed that while there are some differences between the PIP implants and other brands of silicone breast implants, the differences are small and do not indicate an elevated safety risk.
With respect to all silicone gel filled breast implants:

- There is a limited life span and the risk of rupture increases with time to about 10-15% by 10 years.
- While ruptures may not present with any clinical sign or symptom, an MRI scan is the most effective method of detecting a rupture.
- There is a possible risk between all silicone breast implants and a rare cancer, Anaplastic Large Cell Lymphoma (ALCL), although the risk appears to be limited.

While the Therapeutic Goods Administration (TGA) and its international counterparts continue to accumulate data with respect to PIP breast implants, the following is a summary of the current evidence:

- The TGA has not identified any serious safety concern with PIP implants.
- The possibility of PIP implants rupturing at a higher rate than other silicone implants cannot be excluded nor confirmed, although the data available suggests that rupture rates for PIP implants in Australia are within the expected range.
- There is no evidence that the risk of ALCL is higher in PIP implants than other silicone implants.
- Medicare rebates are available for the cost of medical services related to managing PIP implant concerns including GP and surgeon consultations, diagnostic tests and surgery and related anaesthetic services to remove and replace implants when clinically indicated.

We suggest you periodically review the following websites:

- Therapeutic Goods Administration – tga.gov.au

If you have any concerns about these or other emerging risks, please contact our 24 hour Medico-legal Advisory Service on 1800 011 255.