# Consent and Checklist Recommendation
# Intravitreal Injections

The ROYAL COLLEGE of OPHTHALMOLOGISTS

## Background and Current Clinical Practice

Intravitreal injection therapy has been rapidly increasing since the NICE approval of ranibizumab in 2008.

The process of taking informed consent can be a time consuming process which affects the capacity to deliver intravitreal injection services especially if many patients require it during a clinic session. New drugs have been introduced over the years. At the time of writing the following drug options are available.

1. Ranbizumab (Lucentis)
2. Ranbizumab Biosimilars (Ongavia, Byooviz, Ximluci + other products pending)
3. Bevacizumab (Avastin) – used off label
4. Aflibercept (Eylea)
5. Brolucizumab (Beovu)
6. Faricimab (Vabysmo)

Depending on commissioning requirements and local practice the preferred first line choice of drug varies between ophthalmic units. If response could be better either in terms of efficacy or duration of treatment effect, there may be a clinical need to switch treatment. Switching of patients who are stable on treatment to a biosimilar agent may be also be a commissioning requirement to manage costs. An individual patient may switch between multiple agents and each time such a switch occurs, additional time is required in the clinic for consultation and consent documentation.

Another important aspect of intravitreal injection therapy is ensuring safe prescribing and administration of the correct drug to the correct patient in the correct eye. Ophthalmic units vary in how safety is ensured; some relying partly on the consent form, others on separate checklist processes. If relying on written consent forms, multiple consent forms in the hospital records also adds a level of risk unless robust processes are in place to link the correct consent form with the checklist process and / or ensure expired consent forms are clearly indicated.

Current clinical practice appears to vary between ophthalmic units and may consist of a variation of the following:

1. Generic blank NHS consent forms on which the procedure, the specific drug and risks / benefits are specified each time. This introduces variability in the detail covered on the form dependent on the clinician taking consent.
2. Generic consent form for the intravitreal injection procedure with no consent form specific to the drug. Drugs recorded in the notes and on checklist documentation.


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3. Bespoke consent forms for both the intravitreal injection procedure and separate forms for each specific drug.
4. Checklist processes which rely on the contents of the consent form.
5. Checklist processes separate from the consent form.
6. Variable methods of prescribing the drug as required by local pharmacies.

The Royal College of Ophthalmologists convened a group to review this process and offer guidance with the aim of simplifying the process whilst also ensuring safe clinical practice. The documents provided are editable to allow digital completion and printing and editable in relevant places to facilitate variation based on local practice.

## Essential requirements

An actual signed consent form is good practice when an invasive interventional procedure is conducted. The consent form is only one evidence of the consent process which should also include a discussion with the patient and documentation in the notes of the key points of discussion between the healthcare personnel taking consent and the patient. Patient attendance in clinic and acceptance of a procedure is also evidence of consent.

Key material risks need to be documented on a consent form and the specific drug chosen does not have to be specifically recorded on the consent form as long as the discussion with the patient related to rationale of use, reason for choices made and risks / benefits specific to the chosen agent are recorded in the notes.

The timescale over which a consent form is considered valid is also variable between eye units. There is no legal limit on consent form validity so local agreement may guide a pragmatic time scale which does not cause the capacity issues associated with needing to reconsent whilst also demonstrating periodic renewal of consent. Assessment of patient capacity and consent to continue treatment is expected at all visits but this may be recorded in the notes and does not need a consent form at every visit.

## Recommendations

Sample documentation is provided to guide the process of consent and safety checklist in patients undergoing intravitreal injection therapy of anti-VEGF and related drugs as listed in the background above. This consists of the following elements:

### 1. A template consent form for intravitreal therapy

This does not specify the drug used or the eye treated but ensures all the material risks associated with the injection procedure are documented. The content primarily relates to anti-VEGF drugs (some of which have additional modes of action).

Consent may be taken by any healthcare professional with training in the principles of consent and who has sufficient understanding of the procedure to ensure informed consent.


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The sample provided is for patients who have capacity to consent. In patients who lack capacity local protocols will need to be followed for capacity assessment, best interests meeting and consent form according to NHS standard consent form 4.

This guidance does not replace the option of bespoke consent forms for each individual drug if that is a local preference but it offers a pragmatic alternative option which may assist with managing capacity in busy clinics.

### 2. Site and drug list accompanying consent form

The specific drug used and discussion related to it may be recorded on the accompanying sheet. If a drug treatment is changed, this may be recorded on this sheet including the rationale and patient discussion without requiring a patient signature. By retaining these on a single document the treatment history is clear reducing the risk of incorrect drug administration. It also simplifies the process of switching treatments. A new sheet is only needed if the eye or eyes treated changes.

### 3. Checklist on the day of treatment

A separate checklist document is advised for use on the day of the treatment which references the consent and drug list. The sample attached may be adapted to local drop preferences and reference any relevant local clinical clinical guidelines.

Some departments have electronic methods for consent and checklist. The principles of these documents may also be applied in this setting.

## References

Consent guides for healthcare professionals. UK Department of Health.
**www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition**

Decision Making and Consent – General Medical Council
**www.gmc-uk.org/-/media/documents/updated-decision-making-and-consent-guidance_pdf-84160128.pdf**

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