

TOP TIPS

Informed consent in ophthalmology care in the UK: A critical component of patient-centred practice

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Informed consent is a cornerstone of ethical and legal practice in healthcare, particularly in fields like ophthalmology where specialised interventions can have significant implications for a patient's vision and quality of life. In the UK, informed consent is not merely a procedural requirement; it is a dynamic process grounded in respect for patient autonomy, professional accountability, and the principles outlined by the General Medical Council (GMC). This article explores the essential components of informed consent in ophthalmology, key challenges, and best practices to ensure compliance and enhance patient care.

Legal and ethical framework

The doctrine of informed consent is enshrined in UK law, particularly following the landmark Supreme Court judgment in *Montgomery v Lanarkshire Health Board* (2015). This case emphasised the need for a patient-centred approach, requiring clinicians to disclose risks that a reasonable patient would consider significant, as opposed to those the doctor deems important.

In ophthalmology, informed consent involves not only the provision of information but also ensuring that patients comprehend the nature, purpose, benefits, risks, and alternatives of proposed interventions, whether they involve routine cataract surgery, laser procedures, or repeated treatments like intravitreal injections as well as new treatments such as minimally invasive glaucoma surgery. The GMC's guidance on decision-making and consent reiterates the necessity of tailoring information to individual patient needs, considering factors such as their health literacy, cultural background, and personal values.

The informed consent process in ophthalmology

1. Disclosure of information

In ophthalmology, the technical nature of procedures necessitates clear communication. For example, in cataract surgery, patients must be informed about

potential complications such as posterior capsule rupture, endophthalmitis, or residual and unexpected refractive errors. Similarly, those undergoing intravitreal injections need to understand risks like infection or retinal detachment.

Visual aids, diagrams, patient information leaflets and videos can be instrumental in enhancing patient understanding. Discussions should also address other options including no treatment and non-surgical options and the implications of choosing no intervention.

2. Assessment of understanding

It is crucial to verify that patients fully understand the information provided. Open-ended questions and the 'teach-back' method, where patients repeat the information in their own words, can help clinicians gauge comprehension.

3. Voluntariness

Patients must make decisions free from coercion or undue influence. In ophthalmology clinics, where patients may feel pressured by the urgency of their condition or the authority of the clinician, fostering a supportive environment is essential. Giving patients full information and time to think and consider options improves the validity of the consent process.

4. Capacity assessment

In cases involving elderly patients or those with cognitive impairments, such as dementia, assessing decision-making capacity is critical. The Mental Capacity Act 2005 provides a framework for determining capacity and supports clinicians in making decisions in the patient's best interests if they are unable to consent.

Challenges in achieving informed consent

Despite its importance, achieving truly informed consent in ophthalmology is not without challenges. These include:

- **Time constraints:** Busy clinics often limit the time available for detailed discussions.

- **Complexity of information:** Ophthalmological procedures involve intricate technical details that may overwhelm patients.
- **Language and cultural barriers:** Non-English-speaking patients or those from diverse cultural backgrounds may require interpreters or culturally sensitive communication strategies.
- **Emerging technologies:** New treatments like gene therapy or artificial intelligence-based diagnostics raise unique ethical considerations that may complicate the consent process.

Best practices for enhancing informed consent

1. Early and ongoing communication

Consent should be viewed as a process rather than a one-time event. Early and multiple discussions, reinforced by follow-up conversations, allow patients to reflect and ask questions.

2. Patient-centred materials

Providing written leaflets, digital resources, or interactive tools tailored to the patient's condition can reinforce verbal discussions.

3. Multidisciplinary team collaboration

Optometrists, nurses, and other healthcare professionals can play a vital role in educating patients and supporting the consent process.

4. Training and auditing

Regular training on communication skills and informed consent, coupled with audits of consent practices, can identify and address gaps.

What happens when a patient claims that their consent was not valid or taken properly?

When a patient claims that they did not consent to a treatment, it raises serious legal, ethical, and professional concerns for the clinician and healthcare organisation. Such situations require careful management to determine the validity of the claim, address the patient's concerns, and mitigate potential repercussions.

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An outline of what actions should be taken, the legal considerations, and steps to prevent such situations in the future would be:

Immediate actions

1. Documentation review

The first step is to review the patient's medical records and consent documentation. It is important to verify that the consent process was appropriately documented, including details of the information provided to the patient, their expressed understanding, and the signed consent form (if applicable).

2. Listen to the patient's concerns

It might be necessary as part of the response to meet with the patient to understand their perspective. It would be important to determine whether the patient is disputing the entire consent process or if they feel inadequately informed about certain aspects (e.g. risks or alternatives). For example, many patients would say that they were not fully informed about the pain associated with the local anaesthesia procedure before their cataract surgery. They would feel that they did not sign for it and did not know that it might be a very painful part of the procedure.

3. Notify relevant parties

Patients' complaints are usually managed through specific teams that deal with patient safety or governance issues with the support of Patient Advice and Liaison Service (PALS). It might be necessary to inform the hospital's legal or risk management team immediately if there is risk of litigation. It might also be necessary to notify the indemnity provider for advice and support.

4. Maintain a professional position

It is important to note that doctors should avoid being defensive; instead, approach the matter with empathy and transparency. Reassure the patient that their concerns are being taken seriously and will be thoroughly investigated.

Legal and ethical considerations

1. Burden of proof

Under UK law, healthcare providers must prove that they obtained valid informed consent before administering treatment. Therefore, documentation plays a critical role in demonstrating that the patient was adequately informed and voluntarily agreed to the procedure.

2. Montgomery principles

Ensure that the patient was informed of risks that a "reasonable person in

their position" would consider material. This includes for example the risk of severe visual loss even if that risk is very small.

3. Capacity and coercion

If the patient lacked capacity at the time of treatment or felt coerced, the consent may be deemed invalid. Therefore, it is important to assess the patient's capacity and understanding of the proposed procedure along with risks and benefits.

4. Clinical negligence or misunderstanding

Distinguish between a claim of negligence (e.g. failure to disclose risks) and a potential misunderstanding or communication breakdown during the consent process.

Steps to mitigate and resolve the situation

1. Open disclosure and duty of candour

If there was a genuine lapse in the consent process, acknowledging this and providing an explanation and apology might be appropriate.

2. Mediation or complaint resolution

If the patient raises a formal complaint, it is important to work with the hospital's complaints team to resolve the matter and respond to the patient's concerns. Mediation can sometimes help clarify misunderstandings.

3. Legal proceedings

If the matter escalates to a legal claim, then the hospital legal team will work with the doctors to support and provide evidence of informed consent.

Preventing future issues

1. Enhanced and detailed documentation

It is important to document not only the signed consent form but also details of the discussions with the patient, including specific risks and alternatives explained. It is also important to document any questions asked by the patient and their responses to indicate understanding.

2. Use of witnesses

When appropriate, it might be possible to involve a nurse or other healthcare professional as a witness to the consent discussion.

3. Patient education tools

These are great assets to use in the consent process. Providing patients with written or digital materials to reinforce verbal discussions and support evidence of the informed consent process.

4. Reconfirm consent before treatment

For elective procedures, reaffirm

consent immediately before treatment to ensure patients still agree to proceed.

- **Regular consent training:** It is always good practice to train all staff involved in the consent process on the latest legal and ethical standards, including the Montgomery ruling.

- **Feedback mechanisms:** It might be possible to encourage patients to provide feedback on their understanding of the consent process and guide future training and auditing.

Conclusion

Informed consent in ophthalmology care in the UK is a multifaceted process that requires clear communication, empathy, and adherence to legal and ethical standards. By prioritising patient-centred practices and addressing challenges proactively, ophthalmologists can empower patients to make informed decisions about their care, enhancing both clinical outcomes and trust in the patient-healthcare provider relationship.

The evolving landscape of ophthalmology treatments and procedures underscores the need for continuous education and innovation in consent practices, ensuring that patients remain at the heart of care delivery.

When a patient claims that they did not consent to treatment, it highlights the critical importance of a thorough, patient-centred informed consent process. Proactively addressing the patient's concerns and maintaining detailed documentation are essential to resolving disputes effectively. While the immediate focus should be on addressing the individual case, lessons learned should inform improvements to consent practices to prevent similar issues in the future.

Recommended reading

- Good Medical Practice (GMC): <https://www.gmc-uk.org/professional-standards/good-medical-practice-2024>
- Consent guidance (GMC): <https://www.gmc-uk.org/professional-standards/the-professional-standards/decision-making-and-consent>
- Standards of Consent for Ophthalmology Procedures (RCOphth): <https://www.rcophth.ac.uk/wp-content/uploads/2020/05/Standards-Of-Consent-For-Ophthalmology-Procedures-COVID-19.pdf>
- Montgomery vs. Lanarkshire Health Board: <https://www.supremecourt.uk/cases/uksc-2013-0136>

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