EIDO HEALTHCARE

Annual Consent Review 2018

EIDO Healthcare Annual Consent Review

Professor Vivienne Harpwood
Preface by Mr. Simon Parsons DM FRCS

United Kingdom
0115 878 1000
info@eidohealthcare.com

Australia
1800 211 511
info@eidohealthcare.com.au

South Africa
083 449 7682
info@eidohealthcare.co.za


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Preface

Welcome to the second edition of EIDO Healthcare's Annual Consent Review.

Over the past 19 years, EIDO has established itself as the UK's leading expert in patient information to support consent to treatment.

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 three 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.

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

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

The Royal College of Surgeons of England is keen to address the potential increase in consent-related litigation resulting from *Montgomery*. Therefore the College is sponsoring 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***

Mr Simon Parsons DM FRCS
Consultant General and Upper GI Surgeon
Honorary Associate Professor
Divisional Director of Surgery
Nottingham University Hospitals NHS Trust
Technical Director - EIDO Healthcare

Introduction

Scope

Healthcare professionals will be aware of the importance of obtaining consent from their patients before carrying out treatment, and of the requirements of their professional regulators to keep up to date with the law relating to their practice. The information in this update is concerned exclusively with the developing law on informed consent as it affects adults with capacity.

However, a range of wider matters has also been considered by the courts. These are worth bearing in mind and include, for example, applications for judicial intervention in cases involving seriously ill children and terminally ill adults. There has also been an interesting development in the law on confidentiality and the circumstances in which it might be appropriate to disclose confidential information about a patient without the patient's consent.

Focus

The decision of the Supreme Court in *Montgomery v Lanarkshire Health Board [2015]* has given informed consent to treatment a higher profile. This reflects changing social attitudes and government policies, which recognise the right of individuals to make decisions about what happens to their bodies.

Over the past year there have been several decisions in the courts concerning the law on consent to treatment, indicating a progression of the principles established in the *Montgomery* case.

The key questions in this second EIDO annual consent review are:

1. How has the law been developed or been clarified since the *Montgomery* decision?

2. Is there scope for "stand-alone" *Montgomery*-based damages for distress caused by failure to respect the autonomy of patients?

Recent cases are explained, and the significance of each development is highlighted, followed by basic advice for clinicians.

1. Key informed consent issues since the *Montgomery* ruling

The details of the landmark Supreme Court ruling in ***Montgomery v Lanarkshire Health Board [2015]*** are now well-known to those who work in the field of medical law. In addition, many clinicians, patients and their representatives will also be broadly familiar with the case. In short, the Supreme Court confirmed in *Montgomery* that, in the light of changes in the culture of the doctor-patient relationship in the modern world, it was time for the law to keep pace with modern attitudes. The basic principles were stated as follows:

"An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore 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."

Furthermore:

"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."

In summary, the Bolam test no longer applies in cases involving patients with capacity to consent. Doctors are now required to take reasonable care to ensure that any information provided to patients is explained clearly, and that each individual patient understands the medical condition, the material risks and benefits of the proposed treatment and any alternatives which the clinician thinks that a reasonable patient in the same circumstances would consider significant.

Patients are also expected to take appropriate care of themselves, as the leading judgment points out:

"The social and legal developments point away from a model of the relationship between the doctor and the patient based upon medical paternalism. What they point towards is an approach to the law which, instead of treating patients as placing themselves in the hands of their doctors…treats them so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices."

Clearly, there are some risks and benefits that are likely to be regarded as significant by the vast majority of patients, but in certain circumstances individuals might have special requirements. In the *Montgomery* case, the following statement appeared in the lead judgment:

"It would…be a mistake to view patients as uninformed, incapable of understanding medical matters, or wholly dependent upon a flow of information from doctors. The idea that patients were medically uninformed and incapable of understanding medical matters was always a questionable generalisation."

The Supreme Court placed some emphasis on the fact that Mrs Montgomery was well-equipped to understand scientific/clinical information, which the Supreme Court considered might have placed her in a different category in terms of decision-making. She had a BSc in molecular biology from Glasgow University, and had worked for a pharmaceutical company as a hospital specialist. She was described by the Lord Ordinary as "a clearly highly intelligent person". Her mother and sister were both general medical practitioners.

The concept of material risks was clarified by the Supreme Court in *Montgomery*. Materiality is based on a range of factors, including for example the nature of any risks, their potential effect on the life of the patient, the importance to the patient of the benefits of the treatment, any possible alternatives (including that of doing nothing) and the risk that such alternatives carry. It is not surprising that in recent cases lawyers have been exploring the limitations and implications of the *Montgomery* case, seeking clarity on the scope of the ruling, the possibility of further developments in the law and the potential for an extension of liability.


EQUAL JUSTICE UNDER LAW

Further clarification of the *Montgomery* ruling

(i) The continuing nature of the consent process

Gallardo v Imperial College Healthcare NHS Trust [2017] EWHC 3147 (QB)

The High Court added clarity in this case about the process of obtaining consent, highlighting the continuing nature of the consent process. The High Court was required to determine whether, as soon as he was well enough to participate in the discussion, the patient had the right to be informed about the outcome of his treatment, the prognosis, and the options for further care and treatment.

The facts of the case

In January 2001 the claimant, a Spanish citizen living in the UK, had undergone major abdominal surgery immediately after having a CT scan which had indicated a mass in his stomach. He thought at the time that he had a bleeding ulcer, but during surgery a malignant gastrointestinal stromal tumour (GIST) was removed, and complications developed requiring further surgery. After spending five weeks in intensive care, the claimant returned to the ward for 25 days before moving to a private wing. He was discharged from hospital in April 2001, and was seen privately by his consultant as an out-patient on a few occasions until the beginning of 2002 when he returned to Spain.

In 2010, the claimant sought advice at a specialist cancer hospital after a series of unsatisfactory diagnoses, and he was eventually diagnosed with pseudomyxoma peritonei, a rare cancer of the abdominal lining. He was very distressed to discover only then that for ten years he had not known he had cancer, with the risk of a recurrence requiring regular check-ups and CT scans. More tests revealed that he had a GIST in the same site as the original tumour, and he had further surgery to excise the tumour.

That operation was very complex as a result of the delay in treatment, and although it was successful, it was thought that another operation might be required at a later date. The claimant alleged that there had been negligence in his post-operative care and treatment at the defendant Trust.

The medical expert witnesses were in agreement that the consultant, following the surgery in 2001, should have advised the claimant that regular CT scans would be necessary. If these had been undertaken, the fresh tumour would have been diagnosed in 2006, so that less complex surgery would have been carried out four years sooner when the tumour would have been smaller.

The defence asserted that the claimant had been informed of his cancer after his first operation, and that he must have forgotten about it. However, there was no written record or evidence to support that suggestion, which the claimant's legal team described as "preposterous".

The defendant argued that the Bolam defence should be applied, and that a reasonable body of medical opinion at the relevant time would have supported a delay in giving the claimant details about his condition until his first out-patient follow-up appointment, by which time he had become a private patient and was no longer owed a duty of care by the defendant Trust.

The decision

The judge found that the evidence supported the conclusion that the patient had become aware of his diagnosis and its seriousness only when he received the information in an email in 2010. Yet the diagnosis of a possible GIST had first emerged in a CT scan report of January 2001, and at that point he was not informed about the possible malignancy. That diagnosis was confirmed in February 2001 in a histopathology report, but the information was not given to the patient, apparently because he was being treated in intensive care.

There was no evidence that there had been any discussion with the patient about the treatment and prognosis before he had been admitted to intensive care, or when he was discharged from hospital. Although the discharge letter referred to the GIST, it was only by the name used to describe the condition before it was recognised that GISTs are a distinct type of cancerous tumour. A letter sent to the patient's doctor in April 2001 referred to a malignant tumour, but not to the need for regular check-ups and scans.

It was difficult to defend the claim because there was no evidence of any record that the letter had been discussed with the patient, and no notes of the final consultation with the consultant were available.

Nor was there evidence that the claimant or his GP had been given any advice about the need for regular scans. The judge reached the conclusion that the patient had never been provided with a detailed explanation of his serious condition, and it transpired that failures on the part of his clinicians to set out all relevant information in writing amounted to a serious error.

Emphasising the importance of post-treatment discussions with patients, in what appears to be an extension of the *Montgomery* principles, the judge focused on the right of patients to be informed of the outcome of any treatment, the prognosis, and the options for follow-up care and treatment.

The defence attempted, unsuccessfully, to rely on the therapeutic exception, which enables some information to be withheld on some occasions, but the judge explained that this applied only in exceptional circumstances. Only in rare cases does this exception allow clinicians to withhold information on the grounds that disclosure would be seriously damaging to the health of the patient.

The judge took the view that the timing of discussions between clinician and patient was flexible, depending on the circumstances, and it could be affected by various factors, but he indicated that due regard should always be had for the patient's right to be told. In this case, the judge found that the discussion should have taken place as soon as the patient was well enough to participate fully, and it should not have been delayed any longer than necessary without good reason, and not on therapeutic grounds, unless it would have been seriously detrimental to the patient's health. The emphasis in the judgment was on the principle that information provided to patients should be recorded, and communicated in writing to the patient's doctor.

The judge concluded that the claimant should have been informed, during the 25-day period when he was on the ward, that a malignant tumour had been removed, and that regular check-ups and scans were needed because there was a risk of recurrence of the cancer. There had been no justification for the delay.

Finally, the judge held that the Trust had been under a duty to provide accurate and timely information to the patient and that this duty arose as a result of the treatment, as a necessary part of it because the claimant was not being treated privately when the surgery was carried out and the histopathology report became available.

He found that this duty had never been discharged, because the information should have been provided before the claimant moved to the private wing.

Causation was established, as there was evidence that the operation in 2011 would have been more straightforward if the claimant had known about the tumour sooner, so there probably would have been no need for post-operative chest drains and the patient would have avoided four years of pain.

The claim was successful and the claimant received a substantial award of damages which reflected the shock and distress he had experienced on discovering the true position nine years after it should have been explained to him. The award also took into account the additional pain he had suffered between 2007 and 2011, the anxiety he had suffered in trying to discover the true nature of his condition, the need for more complex surgery and the more difficult post-operative recovery period, and the greater challenges for future treatment.

The significance of the decision

It can be difficult to decide on the most appropriate time to inform patients about the details of their condition, especially if the patient is very ill after surgery and recovery is slow. However, as this case demonstrates, it is vital to recognise the importance of being honest with patients, particularly when further monitoring and tests are crucial to their recovery and long-term prognosis, because there is a risk of complications or the progression of a disease. This approach acknowledges the autonomy of patients, enabling them to take appropriate responsibility for ensuring that they attend for monitoring in a timely fashion, in line with the NHS Constitution which encourages patients to take some responsibility for their care.

Consent is a continuing process, and clinicians should give essential information to the patient once he or she has recovered sufficiently to satisfy the test for capacity, in accordance with the requirements of the Mental Capacity Act 2005. The characteristics of the individual patient should be taken carefully into account, as any unnecessary delay could be negligent. The defence of therapeutic privilege is very unlikely to be successful if a delay is unjustified because the patient has recovered sufficient capacity to understand.

Further information may need to be provided before, during and after treatment, tests and other procedures, especially when diagnostic tests are involved as well as surgery.

Also important is the lesson to be learned from this case about the need to make adequate notes and to record in writing every stage in the course of treatment, giving details of conversations with the patient and the information that was provided. If the provision of information is delayed, reasons for the delay should be recorded. Clinicians are advised to discuss with colleagues any decision to delay giving information to a patient, or to withhold information for therapeutic reasons.

Opening his judgment, the judge summed up current judicial attitudes to informed consent and its importance in modern medical law:

"Whatever uncertainty there may have been in the past, the requirement of informed consent to medical treatment is now a fundamental and settled principle of the law in England and Wales and Scotland."

In summary, clinicians should:

• Provide patients with appropriate clear information about risks involved in treatment which are likely to be regarded as significant by a reasonable patient in the same circumstances. The information should cover the material risks, side-effects and likely outcomes of each treatment option, including that of doing nothing.

• Inform the patient of risks and alternatives about which they are aware, or should reasonably be aware, that the patient, as an individual, is likely to consider significant.

• Respect every patient as an individual, giving patients information about test results and the outcome of surgery as soon as they recover sufficient capacity to have a meaningful discussion.

• Be aware that the duty to provide information does not end at the point when the patient moves to the independent healthcare sector. Test results and diagnoses need to inform future treatment of the patient, and are an essential part of what the patient needs to know.

• Advise patients about any further monitoring and tests that might be necessary to enable the patient to take some responsibility for his or her own health.

• Encourage patients to describe their circumstances and what is important to them, and to explain future intentions such as moving to other areas of the UK or abroad, in order to facilitate decisions about what information they need.

• Keep accurate records with the patient's notes, with dates and details of conversations about future treatment.

• Consult with colleagues before deciding to withhold information from a patient on the grounds of therapeutic privilege. Records of such decisions should be filed.

(ii) The scope for very large awards of damages

Hassell v Hillingdon Hospitals NHS Foundation Trust [2018] EWHC164 (QB)

The level of compensation awarded depends on a complex range of factors which the claimant is required to prove after succeeding in establishing liability and causation. Clearly, the more serious the consequences for the claimant of not being able to make an autonomous choice from among the treatment options, the higher the award. In the case of *Hassell*, the claimant was awarded £4.4 million in a claim involving failure to provide adequate information prior to surgery. During surgery she had suffered a spinal cord injury resulting in tetraparesis which left her permanently disabled.

The facts of the case

The claimant was aged 41, with three children at the time of surgery to her neck in 2011, and was in full-time employment in a secondary school. She had undergone two previous operations, but had continued to suffer pain, which did not resolve after physiotherapy and other treatment. Her surgeon advised her to undergo anterior cervical discectomy, with either fusion of C5 and C6 or disc replacement, depending on what was found during surgery. She had a pre-operative assessment on 27 July 2011, and there was a tick in her medical record by the heading 'no limitation of physical activity' and the handwritten comment "limited by back/neck problems only". In addition there was a statement next to the airway assessment, "very limited neck movement – hence planned op!".

The operation was carried out on 3 October 2011, when the claimant signed a consent form that listed the risks, which included 'cord injury'. Her circumstances at the time were similar to those of many patients immediately before surgery. She was feeling nervous about the surgery.

However, she was different from many others in that her husband had gone to the shop when the surgeon and a porter arrived earlier than expected to take her to theatre, and she complained about the rush, signing the consent form which stated a number of risks including 'nerve damage (numbness)'.

The claimant alleged that the surgeon had not warned her that this operation might leave her paralysed, and had not explained to her that there were other conservative treatments available.

The Trust argued that the surgeon had warned the claimant about the risk of paralysis and had discussed other more conservative treatment options, relying on the consent form that she had signed on the day of her operation. In the course of his evidence the surgeon said he had explained that 'nerve injury' could include numbness, weakness or paralysis.

The decision

The claim was successful. The judge found that the operation had not been performed negligently, and that the cause of the injury suffered by the claimant was unknown.

Therefore, the case turned on whether the claimant had given informed consent to the operation, and if so, whether she would not have gone ahead with the operation had she been given adequate advice and information.

The judge found, on the evidence, that the claimant had neither been warned of the risk of spinal cord injury nor advised of alternative treatments, and ruled that the surgeon had not complied with the guidance in *Montgomery*. Therefore, whatever his skills as a surgeon, he was "not a good communicator" about the risks of operations. In his judgment, the judge referred to the statement in *Montgomery*, 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 treatment...",

and

"...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 risk of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed if the information provided is comprehensible."

The judge was influenced by the fact that the claimant was a good witness and that her recollection about what she had been told by her surgeon was clear. This was especially the case since she was a busy working mother of three children, and would have been concerned about the risk of paralysis. He also commented on the fact that the claimant was rushed, and distressed due to the absence of her husband immediately before going to theatre.

The surgeon referred patients to his website for 'all the relevant information', but there was no mention on the website of the risk of paralysis. Even though the claimant was told about the risk of 'cord damage' on the day she had the operation, the judge concluded that a warning was not sufficient at that point, because after not being able to say goodbye to her husband, "her mind was not engaged on the consent form on the day".

The surgeon's evidence was that a letter had been sent to the patient on 1 July 2011, which he had dictated in front of her. That letter did not mention the risk of paralysis, and the judge did not accept the surgeon's evidence that this was the result of a transcription error. In addition, the absence of the phrase 'cc patient' indicated that the letter was not sent to her.

The significance of the decision

This case contains a salutary lesson for busy surgeons. It indicates that it is important to give adequate time to patients to ensure that they are able to understand the risks involved in each option available to them, and to take account of the factors that are important to each patient in his or her individual circumstances.

In this case, as a teacher holding a responsible post, and a working mother, the surgeon should have been able to appreciate the importance to her of the risk of paralysis. Indeed, the more serious the potential effects of a risk should it materialise, the more important it is to discuss it with the patient. Her individual circumstances immediately before surgery were also significant.

While it might be a good idea for clinicians to refer patients to a website as a means of enabling them to check what had been said in the course of a consultation, it is important to ensure that accurate information and sufficient detail is posted on the website and regularly updated.

Letters sent to patients should be checked carefully before they are sent.

In summary, clinicians should:

• Check the patient's medical history, even if the clinician has treated the same patient over a number of years.

• Provide clear explanations to patients in language that is easily understood by those without a clinical background.

• Make careful notes of information provided by patients about their lives and work, and advise them about risks which are likely to affect them.

• Make every effort not to rush patients into making up their minds.

• Discuss the proposed treatment and any alternatives in detail with patients, and provide information about the risks and benefits of all options.

• Be aware that it is not always ideal to ask a patient to sign the consent form on the day of surgery, especially if the patient is nervous and distracted by particular factors at the time.

• Ensure that the contents of letters sent to patients are checked carefully for typographical and other errors, and that they are easy for laypeople to understand.

2. Attempts to expand the scope of *Montgomery*

Two categories of civil claims arise as a result of consent issues, depending on the circumstances. If there is a claim based on treatment being given without obtaining consent, or when a patient has refused or withdrawn consent, the correct procedure is to bring a claim for trespass to the person, which consists of the torts of assault, battery and false imprisonment.

If the claim is based on an allegation by the patient that consent was given, but on the basis of inadequate information, the correct procedure is to bring a claim for negligence. For example, in the *Montgomery* case, the correct basis for the claim was negligence, based on a failure to provide adequate information to the patient. For a negligence claim to succeed, it is necessary for the claimant to prove not only that there was a negligent breach of duty, but that the breach resulted in damage or injury of some kind. In cases involving failure to inform, a claim is unlikely to succeed if it is possible to convince the court that the patient would have decided to have the procedure in any event, even if adequate information had been provided.

That position became confused to some extent when the House of Lords decided the case of ***Chester v Afshar*** in 2004. In that case it was held that if there had been negligent failure to warn of a particular risk from surgery, and the injury suffered by the claimant was intimately connected with the duty to warn, the injury should be regarded as having been caused by breach of that duty to warn. However, the House of Lords emphasised that the facts of the case were very unusual, and that the ruling should be viewed as establishing only a modest departure from established principles of causation.

(i) Inclusion of additional allegations in conventional negligence claims

There is no doubt that clinicians need to be aware of the need to respect patients' autonomy and provide them with adequate information about treatment options. However, it is becoming more common for claims for negligent treatment to include additional allegations that the patient consented to undergo the procedure, but on the basis of inadequate information about the risks, side-effects and alternative treatment options.

This is sometimes used as a default position by claimants' lawyers, and clinicians need to keep notes recording conversations with patients, stating what information was provided. It is important for clinicians not to be caught out because insufficient evidence is available by which to defend the claim. There is anecdotal evidence from defence lawyers that these dual claims are becoming more common since the decision in *Montgomery* established more rigorous requirements for informed consent.

In the case discussed below, it was asserted that failure to provide adequate information to the patient during the consent process gave rise to a new category of damages, based on the distress experienced by the claimant through the failure to respect her autonomy.

Shaw v Kovak and University Hospitals of Leicester NHS Trust [2017] EWCA Civ

The categories of damages under which compensation is awarded for non–financial losses are long established, and cover general damages for pain and suffering, and loss of amenity. It would be very unusual for the courts to approve an additional category of damages covering loss of autonomy occasioned by a clinician's failure to explain treatment options and the risks involved in each. On that basis, in the *Shaw* case, the Court of Appeal rejected the claimant's assertion, and held that failure to obtain informed consent does not give rise to a separate claim under a new category of damages, independent of the award of damages for pain, suffering and loss of amenity.

The facts of the case

The claimant was the daughter of a man who had died during a procedure for transcatheter aortic valve implantation (TAVI). In this action, she was bringing the claim on behalf of her father's estate.

The claimant's father had been diagnosed with aortic valve stenosis in September 2006, and he was advised to undergo TAVI. He died as a result of a complication involving bleeding from the aorta, and the claimant contended that if her father had been warned about the risks involved in TAVI, he would have opted for more conservative treatment, such as open heart surgery, and he would not have died when he did.

Liability was conceded by the defendant in the course of the trial, and damages of £15.6m were assessed at a later hearing which included a sum for pain, suffering and loss of amenity, funeral costs and expenses. However, the trial judge had rejected the additional argument of the claimant that there should be a separate claim for extra compensation based on failure to obtain informed consent.

The claimant contended that this was not a claim for personal injuries or loss of expectation of life, but was based on denial of the patient's autonomous right to choose what treatment to accept. On this basis the claimant's legal team argued for a separate additional award of damages.

On appeal, the claimant, relying on *Montgomery v Lanarkshire Health Board*, and in particular, the earlier decision in *Chester v Afshar [2004]*, again argued for an award of a distinct additional sum for the patient's "loss of personal autonomy" through the defendant's failure to provide adequate information.

The decision

The Court of Appeal, like the trial judge, rejected that argument, and held that the failure of the duty to warn involves one single cause of action, which is a claim for negligence. That had been recognised in the case of *Chester v Afshar* itself, on the basis of other authorities such as ***Pearce v United Bristol Healthcare Trust [1999]***, as well as in the leading case of *Montgomery*, where although it was almost taken for granted, it was stated that the duty to inform the patient of material risks involved in treatment was within the traditional negligence framework. Accepting that point as correct, the claimant argued for an additional category of damages.

The Court emphasised that the correct procedure in the event of the failure to obtain informed consent is an action for negligence, and that there is no independent cause of action available against a doctor for failing to obtain informed consent. In the view of the Court, to allow such a development would "open the floodgates" to patients who had received excellent care and successful treatment, but who had experienced omissions during the consent process.

If a person's suffering had been increased by the knowledge that his or her personal autonomy had been compromised because of a failure to provide informed consent, that could be reflected in the award of general damages covering pain and suffering.


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The significance of the decision

This ruling by the Court of Appeal will be reassuring for clinicians, and is an indication that the common law is unlikely to develop in an unwieldy fashion following the Supreme Court decision in *Montgomery*. As one of the Court of Appeal judges commented:

"The risk of a proliferation of claims of that kind would have very real, even if unquantifiable, financial, practical and other implications."

The common law in the UK develops incrementally and in such a way as to provide certainty for litigants as far as possible, so the sudden addition of either a new cause of action or a new category of damages would be an unlikely progression. The *Montgomery* case is an indication of the maturity of the common law, because the Supreme Court recognised the need for the law to reflect the evolution of social attitudes, but within the conventional negligence framework.

On what is a rather technical point, the Court of Appeal reassuringly confirmed that the unusual decision of the House of Lords in *Chester v Afshar* is very much confined to its own particular facts. While lawyers have long understood that this was the case, that reassurance will come as a relief for clinicians and their employers in the present climate.

In summary, clinicians should:

• Be reassured that failure to obtain informed consent does not give rise to a separate or distinct category of damage. However, the award for any pain and suffering may be increased if the patient's knowledge that his or her personal autonomy has been invaded through lack of informed consent has caused additional distress. That would be reflected in the award of general damages for pain suffering and loss of amenity.

• Be aware of statements made by the Court of Appeal that the importance of personal autonomy was given full prominence and recognition by the Supreme Court in *Montgomery*. That case demonstrates that negligence is the appropriate basis for a claim for damages for failing to inform the patient about the material risks involved in treatment.

• Be reassured that the Courts are clearly reluctant to extend the scope of the *Montgomery* ruling too quickly. The rather troubling decision of the House of Lords in *Chester v Afshar* is confined to its own facts and is unlikely to lead to a further extension of liability. Any claim brought on the basis of *Chester v Afshar* would only be successful if the facts of the case fall squarely within those in the *Chester* case.

• Always bear in mind that the importance of keeping an accurate record of information given to the patient during the consent process cannot be over-emphasised.

• Be aware that patients' solicitors report clinicians to their professional bodies for failing to provide the patient with adequate information in the course of obtaining consent. This trend makes detailed and accurate record-keeping even more important.

(ii) Attempts to push the boundaries of informed consent law

There are two recent cases in which there were attempts to expand the scope of the law on informed consent. The first is the case of *Correia v University Hospital of North Staffordshire NHS Trust [2017] EWCA Civ 356*, in which lawyers acting for a claimant attempted to use the *Montgomery* principles to push the boundaries of the law on informed consent. The second is the case of *Diamond v Royal Devon & Exeter NHS Foundation Trust [2017] EWHC 1495 (QB)*, which also challenged the scope of the *Montgomery* principles.

It is necessary at this point to provide a brief summary of the facts of *Chester v Afshar*, as it has been relied upon in argument in several recent cases discussed in this update. The case is concerned not only with consent to medical treatment but also with the wider issue of causation in tort. The House of Lords ruled, by a majority of three to two, that in a claim for negligence on the basis that insufficient information was provided to the claimant about the risks involved in medical treatment, it is possible in limited circumstances for the claimant to succeed, even when the conventional principles of causation have not been satisfied. Consent and causation are bound together inextricably in this instance.

The claimant had been referred to the defendant, a consultant neurosurgeon, because she had been suffering from back pain since 1988. After recurrence of the pain, and difficulty in walking, with bladder control problems, she thought she might need disc surgery. In a letter of referral, her doctor explained that the claimant wanted to avoid surgery if possible, and in her consultation with the defendant, the claimant said she had heard what she called "horror stories" about back surgery and asked about the risks associated with the proposed operation.

The trial judge found, on the evidence, that paralysis had not been mentioned by the defendant as a possible side-effect or risk of the surgery, and that the defendant had merely said he had "not crippled anyone as yet". The claimant argued that if she had been warned of the small risk of paralysis (around 1 to 2%), she would not have agreed to have the operation on the day she did, but would have made further enquiries and taken other advice about whether surgery was necessary. She did accept, however, that she would probably have had the operation eventually.

The operation, involving L2/L3 disc removal, was carried out by the defendant on the planned day, and following surgery, the claimant suffered motor and sensory impairment and further pain, probably caused by cauda equine contusion during surgery. No other patient on whom the defendant had carried out the procedure had experienced this outcome, and he expressed disappointment that it had occurred in this instance.

The trial judge found that the operation had been carried out with appropriate care and skill, and that there was no negligence in the surgical procedure itself. Therefore the case turned on whether the defendant had been negligent in failing to warn the claimant about the small risk that even if the procedure was carried out carefully, it was possible that she could suffer paralysis of some kind. This raised the question of how much information should have been given to the claimant before obtaining her consent to the operation.

The trial judge found in favour of the claimant on the basis that she had established negligence on the part of the defendant through his failure to warn her about the risks of the operation, and in particular the risk that she would suffer as she did.

He also found a causal link between the failure to warn and the injury that the claimant sustained.

The Court of Appeal agreed with the trial judge.

The surgeon appealed to the House of Lords, arguing that in order to succeed in proving causation where there had been a failure to warn about the relevant risks, the claimant would need to prove that she would not merely have decided not to have the surgery when she did, but also that she would never have had the surgery.

The House of Lords held by a majority of three to two that the defendant had been negligent in failing to inform the claimant of the small risk of paralysis, and that the claimant was entitled to damages.

The Court ruled that it was not necessary for her to prove, in order to establish causation, that she would never have had the surgery. It was sufficient that she could prove that if properly warned, she would not have had the operation that was in fact performed and that resulted in her injury.

The fact that the claimant was honest and did not try to argue that she would have refused the surgery if she had been warned of the risk, gave rise to a difficulty. She argued that she would not have had the operation when she did, but she would have had the operation eventually.

The usual rules of the law of tort require the claimant to prove that the defendant is in breach of a duty of care, and that the breach caused or substantially contributed to the resulting damage.

However, in the very unusual circumstances of this case, The House of Lords held that since the injury suffered by the claimant was intimately connected with the duty to warn, the injury should be regarded as having been caused by breach of that duty to warn.

Correia v University Hospital of North Staffordshire NHS Trust [2017]

This case began as a conventional negligence claim with no mention of failure by the surgeon concerned to provide adequate information. The claimant had been suffering pain in her right foot for several years, and on two previous occasions she had undergone surgery to remove a neuroma, a benign tumour of the nerve tissue. A surgeon employed by the defendant NHS trust carried out a further operation, and explained in advance to the claimant that the operation would involve a three-stage process. This included exploration and location of any neuroma, excision of the neuroma and relocation of the proximal nerve ending, in order to minimise the recurrence of a neuroma.

A High Court judge found, on the evidence, that the operation had been performed negligently because there had been no relocation of the nerve ending. However, the judge concluded that although the claimant continued to suffer pain after undergoing surgery, she had not succeeded in proving that the substandard surgery had materially contributed to her continuing pain. Therefore the claim failed, and the claimant appealed to the Court of Appeal.

In her appeal against the decision on causation, the claimant argued that the judge had not given sufficient reasons for rejecting the evidence of the claimant's expert that a re-formed neuroma materially contributed to the pain from which she continued to suffer.

The claimant also introduced the issue of lack of informed consent. She argued that the trial judge should have found that there had been a breach of duty on the part of the defendant, because she had not been warned about the material risks of an operation which omitted the third and crucial step of relocation.

She submitted that if she had been so warned, she would not have had the surgery, and that the surgeon's failure to warn entitled her to damages on the basis of the principle established in *Chester v Afshar [2004]*.

The decision

The Court of Appeal rejected the argument based on *Chester v Afshar*, pointing out the facts of that case were extremely unusual. In that case there had been a negligent failure to warn of a particular risk from surgery, and since the injury was intimately connected with the duty to warn, it should be regarded as having been caused by breach of the duty to warn. However, the House of Lords emphasised that the ruling should be viewed only as establishing a modest departure from established principles of causation.

The view of the Court was that the case of *Correia* was distinguishable on the facts from *Chester v Afshar*. The surgeon had carried out the operation on the planned day and the patient had consented to that operation, details of which had been explained to her in advance. Although there had been negligent failure by the surgeon to deal appropriately with the proximal nerve ending, for the purposes of consent that did not mean that a different operation was performed, nor was it an operation for which specific separate consent was required.

The claimant had given her informed consent to undergo the operation, and the injury was not "intimately linked" (as required by the *Chester v Afshar* decision) with the failure of the duty to warn.

The Court urged caution about expanding the scope of the law because of the implications of that development which could have far-reaching repercussions.

An important finding in the case of *Chester v Afshar* was that if she had been warned of the risk, the claimant would have not have had spinal surgery when she did, and she would have deferred the operation until a later date. Any claimant in a later case intending to rely on the exceptional principle of causation in *Chester v Afshar*, would be required to plead that point specifically and support it with appropriate evidence. The evidence heard by the trial judge did not support the claimant's case on that point in *Corriea*, as the claimant had not stated that she would not have had the operation at all had she been given different information prior to surgery.

Dismissing the appeal, the Court concluded that the trial judge had accepted that the claimant was clearly suffering pain. However, he had found that the evidence was insufficiently clear to satisfy him that the surgeon's alleged breach of duty through the failure to relocate the nerve ending, was the cause of the pain. The judge had been entitled to reject the view of the claimant's expert on that causation point, and his reasons for doing so were adequate.

The significance of the decision

This was an attempt, at a late stage in the proceedings, to bring a claim under the *Chester v Afshar* case, which allows for an exception to the usual rules of causation. The decision of the Court of Appeal in *Correia* was that negligent failure by the surgeon to perform the third stage of the surgery did not negate the claimant's consent, and that this was not an operation for which specific consent for a particular risk was required.

The Court of Appeal issued clear guidance for any claimant contemplating reliance on the *Chester v Afshar* principles. As Simon LJ explained, the position is as follows:

"The crucial finding in Chester v Afshar was that, if warned of the risk, the claimant would have deferred the operation. In contrast, in the present case, it was not the appellant's case that she would not have had the operation, or would have deferred it or have gone to another surgeon…".

In summary, clinicians should:

• Be reassured that current judicial thinking appears to be reluctant to accept claims which attempt to push the boundaries of the *Chester v Afshar* ruling. There is little appetite on the part of judges for the introduction of a separate tort based on failure to inform. The controversial case of *Chester v Afshar* is very much confined to its own set of unusual facts, and only in the most unusual circumstances would a claim based on that case be successful.

• Ensure that surgical procedures are explained in clear terms, and that patients understand the various stages in these procedures and any risks and outcomes that would be significant to a reasonable person in the circumstances of the particular patient.

Diamond v Royal Devon and Exeter NHS Trust [2017] EWHC 1495 (QB)

In this case a High Court judge concluded that an NHS trust had been in breach of its duty of care to a patient, through the failure of its staff to examine her abdomen at a post-operative review. She also argued that staff had failed to ensure that she had given adequately informed consent before proceeding to repair an incisional hernia with a mesh. Although the patient was entitled to damages for the failure in respect of the examination of her abdomen, she did not succeed on the informed consent argument because the judge found that even if she had been in a position to give informed consent, she would have opted for the mesh repair.

The facts of the case

The claimant had undergone spinal fusion surgery in December 2010, and she attended for a follow-up review in January 2011, when she complained of back pain and abdominal distension. In March 2011 she was diagnosed with a post-operative incisional hernia, which was confirmed by an ultrasound scan in April 2011. In May 2011, the patient had a consultation with a surgeon who thought she should undergo an open mesh-based repair of the hernia with abdominal wall reconstruction. That procedure was undertaken in June 2011, but the claimant asserted that only after the operation had she learned that there were certain risks associated with the mesh repair in the event of her becoming pregnant.

The decision

The judge held that failure by the doctor, at the review appointment in January 2011, to examine the patient's abdomen amounted to a breach of duty of care in negligence. There was evidence that she had mentioned problems with her stomach at that appointment when the hernia would have been present.

The judge reached the conclusion that if the patient had been sent for an ultrasound scan after the review, the entire process would have been expedited, and surgery would have been undertaken approximately two months earlier. It followed that the breach of duty had caused the patient to suffer pain and anxiety over that two-month period, and that the delay in surgery had caused the hernia to increase in size. Despite the success of the first part of her claim, it was difficult for the claimant to succeed on the argument concerning lack of informed consent. There was evidence that the surgeon had failed to discuss with the patient the potential risks in having a mesh repair should she become pregnant in the future, which did amount to a breach of duty.

However, the judge found that even if the surgeon had explained the problem, and the possibility of having a suture repair, he would also have informed the patient about the very high rate of recurrent hernias following a suture repair, and would have recommended a mesh repair. In the view of the judge, that advice would have been entirely reasonable and within the range of what a competent surgeon might say. He concluded, therefore, that even if the patient had been in a position to give informed consent, she would have decided to have the mesh repair. The judge emphasised, under the principles established in *Montgomery*, that the mere failure to warn of risks, without more, did not give rise to a free-standing claim for damages.

In the circumstances of the case, the patient did not fall within the scope of the exception established in *Chester v Afshar*, because it was difficult to see how it could be argued that she had suffered an injury as a result of the operation. In addition, it could not be argued that advice given later not to become pregnant was an outcome that was intimately connected with the duty to warn, such that it should be regarded as being caused by the breach of the duty to warn.

The judge explained the position in this way:

"I conclude that the claimant genuinely believes and has convinced herself that she would have opted for a suture repair if she had been provided with all the relevant information. Accordingly, what she said to me in evidence accords with her honestly held belief. But it does not of course, automatically follow that what she now believes to be the case would in fact have been the position at the material time."

In the context of the decision in *Correia* outlined above, *Chester v Afshar* did not provide a claimant with a free-standing remedy whenever there had been a failure to warn of risks of surgery. Therefore, although there had been negligence on the part of the surgeon giving pre-operative counselling, no damage had resulted, and the claim based on failure to warn could not succeed.

The judge emphasised:

"As it seems to me, Chester v Afshar is not authority for the proposition that a claimant does not need to prove causation, in the conventional sense, as a result of failure to provide informed consent… It is apparent, therefore, that the facts in Chester were striking and very different from the instant claim. The important point, however, as emphasised by Simon LJ in Correia (and by other judges in recent cases) is that Chester permits only a very modest departure from established principles of causation."

The claimant was awarded general damages for pain, suffering and loss of amenity as a result of the delay of two months in diagnosing the hernia. The hernia had caused the patient discomfort and as well as being unsightly, it would have extended in size over that period of time. £7,500 was considered a realistic sum in the circumstances.

The significance of the decision

This case is further confirmation of the basic principle that there is no free-standing claim available merely for failure to inform, when no damage results. It reinforces the view that the decision in *Chester v Afshar* is very limited in scope.

In summary, clinicians should:

• Make every effort to understand what the claimant's future requirements might be, and advise about any risks that might materialise in the future.

• Be aware that a claimant who suffers no actual injury or damage as a result of failure to inform will be unlikely to succeed in a claim based on the unusual ruling in *Chester v Afshar.*

• Be reassured by recent cases which reinforce the view that the case of *Chester v Afshar* is confined to its own set of unusual facts, and that only in very rare circumstances would a claim based on that case be successful.

Concluding comments

This update has focused exclusively on recent case law which has clarified some of the more uncertain issues arising since the *Montgomery* case was decided. The Supreme Court in *Montgomery* approved the advice in the guidance issued to doctors in "Good Medical Practice" and "Consent: Patients and doctors making decisions together" which emphasised the need for a true partnership between doctor and patient, based on openness, trust and communication.

The cases outlined in this update reflect the importance of that approach, while also suggesting that there is little appetite among judges for allowing the law to develop too quickly. In particular, any litigation arguments presented for a free-standing claim for damages on the basis of *Chester v Afshar*, decided almost fifteen years ago, are unlikely to succeed.

There are a number of lessons to be learned from the cases, and one of the most important of these is the need for clinicians to make an effort to appreciate the circumstances of individual patients by encouraging them to explain their current lifestyle and aspirations for the future. Patients need to be made aware that they have a reciprocal duty to be open with healthcare staff about their needs.

As stated in the latest iteration of the NHS Constitution in its advice to patients, they do have a number of important rights. For example:

"You have the right to accept or refuse treatment that is offered to you, and not to be given any physical examination or treatment unless you have given valid consent. If you do not have the capacity to do so, consent must be obtained from a person legally able to act on your behalf, or the treatment must be in your best interests.

You have the right to be given information about the test and treatment options available to you, what they involve and their risks and benefits.

You have the right to be involved in planning and making decisions about your health and care with your care provider or providers, including your end of life care, and to be given information and support to enable you to do this. Where appropriate, this right includes your family and carers. This includes being given the chance to manage your own care and treatment, if appropriate."

Responsibilities of patients are also listed:

"Please recognise that you can make a significant contribution to your own, and your family's, good health and wellbeing, and take personal responsibility for it. Please provide accurate information about your health, condition and status."

Key lessons learned from the cases in the 2018 update

• Patients should be provided with appropriate information in clear terms about risks involved in treatment which are likely to be regarded as significant by a reasonable patient in the same circumstances. The information should cover the material risks, side-effects and likely outcomes of each treatment option, including that of doing nothing. Explanations should be given to patients in language that is readily understood by people with no clinical background.

• Every patient should be treated as an individual, and receive information about test results and the outcome of surgery as soon as they recover sufficient capacity to have a meaningful discussion.

• Consent is an ongoing procedure which should involve a dialogue and joint decision between clinician and patient. There are many instances in which the risks and/or side effects involved in a particular treatment would be regarded as important by any patient for whom the treatment is proposed.

However, in some circumstances a particular patient may attach special significance to certain risks and side effects because different people naturally have their own concerns, preconceptions, lifestyles and/or exceptional clinical circumstances. It is therefore important for an individual profile to be established for each patient. Generalised advice cannot possibly cater for individual exceptional circumstances, and it is in marginal cases that disputes are likely to arise.

• Consent is a continuing process and the duty to provide information does not end at the point when the patient moves to the independent healthcare sector. Test results and diagnoses need to inform future treatment of the patient, and are an essential part of what the patient needs to know.

• Patients should be advised about any further monitoring and tests that might be necessary. This information will enable them to take some responsibility for their own health.

• In order to facilitate decisions about what information they need, patients should be encouraged to describe their circumstances and what is important to them, and to explain their future intentions such as moving to other areas of the UK or aboard. Careful notes should be made of information provided by patients about their lives and work, and advice should be given to them about risks which are likely to affect them in that context.

• It is advisable for clinicians to demonstrate reasonableness by consulting with colleagues before deciding to withhold information from a patient on the grounds of therapeutic privilege. Records of such decisions should be filed.

• It is important to check the patient's medical history for matters that might affect current decisions, even if the clinician has treated the same patient over a number of years.

• Every effort should be made not to rush patients into making up their minds.

• It is not ideal to ask a patient to sign a consent form on the day of surgery, especially if the patient is nervous and distracted at the time.

• When clinicians write to patients, it is important to ensure that the contents of letters are checked carefully for typographical and other errors, and that they are easy for laypeople to understand.

• Failure to obtain informed consent does not give rise to a separate or distinct category of damages.

• The award for the patient's pain and suffering may be increased if the knowledge that his or her personal autonomy has been invaded through lack of informed consent has caused additional distress or illness. That would be reflected in the award of general damages for pain, suffering and loss of amenity.

• The importance of personal autonomy was given full recognition by the Supreme Court in *Montgomery*, and that case demonstrates that the negligence action is the appropriate basis for a claim for damages for failing to inform the patient about the material risks involved in treatment. The Courts are clearly reluctant to extend the scope of the *Montgomery* ruling too quickly.

• The decision of the House of Lords in *Chester v Afshar* is confined to its own facts and is unlikely to lead to a further extension of liability. Any claim brought on the basis of *Chester v Afshar* would only be successful if the facts of the case fall squarely within those in the *Chester* case.

• Accurate records should be kept with the patient's notes, with dates and details of conversations about future treatment. The importance of keeping an accurate record of information given to the patient during the consent process cannot be over-emphasised. There appears to be a growing trend for clinicians to be reported by patients' solicitors to their professional bodies for failing to provide the patient with adequate information in the course of obtaining consent.


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About the Author

Vivienne Harpwood is 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 lectures and publishes 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 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.

Among her more recent advisory work is 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.

She chairs the Individual Funding Requests Panel and Prioritisation Panel for medical treatment in Wales. After taking partial retirement from Cardiff University to serve 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.

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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:

INFORM:
Trusted Content For Informed Consent

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

EDUCATE:
Medico-legal E-learning Resources

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

VAULT:
Reliable Digital Consent

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

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***