CONSENT TO TREATMENT WHILE COVID-19 IS PRESENT IN SOCIETY

Royal College of Surgeons
ADVANCING SURGICAL CARE

Since the rise of COVID-19 in the UK, many consultations between surgeons and patients take place remotely, via phone or video. These consultations include pre-operative assessments, discussions between surgeons and patients about the benefits and risks of their surgery, and gaining the patient's consent to proceed with treatment. This transition to remote consultations has been central in the healthcare system's effort to prevent transmission of COVID-19, and has required a series of adjustments by patients, hospitals and members of the surgical team. However, when it comes to the consent process, the same principles and requirements should apply as set out by the GMC and The Royal College of Surgeons of England, regardless of whether the conversation takes place face-to-face or via phone or video. In addition, during the COVID-19 period, the consent discussion should include further considerations to ensure that patients have the necessary information to make an informed decision about their treatment.

This guide sets out the main principles of the consent process and provides advice on what additional information should be included in conversations with patients while COVID-19 is still prevalent in society.

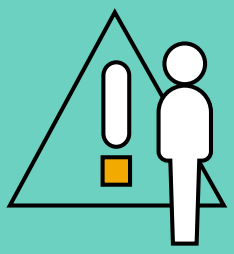
1. DISCUSSION ABOUT OPTIONS FOR TREATMENT

In line with the RCS guidance on consent (see RCS, 2016. Consent: Supported Decision-Making), surgeons must ensure that the patient is provided with the information they need to make an informed decision about treatment. It may be appropriate to send information to the patient in advance. In practice, surgeons should provide information about:

- The patient's diagnosis and prognosis.
- All options for treatment, including options that are not provided by the particular hospital, and including non-operative care and no treatment.
- Advice on lifestyle and preparing for surgery that may modify the disease process and the recovery from surgery, and reduce the risk of complications.
- The purpose and expected benefit of the treatment.
- The nature of the treatment and what it involves.
- The likelihood of success.
- The right of the patient to decline treatment and make their own decisions about their care.
- The names of clinicians who will be involved in their treatment.
- Potential follow-up treatment.
- The risks inherent in the procedure and in the alternative options discussed, and the risks that are material for the particular patient (for materiality, see below).
- For private patients, costs of treatment and potential future costs in the event of complications.

Options should be presented side-by-side and relative risks and benefits of the different options for treatment should be discussed. Surgeons should not make assumptions regarding the wishes of a patient and what they might perceive as the best option available. They should also not assume that the patient has the same set of values, wishes or life priorities as they would have in a similar situation.

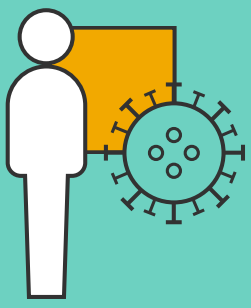
An accurate record of the discussion (including contemporaneous documentation of the key points of the discussion, hard copies or web links of any further information provided to the patient, and the patient's decision) should be included in the patient's case notes. This is important even if the patient chooses not to undergo treatment.



2. MATERIAL RISKS AND STANDARD OF CARE

Clinical negligence claims are often built upon a lack of adequate documentation of what was said and allegations that patients have not been properly informed about the risks and alternatives open to them. In line with the 2015 decision of the Supreme Court in the case of Montgomery vs Lanarkshire Health Board, doctors have a duty to warn a patient of a material risk inherent in the proposed treatment and discuss this with them.

What constitutes a material risk will vary from patient to patient. The criterion for materiality, and therefore for appropriate informed consent, is no longer the opinion of a body of expert medical practitioners, but 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 likely attach significance to it. Therefore, consent must be patient-specific.



3. UNIQUE CONSIDERATIONS DURING THE COVID-19 PANDEMIC

The rapid spread of COVID-19 around the world means that the notion of materiality must include a series of additional considerations that should be discussed with the patient as part of the informed consent process. These include:

A. **The risk of contracting COVID-19 while in the hospital.**

B. **The risk of operation for patients who have tested positive for COVID-19.**

C. **Changes in the coordination of care due to the pandemic response and possible scarcity of resources (eg ICU bed capacity or ventilator availability).**

D. **The importance of advance directives.**

The lack of certainty that surrounds the above considerations is amplified by the uncertain timeframe of recovery from the pandemic and further uncertainty regarding any future scheduling restriction. It is therefore important to be transparent about potential and unknown risks, and about the limited data available regarding the surgical outcomes of patients who have tested positive for COVID-19. It is imperative that the consent discussion with the patient is conducted by the operating surgeon who has the most in-depth knowledge of the patient and their individual circumstances.

A. The risk of contracting COVID-19 while in the hospital.

It is currently not possible to give an accurate estimate of the risk of contracting COVID-19 while in hospital. Studies conducted in the US estimate the risk to be 0.45% if a patient has close contact with a COVID-19 positive person while in hospital. This is a similar risk to hospital-acquired infection before the pandemic. However, such an estimate will vary based on the prevalence of COVID-19 in each hospital and in the local community, so this should also be taken into consideration when discussing with patients.

B. The risk of operation for patients who have tested positive for COVID-19

Research from a CovidSurg prospective observational cohort study suggests that elective patients who develop hospital-acquired COVID-19 have a postoperative 30-day mortality of 16.2%, with the two-thirds who experience pulmonary complications having a mortality rate of 23.8%. In line with the RCS recovery guidance, surgeons should therefore consider alternative treatments to non-emergency surgery in COVID-19 positive patients. Patients' comorbidities should be taken into account when evaluating the risk of surgery, and where relevant, patients' health should be optimised (eg people with diabetes) to reduce the possibility of complications. Consideration should also be given as to whether the use of local or regional anaesthetic might be safer than general anaesthetic, where such an option exists.

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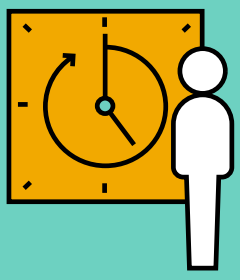
C. Changes in patient pathways and coordination of care due to the pandemic response, and possible resource scarcity.

The pathway of care for patients is likely to be different to that before the pandemic. This includes the requirement for patients to undergo testing for COVID-19 as close to the day of surgery as possible (and certainly no later than 72 hours from the day of surgery), and the expectation to carry out a period of self-isolation prior to their surgery. In most hospitals, visits are not allowed or they are severely limited to minimise the risk of infection. In some cases, ICU bed capacity may be limited, which can have an impact on the patient's postoperative journey depending on the complexity of their surgery. Discharge home or to another facility may also be more complicated, as appropriate infection prevention and control measures will need to be in place to ensure that patients are not released to environments that are high-risk from COVID-19. In a locality with high COVID-19 prevalence, patients may be advised to continue self-isolating for the first four weeks after surgery.

The above considerations should be part of a conversation with the patient and the consent process as this applies to the circumstances of each individual patient and the specific characteristics of each hospital (eg risks will be different if a hospital is a COVID-light site).

D. The importance of advance care planning.

Patients and their carers should be assisted to develop realistic expectations of treatment, its objectives and potential outcomes (see also RCS, 2020, COVID-19 – A Guide to Good Practice). The surgical care team should be informed about advance care plans, including advance decisions to refuse treatment, and should encourage and assist patients to put one in place before the need arises. Surgeons and other healthcare professionals should honour the wishes of the patient as expressed in an advance care plan.



4. TIMEFRAME OF THE CONSENT PROCESS

Patients must have the opportunity to consider all relevant information and have sufficient time (no less than 48 hours) to make an informed decision regarding their treatment. In some cases, this may require that the discussion takes place over more than one session. The process of consent should begin well in advance of the treatment, and consent should be obtained before the patient begins their pre-operative isolation. All decisions about a patient's treatment and care should be documented in the patient's record even if written consent is not obtained.

In a virtual consultation, the consent form can be sent to the patient either electronically or by letter after the discussion, providing that the patient has reached the decision to go ahead with a treatment. This will allow the patient to reflect on the form and all relevant information before signing and returning to the surgical unit.

At the time of admission, the surgeon should check with the patient if anything has changed since the consent discussion and that they still wish to proceed with the planned treatment. If there has been a significant delay since the original signing, the relevant section on the consent form should be signed by the surgeon to confirm consent. The patient does not need to sign again.

REFERENCES

- **RCS Eng** – Consent: Supported Decision-Making – A Guide to Good Practice
- **RCS Eng** – COVID-19: A Guide to Good Practice for Surgeons and Surgical Teams
- **NHSE/NHSI and Surgical Royal Colleges** – Clinical guide to surgical prioritisation during the coronavirus pandemic
- **GMC** – Consent: patients and doctors making decisions together
- **Society of American Gastrointestinal and Endoscopic Surgeons** – What is the correct risk to quote a patient undergoing urgent surgery for contracting COVID-19?
- **The Lancet** – Pulmonary complications occur in half of patients with SARS-CoV-2 infection who undergo surgery, increasing mortality risk
- **Annals of Surgery** – Unknown unknowns: Surgical consent during the COVID-19 pandemic