Consent forms for intravitreal injection at a UK district general hospital: do they meet the standard for informed consent?

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Background

Informed consent plays a vital role in doctor-patient interactions. Ethically, it aims to protect patient autonomy. Legally, it protects clinicians from charges of battery and/or clinical negligence where treatment is medically appropriate.

The purpose of consent forms is to provide evidence of a patient's written informed consent. However, not all consent forms are equal and not all meet the standard for evidencing informed consent.

Much has been written about what constitutes informed consent. Of note is the case of Montgomery v Lanarkshire Health Board, which set a new standard of informing side effects that a patient may attach significance to. In practice, this has largely been interpreted as including not only the risk but the likely incidence of that risk occurring, with the discussion of specific or material risks to the patient[1].

Aims of the Audit

1. To assess whether the current consent form for intravitreal injections meets standards for informed consent in line with local, Royal College of Ophthalmology (RCOphth) guidance[2] and common law, in the following ways:

A) Relevant risks for intravitreal injection are consistently recorded, as per the RCOphth consent form for intravitreal injection model[3]

B) Relevant risks are listed with their associated incidence

C) Risks specific or material to the individual are considered and recorded

2. To assess whether the current consent form is accessible and understandable to patients, in the following ways:

A) Language used to describe the consenting procedure, associated risks and benefits.

Methodology

Data Set:

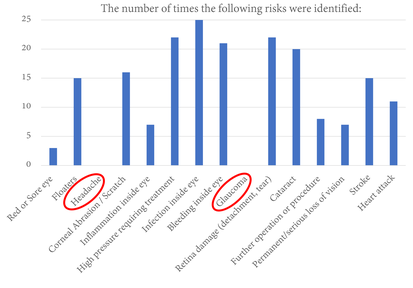
- 25 consent forms for intravitreal injection, from outpatient intravitreal injection and general Ophthalmology clinics between 23-25th August 2022.

Analysis:

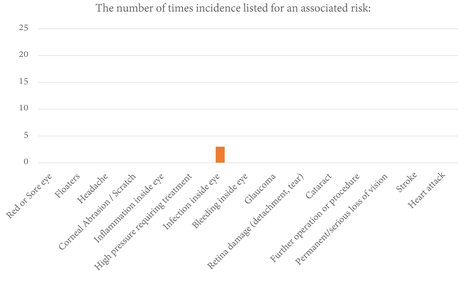
- Consent forms were scrutinised against the following criteria, as per the aims of the project.
- Data was inputted onto an Excel spreadsheet and populated into a graphical format.
- We presented our findings to our local departmental clinical governance meeting, attended by consultant ophthalmologists, specialist nurses, administrative staff and allied health professionals.

Results

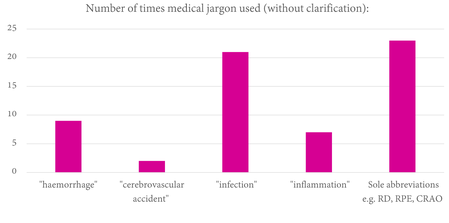
Relevant risks for intravitreal injection were not consistently recorded, or not included at all



Risks were almost never listed with an associated incidence; in only 3 consent forms, the incidence for infection inside eye (endophthalmitis) was noted



Medical jargon was frequently used, without clarification

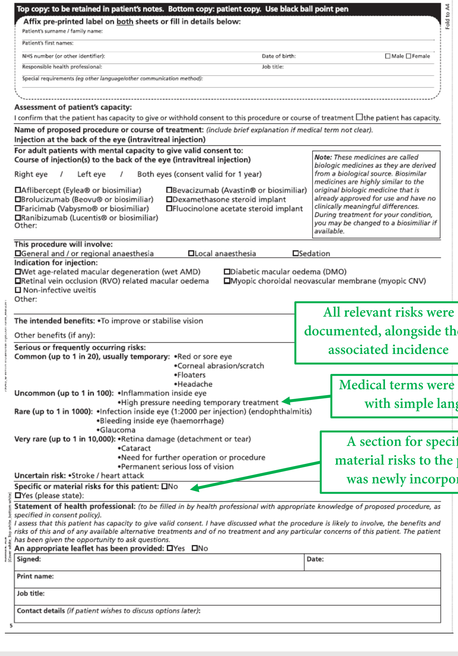


Risks specific or material to the patient were not documented in any consent forms



Action Plan

The results of our audit highlighted that a revised consent form was necessary to appropriately facilitate informed consent. In response, a new A3-size consent form was developed which helped to address our identified aims (see green boxes):


Top copy: to be retained in patient's notes. Bottom copy: patient copy. Use black ball point pen

Affix pre-printed label on both sheets or fill in details below:

Patient's surname / family name:

Patient's first names:

NHS number (or other identifier): Date of birth: ☐Male ☐Female

Responsible health professional: Job title:

Special requirements (eg other language/other communication method):

Assessment of patient's capacity:

I confirm that the patient has capacity to give or withhold consent to this procedure or course of treatment ☐the patient has capacity.

Name of proposed procedure or course of treatment: (include brief explanation if medical term not clear).

Injection at the back of the eye (intravitreal injection)

For adult patients with mental capacity to give valid consent to:

Course of injection(s) to the back of the eye (intravitreal injection)

Right eye / Left eye / Both eyes (consent valid for 1 year)

☐Aflibercept (Eylea® or biosimiliar)
☐Ranibizumab (Lucentis® or biosimiliar)
☐Faricimab (Vabysmo® or biosimiliar)
☐Bevacizumab (Avastin® or biosimiliar)
☐Dexamethasone steroid implant
☐Fluocinolone acetate steroid implant
☐Brolucizumab (Beovu® or biosimiliar)
Other:

Note: These medicines are called biologic medicines as they are derived from a biological source. Biosimilar medicines are highly similar to the original biologic medicine that is already approved for use and have no clinically meaningful differences. During treatment for your condition, you may be changed to a biosimilar if available.

This procedure will involve:
☐General and / or regional anaesthesia ☐Local anaesthesia ☐Sedation

Indication for injection:
☐Wet age-related macular degeneration (wet AMD)
☐Retinal vein occlusion (RVO) related macular oedema
☐ Non-infective uveitis
☐Diabetic macular oedema (DMO)
☐Myopic choroidal neovascular membrane (myopic CNV)
Other:

The intended benefits: •To improve or stabilise vision

Other benefits (if any):

Serious or frequently occurring risks:

Common (up to 1 in 20), usually temporary: •Red or sore eye •Corneal abrasion/scratch •Floaters •Headache

Uncommon (up to 1 in 100): •Inflammation inside eye •High pressure needing temporary treatment

Rare (up to 1 in 1000): •Infection inside eye (1:2000 per injection) (endophthalmitis) •Bleeding inside eye (haemorrhage) •Glaucoma

Very rare (up to 1 in 10,000): •Retina damage (detachment or tear) •Cataract •Need for further operation or procedure •Permanent serious loss of vision

Uncertain risk: •Stroke / heart attack

Specific or material risks for this patient: ☐No ☐Yes (please state):

Statement of health professional: (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy).
I assess that this patient has capacity to give valid consent. I have discussed what the procedure is likely to involve, the benefits and risks of this and of any available alternative treatments and of no treatment and any particular concerns of this patient. The patient has been given the opportunity to ask questions.

An appropriate leaflet has been provided: ☐Yes ☐No

Signed: Date:

Print name:

Job title:

Contact details (if patient wishes to discuss options later):

All relevant risks were documented, alongside their associated incidence

Medical terms were explained with simple language

A section for specific or material risks to the patient was newly incorporated

References

1. Montgomery v Lanarkshire Health Board [2015] UKSC 11
2. The Royal College of Ophthalmologists, Consent for Ophthalmology Procedures Policy, 2020/PROF/415, https://www.rcophth.ac.uk/wp-content/uploads/2020/05/Standards-Of-Consent-For-Ophthalmology-Procedures-COVID-19.pdf, [Accessed online: 17/04/2023]
3. The Royal College of Ophthalmologists, Intravitreal Injection Consent Form, https://www.rcophth.ac.uk/wp-content/uploads/2022/01/Intravitreal-Injection-Consent-Form-1_COVID19_.pdf [Accessed online: 17/04/2023]

Impact of Intervention

27 new consent forms, from 6th – 21th April 2023, were analysed against our model criteria. All consent forms now consistently recorded the relevant risks for intravitreal injection. All risks were listed with an associated incidence. Medical jargon was avoided where possible, with corresponding explanations of medical terms now used. 77% of consent forms now documented if there were specific and/or material risks to the patient, which improved furtherly following departmental reminders emailed to all staff.