EIDO HEALTHCARE

# Consent Review

## Third Edition (2019)

in association with

brownejacobson LLP

**EIDO Healthcare Consent Review**

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## Table of Contents

## EIDO Healthcare Preface

Welcome to the third edition of EIDO Healthcare's *Consent Review*.

Over the past 20 years, EIDO has established itself as the UK's leading expert in patient information to support consent to treatment. 2019 will see the launch of our suite of new digital products that allow patients to understand the procedure they are about to have, and support healthcare professionals through the consent process.

Consent law is a highly complex area, and one that is constantly evolving as new cases are decided by the courts. Never before has it been so important for clinicians to have a proper understanding of their responsibilities, and to obtain consent to treatment within the boundaries set by the law.

It is now four years since the Supreme Court gave its landmark ruling in *Montgomery v Lanarkshire Health Board [2015]*. The new approach to consent is now unambiguously patient-centred, and healthcare professionals must learn how to adapt to it and ensure that each patient's individual circumstances are being considered and discussed before consent is sought.

A comprehensive picture is now emerging about the scope of the *Montgomery* case and its influence on clinical practice.

This third edition of our *Consent Review* seeks to answer further questions arising since the Supreme Court decision, examine notable recent cases, and discuss the key learnings from them.

In just three years since the *Montgomery* ruling, consent litigation costs for "failure to warn" have more than doubled. In the past ten years, consent litigation costs for "failure to warn" have risen by nearly 300%.

However, recently-acquired data shows that hospitals using EIDO's library paid out 25% less in consent litigation costs, when compared to hospitals using other sources of information.

EIDO continues to partner with The Royal College of Surgeons of England in addressing this increase in consent-related litigation resulting from *Montgomery*. The College continues to sponsor a free six-month trial of EIDO's consent library for NHS trusts that aren't already using it.

**For more information, please visit *eidohealthcare.com/rcs-trial***

**Alistair Firth**
Chief Executive – EIDO Healthcare

## Browne Jacobson Preface

It has now been over four years since the Supreme Court decision in *Montgomery v Lanarkshire Health Board*.

The case brought the legal test for obtaining consent from patients into line with GMC Guidance ("Patients and Doctors making decisions together; 2 June 2008") by codifying the requirement for clinicians to ensure that an individual patient is aware of any material risks involved in any proposed treatment and reasonable alternatives to that treatment.

Since the decision of the Supreme Court, there have been a number of decisions which have refined and clarified the law in this area and these have been covered in previous annual versions of this review.

As solicitors, we frequently still see claims where the adequacy or otherwise of the consent process is a central issue in the case, with some cases pursued entirely on the basis of alleged lack of informed consent, where there are no allegations of negligence relating to the management of the treatment itself.

As highlighted by the two cases covered in this review, the key issues in assessing liability continue to be, in terms of breach of duty:

- What constitutes a material risk; and
- What constitutes reasonable alternative or variant treatment options?

In terms of causation:

- What, if anything, would the patient have done differently in terms of deciding what treatment to undergo and the timing of that treatment and what difference, if any, would that have made to the outcome?

The recent case law covered in this review also highlights the crucial role that documentary evidence plays in the assessment of liability.

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## Introduction

### Building on the *Montgomery* principles

Four years have passed since the decision in *Montgomery v Lanarkshire Health Board [2015] UKSC*. In this landmark case, the Supreme Court issued guidance for healthcare professionals on the correct approach to enabling patients to give consent to proposed treatment on the basis of appropriate information.

Since then, UK courts have been developing a better understanding of the principles of informed consent, and EIDO's *Annual Consent Review* has been at the forefront of reporting these developments.

### The scope of the third edition

This year's *Consent Review* provides further insight into the way in which the law is continuing to keep pace with twenty-first century social attitudes, focusing again on informed consent in the context of adults with capacity.

Interestingly, as the guidance in *Montgomery* becomes more deeply entrenched, there are fewer cases coming before the courts in which queries are raised about scope of the guidance, and fewer challenges are being made to the modern approach.

The cases outlined in this edition contribute to the expanding body of knowledge and provide assurance to healthcare professionals and policy-makers that patients have an important part to play in their treatment decisions.

## The basics

An accepted definition of consent to medical treatment is as follows:

***"Consent is the voluntary and continuing permission of a patient with capacity to receive a particular treatment, based on an adequate knowledge of the purpose, nature and likely risks of the treatment, including the likelihood of its success and any alternatives to it. Permission given under any unfair or undue pressure is not consent".***

This definition has underpinned the legal position for many years, and every phrase contained in it is important. The *Montgomery* decision clarified the nature and extent of appropriate involvement of patients in the consent process, aligning the law with recent changes in social attitudes.

## Modern models and *Montgomery*

The facts of the *Montgomery* case are generally well-known by healthcare professionals, and are summarised in brief here. The claimant, Mrs Montgomery, suffered from diabetes and was small in stature. She was from a medical family, holding a science degree herself. Whilst expecting her first child, she was aware that as a mother with diabetes, there was a risk that she would be carrying a larger-than-average baby. The consultant obstetrician responsible for her care did not inform her about the risks involved in delivering a large baby, including the risk of shoulder dystocia and its consequences. Furthermore, she did not advise Mrs Montgomery about the option to have a caesarean section delivery rather than a vaginal delivery. In the event, the delivery was very difficult as the baby's shoulders became lodged in the birth canal, and as a result he was starved of oxygen, suffering a brachial plexus injury and cerebral palsy.

The Supreme Court held that there had been a breach of the consultant's duty of care in negligence through her failure to inform Mrs Montgomery of the risk of shoulder dystocia if the baby was delivered vaginally. The Supreme Court found in Mrs Montgomery's favour, as she was able to establish that if she had been made aware of the possibility of having a caesarean section delivery she would have opted for that, and the injuries sustained by her baby would have been avoided.

The Court rejected an attempt by the defendant to rely on the defence of therapeutic privilege, concluding that if Mrs Montgomery had been given the relevant information she would have opted for a caesarean section. In the course of the judgment, guidance was issued by the Court about the need to inform patients about the risks of harm involved in proposed treatment. The principles stated in the case reflect the importance of the autonomy of patients, alongside self-determination on the basis of appropriate information about proposed treatments and their alternatives, setting out the advantages and disadvantages of the available options.

The Supreme Court concluded that:

***"The doctor is…under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, 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."***

Recognition is given to the *Montgomery* decision in recently-revised guidance issued by organisations responsible for advising patients and healthcare professionals. For example, in the past year NICE has issued guidance on consent to procedures for which the risks and benefits are uncertain. In addition, the GMC has undertaken a public consultation on a revised version of its consent guidance issued in 2008, setting out good practice principles in accordance with what it described as "shifts in the legal, policy and workplace environments".

The draft GMC guidance focuses on the importance of communication, personalised conversations, and doctors and patients making decisions about treatment and care together. It emphasises that doctors need to support patients as individuals in their decision making, helping them to make choices about their own treatment and providing them with information in a way they understand. It also encourages listening to patients and allowing them time to ask questions, tailoring answers to reflect their particular concerns, respecting their decisions and not pressurising them in any way.

The GMC guidance avoids legal terminology, and in the context of patients who lack capacity, the term 'overall benefit' is used to describe the ethical basis on which decisions are made about treatment. This involves weighing up the risks of harm, benefits and burdens for the individual patient.

The current NHS approach also recognises the importance of encouraging patient involvement in wider health policy developments. Modern healthcare models found in a range of policy documents, including the NHS Constitution, emphasise the need for patients to take some responsibility for themselves. This is because social and legal developments have progressed away from a model in which the relationship between doctor and patient is based upon medical paternalism. Instead, patients who have decision-making capacity are treated as adults capable of understanding that medical treatment involves certain risks and that success cannot always be guaranteed. They are invited to accept responsibility for assessing and taking risks that may affect their own life, and for living with the consequences of their choices.

## The recent case law

A number of key points emerge from the cases decided over the past year. These are outlined here in brief.

**i) It is important for the claimant to establish a causal link before a claim can succeed**

***Keh (Administrator of the estate of Adeline Keh) v Homerton University Hospitals NHS Foundation Trust [2019] EWHC 548 (QB)***

This was a claim for damages against the defendant NHS trust. It was based on an allegation of clinical negligence in the care of the claimant's wife, who had died as a result of sepsis following an emergency caesarean section.

**The facts of the case**

The claimant's wife had attended the trust's hospital for a routine blood pressure check at nearly 37 weeks into her first pregnancy. She was admitted to the hospital because of concerns about the baby, and an induction of labour was begun on the advice of a consultant obstetrician. However, labour did not progress, and it was decided that an emergency caesarean section was necessary. The operation began an hour and a half later and the child was born safely. A few days later it was decided to treat the claimant's wife with antibiotics for post-natal sepsis. A CT scan was performed after another few days, and the antibiotics appeared to have improved her condition. However, the deceased's condition subsequently deteriorated and she died in hospital 18 days after the delivery of the baby.

The claimant argued that his wife should have been offered a planned caesarean section, which should have been carried out sooner, so that the risk of infection would probably have been avoided. The evidence of an expert obstetrician was that the need for a planned caesarean section was indicated by a number of factors, including the age of the mother (40) and the fact that she was overweight.

In addition, as a Jehovah's Witness she could not accept blood transfusions, so action to minimise the need for a transfusion was advantageous.

The claimant also alleged that there had been negligence because the team treating his wife had failed to perform a hysterectomy. The trust agreed that the source of the infection had been the uterus and that a hysterectomy performed at an earlier stage would probably have prevented the death.

**The legal principles**

The judge explained the need for the claimant to prove that there had been a breach of duty on the part of the consultant, in failing to inform the claimant's wife about the various options for her treatment. After that it would be necessary to prove, on the balance of probabilities, that the claimant would have opted for a safer procedure, thus demonstrating that the death had occurred as a result of that breach of duty. Unsurprisingly, the Montgomery case was cited in the judgment.

The steps in the consent process that the judge highlighted as important were as follows:

- The need for an advisory conversation with the patient:

  ***"The doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision."***

- The need to give comprehensible information in non-technical language:

  ***"This role will only be performed effectively if the information provided is comprehensible. The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form".***

**The decision**

In respect of the caesarean section, the claimant's wife should have been informed that she had a significantly higher risk than the average woman of needing an emergency caesarean section, and that a planned section was an alternative to an induction of labour. The judge found that, on the balance of probabilities, she had not been told of the risk or of the option of a planned section, and that this amounted to a breach of duty.

However, the judge held that even if she had been properly advised, she would probably not have chosen to have a planned section, and would have followed the plan suggested by the consultant to opt for an induction.

As regards the hysterectomy, the judge found that there had been no breach of duty in not removing the uterus. The evidence was that a hysterectomy was difficult and risky so soon after birth, and the deceased had not been feeling particularly unwell at the relevant time. Also, the antibiotics had recently been changed and there had been no significant findings on her CT scan. Accordingly, the claim failed, and judgment was entered for the defendant.

**The significance of the decision**

This case reinforced the need for claimants to prove that even if information had been provided as required by the *Montgomery* principles, their claim will not succeed unless it can be proven that:

1) the patient would have acted on the advice/information; and

2) that this would have led to a different outcome in that the injuries would not have been sustained.

In this case, the NHS trust had breached its duty by failing to advise the claimant's wife that she had a significantly greater risk than average of needing an emergency caesarean section, and that a planned caesarean section was an alternative to the induction of labour. However, if she had been properly advised she probably would have opted for the induction in any event. There was no causal link between the breach of duty and the infection that she had contracted after the caesarean, which had led to her death. The emphasis in the judgment is on the need for a dialogue between doctors and patients, explaining in a way that can easily be understood, the seriousness of the patient's condition and the potential harms and benefits of the various alternatives.

Previous case law at County Court level indicates that this dialogue should cover matters such as which surgeon will be performing the surgery. Failing to inform a patient in a timely fashion that an operation will be carried out by somebody different from the person in the original plan may amount to a breach of duty (see *Jones v Royal Exeter and Devon NHS Foundation Trust [2015]*).

### ii) There is no duty to warn patients about unknown risks

***Duce v Worcestershire Acute Hospitals NHS Trust [2018] EWCA Civ 1307***

The Court of Appeal considered this case in 2018, in which the claimant argued that an NHS trust had been in breach of its duty of care. The claimant stated this breach was due to a failure to warn her about the risk of developing chronic post-surgical pain after undergoing a total abdominal hysterectomy and bilateral salpingo-oophorectomy.

### The facts of the case

The appellant had been suffering from gynaecological problems, including heavy and painful periods, and in 2008 had undergone a total abdominal hysterectomy and bilateral salpingo-oophorectomy. She had also suffered from lower back pain since 2006.

Before her operation, the appellant met the surgeon and the registrar at 8:20 a.m. As she was having difficulty understanding the surgeon's accent, the registrar had dealt with the consent process, filling out the consent form and passing it to the patient to read and sign. Despite saying that she felt under pressure because the staff seemed to be in a hurry, she did sign the form, which did not refer to post-operative pain. After surgery, the appellant suffered neuropathic post-operative pain, and she argued that the trust was in breach of duty because she had not been warned about the risk of developing chronic post-surgical pain (CPSP).

The consent form did not mention the possibility of pain after the operation. However, the judge accepted that there had been a discussion between the appellant and the registrar to the effect that the operation might not relieve the appellant's existing pain, and this was confirmed as having been recorded in the surgeon's notes at the time.


Signature 4.

**The High Court trial**

At the trial, the registrar had accepted that in 2008 she would not have said that there was a risk of developing chronic pain or neuropathic pain as a result of the surgery. However, she said she would have warned the patient about the post-operative pain normally associated with surgery. The evidence of the anaesthetist was consistent with that of the registrar.

It was accepted that the operation had been carried out without negligence. However, following the surgery, it transpired that the appellant had sustained nerve damage, resulting in pain in her abdominal wall which was "significantly different in type to the pain she was suffering prior to her operation". The pain experts indicated that this was consistent with what is now recognised as CPSP. CPSP was not recognised at the time, but knowledge of the condition has developed since that date.

The trial judge found, on the facts, that the appellant understood that the operation would cause her some pain, and that although she was warned about the risk of 3-6 months of numbness and/or pain, she was not warned about chronic or neuropathic pain.

The RCOG guidance in 2008 did not refer to a risk of chronic, long-term or neuropathic pain. However, it did distinguish between "Serious risks, (including death)" and "frequent risks", which included "numbness, tingling or burning sensation around the scar (which the woman should be reassured that this is usually self-limiting, but warned that it could take weeks or months to resolve)". The experts agreed that CPSP was not common knowledge amongst gynaecologists in 2008.

The basis of the claim was that there had been a duty to warn the patient about the risk of chronic or neuropathic pain, and that if she had been warned, she would either have opted not to have the operation, had second thoughts, sought a second opinion or at least delayed surgery.

The trial judge found that there had been no breach of duty on the part of the staff at the trust because they would not have been aware of the risk of developing pain of the type experienced by the appellant. In addition, given the history of the appellant and failed attempts before the operation by staff to steer her towards having other treatment, she would not have changed her mind about having the operation. The only question was whether she might have paused to explore further what the detailed risks might be.

**The appeal**

On appeal, the appellant argued that the trial judge had:

1) failed to consider whether the risk of CPSP was "material" under the test established by the Supreme Court in *Montgomery*;

2) failed to apply the test of causation established in *Chester v Afshar [2004] UKHL 41*; and

3) been in error in finding that even if she had been warned of the risk of CPSP, she would still have undergone the surgery.

Dealing first with the issue of breach of duty, the Court observed that the trial judge had correctly directed his mind to the *Montgomery* test when making his findings. He had been referred to the case in opening and closing submissions and had made reference to it himself. The reason he had not specifically addressed the issue of materiality was that he had found that the claim would fail at the first hurdle:

***"In these circumstances it is inconceivable that he did not have Montgomery well in mind when making his findings on breach of duty in the very next paragraph. Indeed para [50](i) refers to the fact the appellant was aware of alternative treatments, one of the matters specifically referred to in Montgomery."***

The judge had found that the knowledge and awareness among gynaecologists in 2008 that the operation carried a risk of "chronic pain, or of neuropathic (or nerve) pain, whether that was long term or short term" was insufficient to justify the existence of a duty to warn the patient of that risk.

In the view of the Court of Appeal, the trial judge's reasoning had been correct and was consistent with the *Montgomery* approach. A clinician would not be required to warn of a risk of which he could not reasonably be aware.

On the issue of causation, the appellant had argued that Lord Hope's judgment in *Chester v Afshar* created an alternative approach to causation in consent cases, subject to three requirements, and that all three of those requirements were satisfied in this case. These were first, that the injury was intimately involved with the duty to warn; second, that the duty was owed by the doctor who performed the surgery to which the patient had consented; and third, that the injury was the product of the very risk that the patient should have been warned about when they consented to undergo the surgery.

However, the Court of Appeal took the view that when Lord Hope's judgment was taken in context it was clear that he was not establishing a free-standing test, but was instead setting out the circumstances justifying a modification of the usual approach to causation. This meant that the modification did not refer to an effective cause of injury as a sufficient cause in law in the unusual circumstances of the particular case.

Referring to the more recent case of *Correia v University Hospital of North Staffordshire NHS Trust [2017] EWCA Civ 356*, the Court of Appeal emphasised that if "the exceptional principle of causation" established in *Chester v Afshar* was to be relied on, it was essential to plead and prove that, if warned of the risk, the claimant would have deferred the operation.

In any event, in this case there was sufficient evidence to support the trial judge's finding on causation, because the appellant had been urged by medical practitioners on several occasions to consider less invasive alternatives, but she still opted for surgery. Moreover, she was willing to go ahead even though she had been alerted to the fact that there were "a number of other quite serious risks".

The trial judge had clearly taken into account the appellant's long history of symptoms from which she hoped to gain relief through surgery. That history had been correctly considered to weigh in favour of her choosing to undergo the operation when she did, even if a different warning about the risk of pain had been given.

Leggatt LJ on appeal summed up the position on causation in this case, concluding:

***"These are all matters which may be thought ripe for further consideration by the Supreme Court when the opportunity arises. They do not, however, assist Mrs Duce, as there is no reasonable interpretation of the decision of the House of Lords in Chester which justifies extending liability for negligent failure to warn of a material risk of a surgical operation to a situation where, as here, it has been found as a fact that, if she had been warned of the risk, the claimant would still have proceeded with the operation as and when she did".***

Accordingly, the appeal was dismissed.

**The significance of the decision**

This case is important for two reasons. It considers a particular aspect of the *Montgomery* test which has not often arisen since that case was decided, namely the issue of material risks from the doctor's perspective.

It also clarifies *Chester v Afshar* and reinforces more recent decisions and dicta made about the limited scope of the principles stated in that case.

**The doctor's perspective**

*Montgomery* established that the doctor must take reasonable care to ensure that the patient is aware of any material risks and of any reasonable alternative treatments by considering what risks were or should have been known to the medical professional. The Courts treat that as a matter for the experts. Then the doctor should take into account whether the patient should have been told about such risks by reference to whether they were material. The Court will be assisted by expert evidence when dealing with that issue.

In the *Duce* case the Court focused on the first aspect of the *Montgomery* treatment of the question of materiality – i.e. risks that were or should have been known at the time to the medical profession. Logically, a defendant cannot be liable for not warning about a risk of which the medical profession was unaware at the relevant time, as demonstrated by the case of *Roe v Minister of Health [1954] 2 WLR 915*.

In the context of the first aspect of the *Montgomery* test, the trial judge in *Duce* had been correct in his decision, following his findings on the evidence of the medical experts.

Therefore, it would not have been necessary to proceed with in-depth consideration of the arguments presented by the appellant in respect of the controversial case of *Chester v Afshar*.

**Causation**

In the *Duce* case, the Court of Appeal did look in some detail at the arguments on causation, perhaps because Philip Havers QC, Counsel for the appellant, stated that he reserved the right to argue that *Chester* was wrongly decided in the event of an appeal to the Supreme Court.

The appellant had argued that if a warning had been given, she would not have had surgery on that day, but the trial judge had rejected that argument on the basis of the evidence, finding that even if there had been a warning, the appellant would have had the operation that day. However, when the case reached the Court of Appeal, relying on Lord Hope's judgment in *Chester v Afshar*, the appellant contended that there was no need to prove this, suggesting that there may be a range of complex factors which influence a patient struggling to reach a decision about whether and when to undergo a particular surgical procedure.

Lord Hope had said:

***"For some the choice may be easy—simply to agree to or to decline the operation. But for many the choice will be a difficult one, requiring time to think, to take advice and to weigh up the alternatives. The duty is owed as much to the patient who, if warned, would find the decision difficult as to the patient who would find it simple and could give a clear answer to the doctor one way or the other immediately".***

The Court of Appeal concluded in *Duce* that it remains essential to establish causation on a correct application of *Chester*, by establishing that if the claimant had been adequately warned she would not have consented to the operation on the day when it took place. Moreover, the majority in *Chester* did not deny the requirement for claimants to demonstrate "but for" causation as a result of the breach of duty – i.e. "but for" the failure to warn the injury would not have occurred.

Attempts to resurrect arguments based on an interpretation of *Chester v Afshar* will no doubt continue to be made. However, it is hoped that in due course the Supreme Court will have a fresh opportunity to examine the scope of the so-called "departure from traditional causation principles" established in that case. More fundamentally, it is hoped the Supreme Court will reconsider whether *Chester v Afshar* had been wrongly decided by the House of Lords.

## Further considerations

This update has concentrated on the law relating to adult patients with capacity. However, it should also be recognised that, as required by the Mental Capacity Act 2005 and its Code of Practice, all patients should be involved in decisions about their treatment in so far as they are able to do so. A large number of cases decided by the Court of Protection emphasise this point. It follows that attempts to administer medication covertly to patients suffering from mental illness are frowned upon by the courts.

This is a matter which came to light in *M v ABM University Health Board [2018] UKUT 120 (AAC)*. In this case, the Mental Health Tribunal for Wales was criticised by the upper tribunal and was found to have been in error when making an order prohibiting healthcare professionals from telling a patient with schizophrenia that he had been given medical treatment covertly. The Tribunal had failed to take into account that it had an obligation to ensure, as far as practicable, that the patient was able to participate fully in the proceedings.

There are obviously numerous reasons why patients refuse medication, and this is not an uncommon problem, especially in patients suffering various forms of psychosis and when treatment might involve unpleasant side effects. A number of organisations, including the Bar Council giving evidence to a recent Ministry of Justice consultation, have highlighted that the issue of covert medication was not currently discussed in the Code, but had been addressed by the courts - see *An NHS Trust v A Patient [2014] EWCOP 54*. The advice is that administering covert medication is a serious interference with the right to respect for private life under Article 8 of the European Convention on Human Rights. There is a clear need to balance that right against the need to act in the best interests of each individual patient, and in every case the patient should be carefully assessed and treated sensitively.

## EIDO Healthcare concluding comments

The flow of cases through the Courts that deal with the *Montgomery* principles appear to be drying up at present. This is most likely due to the law being now more settled, so that challenges to the accepted approach are less likely to succeed. This is good news for patients, and it has become more important than ever for healthcare professions to keep abreast of recent developments in such a vital area of their work.

## Browne Jacobson concluding comments

The cases reported in this review serve as a helpful reminder to clinicians as to what the law requires of them and what the courts will look at when assessing liability in consent cases. In particular, clinicians need to consider the following points when discussing material risks and reasonable alternative or variant treatment options with their patients:

**1. Materiality**

- An assessment needs to be done as to the recognised and reasonable treatment options.
- There follows on from this the need to analyse the known risks of a procedure and the treatment options. This includes an analysis of current clinical guidance and research papers around that treatment option.
- Crucially the next point is to focus on the patient and what the material risks are of the reasonable treatment options for that particular patient. Is there anything in particular with regard to the individual patient (for example their previous medical history, religious beliefs, lifestyle choices) that should alert the clinician to the fact

that a particular risk might be material to this specific patient?

- This then needs to be addressed with the patient directly by the clinician, importantly ensuring that the patient engages with their treatment, clearly understands the treatment options and the material risks and allowing the patient to make an "informed" decision as to how to proceed when they are in receipt of all of the information.

**2. Reasonable alternatives**

- Are there appropriate alternative treatments which should be mentioned to the patient, even if they are not offered by this healthcare provider?
- What were the patient's concerns and preferences?
- Did the patient give any indication with regard to a particular preferred route of treatment (or was there anything that that individual patient wanted to avoid in terms of outcome)?

Conversations around should be clearly documented at all times during the process. This includes outlining what was discussed with the patient about material risks, what the patient said in response to that, and confirming that the patient understood what they were being told.

Technology, pre-printed consent forms and brochures are tools to assist the clinician. However, the clinician must ensure that the process of taking informed consent is thorough, and ensure the patient is engaged and the process is well-documented.

As the GMC guidance tells us, informed consent is about patients and doctors making decisions together.

## About the Author

Vivienne Harpwood is an Emerita Professor of Law at Cardiff University where for many years she directed the LLM (Legal Aspects of Medical Practice) degree which she established in 1987, the first of its kind in the UK, which continues to attract students from all over the world.

She continues to publish widely in the fields of tort and medical law in the UK and internationally, and has given many media interviews on medical law topics. She is a founding editor of Butterworth's Medico-Legal Reports and she established the journal Medical Law International. Among her publications are the books "Legal Issues in Obstetrics", "Medical Negligence and Clinical Risk", "Medicine, Malpractice and Misapprehensions", and "Modern Tort Law", now in its 7th edition.

Professor Harpwood, who has practised as a barrister, served on the UK Government's NHS Complaints Review Committee, whose recommendations in 1994 formed the basis of the modern NHS Complaints Systems in all four UK jurisdictions. She was also a member of the Silicone Gel Breast Implant Review Group between 1998 and 2003.

She has been Chair of Powys Teaching Health Board since 2014 following five years as Vice Chair of Cwm Taf University Health Board, where her remit was to maintain an overview of Primary Care, Community Care and Mental Health Services. She has recently been appointed Chair of the Welsh NHS Confederation.

Among her advisory work has been chairing the Wales Cancer Research UK Centre Governance Board; membership of the Wales Information Governance Advisory Board; of the Wales DNAR-CPR Core Group; and of the Human Transplantation (Wales) Act 2013 Expert Reference Group.

## About EIDO Healthcare

Established in 2000, EIDO Healthcare was the brainchild of Consultant Surgeon, Simon Parsons. EIDO was created in response to the total lack of medico-legally valid surgical and medical procedure information, in language easily understandable to patients. EIDO began developing a library of information documents covering surgical procedures to help educate patients, protect clinicians and address the ever-increasing consent related litigation bill faced by the NHS.

Today EIDO's library comprises nearly 400 titles and a customer base that extends to over 700 healthcare organisations across three continents and is widely recognised as the standard for informed consent written information.

The full library is endorsed by:

- The Royal College of Surgeons of England
- The Royal College of Surgeons of Edinburgh
- The Association of Surgeons of Great Britain & Ireland

The prestigious Plain English Campaign has awarded Crystal Marks to all EIDO titles (Crystal Marks are awarded for the clarity of the language used). Chrissie Maher, Founder and Director of the Campaign, praised EIDO:

***"Expecting patients to sign a consent form they can't understand is nothing short of a cruel joke. EIDO have shown that, no matter what the medical or surgical procedure is, you can produce clear information that truly allows patients to understand what they are agreeing to. By achieving plain English in every document, EIDO have become a guiding light for the entire healthcare industry."***

EIDO is also accredited under the UK Department of Health's Information Standard Accreditation Scheme as a producer of "high quality informed consent patient information".

EIDO has expanded its product base and now supports healthcare professionals around consent more broadly:

**EIDO Inform:**
**Trusted Content for Informed Consent**

EIDO Inform is a library of nearly 400 treatment-specific informed consent patient information leaflets.


**EIDO Educate:**
**Medico-legal eLearning**

EIDO Educate provides training for health professionals in the medico-legal principles of informed consent.


**EIDO Vault:**
**Reliable Digital Consent**

EIDO Vault is a reliable digital solution for obtaining and recording patient consent.


**EIDO Verify:**
**Insightful Patient Communication**

EIDO Verify is a digital communication system that informs and surveys patients before and after a hospital procedure.


***For more information about EIDO and these products, please visit eidohealthcare.com.***

## About Browne Jacobson

The Browne Jacobson health law team is a recognised leader in the provision of legal services to the health and social care sector having had a sizeable health law practice for many years. Our experience in both the public and private sector results in the firm being ideally placed to advise health organisations in a rapidly changing environment.

Our clients include over fifty aspirant and established foundation trusts, acute trusts and hospital groups, mental health and well-being trusts, ambulance trusts, commissioning organisations, health regulators, clinical litigation organisations, private sector providers, independent healthcare groups and healthcare social enterprises. We are panel members of many of the public sector purchasing consortia.

Health law is one of Browne Jacobson's key sectors and our health law team comprises of over one hundred lawyers from across all legal disciplines. We represent clients throughout England and Wales from our five regional centres.

Our understanding of the health and social care sector and our experience representing and advising clients on a range of highly emotive or contentious issues makes us ideally placed to provide timely, considered and focussed advice.

As a direct result of the strong relationships we have with our clients, we have developed a range of legal services that allow you to access our services at fixed fees and budget accordingly.

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