

I am an long in the tooth clinician and it looks like all the patient has to do is say I didn't fully understand the information I was given, for a claim to succeed.

For a claim to succeed, the patient will need to prove that he or she was not told about the material risks of the treatment/procedure and/or any reasonable alternative or variant treatment options, or that it was clear he or she did not understand the information provided by the clinician.

The Courts are alive to the fact that by the time a claim is brought, considerable time will have elapsed since the consent process and the relevant discussions between a claimant and clinician.

In assessing liability in these cases, the court will look at all the evidence and the contemporaneous notes made by the clinician about the detail of the discussion with the patient and any other sources of written information (e.g. electronic or hard copy patient information leaflets) will be absolutely crucial.

The case of *Olloson v Lee of [2019]* related to an alleged failure to obtain informed consent for a vasectomy procedure. The Claimant developed chronic testicular pain following a vasectomy in November 2012 and alleged that he was not adequately informed about the risk of this outcome. The risk of chronic pain after vasectomy of the severity suffered by the Claimant was acknowledged by the experts to be much less than 1%. It was not disputed by the Claimant that a small risk of chronic pain was mentioned in the information booklet provided to him ahead of the procedure and also on the day of the procedure when he signed a consent form. The Claimant's case was that the warning given to him about the risk was not adequate in that the magnitude of the risk and the range of severity of the possible outcomes were not explained.

The Court found the Claimant and his wife to be decent, honest people but their memory of what they were told was imperfect and that an adequate warning had in fact been provided. On the balance of probabilities, following an analysis of the evidence, including the contemporaneous notes of the consent process, the Claimant had been adequately informed and told of a small risk of chronic pain, and of the range of severity and possible efe.(p)-1.6c pa

If a patient has been provided with all relevant information in advance of treatment/a procedure and given adequate time and space to reflect, ask questions and change their mind about how they want to proceed, it will, in most cases, be acceptable for them to sign the consent form when they attend for the treatment/procedure.

In these circumstances, it is absolutely crucial that there is a conversation between patient and clinician and that the content of that discussion is recorded in writing and that it is clear that the patient is making an informed decision based upon the information they have been given on material risk and reasonable alternative treatment options.

In the current climate, and moving forward more consultations are taking place over a video link. How acceptable would an affirmation email from the patient in place of a wet signature for consent?

Whilst it is reasonable to expect a signature on a consent form just proves a patient can sign their name, it remains a matter of clinical judgement as to whether a patient's signature on a consent form is sufficient to prove that they have understood the risks and benefits of the proposed treatment and procedure.

Reasonable alternatives - if a patient is booked in for an abdominal hysterectomy, do we have to discuss the option of doing the procedure laparoscopically, even if we don't have the equipment available in our hospital or the skills to carry out this procedure. Especially with COVID-19 now? Laparoscopic operations carry more risk than open operations.

Firstly, in general terms, the case of *Bayley v George Eliot Hospitals*

We use the EIDO forms at work; I printed out two 'leaflets' for GenSurg operations last week and there was no COVID information there. Is it in a separate area?

The EIDO forms have the COVID-19 information on the first page after the cover. If you are printing out copies from locally saved files, then you should download up-to-date copies direct from the EIDO Download Centre. You can contact the account manager for your hospital using the 'help' button on the Download Centre.

What are the implications for information provided in a format the patient cannot access? 8.9% of Nottingham adults have low or no literacy. Others have sight or language issues - our Trust's EIDO consent information is in a tiny font that doesn't meet standards etc. Thank you.

EIDO information is available in 12pt font as standard, as well as Large (18pt) and Giant (22pt) Print, and Screen Reader options. A subset of the library is available in Easy Read. These help Trusts and Boards meet the Accessibility Standard. Each EIDO document bears a unique Plain English Campaign Crystal Mark for the clarity of the language used. Inform Digital allows your patients to have the document read to them using voiceover software and change the font and background colour to improve their access to the information and meet web content accessibility (WCAG 2.1) guidelines. Please contact EIDO to discuss your Trust's requirements in this regard with your EIDO Customer Care Manager.

One of the key difficulties is ensuring a patient has comprehended the information and recording this. It's all very well giving information, but literature shows retention and comprehension is extremely poor in many patient groups. How do we improve this?

An upcoming release of the EIDO Consent suite will include an optional Q&A session for the patient to complete. This is aimed at encouraging better learning and engagement of the patient and is recorded and available to help focus subsequent clinician patient consultation(s), whether virtual or face to face.

How do you use eConsent/digital process if patient doesn't have IT/computers in virtual consultation world of COVID-19?

EIDO's Home Consent offering can work alongside, or separate to, your Trust's virtual consultation; however, it does require the patient to have access to a computer/tablet/phone and internet connection. Patients could record consent at home via a hard copy consent form posted out to them, a clinician could complete part of the consent form in discussion over the phone with the patient. Hospitals using EIDO's Vault app can take consent from a patient digitally in hospital, using hospital IT equipment.

Is there a facility for getting the signed consent form back from the patient digitally on EIDO platform?

Yes. The Home Consent draft form is stored and available via the Inform Digital dashboard. If the hospital chooses to integrate the system with the hospital network, then consent forms and patient engagement reports can also be sent securely to the hospital to be accessed locally. The EIDO Vault app, when linked to the Home Consent form, can allow clinicians to fully complete the consent form, including signatures, digitally.

What is the cost of using EIDO to the trusts?

The cost depends on the number of titles licenced, the languages and formats licenced and length of contract; please contact EIDO at info@eidohealthcare.com for a quote.

When decisions are shared one outcome is a fall in the number of invasive interventions. How much of the EIDO impact on Trust legal ££ might be due to that?

The figures presented during the webinar were all connected with the reduction in monies paid out as a result of successful litigation claims. We don't have any evidence on the impact on numbers of invasive interventions.

Are there any plastic surgery leaflets on EIDO?

Yes, the EIDO library currently contains approximately 20 Plastics titles. All specialties in the library are continually growing.

How much of the EIDO information focusses on the other options in respect of the decision - especially the choice not to intervene?

The EIDO documents each have a section on alternative treatment options, including the option of not having the procedure, as this is an important part of the informed consent conversation.

