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Consent in the Covid-19 world and beyond

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Please note: the information contained in this legal update is correct as of the original date of publication.

Following the suspension of all non-urgent elective surgery to help free up general and acute care capacity in the wake of the pandemic, services are now starting to resume, and steps are being taken to recommence routine elective procedures where possible.

However, these are steps towards a 'new' normal. The landscape for the provision of clinical services remains very different and whilst the law on consent has not changed, clinicians will need to carefully consider the ongoing impact of COVID-19 when considering consent to ensure that patients have all the relevant information needed to make an informed decision about treatment.

Following the landmark case of Montgomery v Lanarkshire Health Board [2015], clinicians are required to take reasonable care to ensure that patients are aware of any material risks involved in the recommended treatment and any reasonable alternative treatments. In this respect, COVID-19 has brought about a number of changes which are highly relevant to consent including:

- increased risks associated with COVID-19;
- changes to the availability of some procedures and treatments in some areas; and
- changes in how consultations are taking place, with an increase in remote consultations.

This article explores the potential impact of each of these issues in the context of the law.

Material Risks - increased risks associated with COVID-19

In general terms, determining whether a risk is material to an individual patient requires a two-stage approach involving both objective and subjective assessment:

1. what risks would a reasonable person in the patient's position be likely to attach significance to? and
2. What risks should a doctor reasonably be aware that the particular patient would be likely to attach significance to?

As evidenced in a paper published in the Lancet at the end of May 2020 'Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study' COVID-19 has brought about new and increased risks. Are these risks which should be included in discussions with patients? In our view, they should be. We consider that the risk of infection, pulmonary complications and death are likely to be risks that a reasonable patient would be likely to attach significance to and as such, they should be discussed with patients. However, the situation is evolving, and as time passes and more evidence is available these risks will change and therefore need to be kept under review.

This is a point recognised by Guidance published by Royal College of Surgeons on 30 June 2020. 'Tool 5 – Consent to treatment while COVID-19 is present in society' which is part of the 'Recovery of Surgical Services Guidance' makes it clear that the additional risks associated with COVID-19 should be discussed with patients as part of the consent process and that clinicians should be 'transparent' about potential and unknown risks and the limited data available around the surgical outcomes of patients who have tested positive for COVID-19. Discussions should take account of the prevalence of COVID-19 in each hospital and the local community.

A separate COVID-19 consent form is not necessary because consent is a process and it is the discussion about the additional risks presented by Covid-19 - which are part and parcel of the procedure/intervention being done - that is key. However, it is important that clinicians document the relevant COVID-19 risks discussed with a patient in the same way as they would document other material risks.

Reasonable alternative or variant treatment - changes to the availability of some procedures and treatments in some areas

In addition to material risks, clinicians must ensure that patients are aware of any reasonable alternative or variant treatment options. Where appropriate, this may include doing nothing, conservative treatment and/or delaying treatment.

The Courts have not yet had to consider what might constitute reasonable alternative treatment options in the context of COVID-19, when some hospitals or Trusts may not be offering a specific treatment due to the deviation of resources or, for example, in the case of laparoscpic surgery, the potential increased risks arising from aerosolisation. However, based on the priniciples from Montgomery and subsequent case-law, the alternative treatment option should be "realistic and available" and it is therefore arguable that it is not necessary to advise patients about reasonable alternative procedures which may have been an option prior to the pandemic but are not longer available.

Having said this, as part of an open and transparent discussion, there are clear benefits of discussing how and why reasonable alternative or variant treatment options have changed as a result of the pandemic. It provides the patient with context and an explanation as to why certain alternative treatment options are not available. Understanding this at the time of the decision-making process may be helpful in the event that any of the risks materialise and help prevent or minimise dissatisfaction.

The other point to consider is that is that reasonable alternative or variant treatment options may in some cases include a discussion about alternatives offered by colleagues at other NHS Trusts e.g. what if another NHS Trust does offer a laparoscopic procedure? Is there a duty to discuss this as part of the conversation about reasonable alternative treatment options?

Again, this is something that has not yet been tested by the Courts since COVID-19 but it is our view that the Courts would need look at whether this was an ‘appropriate option’ in the context of the pandemic as a whole and whether it would be appropriate in these circumstances for patients to be travelling to/from hospitals which are not necessarily local to them to undergo treatment. It would certainly not seem appropriate in terms of safety, logistics or resources for all patients to be referred to another Trust in these circumstances but there could be some limited circumstances in which it is appropriate for some patients e.g. a patient with a particular risk factor which can be mitigated by reasonable alternative treatment offered at another hospital/Trust.

Remote consultations

COVID-19 has also brought with it changes to the way clinicians see patients, with an increase in the use of remote consultations and the use of digital and online tools to support the sharing of information.

This presents a fantastic opportunity for the future, but it comes with its own health warning. In the context of consent, clinicians need to ensure they have sufficient information to enable them to assess what risks will be material to each individual patient and also be confident that the patient has understood the information discussed so he or she can make an informed decision. To assist with understanding, any relevant information leaflets/electronic resources about the proposed treatment/procedure, should be sent to the patient, ideally, in advance of the consultation.

If there are any potential barriers for individual patients in terms of them being able to access the information (e.g. difficulties with literacy, being able to read or hear/understand information provided remotely, English as a second language etc) or any other concerns, consideration should be given to organising a face to face consultation. An effective consent process should flag any barriers to understanding.

The key to all of this is that consent is an ongoing and patient centred process. There is no ‘one size fits all’ approach and clinicians need to consider the individual patient when considering what information should be shared and discussed, both generally and in relation to relevant information relating to COVID-19 and associated risks and/or changes to standard management of conditions and available treatment.

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