

## Clinicians in the cross hairs

How practitioners of Aesthetic Medicine can protect themselves from claims through good clinical governance & risk management.

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Practitioners in Aesthetic Medicine are perhaps more susceptible to compensation claims alleging lack of informed consent, where patients can easily say the treatment was not essential and they would not have agreed to the treatment at all had they been advised properly of the risks, benefits and alternatives.

Consent cases are very common, even where the procedure itself may have been carried out with all appropriate skill and care. The patient may say even non-negligent complications would have been avoided had they not undergone the procedure at all following adequate counselling. In some cases under English law, it may not even matter if the patient cannot say whether they would have gone ahead or not.

As a timely warning to the industry of 'There but for the grace of god...', the former super-model Linda Evangelista Cool, famously reputed to have once said she wouldn't get out of bed for less \$10000, is suing Zeltiq Aesthetics (a subsidiary of Allergan) in America after a CoolSculpting procedure left her face "brutally disfigured", saying that she wasn't educated about the potential risk before signing up for CoolSculpting. Whilst it is not uncommon for a manufacturer or distributor to be sued, practitioners and clinics should not draw any false comfort that they will not be in the firing line if they do not take steps to mitigate their risk.

### What actually is informed consent?

Since 2015 the legal standard for consent in the UK is called the Montgomery test, named after a case in the Supreme Court. Briefly, a doctor is under a legal duty to take reasonable care to ensure that the patient is aware of any material risk involved in the recommended treatment and of any reasonable alternative or variant in the treatment. There are only two limited exceptions which are unlikely to apply for practitioners of Aesthetic Medicine. First, a doctor is entitled to withhold information if they reasonably consider that its disclosure would be seriously detrimental to the patient's health; and second, where emergency treatment is required for a patient who is unconscious or otherwise unable to make a decision. A material risk is something which in the circumstances of the particular case, either:

- A reasonable person in the patient's position would be likely to attach significance to the risk; or
- The doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

Hence, the answer to this test is specific to the patient and no longer determined by a body of responsible practitioners. While it is not necessary to warn of every academic or hypothetical risk, it can be very difficult for a practitioner to know where to draw the line.

It is not uncommon to see the manufacturer, clinic and practitioner all named as defendants to the same claim and these may be very expensive to defend in England, where the patient will be entitled to recover their own legal costs from the losing party (often several times higher than the value of the claim itself) but a successful defendant is often expected to bear its own costs of successfully defending a claim. Hence a little bit of prevention is certainly better than cure!

### What can practitioners do to protect themselves?

Before providing any treatment, to comply with the law a doctor has to engage in a dialogue with the patient about the nature of all material risks, the effect which the risk would have upon that patient if it materializes, the importance to the patient of the benefits of the proposed treatment, as well as any alternatives or variants available. In addition to the opportunity for asking questions, patients should

have sufficient time to consider whether to proceed or not, perhaps after going away to think, carrying out research, speaking with friends or family or getting a second opinion. It is no longer about risk percentages or what a reasonable practitioner would deem it necessary to mention.

As ever, clear notes must be kept contemporaneously – a “consent” tick-box is not enough, and pro-forma consent forms where the patient is just asked to sign at the bottom may have limited value, especially where only provided a short time before the treatment begins, or where the process was delegated to a junior member of the team without the experience to answer questions. The presence of a chaperone (who also signs the written consent) can help save a practitioner from a consent claim. This can also be very helpful where a patient is vulnerable, has mental health issues or unrealistic expectations. Refusing treatment or referring some patients for a second opinion and/or psychological care may be the best decision in some cases, though depending on the treatment, ethical practitioners would unlikely go ahead with the procedure in a case like this anyway.

At times this can be very challenging to comply with and difficult commercially, hence trying to bring consent forward as part of a process of shared decision making that begins when doctor and patient first meet. Warnings about material risks to treatments displayed on a clinic or practitioner website can be a powerful source of evidence in defending a claim, especially where patients self-refer through the website (via a contact form, for example) and the warnings can be embedded in the process. Information leaflets can also be a useful adjunct to the consent process, but patients will often forget them later or will deny that these leaflets were provided at all; and you may be unable to locate the correct version if a claim is brought several years later. There are now several interesting digital consent aids on the market that are worth exploring such as Vault by Eido Healthcare. More technology including AI will undoubtedly play a greater role in the future, but for now these aids should be seen as augmentation and not a substitute.

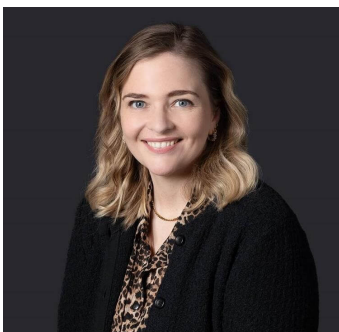
All indemnity/insurance options are not alike and a specialist broker is a good idea. “Medmal” (medical malpractice) insurance policies will also have a variety of different terms including financial caps per claim or in the aggregate, exclusions, or else reporting requirements that can result in claims being “bounced”. Some will specify that they do not cover treatment on celebrities or sports people at all. A traditional medical defence organisation does not provide a contract of insurance that is enforceable in the usual way and are not subject to a regulator or the Financial Ombudsman; they are effectively members’ organisations providing discretionary cover. There are pros and cons of different forms of cover and clinics relying on their practitioners to have their own indemnity/insurance are taking a huge gamble.

Where the practitioner or clinic does not have indemnity/ insurance cover, or for some reason they are not being covered by their indemnity/ insurance provider, the patient will look for another pathway to compensation and often another Defendant with insurance cover or deeper pockets. This may not seem fair to whoever is left in the frame! I have seen numerous claims after the practitioners did the treatment as a favour for a “friend” and were very surprised to hear that they can still be sued. The old legal maxim is ‘No good turn goes unpunished’!

Fortunately most consent claims can be avoided by common sense augmented by good clinical governance and risk management.

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