This edition of Defence Update examines an emerging issue for all medical practitioners - your online presence. A number of rating websites now exist which include ratings and commentary regarding individual medical practitioners. This developing trend is discussed on page 8.

Many medical practitioners also have websites which provide information about their practice and services. The importance of ensuring that the information on these sites complies with professional guidelines and legislation is highlighted on page 18.

Another emerging issue is that of the silicone gel implants manufactured by the French company Poly Implant Prothese (PIP) and Julian Rait discusses the challenges of monitoring implanted medical devices on page 3.

I would like to thank those Members who contributed their interesting and varied in-flight and holiday medical emergency experiences in response to our article “Is there a doctor on board this flight?” which was published in the Summer 2011 issue of Defence Update. With the permission of the individual Members who provided the stories, we’ve included some of these in our new online version of Defence Update. More about this initiative and how to access it is on page 4.

We look forward to sharing more of your stories in 2012.

Dr Sara Bird
Manager, Medico-legal and Advisory Services
This Time it’s Different

Silicone breast implants have a contentious history. The United States imposed a 14-year moratorium on their use that ended in 2006, after numerous lawsuits contending that they had caused cancer and/or systemic disease. The US Institute of Medicine and the Food and Drug Administration (FDA) eventually concluded that there was no evidence that silicone implants were harmful. In fact, the weight of the medical literature failed to support any association between silicone gel implant devices and cancer or systemic disease (such as fibromyalgia or SLE).

Furthermore since the 1990s, silicone breast implants have been made of a semi-solid purified gel that mostly eliminates filler leakage (silicone gel bleed) and silicone migration from the breast to elsewhere in the body.

However despite these advances, health officials in 65 countries have recently been grappling with a different dilemma: how best to respond to the intense anxiety of tens of thousands of women who received breast implants that were made with substandard silicone. The French company Poly Implant Prothese, or PIP, has manufactured silicone testicle, chest, buttck and breast implants for 20 years. At one point the company was number three in the international breast implant market and exported more than 80% of its products, including around 9,000 breast implants to Australia.

It has been reported that PIP began to cut costs by using a cheaper industrial grade silicone shortly after the company began production in 1991. Those reports suggest that purified medical grade silicone was stored in one tank for inspection, while another gel, much cheaper, was stored elsewhere and substituted in the actual manufacturing of many implants.

The US FDA never approved these implants for use in the United States. PIP saline-filled implants were available in the US but their authorisation was revoked after a re-evaluation by the FDA in 2000 found 11 deviations from “good manufacturing practices” including PIP’s failure to investigate the deflation of its saline implants and a failure to report more than 120 complaints in France and elsewhere.

Recent studies by the French authorities (based on their medical device vigilance system) have determined an overall rupture rate of 11.1% for PIP implants vs. 2% for other implants over the same time period. The durability of these PIP implants therefore appears from the reports substandard with a rupture rate that may be five to six times higher than other implants. This is particularly problematic given the reported use of industrial grade silicone which I understand incites a greater inflammatory response from tissue and is more likely to spread than semi-solid medical grade gels.

But what can we learn from such failures?

The first lesson is that there could be more collaboration and decision making with foreign regulators. Indeed while the US FDA has frequently been criticised for being too tough on industry, in this case they were the first to conclude there were issues with the manufacture of the implants and deregistered them.

We have the unfortunate situation where the French, German, Czech and Dutch Governments say that PIP implants are dangerous and should be removed, while the United Kingdom and Australian regulatory agencies say that they are safe, while the US Government never registered them in the first place.

There is potential to gather better evidence, including data on any adverse impacts of implanted devices. In addition there is potential for longitudinal studies of how all breast implants perform, and to achieve this, we would need to know who is getting these implants and who their surgeons are. Our orthopaedic colleagues took the lead (with funding from the Department of Health and Ageing) and created a comprehensive Australian joint replacement registry, while the Australian Society of Plastic Surgeons (ASPS) also maintained an incomplete register for many years. Unfortunately, as the latter was an opt-in model with the patients paying to be included, it had very limited usefulness. So Australia could aim to have an inclusive opt-out model that includes all devices and has outside funding so that almost everyone will come to the party.

This event is an example of the minefield through which doctors must negotiate when dealing with new technologies and things may not always be as straightforward as they seem.

Continued vigilance and awareness will help protect the wellbeing of the profession and patients alike.

A/Prof. Julian Rait
MDA National President
Wholly-Owned WA Office Launched

MDA National officially opened its new office in its wholly-owned 2876 square metre building located at 88 Colin Street, West Perth late last year; MDA National’s WA team now occupy the entire third floor.

Associate Professor Julian Rait, MDA National President, said the move represents a significant milestone in our 87 year heritage demonstrating long term financial stability and Member loyalty.

“Purchased for the benefit of Members in December 2008, the new office accommodates our growing Member support services and is the cornerstone of our national operations.”

Top: A/Prof Julian Rait and Dr Beres Wenck with Victoria Astill-Smith, Claims Manager (Solicitor) and Leah Proctor, WA Relationship Manager
Bottom Right: CEO, Mr Peter Forbes with Joanne Webb, National Brand & Communications Manager
Bottom Left: Dr Reg Bullen and Pip Brown, WA Relationship Manager

MDA National partners with MJA for Medical Research Award

As part of our commitment to supporting Members and the wider medical profession, we proudly announce the MJA, MDA National Prize for Excellence in Medical Research which offers a $10,000 prize for authors of the best clinical research published in the MJA.

To find out more visit www.mja.com.au

Moving from Strength to Strength

MDA National has expanded the Sydney office facilities while the SA team has moved into Adelaide’s AMA House to accommodate continuing growth.

Adelaide Office: Our Adelaide office has moved to Unit 7, 161 Ward Street, North Adelaide.

Sydney Office: Our Sydney office continues to operate out of the AMA Building on 69 Christie Street, St Leonards. The expansion now enables the entire NSW team to be located on the fifth floor.

This is an exciting phase of MDA National’s evolution and further cements our national footprint and local commitment.

Defence Update Moves in Online

Members can now read Defence Update online for more detailed information and related links on emerging issues, case studies and practical medico-legal resources. Access our online publication at your convenience via your computer, smart phone or tablet today, share articles, save them to file and tell us what you think.

This initiative is a result of Member feedback for a greener alternative to the hardcopy version and provides Members with a choice on the way Defence Update is received.

To find out more visit www.defenceupdate.mdanational.com.au

Medicare Australia Compliance Audit Program

Recent legislative amendments to the Health Insurance Act 1973 have introduced important changes to the way in which Medicare Australia conducts their compliance audits. Financial penalties have been introduced where doctors cannot substantiate the amount paid for a service. The penalties are designed to encourage early voluntary compliance. These penalties can be increased or decreased depending on how promptly a doctor responds during the course of a compliance audit process.

Members are encouraged to seek advice from our Medico-legal Advisory Service as soon as they are notified of a compliance audit because this could result in a reduced financial penalty against the Member in some cases.
2012 Medico-legal Minefield Forums

Topic: Professional Relationships & Understanding Patient Complaints

Our 2012 forums feature our innovative new DVD “The Doctor’s Life” as a true-to-life case study for participant interaction and lively panel discussions with industry experts.

Join us for an engaging evening of discussion, exploration, learning and reflecting on how your professional relationships can impact patient care, the patient’s experience, and your own personal resilience.

93% of attendees have indicated that they have a greater understanding of the medico-legal issues discussed after attending MDA National forums.^

Cost
This event, which normally costs $250 per person, is complimentary to all MDA National Doctor in Practice and Doctor in Specialist Training Members.

Places are limited and advance bookings are essential.

CPD accreditation
Continuing Professional Development (CPD) points are available. You will also come away with some useful information and practical resources to support you in your practice.

Speakers
An experienced medical practitioner will facilitate the forum, supported by a panel of experts from the healthcare and medico-legal environment. Biographies for panelists are available online.

Online forum available - June 2012
This year, Members will be able to experience one of our forums online in multi-media format combining visual and audio footage, power point slides and segments from “The Doctor’s Life” DVD. This new initiative is a direct response to Member feedback from previous forums.

To register click on Medico-legal Minefield Forums.
www.mdanational.com.au

MDA National would like to acknowledge the contributions of MDA National staff, Members, friends and colleagues in the production of “The Doctor’s Life”.

Follow us on Twitter or email events@mdanational.com.au if you would like to be notified when our online forum is launched.
Anticoagulants and Surgery

In the Summer 2011 issue we featured Part I of our series about the challenges of perioperative management of anticoagulation from the perspective of a GP and physician. Part II of this series is from the point of view of an anaesthetist and a surgeon.

An Anaesthetist’s Perspective

There is a process problem for community anticoagulated patients having procedures because of:

• increasing usage of anticoagulants in the community (warfarin at 9% p.a.)
• introduction of new anticoagulants (direct thrombin inhibitors and thienopyridines)
• changes in the imperative for their continuation
• use of over-the-counter antiplatelet drugs
• increased productivity through same day admission for procedures.

There is a risk that fragmentation of care and specialist silos result in problems with:

• timely identification of who is anticoagulated, with what and why
• whether and when to stop anticoagulation for a procedure
• whether to bridge with other therapy
• when to reinstitute, and with what.

The judgement on this will require a detailed knowledge of:

• the indication for anticoagulation
• any comorbidities and treatments
• the details of the procedure and anaesthesia to be performed.

The decision and implementation of an action plan can be the role of the GP, the proceduralist, the anaesthetist or another physician, e.g. a treating cardiologist or haematologist.

Whoever is responsible should be prepared to:

• be explicitly nominated for that role so everyone knows who is making the decisions
• remain up to date on the drugs and their indications and management
• communicate with all parties and be available to discuss the issues at odd times
• ensure patients understand and comply with directions.

Some surgeons and proceduralists are comfortable coordinating this but if not they should ensure someone else is nominated.

These duties cannot be reduced to an algorithm or guidelines due to the multiplicity of clinical scenarios; however the relevant guidelines are a building block that all physicians should be familiar with in order to avoid departure from accepted clinical standards.

Mixups over the handling of perioperative anticoagulation cause unnecessary productivity loss as well as distress for the patient when delays result.

Challenges faced by anaesthetists

Anaesthetic blocks

The use of spinal, epidural and ophthalmic regional local anaesthetic blocks in anticoagulated patients is relatively or absolutely contraindicated due to the risk of haematoma causing disastrous complications. However for many patients, this is a safe technique and a most accepted technique for anaesthesia, e.g. for an obese diabetic having foot surgery. If that patient has AF and is on warfarin, are they better off continuing the anticoagulant and having a GA, or ceasing it and having a spinal block? That decision should be made after discussion with both the physician who understands the risk of stroke in that patient, and the patient themselves.

Bleeding

Significant bleeding can itself cause coagulopathy which can be challenging to manage even without anticoagulants complicating the picture. The location of the bleeding is also relevant - in the retina or the brain or spinal column the consequences can be severe from small quantities. Occult bleeding, for example inside the GI tract after polypectomy, can be a disaster due to delayed diagnosis and the day procedure nature of the service. Management of difficult airways is more complicated if bleeding occurs during instrumentation of the nose or throat. Ear, nose and throat or airway surgery can be difficult to perform at all if brisk bleeding occurs during the procedure, thus frustrating the entire enterprise.

Emergency surgery

Emergency surgery, particularly for trauma and multi-trauma or to treat complications of overdose of anticoagulant (e.g. leading to extradural haematoma) may require reversal of vitamin K antagonist drugs and careful management of the replacement of blood products.

Patients particularly sensitive to blood loss, such as those with severe cardiac or respiratory comorbidity, and seriously ill patients, pose additional challenges, often out of hours when advice is harder to access.

Conclusion

The challenge is not only to know what should be done, but to make sure it actually happens at the right time, every time, year in and year out in a busy practice where you need to:

• identify who is anticoagulated, with what and why
• whether and when to stop anticoagulation for a procedure
• whether to bridge with other therapy
• when to reinstitute, and with what.

By Dr Andrew Miller
MBBS LLB(Hons) FANZCA FACLIM
A Surgeon’s Perspective

The perioperative management of the anticoagulated patient is an exercise in balancing the risks of bleeding versus the risk of thrombosis. Exactly quantifying these risks in an individual patient though can be highly problematic and few randomised controlled trials exist to justify particular regimens. Furthermore, surgeons often feel that physicians don’t understand the risks and consequences of bleeding and physicians feel that surgeons don’t understand the risks and consequences of thrombosis.

What is the risk of thrombosis?

It is important to understand that thromboembolic risk varies significantly with patients and, in the case of mechanical valve replacement, device related factors. Table 1 summarises those at highest risk.

<table>
<thead>
<tr>
<th>Coronary stents</th>
<th>Mechanical heart valve</th>
<th>Atrial fibrillation</th>
<th>Venous thromboembolism (VTE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bare metal stents within 6 weeks of placement.</td>
<td>Any mitral valve prosthesis.</td>
<td>CHADS, score of 5 or 6.</td>
<td>VTE within 3 months.</td>
</tr>
<tr>
<td>Drug-eluting stents within 12 months of placement.</td>
<td>Older (caged-ball or tilting disc) aortic prostheses.</td>
<td>CVA or TIA within 3 months.</td>
<td>Severe thrombophilia (e.g. protein C, protein S or antithrombin deficiency).</td>
</tr>
<tr>
<td></td>
<td>CVA or TIA within 6 months.</td>
<td>Rheumatic valvular disease.</td>
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Table 1 High risk factors for thrombosis/thromboembolism (adapted from Douketis et al.)

What is the consequence of thrombosis?

Embolic stroke can result in major disability or death in 70% of patients; thrombosis of a coronary valve is fatal in 15% of patients. Perioperative myocardial ischaemia increases mortality by two to four times.

The use of dual antiplatelet agents (aspirin and a thienopyridine - clopidogrel or ticlopidine) in patients with coronary stents creates frustration for cardiologists and surgeons alike. The message for surgeons is that indiscriminate cessation of antiplatelet agents in patients who have undergone recent coronary stenting (6 weeks for a bare metal stent and 12 months for a drug-eluting stent [DES]) very significantly risk coronary occlusion (up to 29% of DES patients). In the majority of cases, stent thrombosis will result in myocardial infarction and a 25-40% mortality rate. Conversely, the message for cardiologists should be to not go placing stents without thought as to imminent surgical requirements that might be safely achievable before the patient is committed to a period of mandatory anticoagulation.

Surgeons: listen to your physicians. Negotiate a plan of management with regard to perioperative anticoagulation long before the patient is admitted. Don’t stop anticoagulation without reference. Stay abreast of anticoagulant drug therapy (including the newer oral agents like rivaroxaban and dabigatran). Where possible, avoid discontinuing aspirin therapy. The use of aspirin in the perioperative period increases risk of bleeding by only a minor degree (by a factor of 1.5 times in a meta-analysis of 474 trials) but reduces the risk of major cardiac events by 80%.

What is the risk of bleeding?

Physicians: listen to your surgeons. Don’t commence anticoagulation in the perioperative period without careful discussion regarding the risks of bleeding; the clinical consequences may range from annoying to catastrophic. Furthermore, postoperative bleeding will delay recommencement of anticoagulation, further increasing the risk of thromboembolism. Particular procedures associated with a high risk of bleeding include coronary bypass surgery, heart-valve replacement surgery, intracranial and spinal surgery, aortic aneurysm repair, peripheral bypass vascular surgery, major orthopaedic procedures, reconstructive plastic surgery and prostate and bladder surgery.

It may not be all or none

Interuption of anticoagulation is not required for all surgical procedures. For example, minor dermatologic procedures, dental extractions and even cataract surgery can generally be safely performed in the warfarinised patient.

In those patients at significant risk off anticoagulant therapy the use of bridging anticoagulation using a short-acting anticoagulant (such as heparin) allows anticoagulation to be continued right up to just before the time of surgical intervention and recommended as soon as haemostasis has been safely achieved afterwards, thereby minimising the time off treatment. Where temporary cessation of anticoagulation is deemed surgically necessary and the risk of VTE is unacceptably high, then placement of an inferior vena cava filter can be considered.

Conclusion

Navigating the issues surrounding perioperative anticoagulation begins and ends with dialogue. Individualize patient management. Don’t act without consultation.

By Dr Robert Davies
MBBS, FRACS

Further reading

The eRating of Doctors

There are a number of websites which allow anonymous users to post ratings and commentary regarding medical practitioners. These websites have been described as “the 21st century’s answer to word of mouth or over-the-garden-fence chit chat”, and “chaotic and unregulated activity which brings to mind the notorious witch trials of Salem”.

Most medical practitioners find these websites fundamentally flawed. The anonymity means there is generally no ability to identify the person who has posted the rating - is it a patient, a person with a grudge or even a colleague who is in “competition” with them? How can a handful of ratings properly represent an appropriate assessment of a medical practitioner who may see more than a hundred patients each month, and many thousands over a career? Is this an appropriate method of assessing a practitioner’s skills as a doctor?

Members who contact MDA National about these websites generally want advice about what recourse they have when they are subjected to criticism on a site.

Potential legal remedies

The law as it relates to the web is new and evolving. One of the potential legal remedies available to medical practitioners is defamation. Defamation is an injury to an individual’s reputation. A publication is defamatory of a particular medical practitioner if, when published to a third person, it is likely to cause an ordinary person to think less of the medical practitioner. The publication needs to be more than negative or critical. It must injure the practitioner’s reputation; for example, give rise to contempt, hatred or ridicule, or be likely to cause an ordinary reasonable person to shun or avoid the medical practitioner.

One of the defences available for a defamation claim is that of honest opinion. A defence established under this provision is defeated only if it can be proved the comment, the poster must be able to be identified. Medical practitioners are unlikely to be able to obtain a court order requiring disclosure of the poster in an overseas jurisdiction (e.g. the US where most of these websites are incorporated). If the identity of the person making the comments on the website cannot be adequately proven, then there is likely to be very little a medical practitioner can do.

Given the anonymity of posters on these websites, it may be tempting for medical practitioners to post positive but fictitious comments about themselves but, in certain circumstances, this can create additional problems for the practitioner.

With regard to the website proprietor or ISP, under Australian defamation law, a defamation action may be brought against anyone who takes part in the publication or re-publication of the material. However, it is unlikely that any judgment made in Australia would be enforceable overseas. In particular, US legislation effectively prohibits providers of an interactive computer service being treated as the publisher of any information provided by another information content provider.

In summary, while comments posted on these websites may be defamatory, there is often very little that can be done to have the comments removed, particularly if sites are companies which are incorporated and/or based in the US. While a letter demanding removal can be sent to the website proprietor, and may result in its removal, on occasion this step may simply draw attention to the existing adverse posting, and the letter of demand may be then posted on that website and others. For example, there are specific websites which post these types of letters to try to embarrass and further criticise the medical practitioner.

Conclusion

Some commentators have suggested there may be value in monitoring your online presence and reading patients’ stories, suggesting these “stories are nuggets of qualitative data on patients’ attitudes regarding the quality of care and their needs and preferences in their relationships with their doctors”. However, our experience is that individual practitioners find adverse postings immensely distressing and anxiety provoking. Perhaps the best solution is to resist the temptation to look at these sites and/or Google your name. After all, in the past we were not aware of the “over-the-garden-fence” comments and perhaps this new cyber feedback does not enhance our ability to practise safely and to a high standard, and only serves as a source of distress.

By Dr Sara Bird, Manager
Medico-legal and Advisory Services

Medical Records
Part 1

‘...the records are likely to be a far more reliable source of truth than memory. They are often the only source of truth.’

\(^1\)
Medical Records

What are medical records?
“Medical records” is a broad term which incorporates a range of data and information storage mediums containing patient information. Medical records can be either paper based or electronic and include: clinical notes, investigations, specialists’ letters, appointment records, diagnostic reports, accounts and diary systems.

It should be noted that information exchanges between a medical practitioner and MDA National or a solicitor seeking legal advice, or in contemplation of litigation, are likely to be privileged and are not considered “medical records”. Accordingly this information should be stored separately from the patient’s medical records in a secure place.

What is the purpose of the medical record?
Medical records are an integral part of good quality patient care. The primary purpose of the medical record is to facilitate patient care and allow you or another practitioner to continue the management of the patient. Good medical records can also significantly improve the defensibility of a claim or complaint, particularly in cases where there are conflicting versions of events between the patient and practitioner.

What are the professional requirements with regard to medical records?
The Medical Board of Australia’s guidelines, Good Medical Practice: A Code of Conduct for Doctors in Australia, state in Section 8.4 that maintaining clear and accurate medical records is essential for the continuing good care of patients. Good medical practice involves:
• keeping accurate, up-to-date and legible records that report relevant details of clinical history, clinical findings, investigations, information given to patients, medication and other management
• ensuring that your medical records are held securely and are not subject to unauthorised access
• ensuring that your medical records show respect for your patients and do not include demeaning or derogatory remarks
• ensuring that the records are sufficient to facilitate continuity of patient care
• making records at the time of the events, or as soon as possible afterwards
• recognising patients’ right to access information contained in their medical records and facilitating that access
• promptly facilitating the transfer of health information and when requested by the patient.

Why are medical records important medico-legally?
Medical records may be used as evidence in legal proceedings, including medical negligence claims, disciplinary hearings, criminal proceedings or Coronial Inquests.

Medical negligence claims may involve a dispute of the facts, which is why comprehensive and accurate medical records are often essential in establishing the facts when defending a claim or complaint. Where there is no supporting documentation, the patient’s recollection may be preferred to that of the practitioner, particularly where the practitioner is unable to fully recall the event or the patient.

After receiving a claim or complaint, you may feel tempted to change the medical records or include in the records all of your recollections of the event. This may result in a defensible claim becoming indefensible. Poor medical records may make a claim difficult to defend, but altered medical records may make a claim virtually impossible to defend. Once you are aware of a claim or complaint, no changes of any sort should be made to the medical records.

How long should I keep the medical records?
From a medico-legal perspective, medical records should be kept until there is little or no risk of litigation regarding the patient’s treatment. This will depend on the statutory limitation period within the relevant jurisdiction, and in some jurisdictions this is also impacted by specific legislation governing medical records.

Unfortunately it is difficult to be definitive regarding the exact limitation period, as the courts generally have discretion to extend the period in certain circumstances.

Where there has been a patient complaint, an adverse outcome or foreshadowed legal proceedings, then the medical records should be kept indefinitely (or advice sought from MDA National prior to disposal).

Medical records for a patient with a mental disability should also be kept indefinitely, or until seven years after the patient’s death.

The ACT, NSW and VIC have legislated the minimum period of time which medical records should be kept, being:
• for an adult – 7 years from the date of the last entry
• for a child – until the age of 25 years.

MDA National considers these requirements to be appropriate in all Australian contexts.
Who owns the medical records? Can patients look at and/or obtain a copy of their records?

In general terms, medical records made by you remain your property or that of the medical practice or hospital in which you work. However, for records created or in use after 21 December 2001, the Privacy Act 1988 (Cth) generally grants patients the right to access their medical records. Importantly this includes all of the medical records, including specialists’ letters and reports even if they are marked “confidential”.

This access should usually involve providing the patient with a photocopy or print-out of their records, if requested. Where the patient is deceased, consent may be provided by the executor or administrator of the patient’s estate.

Access by a patient to their medical records cannot be denied unless there are exceptional circumstances such as:

- serious and imminent threat to the life or health of any individual
- unreasonable impact on the privacy of other individuals
- anticipated legal proceedings where legal professional privilege applies.

In all circumstances, a medical practitioner should record when and to whom they have provided a copy of or access to the patient record.

Can I scan records into an electronic form and destroy the paper based records?

Electronic health records are becoming more prevalent in medical practice and medical practitioners are often required to manage the medico-legal and practical issues associated with keeping a mix of paper and electronic patient records.

Whilst current legislation does not specify the format in which a patient’s medical records must be kept, in some instances an original paper document may have forensic value in the event that the document is required at trial.

Nevertheless, if retention of the original paper documents is not possible for some reason, e.g. due to storage limitations, the original, complete documentation should be promptly scanned and saved into the patient’s electronic health record. The original paper documents should then be destroyed in a secure and confidential manner, once the scanning and back up of the documents has been confirmed.

Scanning should be of sufficient quality to allow a complete and legible hard copy to be reproduced from the electronic copy as required.

1 Justice Hope. Albrighton v The Royal Prince Alfred Hospital.
Medical Records
A Medico-legal Perspective

By Dr Rod Moore
MBBS (WA) Grad Dip Sp Med (UNSW), Chair Western Cases Committee

The need to keep good medical records is outlined in the Code of Conduct for Doctors in Australia produced by the Medical Board of Australia.1 It is an essential part of professional practice that such records are kept for all patient interactions. This not only facilitates patient care and ensures continuity of care but is also a valuable resource in reducing the risk of subsequent medical negligence litigation.

The primary purpose of adequate medical record-keeping should always be its role in enhancing patient care. The subsequent benefit in protection against subsequent negligence allegations should be seen as a secondary benefit.

MDA National operates two Cases Committees, one based in Sydney and the other in Perth. These committees provide expert medical input into the management of medical negligence claims involving our Members.

In matters that come before the committees it is a recurring theme that the successful defence of matters is compromised by inadequate record-keeping. There is no doubt that a successful defence is enhanced by good record keeping.

It is worth noting a couple of age-old truisms, “if it is not recorded it did not happen” and “good records equals good defence, poor records equals poor defence and no records equals no defence”.

The existence of a note made contemporaneously at the time of the consultation is often the difference between the court preferring the doctor’s evidence and that of the patient/plaintiff in medical negligence claims.

There have been instances before the committees where doctors have retrospectively added a note which has completely compromised our ability to defend a claim. Even if the subsequent addition is an accurate note of matters which occurred at the time of the consultation, its retrospective nature may engender a negative response from the courts.

Record keeping needs to extend beyond the actual physical consultation to include communication with patients via telephone, SMS or email. Unsuccessful attempts to contact a patient, for instance to convey a test result, need to be accurately documented.

Another recurring theme in claims is the follow up of patients and their tests results. Adequate medical records and practice systems to ensure test results are actually reviewed by the requesting practitioner and communicated to the patient are essential.

What have the courts said about the need to keep medical records?

Kite v Malycha [1998] 71 SASR 321
This claim involved an allegation of delay in diagnosis of breast cancer involving a surgeon, Dr Malycha. The surgeon had seen the 31 year old patient for assessment of a tender and enlarging lump in her left axilla. The surgeon performed a fine needle aspiration (FNA) cytology, although he failed to make any reference to this procedure in his medical records. The surgeon made a provisional diagnosis of suppurative hidradenitis. He asked the patient to phone the practice within a few days to obtain the FNA result and attend his rooms for review in a few weeks’ time.

The patient did not phone for the test result, nor did she attend the follow up appointment. The FNA result, which revealed the presence of cancer, was not received by the surgeon.

When the patient did not attend her follow up appointment, the surgeon reviewed the medical records and, in the absence of any notation in the medical records, he did not recall that FNA cytology had been performed.

The claim proceeded to trial and the court found the surgeon was negligent in failing to follow up and obtain the cytology report, and to act on it in a timely fashion. The patient was awarded damages in excess of $500,000.

The court stated “Dr Malycha did not make a note of having performed the fine needle aspiration. He said that it was his usual practice to make such a note when he performed that procedure. He was unable to explain why he did not do so on this occasion”.

Tai v Hatzistavrou [1999] NSWCA 306
This claim involved an allegation of delay in diagnosis of ovarian cancer. The defendant was a gynaecologist, Dr Tai. Dr Tai had sent a request to the local hospital for the patient to be admitted for investigation of PV bleeding but the request went astray and the patient was not admitted. She was later diagnosed with metastatic ovarian cancer.

At the trial, Dr Tai gave evidence that he had asked the patient to contact him if she had not received notification from the hospital of her admission date within a few months; however, there was no record of this advice in the medical records.

The court noted “Dr Tai fairly and honestly admitted in evidence that he had no recollection, apart from what was written in his notes, of any particular conversation he may have had with the plaintiff. Dr Tai is a busy gynaecologist seeing up to 30 patients in one session. He stated that his consultation time for each patient was usually 15 minutes. Whilst he relies on his notes, they are very brief and do not note all that he did or said. He gave evidence as to his usual practice”.

Ultimately, the court preferred the patient’s version of events that she had not been advised to follow up the referral within a few months and judgment was entered against the gynaecologist.

Receiving a complaint or notification from the Australian Health Practitioner Regulation Agency (AHPRA) can be extremely stressful. Unfortunately, many medical practitioners will be the subject of an AHPRA complaint at some stage during their career. MDA National strongly recommends contacting us immediately upon receiving a complaint or notification from AHPRA or any other regulatory body, so we can assist you to provide an appropriate response.

Under national registration, AHPRA has been tasked to investigate notifications and complaints made against medical practitioners. Anyone can make a complaint to AHPRA, whether it is a patient, their relative, a colleague or employer. Complaints can be made over the telephone, in writing or online.

AHPRA may also request a report from a medical practitioner when their own conduct is not in question. For example, AHPRA may be reviewing hospital systems following receipt of a complaint and ask a practitioner to comment on the appropriateness of existing systems.

Alternatively, practitioners may be asked to comment on the competency of a colleague. Importantly, AHPRA does have the power to compel practitioners to respond, to assist in their investigation of a complaint.

**Preliminary assessment phase**

All complaints go through a preliminary assessment phase, whereby AHPRA determines if the complaint will be investigated by them or referred to another state based Health Complaints Entity. In NSW the co-regulatory system with the Health Care Complaints Commission (HCCC) was retained, therefore in NSW all complaints made to AHPRA are referred to the HCCC.

If AHPRA continues to assess the complaint, the practitioner will be asked to provide a written response. MDA National assists Members in drafting their responses, ensuring all issues of concern are addressed objectively and appropriately. If necessary, an independent expert opinion may be obtained.

Following preliminary assessment, the medical practitioner will be notified of what further action, if any, will be taken. This may include:

1. taking no further action
2. investigating the notification
3. requesting a health assessment or a performance assessment of the practitioner
4. referring the matter to a health or performance panel hearing
5. referring the matter to a tribunal hearing
6. issuing a caution
7. accepting undertakings
8. imposing conditions on the practitioner’s registration, or
9. taking immediate action on the practitioner’s (or student’s) registration.

AHPRA frequently decides that no further action will be taken after conducting a preliminary investigation. In 2010/11 no further action was taken in 86% of notifications.1

**Investigation**

AHPRA will undertake an investigation if, in its opinion, the complaint raises issues of clinical concern or of a disciplinary nature. At this point, the investigating officer may seek additional evidence such as statements from witnesses, further medical records, or phone records. They may also direct the medical practitioner to undergo a performance assessment or an independent health assessment, or refer the practitioner to a health or performance panel or a Tribunal hearing. Following the investigation, a decision may be made to:

1. issue a caution
2. accept undertakings
3. impose conditions
4. refer all or part of the notification to another body, or
5. take no further action.

**Tribunal**

There can be serious consequences for a practitioner if they are referred to a Tribunal and they are found guilty of unprofessional conduct and/or professional misconduct. Generally speaking the Tribunal comprises a District Court judge, two medical practitioners and a lay person, specifically appointed to consider the evidence, and determine if the medical practitioner’s conduct constitutes unprofessional conduct or professional misconduct. The constitution of the Tribunal can vary slightly from state to state.

Following the Tribunal hearing the following actions may be taken:

1. issue a caution or reprimand
2. impose conditions
3. fine registrant
4. suspend registration
5. cancel registration, or
6. take no further action.

If an undertaking or registration condition is applied, the practitioner will be subject to ongoing monitoring to ensure compliance.

**Review of decisions**

If a complainant is not satisfied with AHPRA’s decision, they can write to the Complaints Officer within 30 days of the decision and request a review. The complaint may then be referred to the Chief Executive Officer of AHPRA for internal review. If the complainant remains dissatisfied they can contact the National Health Practitioner Ombudsman, who may also conduct an independent review.

Although AHPRA often determines that no further action should be taken, a complaint may have the potential to result in serious consequences for a medical practitioner. Contacting MDA National immediately when you receive a complaint or notification from APhRA means that we can assist you to ensure the best possible outcome is achieved.

By Sharon Russell
Claims Manager (Solicitor)/ Risk Advisor

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1  AHPRA 2010/11 Annual Report.
At MDA National we understand that when a patient sees a solicitor about making a claim regarding your treatment or care, or when a patient issues proceedings through the court system the process may impact on you emotionally, mentally and physically, as well as having an effect on your work and home life.

Our Cases Committees operate in the Western and Eastern regions of Australia.

Similar to a hospital “Grand Round”, our Cases Committees – comprising medical practitioners – provide medical input and advice to MDA National’s internal Claims and Advisory Services team and are an integral element of our claims process.

Who sits on the Cases Committees?
The committees comprise a chairman and a mix of practising or recently retired medical practitioners – between the committees representing:

• anaesthetics
• general practice
• general surgery
• obstetrics/gynaecology
• oncology
• ophthalmology
• orthopaedics
• physician
• plastic surgery
• radiology
• sports medicine.

What do the Cases Committees do?
Claims Managers present claims to the Cases Committee by introducing the facts, expert evidence obtained and their view of the legal issues involved, including liability and causation.

Before each case is presented internal checks are conducted to ensure that no Cases Committee member has a real or perceived conflict of interest with either the doctor or the patient involved in a case. If a conflict does arise, the member has a duty to declare that interest and must not receive any information regarding the case and absent themselves from the committee during the discussion of that matter.

On presentation of the case, the Claims Manager refers back to the chairman who opens the case up to the Cases Committee for discussion. Such discussion involves in depth analysis and interesting commentary. Opinion can at times be divided and discussion robust, including dissecting the medical records, expert evidence, the patient’s account of events and any other useful information and documentation in order to drill down to the real medical issues of each individual file.

The Cases Committee achieves its purpose in relation to cases presented to it by:

• reviewing all medical issues
• providing a recommendation regarding the standard of care provided by the Member, consistent with the field(s) of expertise of the particular committee member
• commenting on causation issues
• commenting on apportionment of causation between Members and other parties where applicable
• providing other professional input linked to the medical aspects of a case
• where appropriate, providing opinions to management on perceived trends in incident reports
• providing the Claims and Advisory Services team with other advice as requested by the Claims Manager.

At the end of the process the Cases Committee makes:

• a recommendation regarding standard of care
• suggestions regarding the medical management of a case, such as obtaining further expert evidence or information.

All Cases Committee members are bound by MDA National’s obligations under the Privacy Act 1998 (Cth) and have a duty to maintain the confidentiality of information received by them or to which they have access in the course of their role as a Cases Committee member.

Conclusion
Our Cases Committees provide a valuable resource for the benefit of our Members and ensure we achieve the best possible outcome for each of our Members on an individual basis. While you may not necessarily meet or speak with the Cases Committee members, rest assured that they are there to get to the real medical issues through the process of a claim.

By Candice Danby
Claims Manager (Solicitor)
Case history

Mrs Sweet presented with her daughter Ruby, aged 21 months to Dr Jeep. Mrs Sweet gave the history that Ruby had not recovered well from a recent URTI and remained lethargic and off her food. Oddly enough Ruby was extraordinarily thirsty, and was asking for extra drinks and her nappies were more soaked than usual.

Dr Jeep examined the child, who was irritable, but not particularly unwell. He considered diabetes, but the child did not look very unwell, and he felt she was very young. He therefore asked the mother to bring her daughter for a fasting blood sugar test the following day.

Dr Jeep was not at work the following day, but when he returned to the surgery in two days and reviewed his results, he found that Ruby had a fasting BSL of 14mmol/L. He rang Mrs Sweet who informed him that Ruby had become very unwell the previous day and had been admitted to the ICU at the Children’s Hospital with diabetic ketoacidosis.

A few weeks later Dr Jeep received a letter of complaint from Mrs Sweet. While she acknowledged that the delay in diagnosis made no difference to the overall outcome for Ruby, earlier diagnosis could have avoided a stay in ICU.

Discussion

The prevalence of type 1 diabetes in children aged 0–4 years in Australia is 29/100,000 and the incidence is increasing.1 A recent systematic review examined the factors associated with the presence of diabetic ketoacidosis at diagnosis of diabetes in children and young adults.2 The authors found that at the onset of type 1 diabetes, 10 to 70% of the children presented in diabetic ketoacidosis.

Children less than two years of age had three times the risk of presenting in diabetic ketoacidosis. Children presenting with diabetic ketoacidosis had symptoms for a mean of two weeks, and up to a third had at least one medical consultation in the week before diagnosis.

High rates of misdiagnosis have also been found in children presenting with type 1 diabetes without diabetic ketoacidosis, with up to 86% of children not diagnosed at first encounter. Common diagnostic errors included misinterpreting symptoms (such as polyuria misdiagnosed as urinary tract infection); exclusively focusing on one or more symptoms (such as oral candidiasis) and not performing appropriate investigations (such as blood glucose or urine tests).

Lesson learned

Dr Jeep realised in retrospect that he could have done a finger prick test on Ruby at the time of the consultation, which would have established the diagnosis. In the presence of symptoms of polyuria and polydipsia, it is not necessary to perform a fasting BSL and a random blood test or finger prick test would be the first investigation.

By Dr Jane Deacon
Medico-legal Adviser

1 AIHW 2011. Prevalence of Type 1 diabetes in Australian children, 2008 Diabetics series no. 15. Cat. no. CVD 54. Canberra: AIHW.
When Things Don’t Go as Planned

Case history

On 15 November 2010, an 81 year old male patient consulted an ophthalmologist (the surgeon) for assessment and treatment of bilateral cataracts. The patient was diagnosed as having extensive cataracts which were causing significant disturbance, such that his optometrist was unable to give him clear vision with spectacle correction alone.

The surgeon informed the patient of the non-surgical and surgical options available to him. The non-surgical options included continuing to wear glasses and accepting blur and loss of contrast sensitivity. Surgical options included the implantation of either a monofocal or multi-focal lens, as the patient was a suitable candidate for either lens type.

The patient did not like the prospect of wearing reading glasses post-operatively, and elected to have multi-focal lenses inserted.

At the conclusion of the consultation, the surgeon dictated a letter to the referring general practitioner in which he set out the proposed treatment plan. The patient then saw the surgeon’s secretary to have the surgery scheduled and to sign the consent form. When obtaining a blank consent form, the secretary inadvertently grabbed a “Consent for Monofocal Lens Insertion” form, not the “Consent for Multi-focal Lens Insertion” that the surgeon had requested.

On 18 November 2010, the patient was scheduled to undergo a right cataract extraction and insertion of intraocular lens. The surgical team performed a “timeout”. A check of the booking sheet, theatre list and consent form signed by the patient all indicated that a monofocal lens was to be implanted.

The surgeon reviewed the patient post-operatively in his rooms on 19 November 2010. His right eye corrected to 6/9 vision, the lens was central and the cornea was clear. The patient’s vision was slightly myopic, which was appropriate for a person of the patient’s age as he mainly needed intermediate distance vision.

During the consultation, the surgeon told the patient that the lens insertion had proceeded uneventfully and he was pleased with the visual acuity the monofocal lens provided. At this point, the patient asked why a multi-focal lens had not been implanted. When the surgeon checked the medical records and noted that the letter to the general practitioner clearly stated that a multi-focal lens was to be inserted, he realised that an error had occurred. The surgeon apologised to the patient for the mistake.

Although the patient had good post-operative visual acuity, he was angry that the surgeon had not implanted the lens he had requested. When the patient demanded that the surgeon remove the monofocal lens and replace it with a multi-focal one, the surgeon explained that although he had inadvertently implanted the “wrong” lens, the result of lens exchange was unpredictable and as the patient had good post-operative visual acuity, he should leave well enough alone.

Although clearly dissatisfied, the patient agreed for the monofocal lens to remain in situ.

On 30 November 2010, the surgeon performed a left cataract extraction and insertion of a monofocal intraocular lens. The surgery proceeded without incident.

On 1 December 2010, the surgeon reviewed the patient and noted he had good post-operative visual acuity and that both eyes were working well together.

On 17 January 2011, the surgeon received a letter from the Australian Health Practitioner Regulation Agency (AHPRA) informing him that the patient had made a complaint. The letter informed the surgeon that the following aspects of his patient management were to be investigated:

• That he gave the patient incorrect advice in the pre-operative consultation because he implanted a different lens in the right eye to what he said he would.
• That he performed inappropriate surgery on the patient as he implanted a lens other than what the patient had requested.
• That he failed to inform the patient of the error and it only came to light when the patient queried the nature of the surgery he had undergone.
• That he was unable to communicate clearly with patients, given that he implanted a different lens to what the patient had requested.

AHPRA invited the surgeon to provide a written response to the patient’s complaint within 14 days.

The surgeon, with the assistance of MDA National, provided a comprehensive response to AHPRA in which he addressed the various issues raised by the patient.

In his written submission, the surgeon explained how the error had occurred and the steps he had taken to ensure that it did not happen again, including ensuring that only he completed and witnessed the patient’s consent. The surgeon also reiterated his apology to the patient.
AHPRA sought the surgeon’s consent to provide a copy of the response to the patient, which the surgeon agreed to.

Several weeks later, the surgeon received a further letter from AHPRA informing him that although the patient understood the explanation he had provided, he was still angry and felt aggrieved because:

1. he had not received the lens he had requested
2. the surgeon had refused to remove the monofocal lens and replace it with a multi-focal lens.

As the complaint was unresolved, AHPRA reviewed the complaint in conjunction with the Health Complaints Entity (HCE) in the surgeon’s particular state/territory.

The HCE considered that the surgeon’s response was both comprehensive, honest and compassionate, and as the surgeon had taken steps to minimise (and hopefully prevent) such a mistake from recurring, decided that no further action needed to be taken. The HCE proceeded to close the complaint.

Discussion

This case highlights what can go wrong when aspects of a patient’s management are delegated. It would have added very little time to the consultation if the surgeon had completed the consent form with the patient and witnessed the patient’s signature.

The case also exemplifies what can happen when a patient is dissatisfied with an aspect of his or her treatment, even in circumstances when the treatment has been successful.

When a notification/complaint is made about a health system or health service provider, AHPRA and the relevant HCE confer with each other and ensure that each notification is investigated by the appropriate agency.

By Yvonne Baldwin
Claims Manager (Solicitor)
Beware of Advertising Your Wares

Do you have a website, practice brochure, Yellow Pages advert or advertisements in journals or weekly papers which promote your medical business and/or services? If so, it is important to be familiar with the Medical Board of Australia’s guidelines for advertising of medical services.1

Case history
Dr Cheeky was an obstetrician who advertised his services via his website where he promoted being available 24/7, and that he had low rates of pregnancy complications and the lowest rates of 2nd and 3rd degree tears in town. He also stated that he used a special suture closing technique on any caesarean wounds which achieved the “best cosmetic outcome in Australia”.

After finding out she required a caesarean section, Mrs Swimwear Model engaged Dr Cheeky to deliver her first baby because she wished to have the minimal scar possible, post-surgery. She scoured Dr Cheeky’s website and decided to engage him because of the before and after photos he showcased as well as the assurances of other women on the site that he was the best and that the scar would “fade away” and be “hardly noticeable”.

After an uncomplicated caesarean section Mrs Swimwear Model’s incision did not heal and she was left with a large keloid scar. Mrs Swimwear Model complained to Dr Cheeky alleging she had been unable to work since the pregnancy due to the scar, and had suffered significant personal and professional consequences.

Discussion
The Medical Board guidelines prescribe how to advertise regulated health services. For example, a medical practitioner must not “create an unreasonable expectation of beneficial treatment”, “use testimonials or purported testimonials about the service or business” nor offer “inducement to attract a person… unless the advertisement also sets out the terms and conditions of the offer.”

You may think these guidelines won’t apply to or affect your practice as you aren’t touting for work on Hollywood Boulevard but the guidelines are applicable to all registered medical practitioners.

The guidelines state your advertisement (in whatever format) may contain:

- factual, clear statement of your services/products
- contact details
- gender of practitioners
- office hours
- a warning statement (in similar font to the main text) relating to surgical or invasive procedures which provides:

   Any surgical or invasive procedure carries risks. Before proceeding, you should seek a second opinion from an appropriately qualified health practitioner.

- non-enhanced photos or drawings of you in your office
- advice on wheelchair access
- statement of languages spoken

- statement about fees charged, bulk billing arrangements and instalment fees
- statement of qualifications/specialist registration and area of specialty/teaching positions held or formerly held/hospital affiliations or accreditation
- statement of the safety and quality accreditation of the practice
- list of publications
- statements encouraging preventative or corrective care (these should be evidence based).

The guidelines also state that advertising of services must not:

- create or be likely to create unwarranted and unrealistic expectations about effectiveness
- encourage inappropriate, unnecessary or excessive use of health services; for example “achieve the look you want” and “looking better and feeling more confident”
- include misleading use of emphasis, comparison, contrast or omission
- use testimonials
- compare health professionals in the absence of evidence
- claim services are better, as safe or safer than other health professionals
- lead to, or be likely to lead to, inappropriate self-diagnosis or self-treatment
- fail to disclose risks associated and omit warning statements (see guidelines for complete list).

Specifically, the guidelines state that practitioners should cautiously use graphic or visual representations such as client photographs, and all photographs must be of appropriately qualified health practitioner.

In relation to financial matters, the guidelines suggest that it is difficult to provide prices due to the personal nature of services, and the significant number of variables. If price information is included, you should ensure clarity and that all fees are identifiable, together with any conditions which attach to vary the advertised price or fee disclosed.

Medical practitioners must also comply with Commonwealth, state and territory consumer protection legislation. The Competition and Consumer Act 2010 (Cth)permits advertising unless it is misleading and deceptive, or is likely to mislead and deceive. A breach of this legislation can lead to prosecution by the Australian Competition and Consumer Commission and penalties include significant fines for any breaches.

By Helen Baxter
Medico-legal Adviser

1 Guidelines for advertising of regulated health services. Available at www.medicalboard.gov.au
MDA National is promoting your professionalism and wellbeing in 2012 with our Medico-legal Minefield Forums and Cognitive Workshops. We are also supporting Members by sponsoring a number of state and local conferences and events in collaboration with colleges and associations. We welcome you to come and visit us at any of the events below and others which are listed in full on our website.

### April 2012

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<td>17</td>
<td>Medico-legal Minefield Forum Melbourne, VIC</td>
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<td>28</td>
<td>Medico-legal Minefield Forum Perth, WA</td>
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<td>30</td>
<td>Medico-legal Minefield Forum Perth, WA</td>
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### May 2012

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<th>Date</th>
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<tr>
<td>4-6</td>
<td>ACNEM 2nd International Conference of the Science of Nutrition in Medicine &amp; Healthcare (sponsored event) Melbourne, VIC</td>
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<td>8</td>
<td>Medico-legal Minefield Forum Perth, WA</td>
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<td>9</td>
<td>Medico-legal Minefield Forum Brisbane, QLD</td>
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<td>12-16</td>
<td>ANZCA Annual Scientific Meeting (sponsored event) Perth, WA</td>
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<td>Medico-legal Minefield Forum Canberra, ACT</td>
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To find out more or to register for any of these events.
Disclaimer

The information in Defence Update is intended as a guide only. We include a number of articles to stimulate thought and discussion. Those articles may contain opinions which are not necessarily those of MDA National.

We recommend you always contact your indemnity provider when you require specific advice in relation to your insurance policy.

The case histories used have been prepared by the Claims and Advisory Services team. They are based on actual medical negligence claims or medico-legal referrals; however certain facts have been omitted or changed by the author to ensure the anonymity of the parties involved.

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