

Obtaining informed medical consent: a legal

By Violetta Zotti, Law Student, Flinders University; Dr Mario Zotti, Department of Orthopaedics and Trauma, Lyell McEwin Health Service; David Worswick, Lecturer, Schools of Law and Medicine, Flinders University

Consent to treatment is a fundamental legal and ethical obligation that reflects patient autonomy and involves four issues: voluntariness, information, competence to consent, and requirements that the person conducting the treatment obtains the consent. This article explores the provision of information to the patient, the "informed" part of the consent process and employs a clinical study to help analyse issues surrounding the legal requirement to warn of "material risks". While most legal practitioners may have a reasonable sense of the rules of consent, this surveys a group of clinicians administering steroid injections. This article demonstrates how consent rules, particularly those involving the provision of information to patients, are understood by clinicians, and the relative practical difficulties created in complying with them.

Consent to treatment: the legal obligation to provide information

Consent rules have an additional cross-over into civil liability. In the absence of any consent, medical treatment is characterised as battery. However, where there has been some sense of a consent process being initiated, albeit a flawed one, then the patient remedy is usually considered to be in negligence. The need for consent to be obtained prior to performing medical procedures on a patient is well established in law.¹ It is now relatively common in medical litigation to allege both a breach of clinical standards and a failure to adequately warn the patient of risk inherent in treatment. The standard of care required by law for the provision of information has been deliberately formulated by reference to judicial standards, whereas the standard of care for medical professionals required in *diagnosis and treatment* is closer to a medical peer standard based on the test set out in *Bolam v Friern Hospital Management Committee*.²

This is clear from a reading of s 41 of the *Civil Liability Act 1936* (SA) regarding standard of care for professionals.³

As s 41(5) of the *Civil Liability Act 1936* (SA) does not set any standard for information disclosure, the common law expressed by the High Court in *Rogers v Whitaker*⁴ is still therefore applicable. The High Court in *Rogers v Whitaker*⁵ approved the reasoning of King CJ in the South Australian case, *F v R*⁶ that the standard of care in any failure to warn case is a question for the Court to decide, not a decision made solely by reference to a medical peer standard. In *Rogers*, the High Court went further than King CJ in formulating the test of what is a material risk that should be disclosed.⁷ The test to be applied in determining whether a particular risk is "material:" is whether "...a reasonable patient 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 of the risk, would be likely to attach significance to it".⁸ The adoption of the negligence criteria that King CJ⁹ stated and that was approved by the High Court¹⁰ was:

*'What a careful and responsible doctor would disclose depends upon the circumstances. The relevant circumstances include the nature of the matter to be disclosed, the nature of the treatment, the desire of the patient for information, the temperament and health of the patient, and the general surrounding circumstances...'*¹¹

This statement, full of common law flexibility does, however, allow for significant expansion of the duty to warn of medical risk. The expansion of online material about medical information since

these decisions was probably not foreseen by these key judgments in the 1980s and early 1990s.

Legislation on consent to medical treatment and procedures

Legislation regarding consent to medical treatment and procedures varies from State to State. In South Australia, s 15 of the *Consent to Medical Treatment and Palliative Care Act 1995* (SA),¹² sets out the duty that a medical practitioner (defined in the Act to be medical practitioners and dentists) has to explain the proposed treatment to a patient (or their representative) so far as is practicable and reasonable in the circumstances.

There is no reported case on s 15. However, regarding s 15 of the Act¹³ on the doctor's duty to warn and inform the patient of risks, the Court, in cases involving allegations of *negligent failure to warn or inform* the patient regarding risks to treatments and procedures, will consider *Rogers*¹⁴ which is more onerous on the obligation of warning of risks to patient.

Consent in practice: steroid injections

Local injections of musculoskeletal corticosteroids are common diagnostic and therapeutic procedures ordered and administered by clinicians electively to painful musculoskeletal regions. The proposed therapeutic benefit of steroid injections is that they may alleviate pain by suppression of inflammation to the targeted region.¹⁵ Further, they may also give diagnostic information to the clinician who is unsure of the source of pain in the patient when pain relief in the area injected is demonstrated.¹⁶ Relief from steroid injections will vary depending on the type of steroid, region of the body, pathology and patient; generally, therapeutic benefits will be temporary and not a definitive

perspective

treatment.¹⁷ Steroid injections are but one of many management options used in isolation or combination by the clinician, which in musculoskeletal conditions may involve other measures such as orthotics, bracing, activity modification or physiotherapy ranging to operative management.

Steroid injections, while being an "invasive treatment", are generally safe and well tolerated with complications rare. Well documented local side-effects include skin and fat atrophy, haematoma, skin depigmentation, local infection, tendon rupture and haemarthrosis.¹⁸ The literature has reported rare but life-threatening complications including septic arthritis, pyomyositis and gangrene following local corticosteroid injections.¹⁹

Aim of study

The aim was to gauge the current practice of obtaining informed consent for local steroid injections and the specific risks relating to doctors' responsibility recognised by law in Australia regarding

failure to warn of material risk amongst medical practitioners involved in ordering or administering injectable steroids. The results were then compared to the law in Australia and the legal responsibilities of the doctor discussed. Also, the results were compared to a published study regarding informed consent processes prior to steroid treatment amongst shoulder and elbow surgeons in the UK.²⁰

Method: Survey instrument

The authors formulated a short, questionnaire as the principal data tool that was either self-administered or posted. Consent for involvement in the survey was obtained by provision of a statement of the purpose and aims of the study. The questionnaire comprised nine questions which addressed issues relevant in common law and medical negligence literature to be regularly discovered in medical negligence claims.

Results and Discussion

The study supports the hypothesis that

a suboptimal informed consent process is occurring amongst clinicians in South Australia ordering or administering steroid injections where "failure to warn" is a concern. The majority of respondents did not engage the patient in an informed consent procedure that would necessarily be conducive to a favourable legal outcome in the event of rare but grave complications.

To extrapolate from this sample of practitioners, it would appear that most practitioners discuss benefits, alternatives and the consequences of not having treatment and are on the whole familiar with some common law and legislation. However, half or more of the respondents did not use consent forms, did not have a routine method of consent, did not document consent nor *always* mention the risk of infection let alone severe infections, routinely recording less than half of the risks mentioned to patients.

At the time of writing, there was no published study that investigates the current practice of clinicians obtaining informed consent for steroid infection treatment in

Forensic Accounting and Litigation Support Services division

Leading providers of Forensic Accounting and Litigation Support Services, we have extensive experience in the assessment of damages, business valuations, the adequacy of audit opinions, the identification of fraud and accounting reconstructions.

Contacts:

Hugh McPharlin	Brian Morris
Ben Miels	Martin White
Brenton Ellery	Ben Opie
Alex Canale	



Edwards Marshall

Edwards Marshall's reputation in this field is unsurpassed. We are particularly adept at analysing and distilling complex information and enabling efficient comprehension of financial, accounting and valuation issues.

Simple, clear and unbiased advice, without fear or favour.

Obtaining informed medical consent:

a legal perspective (cont)

Australia and only one published study of shoulder and elbow surgeons in the UK²¹ and when compared, the results of the studies demonstrate similar trends.

Approach to informed consent from other medical and legal bodies

Although there are no specific guidelines for obtaining consent for local steroid injections²² there are 1993 National Health and Medical Research Council (NHMRC) guidelines on the provision of information to patients, which have been revised and reissued in 2004.²³ These guidelines do not require written consent. The authors' study indicates that only 13 percent of practitioners are recording consent in writing. In the other UK study this figure is only 2 percent.

Of great concern is that the findings of the study reveal that the majority of respondents *never* mention severe infections. This data is similar to another informed consent study from the UK which reported only 30 percent of surgeons agreeing that major risks of incidence 1 in 10,000 or greater should be disclosed.²⁴ This is a significant result given that in *Rogers v Whitaker*, the patient was successful in her claim despite a 1 in 14,000 risk.²⁵

Therefore, what appears to be occurring in doctors' practices is placing them in a vulnerable position and is in contrast to what legislation and common law requires. By implication, it would take only a patient preoccupied with the risk of severe risk to life or further impairment to the limb, together with the routine practice of the majority of respondents, to result in a successful claim for failure to warn. This is because the causation element of the failure to warn claim is made out in Australia on a subjective test: would *this* particular patient (as opposed to the 'reasonable patient'), if warned, still have gone ahead with the treatment? If the patient convinces the Court that the warning would have prevented them having the treatment, the causation element is made out.

The ALRC further recommends that under a common law duty, doctors should continue to provide patients with information to allow for informed decision making on

medical procedures and should not be replaced with a statutory duty. The authors agree with this recommendation.

Material risk related to steroid injections

As steroid injections are, by nature, elective procedures, patients might reasonably argue that had they known of the rare but severe complications of the procedure rendering them disabled, they may have opted for another treatment modality at the time of the decision being made to undergo steroid administration. For example, should a doctor fail to warn of the risk of severe infection to an otherwise healthy patient with a painful subacromial bursitis of the shoulder, who then goes on to develop severe infection and loss of arm musculature rendering them disabled, then a claim based upon failure to warn may be made.

Authors' recommendations

The authors recommend for optimal medico-legal protection but also for increased satisfaction of all parties involved that the doctor ordering or administering steroid injections undertake the following procedures, which are generally in line with NHMRC "General guidelines for medical practitioners on providing information to patients: informing patients of risks".²⁶

The first step is to discuss how steroid injections fit in the management regime for the patient's condition and its proposed benefits, including expected relief of symptoms and duration. Risks, including minor and severe, should then be explained to the patient along with the possible management and consequences of those complications. Should there be a reasonable amount of time prior to the arranged administration, written information may be given to the patient to consider and the patient may be asked whether they need time to contemplate desire for the intervention. The option for patient contemplation and a longer temporal relationship between the informed consent and surgical procedure has previously been reported as an important factor in reducing the risk of malpractice payments in US lawsuits being brought forward.²⁷

The patient should then be asked if they understand what has been discussed and

whether they would still like to proceed, at which point written documentation should be made (and copies to the referring doctor) that includes stated specific risks.²⁸

The authors conclude that the majority of doctors use verbal consent only and do not document the discussion or the spectrum of risks in the case notes when obtaining informed consent for local steroid injections. The authors recommend clear and sufficient documentation of all informed consent of local steroid injections in the case notes. This is paramount for further reference, in the case where litigation arises and should become standard practice. **B**

Endnotes:

- 1 Trindade F, Cane P and Lunney M, *The Law of Torts in Australia* (4th ed, Oxford University Press, Victoria, 2007) 112.
- 2 *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582, 587 (the *Bolam* test).
- 3 *Civil Liability Act* 1936 (SA) s 41.
- 4 *Rogers v Whitaker* (1992) 175 CLR 479.
- 5 *Ibid*, 490.
- 6 *F v R* (1983) 33 SASR 189, at 192-193 (King CJ).
- 7 *Rogers*, 490 (Mason CJ, Brennan, Dawson, Toohey and McHugh JJ).
- 8 *Ibid*.
- 9 *F v R* (1983) 33 SASR 189 at 192 (King CJ).
- 10 *Rogers*, 488 (Mason CJ, Brennan, Dawson, Toohey and McHugh JJ).
- 11 *F v R*, 192-193 (King CJ).
- 12 *Consent to Medical Treatment and Palliative Care Act* 1995 (SA), s 15.
- 13 *Consent to Medical Treatment and Palliative Care Act* 1995 (SA), s 15.
- 14 *Rogers*, 490 (Mason CJ, Brennan, Dawson, Toohey and McHugh JJ).
- 15 Wong S, Wong C and Li T, "Steroids in regional analgesia" 11(17) *Expert opinion on Pharmacology* (2010) 2839-2848, 2839.
- 16 Brinks A, Koes B, Volkers A, Verhaar J and Bierma-Zeinstra S, "Adverse effects of extra-articular corticosteroid injections: A systematic review" 11 *BMC Musculoskeletal Disorders* (2010) 206.
- 17 *Ibid*.
- 18 *Ibid*.
- 19 Cheng J and Abdi S, "Complications of joint, tendon and muscle injections" 11(3) *Regional Anaesthesia and Pain Management* (2007) at 141-147.
- 20 Lim C, Miles J and Preckham T, "Original Article: Current Practice of Obtaining Informed Consent for Local Steroid Injection among the Shoulder and Elbow Surgeons in United Kingdom" (2010) 55 *SMJ* 32.
- 21 *Ibid*.
- 22 Australian Government National Health and Medical Research Council, *General Guidelines for Medical Practitioners on Providing Information to Patients*, at 11-12, http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e57.pdf, viewed 4 July 2011.
- 23 *Ibid*.
- 24 Jamjoon A, White S, Walton S, Hardman J, Moppett I, "Anaesthetists' and surgeons' attitudes towards informed consent in the U.K: an observational study," *BMC Medical Ethics* 2010 (11):2.
- 25 *Rogers v Whitaker* (1992) 175 CLR 479.
- 26 *Ibid*.
- 27 Bhattacharyya T, Yeon H and Harris MB, "The Medical-legal aspects of informed consent in orthopaedic surgery" (2005) 87(11) *JBJS [Am.]* 87(11) 2395-2400.
- 28 Freckleton I, "The new duty to warn" (1999) 24(1) *AltLaw J* 17.