"Without a consent, either written or oral, no surgery may be performed. This is not a mere formality; it is an important individual right to have control over one's own body, even where medical treatment is involved. It is the patient, not the doctor, who decides whether surgery will be performed, where it will be done, when it will be done and by whom it will be done."

— Linden J Allan v. New Mount Sinai Hospital (1980) 28 OR 356

CONSENT, OUR MEMORIES AND CLINICAL RECORD KEEPING

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It is clear that the required legal standard of assessment for clinician-patient interaction during the consent process is much higher now. We consider the practical implications of the evolution of the law to everyday medical practice.

Medical note-taking

The authors start by highlighting, with some trepidation, the case of Toombes v Mitchell (2021). In 2001, following a specific consultation by a GP with a patient who was asking for pre-conceptual advice, the Court found that the GP failed to mention that not taking a supplement of folic acid prior to conception may lead to the birth of a child with spina bifida. The Court also found that, had the mother been correctly advised, she would have taken such supplementation, delayed conception and subsequently given birth to a healthy child, thereby avoiding the devastating consequences of spina bifida for her child[1]. The claim succeeded on liability. While damages are still to be assessed, the GP's medical insurers potentially have now become liable for the cost of the consequences of the disability throughout the life of the child. In the ensuing internet commentary, some (mainly clinicians) have argued that folic acid supplementation is not guaranteed to prevent spina bifida and the other awful complications of that disease. This, however, misses the point of this liability trial, that is that the finding against the GP is very much based on the paucity of medical note-taking in this case.

On reading the judgment, the arguments around the efficacy of folic acid supplementation are not central but rather the comments of the Judge on the recordkeeping of the GP in 2001. The GP's note was found to be completely inadequate, a fact accepted by the GP, and this was compounded by the fact that the GP himself had no recollection of the consultation and was entirely reliant on stating what would have been his declared usual practice at the time.

> Simply obtaining a signature on a consent form is not indicative of an adequate consenting process

clinicians do not set out to harm their patients, but they are busy and have to rapidly assess any situation to decide what needs to be done. Most of the time they tend to be very good at this. However, the days when the Courts would trust that a doctor would have the best interests of the patient are no longer presumed. Instead, it is left to lawyers, often many years later, to scrutinise the available evidence, which often includes a very detailed patient witness statement, and in such circumstances the doctor flounders, relying on a vague memory, guessing at what they would have typically done or said and often relying on a brief scribbled or a badly typewritten note. In such situations memory has been shown to be remarkably plastic and indeed it changes every time we recall it. Both we clinicians and patients simultaneously can be honestly and completely wrong about a version of events. To recall accurately a brief uneventful conversation with a patient from 20 years ago is asking too much in today's litigious society[2,3].

Decision making

With that in mind, we turn to the Supreme Court judgment in Montgomery (2015) which has put the patient at the heart of decision making. The previous and current GMC guidelines[4] had always made it clear that such an approach was best but the Courts for many years had followed a different legal standard for judging the consenting process. The Courts had followed the Bolam principal that a doctor's action would be assessed by the standard of what a responsible body of doctors would have done, unless, applying the Bolitho principal where an alternative practice was put forward, that standard was found not to withstand logical scrutiny[5]. While such principals still apply in assessing the practice of a doctor in treatment and diagnosis, now, when considering the specific issue of the consenting process, a different legal standard now applies, and indeed is being applied retrospectively. This is not the place to go into the details of the case of Nadine Montgomery but, suffice to say, it is tragic and heart-breaking to read even now. Quoting from the judgment:[6]

"*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.*

"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." [emphasis added]

The MDU[7] has also highlighted a number of other critical points:

- a material risk doesn't only depend on how severe it is or how

frequently it occurs, but on the importance a patients attaches to it

- the clinician's role involves sufficiently communicating with the patient to make sure that they understand the risks of a treatment so that they can make an informed decision
- simply obtaining a signature on a consent form is not indiciative of an adequate consenting process.

The key point in relation to the standard required of a doctor is not just what a responsible doctor considers reasonable to tell the patient about an intended treatment, but what a reasonable patient with that specific patient's characteristic, might attach importance to. The locus of control has irrevocably shifted away from the doctor and towards the patient. When examining in court such a conversation about consent which has likely taken place many years previously, the only way to demonstrate that a doctor followed such principles is to keep detailed records of the consenting process. Otherwise we are simply left with the (unreliable) memories of both the doctor and the patient to go on.

A clinician's responsiblility

Along with the case of Montgomery there are a number of further legal judgments that should be noted by the medical profession. In the case of Pearce v UBH[8], the Court found that if the clinician had told the mother that his advice to delay the birth would increase the risk of stillbirth, she would have opted for an earlier delivery. Instead, the child was stillborn. This judgment emphasises that it is the clinician's responsibility to inform a patient of a risk which would affect the judgement of a reasonable patient. The clinician must provide the information needed so that the patient can make that choice.

In Thefaut v Johnston (2017), the clinician was criticised for being overly optimistic about the likely success of a procedure and under-estimating the risks, and of not providing enough time for the patient to make a decision. In this judgment it was emphasised that as well as the medical characteristics, patient factors including social factors needed to be taken into account in the consenting process.

> The required standard of assessment for clinician-patient interaction during the consent process is much higher now

The issue of recording of the consent was the issue in the subsequent case of Hassel v Hillingdon (2018)[9]. Mrs Hassell was 41 and had undergone two previous lumbar spinal operations. In 2011 she presented with left arm pain and an MRI scan showed a disc lesion at C5/6. Following a neck injection which failed to relieve her symptoms, she was advised to have a cervical fusion of C5 and C6 or disc replacement. The consent process was not well documented and it was neither clear what risks of surgery were referred to, nor whether there was any discussion about an alternative conservative treatment. Mrs Hassell awoke from the operation in 2011 with tetraparesis secondary to spinal cord injury. The surgery was not blamed i.e. there was no breach of duty found by the Court as regards the technical aspects of surgery; it was simply a consequence of the risk of even well-performed surgery. Even though she signed a consent form which listed 'cord injury' as a risk, it was found by the Court that Mrs Hassell had not given properly informed consent to surgery and, had she been given proper advice, would not have gone ahead. The Court found that a brief warning wasn't sufficient. She had neither been (properly) warned of the risk of spinal cord injury nor adequately informed of alternative conservative treatments[10,11,12]. Despite the operation being performed to a reasonable standard, the operation nevertheless should not have gone ahead and the Trust was liable for the complication of tetraparesis and resulting damages of £4.4 million, including all the future care costs.

In Jones v Royal Devon and Exeter NHS (2015)[13], Mrs Kathleen Jones had been added to the waiting list in the expectation of having surgery performed by her Consultant Spinal Surgeon, only to discover on the morning of the operation that it was to be carried out by a more junior and much less experienced spinal fellow at the hospital. Unfortunately, the operation went badly although performed non-negligently, and Mrs Jones was left with serious and permanent injuries as a result. The Court further found that the claimant would not have agreed to have the operation performed had she been told in advance it was not the Consultant of her choice operating, and ruled that it was too late for her to be expected to exercise informed choice when, moments before the operation, she was eventually told by a theatre nurse that her surgeon was not available:

"…although there was no breach of duty to warn the claimant of the risks of the operation, it was an infringement of her right 'to make an informed choice as to whether, and if so when, and by whom to be operated on.' Unless a remedy is provided in the present case that right would be a hollow one."[14]

In Spencer v Hillingdon (2015)[15], the patient

was not warned about a future possible complication of a procedure and suffered as a result. Post-operatively the patient became unwell but did not realise the significance of calf pain as a presenting symptom and then suffered bilateral pulmonary emboli. The Court decided that the patient should have been warned about possible symptoms of a complication. Patients must be warned about the possible consequences of a procedure. If the patient would not have consented to the procedure if appropriately consented and suffers harm then the clinician becomes liable.

Take home message

Clinicians can no longer approach consent with a paternalistic attitude and decide what treatments are best for their patient. The emphasis now is on a patient's choice made following thorough discussion and after being informed in detail of all clinically appropriate options. The patient has the legal right to choose a therapeutic option accepting its possible impact on their health. The medical advice about treatment options has to consider medical factors but must also take into account patient value judgements, including psychosocial factors that are important to the patient.

We as clinicians are required to familiarise ourselves with our patients sufficiently well to understand their views and values and thereby support them in the decision-making process. Practically, this will mean that clinics will run slower with fewer patients. Also, fewer patients are likely to opt for treatment once they are given a realistic assessment of the longer term success rates and risks of a procedure. This aspect is especially pertinent to Pain Medicine. A rushed consent process performed at the bedside by a clinician on a busy day case list with a patient drawn from a pooled waiting list, where the clinician is unfamiliar with the patient and vice versa, is arguably a sad norm. This norm is also, sadly, a recipe for patient harm and litigative threat.

A well-known personal injury barrister once said that if they can't get you on breach of duty (i.e. your standard of treatment was up to scratch), they will get you on consent. The patient (and now claimant) will say, "If I had been told this might happen I would never have consented to go ahead". In that scenario, the clinician becomes liable for ensuing complications, even if the procedure is done perfectly, because it should never have gone ahead in the first place.

The question in the Court's mind in all these cases is, 'Did you as the clinician explain the choices open to the patient properly? Did you spend enough time with them?' With the current way clinics and procedures are recorded, it is often not difficult to assess how much (or little) time was spent with an individual patient. A detailed clinic letter recording not only the relevant medical factors but the relevant patient factors, and those discussed as essential to the decision made, becomes a vital part of the evidence. The clinical letter must be written in a patient-centred, jargon-free fashion. This letter may end up undergoing intense scrutiny in the years that follow: read them carefully before they go out!

The required standard of assessment for clinician-patient interaction during the consent process is much higher now. So, ensure your clinical manager allows you to run your clinics and pooled waiting lists in a fashion which is consistent with the above aims. This will mean fewer patients, and more time spent with each. Dictate a much longer clinical letter which encapsulates what was discussed, even though it means upsetting your secretary.

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Further reading

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