Consent Webinar Q&As

Legal – Damian Whitlam, Ed Pollard and Amelia Newbold, Browne Jacobson LLP

Sadly, we are not in a position to use eConsent currently, but we are already hosting non face-to-face consultations, which result in a recommendation for surgery/procedure. The procedures including risks and benefits can be discussed during the consultation and documented in the notes, but what do you consider is the best way under current circumstances of completing all aspects of the consent process? Should we be posting the consent form and information leaflets out to the patient following the consultation? Should we wait until they are admitted on the day to sign the consent form? Many of our patients are elderly and do not have access to computers.

Consent is an ongoing process, not a one-off event. Whilst the consent form is an important part of this process, the detail of the discussion between the clinician and the patient is key to enable the patient to make an informed decision about how he or she wants to proceed.

During the consultation, the clinician needs to discuss the material risks of any recommended treatment/procedure and the reasonable alternative or variant treatment options.

Determining whether a risk is material requires a two-stage approach involving both objective and subjective assessment:

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

As a result, the material risks will vary between patients and the clinician needs to ensure that he or she has an understanding of each patient's lifestyle, aims and aspirations so that he or she can provide relevant information about material risks to each individual patient. The clinician also needs to be confident that the patient has understood the information provided (which should include a discussion about how the risk will affect the patient if it materialises) and if there are any concerns about this, particularly in the context of remote consultations, a face to face consultation may be required.

Following the consultation, the clinician should record the detail of the discussion with the patient in the patient's notes. Often this will be included in a letter which will be sent to the patient, providing an opportunity for the patient to review the information discussed in the consultation again. If there are relevant information leaflets about the proposed treatment/procedure, these should also be sent to the patient. Ideally, these should be sent in advance of the consultation. If information leaflets are provided, they need to be accurate and up to date. From a legal perspective, it is also helpful to record the sources of any written information shared with patients in the notes/letter to the patient (including the date of the information leaflet so it is clear which version has been shared).

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) consideration should be given to organising a face to face consultation to enable the clinician to be confident he or she is aware of factors relevant to material risks and to ensure the patient has understood the information provided. An effective consent process should flag any barriers to understanding.

If the patient has had an opportunity to discuss the risks and benefits of a proposed treatment/procedure and any reasonable alternative or variant treatment options with the clinician, raise any questions or concerns and been given time and space to reflect on the information provided, it is reasonable to wait until the day of admission/procedure for them to sign the consent form.

However, '*Tool 5 – Consent to treatment while COVID-19 is present in society*' which is part of the '*Recovery of Surgical Services Guidance*' published by the Royal College of Surgeons on 30 June 2020 makes the point that the consent form can also be sent to the patient after the remote consultation to discuss consent, provided that the patient has reached the decision to go ahead with a treatment. This will allow the patient time to reflect on the form and all relevant information before signing and returning to the surgical unit. In these circumstances, it is vital that at the time of admission, the surgeon checks with the patient as to whether anything has changed since the consent discussion and that they still wish to proceed with the planned treatment. The Guidance also states that 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 but that the patient does not need to sign again. (https://www.rcseng.ac.uk/coronavirus/recovery-of-surgical-services/tool-5/).

I am an long in the tooth clinician and it looks like all the patient has to do is say I didn't fully understand the information I was given, for a claim to succeed.

For a claim to succeed, the patient will need to prove that he or she was not told about the material risks of the treatment/procedure and/or any reasonable alternative or variant treatment options, or that it was clear he or she did not understand the information provided by the clinician.
The Courts are alive to the fact that by the time a claim is brought, considerable time will have elapsed since the consent process and the relevant discussions between a claimant and clinician.

In assessing liability in these cases, the court will look at all the evidence and the contemporaneous notes made by the clinician about the detail of the discussion with the patient and any other sources of written information (e.g. electronic or hard copy patient information leaflets) will be absolutely crucial.

The case of *Olloson v Lee of [2019]* related to an alleged failure to obtain informed consent for a vasectomy procedure. The Claimant developed chronic testicular pain following a vasectomy in November 2012 and alleged that he was not adequately informed about the risk of this outcome. The risk of chronic pain after vasectomy of the severity suffered by the Claimant was acknowledged by the experts to be much less than 1%. It was not disputed by the Claimant that a small risk of chronic pain was mentioned in the information booklet provided to him ahead of the procedure and also on the day of the procedure when he signed a consent form. The Claimant's case was that the warning given to him about the risk was not adequate in that the magnitude of the risk and the range of severity of the possible outcomes were not explained.

The Court found the Claimant and his wife to be decent, honest people but their memory of what they were told was imperfect and that an adequate warning had in fact been provided. On the balance of probabilities, following an analysis of the evidence, including the contemporaneous notes of the consent process, the Claimant had been adequately informed and told of a small risk of chronic pain, and of the range of severity and possible effect on lifestyle.

With ever more day case surgery, is a 3 minute chat with the Anaesthetist 'at ten to nine' valid consent?

Patients undergoing elective surgery should be provided with relevant information before admission, preferably at pre-assessment or the time of booking and this is particularly important for patients admitted on the day of surgery where the opportunity for a lengthy discussion may limited.

The duty remains on the Anaesthetist to ensure that the patient understands the information and that the patient has been given sufficient time and space to consider and reflect on the relevant information about their condition, the material risks and benefits of the proposed treatment/procedure and reasonable alternatives or variant treatment options, even if admitted on the same day as surgery. The time required for this will vary depneding on the individual patient and the nature of the procedure. However, for elective procedures, it is not likely to be acceptable to provide a patient with new information immediately before induction of anaesthesia.

Should we move away from verbal consent form for anaesthesia and its associated complications in the post COVID-19 era and if so, should there be a separate form for it?

As things stand, a separate form for anaesthesia is not generally required ((The Association of Anaesthetics of GB and Ireland in its publication on Consent for Anaesthesia (2017). The emphasis is on the *process* - ensuring that a patient is given the relevant information to enable him or her to provide informed consent and documenting the detail of the discussions about this in the records.

Are information leaflets a substitute for a discussion?

No. Information leaflets can be a useful tool to help a patient understand the risks and benefits of a particular procedure but they should not replace a detailed discussion between the patient and the clinician where the individual patient's circumstances can be discussed and taken into account in the determining material risks and reasonable alternative or variant treatment options.

We talk about having tailored discussions, how should we record these, how much detail is needed? Is it time to digitally record interactions?

I am doing telephone consultations and discuss chemotherapy treatment with patients. Is oral consent over the phone and then documenting all that was said in a letter to the patient adequate for consent in this remote setting or do you need a signed written consent form?

The key is that the detail of the conversation between clinician and patient is documented somewhere e.g. in the notes or correspondence with the patient. This record should be as detailed as possible (e.g. it is not sufficient simply to record 'risks and benefits' have been discussed) but it does not have to be recorded digitally.

If a patient has been provided with all relevant information in advance of treatment/a procedure and given adequate time and space to reflect, ask questions and change their mind about how they want to proceed, it will, in most cases, be acceptable for them to sign the consent form when they attend for the treatment/procedure.

In these circumstances, it is absolutely crucial that there is a conversation between patient and clinician and that the content of that discussion is recorded in writing and that it is clear that the patient is making an informed decision based upon the information they have been given on
material risk and reasonable alternative treatment options.

In the current climate, and moving forward more consultations are taking place over a video link. How acceptable would an affirmation email from the patient in place of a wet signature for consent?

Whilst it is arguable that a signature on a consent form just proves a patient can sign their name, it remains important because it helps to demonstrate that prior to and/or on the day of the procedure/treatment the patient provided consent to proceed. However, crucially, this must be in the context of an earlier discussion(s) with the patient about the material risks and reasonable alternative treatment options so that the patient can make an informed decision.

An affirmation email from the patient may help evidence the patient's decision but confirmation of the patient's consent should always be checked prior to the treatment/procedure and confirmation of this will usually be done through a signature on a consent form.

As a secondary care centre for minor oral surgery, where do we stand on single session see and treat consent? Having been referred by their primary care practitioner, does this contribute towards the time to consider risks etc?

It will depend on this individual patient. In some cases, where surgery is minor and the risks (both generally and for the individual patient) are minimal, it may be reasonable for the patient to provide consent following a discussion about the material risks and benefits of the proposed treatment/procedure and any reasonable alternative treatment options. However, there may be cases where a patient needs more time to reflect on the information provided and before they can consider how they want to proceed. For example if a patient raises concerns about the treatment/procedure, they are in any way undecided about whether to proceed and/or there are any concerns about the patient's understanding. It cannot be assumed that appropriate information about the proposed treatment/procedure has been provided to the patient by the primary care practitioner.

Is it appropriate to create a separate consent form in relation to COVID-19 risks or should this just be included as an additional risk in the standard forms used?

A separate consent form for COVID-19 risks is not necessary. 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 important. The nature and extent of COVID-19 risks will change over time and vary in terms of significance and materiality from patient to patient.

This is a point recognised by '*Tool 5 – Consent to treatment while COVID-19 is present in society*' published by the Royal College of Surgeons and referred to above. This 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.

Can an ODP consent for a surgical procedure? Traditionally it is the surgeon who consents. In some instances, trained nurses do

The GMC Guidance (2008) *'Patients and Doctors making decisions together'* states that if you are the doctor undertaking an investigation or providing treatment, it is your responsibility to discuss it with the patient. If this is not practical, you can delegate the responsibility to someone else, provided you make sure that the person you delegate to:

a. is suitably trained and qualified;

b. has sufficient knowledge of the proposed investigation or treatment, and understands the risks involved;

c. understands, and agrees to act in accordance with, the GMC guidance.

If you delegate, you are still responsible for making sure that the patient has been given enough time and information to make an informed decision, and has given their consent, before you start any investigation or treatment.

Reasonable alternatives - if a patient is booked in for an abdominal hysterectomy, do we have to discuss the option of doing the procedure laparoscopically, even if we don't have the equipment available in our hospital or the skills to carry out this procedure. Especially with COVID-19 now? Laparoscopic operations carry more risk than open operations.

Firstly, in general terms, the case of *Bayley v George Eliot Hospitals* has provided some further clarification about reasonable alternative or variant treatment options. In order to establish whether a treatment option is an alternative treatment option of which a patient must be advised:

- There must be knowledge of the alternative treatment option.
- The alternative treatment option must be within the knowledge of the competent clinician (i.e. Bolam standard).
- The alternative option should not be a variant of an existing treatment option and there should be evidence of the alternative procedure being performed for the same purpose (i.e. just because stenting is used in heart surgery does not indicate that it is an alternative treatment option for stenting in other parts of the body).
- The alternative treatment option must be accepted practice.
- The alternative treatment option must be an 'appropriate option', not just a 'possible option'.

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, 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. Notwithstanding this, as discussed in the following article, https://blogs.bmj.com/medical-ethics/2020/04/23/consent-in-the-time-of-COVID-19/, the benefit of discussing how and why reasonable alternative or variant treatment options have changed as a result of the pandemic is that it provides the patient with context and an explanation as to why certain alterative treatment options are not currently available. This is part of an open and transparent discussion. Providing a patient with an understanding this at the time of the decision-making process may also be helpful in the event that any of the risks materialise.

It is important to recognise that a reasonable alternative to surgery or other proposed procedure or treatment may include doing nothing, conservative treatment and/or delaying treatment. The other point to consider is that is that reasonable alternative or variant treatment options may in some cases include a discussion about alternatives that might be offered by colleagues at other Trusts e.g. what if another 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 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.

We are performing virtual clinics, what is legal value of electronic consent or video recording the consent process.

Electronic consent tools may assist in providing evidence about exactly what information was provided to patients in advance or following a remote consultation, and may provide other supportive evidence in the event a claim is subsequently pursued, e.g. how long an information leaflet was being accessed on a screen/device. However, they do not replace the need for clinicians to consider what tailored information should be discussed with each patient, depending on their individual circumstances and the documentation of this.

Video recording would provide evidence of exactly what information was discussed in a consultation but may raise other issues in terms of confidentiality and GDPR. A patient would need to consent to any video recording.

Can we email a relative with information if the patient cannot be online, or just post the information?

From a legal perspective, and in order to prevent a breach of confidentiality, you would need to make sure that you had the patient's written consent to email the relative with this information. If the individual patient lacked capacity to decide whether their medical information should be shared with a relative, that decision would be made on a best interest basis. There should be no presumption that just because of a patient's age or limitations in their ability to access information online, they lack capacity to make a decision about this.

Hard copy information leaflets can be sent by post, although it will still be important to check the patient has received these, read them and understood the information provided. Such generic information is a tool which may support the consent process

but does not obviate the need to have a tailored discussion with patients about their individual circumstances, material risks and resonable alternative or variant treatment options.

From a legal perspective how vital is it that a patient receives their own copy of signed consent forms (not just in the cover world)?

It is helpful for a patient to receive a copy of the signed consent form because it will highlight the risks associated with the treatment/procedure. However, the consent form will not provide the detail of the discussion with a patient and is not, of itself, evidence of informed consent.

Are sedated patients in intensive care subject to DOLS legislation, there are small tweaks to treatment but often there are life and death decisions to make. Is best interests sufficient?

The answer to this question is split into two.

First, sedated patients in an Intensive Care setting who are receiving life-saving treatment (which practically is likely to be all ICU/ITU patients) are very unlikely to require an authorised DoLS to be in place. This is confirmed in the *Ferreira* case (R (Ferreira) v HM Senior Coroner for Inner South London and Ors [2017] EWCA Civ 31).

However, the second aspect is considering the best interests of a patient. Whilst this should be followed in the usual way for intensive care patients (using s.4 Mental Capacity Act 2005 checklist), the fact they are in an intensive care setting and do not require an authorised DoLS does not obviate the need for court involvement in certain circumstances. For instance if there is an unresolvable difference between the clinical team and the family as to what is in the patient's best interests, or, there is a fine balance between two clinical options. Please note these two are just examples and there may well be other scenarios that necessitate legal/court involvement.

Have you guidance for digital best interest meetings

The starting point is that the fundamental aspects of best interest decisions must be followed whether a decision is made 'in person' or 'digitally'. S.4 of the Mental Capacity Act 2005 provides a checklist for matters to be considered and most NHS Trusts/Private Healthcare Organisations have Best Interest Meeting templates that can be used.

Documentation of best interest discussions is always vital, and this is, perhaps, enhanced when they are taking place digitally. Courts, in general, have not been critical of any best interest decision (even if they ultimately came to a different BI decision) when the route to how that decision was made is clear and detailed i.e. the MDT has 'shown its working'.

There has been no specific guidance regarding digital best interest decisions but there has been national NHS guidance regarding assessments under the Mental Health Act 1983 (https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/C0454-mhlda-spec-comm-legal-guidance-v2-19-may.pdf) which may be of use when considering digital best interest meetings under the Mental Capacity Act 2005.

NHS Resolution – Tim Shurlock

Is it correct that the Clinical Negligence Scheme for Coronavirus (CNSC) is for existing CNST members only?

NHS Resolution launched CNSC to meet liabilities arising from the special healthcare arrangements being put in place in response to the coronavirus outbreak.

The scheme has been established in accordance with new powers from the Coronavirus Act 2020. It will provide additional indemnity coverage for clinical negligence liabilities that may arise when healthcare professionals and others are working as part of the Coronavirus response, or undertaking NHS work to backfill others as a consequence, and existing arrangements (CNST, CNSGP or individual arrangements) do not cover a particular activity. This additional indemnity cover will provide an additional safeguard and is complementary to any existing indemnity provision already in place. The additional indemnity provided by the Coronavirus Act 2020 covers NHS services commissioned from non-NHS providers. These arrangements will therefore include healthcare professionals and others from the independent sector, working as part of the Coronavirus response, where there is no existing indemnity arrangement in place.

The scheme will respond to new and alternative ways of working, including new contracts being put in place for the NHS to respond to coronavirus, such as those with the independent sector and organisations supporting testing arrangements. Membership of this new indemnity scheme is not required, and cover will be provided automatically under the relevant contracts or arrangements otherwise approved by NHS England and NHS Improvement.

The new scheme complements the existing indemnity schemes operated by NHS Resolution on behalf of the Secretary of State for Health and Social Care. During the coronavirus outbreak, existing indemnity arrangements will continue, and the intention is that this additional indemnity cover will provide a safeguard, but not duplicate existing provision. Where NHS Trusts are hosting special healthcare arrangements, for example the NHS Nightingale hospitals, then clinical negligence liabilities will be covered by CNST.

For more information, please see: https://resolution.nhs.uk/services/claims-management/clinical-schemes/clinical-negligence-scheme-for-coronavirus/ or for any enquires about the scheme please email CNSC@resolution.nhs.uk.

Clinical – Simon Parsons

In the Lancet 30/5/20 - figures of 19% mortality rate have been quoted for patients undergoing elective surgery if the develop Covid post op. Should we be advising all patients of this risk now?

We should be warning of significant mortality if the patient develops COVID-19 post operatively and demonstrating what the Trust is doing to prevent infection. I don't think the data is mature enough to say it is 20% but it would be reasonable to say up to 20%.

For elective admission should we inform patients that they are going to come to an area with an unquantified extra risk of COVID-19. Given that most patients are elderly and should be shielding

Yes, but we should also be explaining what the trust are doing to minimise the infection rates.

How do you manage those patients that don't have the technology to engage in virtual clinics?

You will always need a "no technology" stream for those who can't or won't engage in the technology. For clinics this means face to face or telephone (most can do telephone) followed by sharing information through the post.

How can we inform patients if we have no data to impart? What is the risk of having a hernia repaired if you are 85 with COPD and are shielding?

We can only inform based on information we have. The risk of dying of COVID-19 in an 85-year-old with COPD is clearly high if they contract COVID-19. We must try to make a balanced judgement of risk. If, as a clinician, you feel the risk of COVID-19 infection outweighs the benefit of hernia repair then you need to explain that to the patient and hopefully they will agree. You can't be forced into operating if you don't think it is the right thing to do.

Do you advise patient and family to self-isolate for 2 weeks AFTER elective surgery?

I think that would be sensible for major surgery though at NUH we don't formally do that. We are planning to contact the patient 1 week after surgery to ensure they haven't gone down with COVID-19 so we can audit it.

In the pathway - how many 'clinic' appointments are needed?

We should aim for only one face to face consultation (single meaningful consultation). This would be when all the necessary investigations are back, and we are making a decision with patients about surgery. Some clinicians may be happy to do this remotely for some conditions, but most will want to see the patient. The consent process should be able to happen virtually as well as face to face.

Again, it is important to emphasise that some patients may need more than one face to face consultation. There is no 'one size fits all' approach to consent and it is important that the clinician is satisfied that the patient has understood the material risks and the reasonable alternative treatment options and has shared in the decision making process with regard to treatment (and that this understanding is evidenced).

Why are some Trusts so reluctant to improve the quality of their consent forms?

In order to make it easier for the clinicians, the consent forms should be prepopulated with the appropriate risks, benefits and alternatives which relates to information the patient has already received. The EIDO system delivers that. The actual wording on the standard consent forms also needs to be updated to make them Montgomery compliant. EIDO have developed a consent form with legal experts in informed consent.

EIDO – Matthew Ravenscroft

We use the EIDO forms at work; I printed out two 'leaflets' for GenSurg operations last week and there was no COVID information there. Is it in a separate area?

The EIDO forms have the COVID-19 information on the first page after the cover. If you are printing out copies from locally saved files, then you should download up-to-date copies direct from the EIDO Download Centre. You can contact the account manager for your hospital using the 'help' button on the Download Centre.

What are the implications for information provided in a format the patient cannot access? 8.9% of Nottingham adults have low or no literacy. Others have sight or language issues – our Trust's EIDO consent information is in a tiny font that doesn't meet standards etc. Thank you.

EIDO information is available in 12pt font as standard, as well as Large (18pt) and Giant (22pt) Print, and Screen Reader options. A subset of the library is available in Easy Read. These help Trusts and Boards meet the Accessibility Standard. Each EIDO document bears a unique Plain English Campaign Crystal Mark for the clarity of the language used. Inform Digital allows your patients to have the document read to them using voiceover software and change the font and background colour to improve their access to the information and meet web content accessibility (WCAG 2.1) guidelines. Please contact EIDO to discuss your Trust's requirements in this regard with your EIDO Customer Care Manager.

One of the key difficulties is ensuring a patient has comprehended the information and recording this. It's all very well giving information, but literature shows retention and comprehension is extremely poor in many patient groups. How do we improve this?

An upcoming release of the EIDO Consent suite will include an optional Q&A session for the patient to complete. This is aimed at encouraging better learning and engagement of the patient and is recorded and available to help focus subsequent clinician patient consultation(s), whether virtual or face to face.

How do you use eConsent/digital process if patient doesn't have IT/computers in virtual consultation world of COVID-19?

EIDO's Home Consent offering can work alongside, or separate to, your Trust's virtual consultation; however, it does require the patient to have access to a computer/tablet/phone and internet connection. Patients could record consent at home via a hard copy consent form posted out to them, a clinician could complete part of the consent form in discussion over the phone with the patient. Hospitals using EIDO's Vault app can take consent from a patient digitally in hospital, using hospital IT equipment.

Is there a facility for getting the signed consent form back from the patient digitally on EIDO platform?

Yes. The Home Consent draft form is stored and available via the Inform Digital dashboard. If the hospital chooses to integrate the system with the hospital network, then consent forms and patient engagement reports can also be sent securely to the hospital to be accessed locally. The EIDO Vault app, when linked to the Home Consent form, can allow clinicians to fully complete the consent form, including signatures, digitally.

What is the cost of using EIDO to the trusts?

The cost depends on the number of titles licenced, the languages and formats licenced and length of contract; please contact EIDO at info@eidohealthcare.com for a quote.

When decisions are shared one outcome is a fall in the number of invasive interventions. How much of the EIDO impact on Trust legal ££ might be due to that?

The figures presented during the webinar were all connected with the reduction in monies paid out as a result of successful litigation claims. We don't have any evidence on the impact on numbers of invasive interventions.

Are there any plastic surgery leaflets on EIDO?

Yes, the EIDO library currently contains approximately 20 Plastics titles. All specialties in the library are continually growing.

How much of the EIDO information focusses on the other options in respect of the decision - especially the choice not to intervene?

The EIDO documents each have a section on alternative treatment options, including the option of not having the procedure, as this is an important part of the informed consent conversation.

How do you ensure the person engaging digitally is the patient and someone else (relative or hacker)?

The system requires two, three or four (hospital defined) points of patient authentication, without which the patient will not be able to proceed digitally. The patient's identity will always have to be ultimately confirmed when they present face to face for the confirmation of consent in order to undergo the procedure. At that point, they will sign to confirm the digital records prepopulated on the form are correct.

Please note:

The information contained in this document is correct as of the original date of publication.

The information and opinions expressed in this document are no substitute for full legal advice, it is for guidance only.