Consent for ophthalmology procedures

There are many sources of information for doctors on how to undertake high quality consenting. This document aims to summarise some key aspects pertinent to elective ophthalmology procedures, in particular, issues where there are recurrent queries to the College and points which patients have told us matter to them. It should be used as a supplement to existing regulations and guidance such as those from the GMC.

The 2015 Supreme Court judgement *Montgomery vs Lanarkshire Health Board* was a landmark decision and moved the standards for consent beyond the previously used *Bolam* principle, which was based on what a responsible body of doctors would do. The Montgomery judgement shifted the focus of consent towards the specific needs of the patient. Doctors must now take reasonable steps to ensure that patients are aware of any risks that are material to them, and they should inform their patients of alternative treatments including conservative management.

Despite the challenges facing ophthalmology including high volumes of patients and limited capacity/resources, obtaining valid consent should not be viewed as a "tick-box exercise" and reliance on generic consent forms without appropriate and documented discussions potentially leaves clinicians liable to medicolegal challenges and litigation. It is also poor patient care. Inadequate consenting is a regular cause of complaints and litigation. A patient-centred discussion must be tailored to the individual to facilitate shared-decision making. This requires time for the clinician to understand the views and values of the individual and empower informed shared decision making within a two-way partnership approach.

KEY PRINCIPLES

Consent should not begin on the day of an elective procedure. Consent begins at the first consultation where a procedure is being considered or an option, and may occur in phases and over time, aiming to give the patient any information they need to make an informed decision about what treatment or procedure (if any) they want.

As much of the consent process as possible should occur before the day of the procedure. If the consent has been obtained and signed before the day of the procedure, unless that was within the last few days, consent should be briefly reconfirmed and recorded on the form or the records**.**

Responsibility for the consent process can be delegated by the surgeon performing the procedure to medical or non-medical clinical staff. Staff who are not surgeons capable of performing the procedure and non-medical staff should have undergone appropriate training and have the competency and methods for keeping knowledge and skills up to date. They must understand the procedure, the risks and benefits and be able to undertake high quality discussions and shared decision making required for valid consent. Ultimately the surgeon performing the procedure must be satisfied that the

patient is happy to proceed with surgery, is aware of the risks, and has realistic expectations for the outcome.

Material risk. All reasonable treatment options (including alternatives and conservative management) and their implications should be explained. This includes material risks tailored to the patient and their specific needs. Test of materiality is two-fold:

> *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.*

The associated **risks must be explained** in a manner that the patient understands and not simply as a list of terms or statistics. Patients like to understand which risks are likely to be temporary and which potentially permanent problems, and find giving a likelihood (eg up to 1 in 10, up to 1 in 100 etc) helpful. They prefer risks to be explained in clear lay terms avoiding medical jargon. The clinician should aim to support the patient in understanding how such risks could impact them as an individual and their approach to risk.

Patients want to understand more than just the risks and benefits of the procedure. They also wish to know the likely practicalities of how long they will be on any waiting list, any preoperative assessments or actions required, and what the day itself and having the procedure will involve for them. They also need to understand what to expect after the operation and crucially any significant commitment to postoperative care for them such as frequent postop attendances after glaucoma drainage surgery or posturing after retinal surgery.

Opportunities for the patient to ask further questions should be available within the consultation and ideally recorded on the consent form and/or clinical notes. Patients should also be given a way of contacting after consenting to have further questions answered and most consent forms have a space for this. It needs to be completed with a contact that will be accessible and reply.

Procedure specific prepopulated consent forms for common procedures can be very helpful to ensure clear and comprehensive statement of risks and as an aide memoire for consenters to ensure they cover key points. However, they must allow for editing for individual patient circumstances, their personal and material risks and questions.

As part of their consent, patients should also have a **discussion of the risks and benefits of different forms of anaesthetic including local anaesthetic types**. This is commonly under-discussed. However, if a patient has a complication relating to the choice of anaesthetic, eg from moving their eye under topical or an ocular perforation due to a sharp needle block and were not given any choice beforehand, this can be very difficult to defend.

Written information**. A copy of the consent form should be provided to the patient in advance of the day of surgery**. It is acceptable to keep the signed copy in the notes and

another non signed copy provided to the patient. The copy must include have any edits or changes for that patient made to the standard from. Where possible for common procedures, **we strongly recommend that more detailed written information on the procedure additional to the consent form is provided** or the patient directed to reliable sources of information such as patient charities.

The dialogue for valid consent must include a patient-centred discussion and the consent form is signed as evidence that the discussion has taken place. This **signature on the consent form does not prove consent was undertaken well but it does help to provide evidence** in support of that, especially where it is clearly recorded in the notes that a copy of the form and an information leaflet were provided

Patients in ophthalmology clinics may have greater requirements for support, given that we have a **mainly elderly population and in particular many with poor vision**. For consent to be valid, and to fulfil the accessibility laws for patient communications, every effort must be made to ensure patients understand and can access the information required and read the consent form and any written information provided.

For ophthalmology patients, particular care is needed around being able to review their consent form when **vision is reduced by mydriasis following dilating drops**. This can be aided by ensuring patients fully understand what is on the form and providing copies of forms to take home before the day of surgery so that they can be reviewed and thought about once dilating drops have worn off.

Where patients are having **a course of repeated treatments** such as intravitreal injections or botulinum toxin injections, it **is acceptable to use a single consent form** for repeated interventions as long as (i) the patient is aware they are agreeing to a course of treatments, (ii) confirmation of consent is obtained prior to subsequently repeated interventions, and (iii) the consent is retaken if the material risks change in any way due to changes in ocular or patient status. Although there is no legal timing for how long a consent form is valid for in such circumstances, it is common practice for practitioners to retake written consent on an annual basis.

Remember – by law (The Accessible Information Standard), patient's with disabilities including sensory loss must be asked and provided with information and communication materials in a format of the patient's choice such as audio, braille, easy read or large print. This includes consent forms and information leaflets.

CONSENTING IN OPHTHALMOLOGY SINCE THE COVID-19 CRISIS

During the Covid-19 pandemic lockdown and the ensuing months of recovery and re-opening services, there are additional factors to take into account. To cope with re-deployment of resources to care for Covid-affected patients and to reduce population

spread, ophthalmic services have been restricted and care delayed, based on clinical priority, and risk of harm from delay in eye care and vulnerability to Covid. In addition, as

services become more available, patients will wish to take into account their personal risk of severe Covid and their attitude to being prepared to risk contracting the disease during healthcare, before deciding whether to attend hospitals and whether to go ahead with procedures.

The clinician now needs to balance the theoretical risk of a patient contracting Covid against the real risks of ocular morbidity and irreversible vision loss or systemic morbidity (eg vision-related falls) associated with not undertaking sight saving or sight-restoring procedures. Deferring an operation until the pandemic issues have abated should be discussed using a shared decision-making process.

During this time, it is important, as part of the consenting process, to:

- discuss with patients what their personal risk of Covid is, recognising the many uncertainties about the actual level of risk in the population and in individuals
- discuss the patient's attitude to taking any such risk of contracting Covid through attending for care or having a procedure
- the ways in which the healthcare provider is reducing the risk
- advise patients who wish to defer care about the risks of that deferral
- record this discussion and its outcome in the records.

MENTAL CAPACITY ACT 2005: THE FIVE STATUTORY PRINCIPLES

The Mental Capacity Act 2005 sets out five statutory principles on which the legal requirements are based. The five statutory principles are:

1. A person must be assumed to have capacity unless it is established that they lack capacity.

2. A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success.

3. A person is not to be treated as unable to make a decision merely because he makes an unwise decision.

4. An act done or decision made for or on behalf of a person who lacks capacity must be done, or made, in his best interests.

5. Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.

What Does 'Lacks Capacity' Mean?

Section 2(1) of the Mental Capacity Act states: 'For the purposes of this Act, a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.'

The impairment or disturbance of the functioning of the mind described in Section 2(1) refers to any disturbance that affects the person's ability to make the specific decision in question at the specific time it needs to be made. This impairment does not need to be permanent and may only be partial.

That a person has been judged to lack capacity in relation to a previous decision regarding their care does not entail that they lack capacity to make decisions in all situations. The patient should be assessed as to their capacity to make decisions on a case-by-case basis. Capacity to make a decision can vary with the nature of the decision and can change over time.

Limited Capacity

A patient's capacity to make decisions regarding their treatment may fluctuate owing to the conditions of their health or other factors and so it is important to ensure that wherever possible a patient is able to offer as much input to the discussions as is within their capability and wishes. Patients should be supported to maximise their ability to make decisions for themselves.

All reasonable efforts to plan for changes in a patient's capacity to make decisions should be made to ensure that discussions about treatment are made at times and in situations where the patient is able to make decisions themselves or, where this is not possible, to maximally contribute to the decision process.

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RESOURCES AND REFERENCES

REGULATION AND GUIDANCE

General Medical Council

- **Good Medical Practice. GMC, 2013**
- **Consent: Patients and Doctors Making Decisions Together. GMC, 2008**
- **Confidentiality. GMC, 2009**

Royal College of Ophthalmologists

- **Standards for Patient Information and Consent for Refractive Surgery, RCOphth 2016**
- **Focus Article Winter 2016 – Consent: The reasonable patient**

Royal College of Surgeons of England

- **Good Surgical Practice. RCS, 2014**
- **Professional Standards for Cosmetic Surgery. RCS, 2016**

Department of Health

- **Reference Guide to Consent for Examination or Treatment, 2nd ed. Department of Health, 2009**

LEGISLATION

The Mental Capacity Act 2005 (England and Wales)

Adults with Incapacity Act 2000 (Scotland)

Mental Capacity Bill: Deprivation of Liberty Safeguards 2015 (Northern Ireland)

Human Rights Act 1998

Accessible Information Standard. 2017

COMMON LAW

Montgomery (Appellant) v Lanarkshire Health Board (Respondent) [2015] UKSC 11

Chester v Afshar [2004] UKHL 41 – The duty to warn patients about risk

Rogers v Whitaker (1992) 175 CLR 479 HC (Aus): This was an Australian ophthalmology case in which the patient developed sympathetic ophthalmitis (after the other eye was removed). The risk was estimated at 1 in 14,000. The patient was not informed. The court held that 'a risk is material if: a reasonable person... if warned of the risk would be likely to attach significance to it'.

Gillick v West Norfolk and Wisbech AHA [1986] AC 112 – Children and young people's competence to consent to treatment