Intravitreal Injections of Anti-VEGF Medication for Macular Diseases by Non-Medical Practitioners Standard Operating Procedure

UHL Ophthalmology (LocSSIPs)

Change Description	**Reason for Change**
□ Change in format	√ Trust requirement

APPROVERS	**POSITION**	**NAME**
Person Responsible for Procedure:	Consultant Ophthalmologist	Mr Vasileios Konidaris Ms Rossella Anzidei
SOP Owner:	Consultant Ophthalmologist	Mr Vasileios Konidaris Ms Rossella Anzidei
Sub-group Lead:	Clinical Director MSS General Manager	Hazel Busby-Earle Zack Sentence

Appendices in this document:

Appendix 1 : UHL Safer Surgery Intravitreal Injection Ophthalmology Department Checklist
Appendix 2: Patient Information Leaflet for *Intravitreal Injection* Available at:
Having an OCT scan of your eye (optical coherence tomography) (leicestershospitals.nhs.uk)
Treatment of diabetic macular oedema (leicestershospitals.nhs.uk)
Treatment of age-related macular degeneration (leicestershospitals.nhs.uk)
Aftercare for an intravitreal injection in your eye (leicestershospitals.nhs.uk)
Appendix 3: Policy on Intravitreal injections of anti-VEGF medication non-medical
Appendix 4: Training programme for non-medical clinicalprofessionals administering intravitreal injections
Appendix 5: Competencies
Appendix 6: Reflective practice template
Appendix 7: SOP
Appendix 8: Risk Assessment
Appendix 9: Patient Satisfaction Questionnaire
Appendix 10: OCT Competency Booklet

Introduction and Background:

In recent years, the injection of drugs into the vitreous has expanded rapidly to become hugely important in the treatment of medical retinal diseases and the commonest ophthalmic procedure performed. Most intravitreal injections are to deliver anti-vascular endothelial growth factor medications (anti-VEGF) or steroid drugs and implants. These intravitreal drugs include Avastin (bevacizumab), Lucentis (ranibizumab), Eylea (aflibercept) and Beovu (brolucizumab) for patients with age related macular degeneration (AMD), diabetic macular oedema (DMO), retinal vein occlusion (RVO) and other macular disorders. Steroids include triamcinolone and dexamethasone and implants include Ozurdex (dexamethasone) and Iluvien (fluocinolone) used to treat DMO, RVO and uveitis. These treatments are governed by NICE guidelines and require repeated timely follow up and treatment. As a consequence, attendances within the eye clinics have increased significantly and put significant demands on the available capacity. The involvement of non-medical healthcare professionals (HCP) in assessing patients and/or performing intravitreal injections has become widely accepted practice to cope with this demand and to support the expansion of non-medical roles, and is supported by the Royal College of Ophthalmologists.

This policy sets out the process required for designated HCP to train and to deliver intravitreal injections as independent non-medical injectors to the standards required by NICE and the Royal College of Ophthalmologists. This will contribute to the efficient delivery of the medical retinal service and will enhance and develop patient-centred care which fulfils national safety and service delivery targets. Service provision will be more flexible and resilient, with the potential for increased capacity for treatment. Staff will be able to develop their roles further, increasing the overall level of expertise in the department and promoting greater job satisfaction.

The policy provides details of:

- the training and competencies
- guidance for the management of patients
- standard operating procedures
- the process to be used for monitoring compliance with the process and outcomes.

This document should be read in conjunction with the joint Colleges' Ophthalmic Common Clinical Competency Framework (OCCCF). https://www.rcophth.ac.uk/professional-resources/new-common-clinical-competency-framework-to-standardise-competences-for-ophthalmic-non-medical-healthcare- professionals/

This policy applies to all trust sites where intravitreal injections are carried out and is relevant to non-medical practitioners, ophthalmic nurses, orthoptists and optometrists who are or wish to become injectors, to ophthalmologists in the adult medical retina service and to those managing ophthalmology retinal services.

It should be read in conjunction with other relevant trust documents:

- Infection Control Policy
- Medicines Management Policy
- Consent Policy
- Clinical Governance/Risk Management Policy.

Never Events:

Injection of intravitreal anti-VEGF agent to the wrong eye.
The pre-operative checklist ensures the correct eye is identified in the management plan recorded in the notes or electronic medical records; this is cross checked with the consent form and confirmed with the patient. In case of doubt, there is always access to the ocular imaging on site. Once the correct side is confirmed, it is clearly marked with a marker and the correct site is recorded on the pre-operative checklist, before the instillation of the drops. The same checks with the notes, consent form, pre-operative checklist, correct side marked and agreement with the patient are done in the operating room, with all involved members of staff present.

List management and scheduling:

Patients are listed for intravitreal treatment following a face to face or virtual consultation, once the diagnosis is established. The intravitreal treatment is prescribed on a specifically designed listing form, which is handed over to the waiting list team, alongside the outcome of the consultation. The waiting list books the appointment for the treatment either for the Clean Room at Leicester Royal Infirmary or at one of the satellite sites where intravitreal treatment is provided. The listing form and the list contain the full name of the patient, the hospital number, the eye to be treated, the name of the drug and the number of the planned injections. Abbreviations of laterality are not to be used. The injection list in on HISS and is requested from the HCP prior to the operating date. Any changes on the list are updated on HISS and an up-to-date list can be printed out prior to the operating time. Urgent additions are communicated directly from the clinician who is doing the listing to the waiting list office and the HCP who is responsible for the operating list on the specific day. DNAs are given a second appointment, with a letter and verbal confirmation. A second DNA will lead to the patient being discharged according to the Trust policy and a letter is sent to the patient and their GP, with contact details for communication should they wish to be referred to the Department in the future.

Patient preparation:

The plan for treatment is discussed with the patient in the consultant led clinics; this includes treatment modality, course of treatment, consent for treatment, and provision of the intravitreal injection patient information leaflet. Patients should be informed about the following risks associated with the procedure:

- Sub-conjunctival haemorrhage
- Corneal abrasion
- Cataract
- Retinal tears/detachment
- Air bubbles
- Raised intraocular pressure
- Vitreous haemorrhage
- Endophthalmitis

The record of the above is documented and kept in the patient's notes / electronic medical records. If translation or interpretations are required, an interpreter will be booked for the patient's consultation or treatment appointment.

Before starting the procedure the HCP must ensure that the patient has been given the relevant information and written consent for the procedure has been obtained prior to the first injection taking place. The HCP should also check the consent for the course of treatment is up to date. This process will ensure that the patient is aware of the rationale for the procedure and of all potential complications.
The HCP must ensure that the drug has been prescribed by a doctor or independent prescriber and that this is documented correctly.
The following checks must take place before the procedure:

- Informed / valid consent
- Reassurance and explanation
- Previous injection history
- Correct area for injection selection
- Any requirement to check IOP
- Appropriate single use equipment
- Aseptic non-touch technique
- Hand hygiene and bare below the elbow
- Eye preparation
- Sharps safety including disposal care and maintenance

Exemptions to treatment by the HCP
The intravitreal injection procedure should not be performed by the HCP if:

- The patient will not provide valid consent or refuses treatment by the HCP
- The HCP does not feel it is safe to proceed or has concerns performing the injection
- The HCP does not have immediate access to medical support (i.e. the doctor should either be present on site or, if the HCP is competent to manage immediate emergencies, by phone with a pathway in place to see a doctor urgently with the appropriate safe timescale if required, once the HCP has undertaken first treatment).
- The consultant or senior fellow decides that the patient requires a member of the medical team to

perform the procedure
• A patient has had repeated previous complications such as central retinal artery occlusion and required paracentesis
• Active eyelid and/or ocular surface disease such as blepharitis
• Other high risk ocular comorbidity e.g. retinal detachment
• Other medical conditions making the administration difficult e.g. Parkinson's disease, difficult positioning or ocular fixation problem such as nystagmus

Prior to intravitreal injection commencing
The HCP will:

• Review the patient's notes and:

- Ensure the patient has been referred for treatment by the consultant or trained assessor in charge of the clinic.
- Ensure that the drug has been prescribed correctly.
- Confirm that a recent retinal and macular examination has been taken place and details of the examination are recorded in the notes. If not, a review must be obtained before intravitreal injection taking place.
- Confirm that the patient has undergone all the relevant checks and tests in accordance with clinic protocols
- Check if the patient has any allergies and if the patient has a definite allergy to povidone iodine ensure that this has been be verified by the consultant so an alternative preparation can be used. When patients are allergic to povidone iodine, chlorohexidine gluconate can be used.
- Check a recent visual acuity test has been performed
- Ensure the patient shows no signs of infection such as conjunctivitis and blepharitis, if there possible signs of infection this must be discussed with the doctor and a clear treatment plan put in place.
- Check the patient's medical history as HCPs must not inject the patient if the patient is suffering from:
  - Unstable angina Uncontrolled hypertension Any evidence of infection Ocular infection
  - Recent MI or CVA
  - Pregnancy
  - Previous allergy to the drugs Too high INR

• If the HCP is trained to instigate initial management of complications, check there is a senior doctor available on the phone and someone who can receive any urgent complications.
• Review the injection room facilities, ensuring it is clean and safe for use.
• Check all equipment is ready for the session.
• Ensure all drugs are present and in date
• Ensure that a designated nurse or healthcare assistant/technician is present in the treatment room to assist with the procedure.
• Ensure that the assistant has followed the correct hygiene precautions and aseptic technique in preparing the patient for the injection.

Preparation of the patient

• The HCP should introduce themselves to the patient and confirm the patient's identity in accordance with the trust policy, ensuring that the patient states their name and date of birth.
• The HCP should explain to the patient that they will be administering the intravitreal injection prescribed by the doctor or independent prescriber.
• The HCP should again verbally confirm with the patient their allergy status and past medical history including checking for hypertension and whether they have suffered a recent heart attack or stroke or attended hospital since their last injection. This will prevent any untoward side effects from medications used during this procedure.
• The patient consent form should be checked and the HCP should confirm with the patient which eye(s) is to be treated. The patient's eye(s) to be treated must be marked according to trust policy, if there is a discrepancy between the notes and patient the consultant or fellow in charge of the clinic should be consulted.
• The abbreviated surgical safety checklist should be completed and both the injecting practitioner and assistant must check and verbally confirm.
• The Correct Identity of the patient.
• The Correct Eye to be injected and eye is marked.
• The drug to be injected.
• If the patient has a history of glaucoma and/ or previous complications from an injection procedure this should be noted
• The procedure should be fully explained, allowing time for the patient to ask questions.

Workforce – staffing requirements:

The minimum staffing for the intravitreal injection procedure includes:

- A trained HCP to perform the procedure following the necessary pre- and post- operative steps as described above
- A nurse / HCA for the admission of the patient, the instillation of the anaesthetic and iodine drops following the necessary checks by the practitioner as stated above, and for discharging the patient with the prescribed medication and the provision of verbal and written information following the procedure
- A scrub nurse / ODP to provide the HCP with the necessary equipment and medicine to perform the procedure

All members of staff mentioned above will have to be present during the final identification and safety checks before the procedure.

There must be a senior doctor available on the phone and someone who can receive any urgent complications (e.g. Eye Casualty Department).

All HCPs in training for the provision of intravitreal treatment will have to adhere to the policy and have had previous theoretical training as described in the Appendix. The HCPs will have to audit their outcomes and complications as well as patient satisfaction with the relevant forms and register and

present their audits annually at the Departmental Audit Meeting. Any serious adverse events will have to be presented and discussed at the departmental M&M meeting.

Ward checklist, and ward to procedure room handover:

The ward checklist is provide in the appendix and it will have to be completed by the HCP responsible for the procedure and checked by the nurse / HCA in the ward and crosschecked with the patient.

Procedural Verification of Site Marking:

Surgical site marking of the eye to be treated is mandatory before the procedure and following the necessary checks and agreement with the patient as described above.
Site marking is performed with an indelible marker designed for that purpose and is:

- Performed shortly before the procedure by the operator
- Remains visible in the operative field and is not obscured bydrapes
- Site marking isdocumented on the pre-operative checklist, once the notes have been reviewed, the consent form and the agreement with the patient have been checked.

Team Safety Briefing:

The Team Safety Briefing occurs at the start of the procedure session.
The operator, the scrubbing nurse and the assistant must be present at the team safety briefing, which takes place in the operating room, before the start of the procedure.
A copy of the team briefing documentation showing the content is provided as an appendix to this SOP.
The completed team briefing form is stored in the patient's notes or scanned on the electronic medical records.

Sign In & Time Out:

The Sign In and Time out will happen in the operating room, just before the start of the procedure

- The scrub nurse or ODP in charge and the assistant will perform the Sign In and Time Out, in the presence of the operator
- The Sign In and Time Out will occur immediately before the procedure start
- All team members must be present and engaged as it ishappening
- That the patient will be encouraged to participate where possible
- The patient is asked about their demographics, and the correct site to be treated is agreed with the

patient.
- Any omissions, discrepancies or uncertainties must be resolved before starting the procedure

The check includes the name, address and date of birth of the patient (participation of the patient is encouraged), the hospital number is checked from the wristband and the notes and consent form, allergy status is checked and correct injection site is confirmed, based the notes / EMR and consent form, the correct side to be treated, the pre-operative check list, the correct marking of the side (confirmed also by the patient), the correct drug, the presence of a valid consent form, and presence / absence of allergies (also confirmed by the patient).

Performing the procedure:

The scrub nurse / ODP positions the patient on the bed.
The HCP will:

- Ensure that the patient knows how to communicate if they are suffering any discomfort during the procedure e.g. asking HCP to pause procedure.
- A strict aseptic technique must be used to prevent potential contamination of the sterile field and the equipment.
- The injection pack should only be opened when patient is on the couch and ready to receive treatment.
- Instil two drops of either proxymetacaine hydrochloride 0.5% or oxybuprocaine hydrochloride 0.4% eye drops as per PGD.
- Wear a face mask.
- Staff must be dressed bare below the elbows to carry out this procedure
- Check that the correct medication is selected for the patient, the expiry date, and the dose to be injected before injecting the prescribed medication.
- Decontaminate hands following hand hygiene policy and using chosen antiseptic (4% Chlorhexidine gluconate or 7.5% Povidine iodine) perform aseptic hand wash
- Dry hands thoroughly and apply sterile gloves
- Instil one drop of prescribed 5% Povidone Iodine eye drops into the eye for injection at least 3 minutes prior to injection. If the patient is allergic to Iodine, instil one drop of Chlorhexidine 0.02% eye drops but ensure this is a true allergy and is discussed with the doctor in clinic as iodine is much more effective.
- Clean the eyelids with 10% iodine aqueous solution skin scrub as outlined in PGD, if patient allergic to iodine use Chlorhexidine gluconate 0.015% and Cetrimide 0.1%
- Apply lid speculum
- Instil additional drop of 0.4% oxybuprocaine
- Mark the injection site by measuring 4.0mm from limbus for phakic eyes and 3.5mm from the limbus in pseudophakic eyes
- Administer drug by injection at marked site
- Establish that patient can see hand movements (to ensure no significant change in vision)
- Apply Chloramphenicol eye drops minims
- Remove eyelid speculum and wash off iodine from skin with sterile saline solution
- Remove used pack and ensure that the needle and any other sharps are disposed of directly in to

the sharps container
Monitoring:
The intravitreal injection procedure under topical anaesthetic does not require monitoring during the procedure.
Drug verification:
During: • The drug is confirmed with the operator to be the correct one – this should include a check of the name, laterality, expiry date, and sterility. Cross-reference with the patient's notes and consent form is mandatory. • State that all drugs not destined for use in the patient will be removed from the immediate area to avoid the wrong drugs being selected After: • GP letter to be completed on records, filing a copy in the notes • Record treatment clearly in the patient's health records –including the drug injected, the eye injected date, time, name and signature. • If an unexpected event occurs, document and complete and report the incident. This is necessary to facilitate communication within the team, meet legal requirements of practice and enable monitoring over a time period.
Prosthesis verification:
Not Applicable.
Prevention of retained Foreign Objects:
Not Applicable.
Radiography:
Not Applicable.
Sign Out:

Sign out must occur before the patient leaves the operative/procedure area.
Discussion of post-procedural care and any concerns and verbal and written advice is provided to the patient.

The Sign Out which should include:

- Confirmation of procedure
- Confirmation that counts (instruments, sharps and swabs) are complete
- Discussion of post-procedural care and any concerns
- Equipment problems to include in team debriefing

Handover:

The patient is transferred to the ward and the notes and discharge letters are passed to the discharging nurse / HCA, who will provide the patient with the after-care information and the drops to be instilled to the operated eye.

Team Debrief:

A team debrief should occur at the end of all procedure sessions. It will occur at the end of every session in the operating room. Present at the debrief are the HCP, the scrub nurse / ODP and the assistant. The debrief should include:

- Drug count and cross check with registry and stock
- Things that went well
- Any problems with equipment or other issues
- Areas for improvement
- An action log
- A named person for escalating issues
-

Post-procedural aftercare:

Avoid rubbing the eye.
Avoid getting water into the eye or swimming for the first 3 days.
Instil the lubricating drops as prescribed. The lubricating drops can be used more frequently during the first few days to lubricate the eyes if helpful.
It is usual to experience the following after the injection:
· A “cloud” of medicine and floaters coming into the eye when the medication is injected.
· Vision is usually blurry immediately after the injection and then gradually clears.

· The eye may be red and can sting or itch.
· It is normal to sometimes have bloody tears after the procedure.
· A small red area or bleed (haemorrhage) at the site of injection is commonly seen in the first few days after injection. This occurs as a result of a capillary being punctured and is nothing to be concerned about. It is similar to a bruise on the outside of the eye, and will resolve completely over 1-2 weeks without affecting vision.
· A sore and gritty eye (often due to the nature of the antiseptic used).
· Floaters, black spots and blurriness of vision immediately after the injection lasting for no longer than 2 days.

If patients experience any of the following problems they must contact the Department immediately:
· If they have increasing pain in the eye after 24 hours following injection.
· The eye becomes progressively red, painful and swollen.
· Vision gets worse after the treatment
This might indicate infection and normally occurs within the first week after the injection.

Discharge:

- GP letter to be completed on records, filing a copy in the notes
- Record treatment clearly in the patient's health records –including the drug injected, the eye injected date, time, name and signature.
- If an unexpected event occurs, document and complete and report the incident. This is necessary to facilitate communication within the team, meet legal requirements of practice and enable monitoring over a time period.

A follow-up appointment is made in 4-6 weeks to assess the retina with an optical coherence tomography scan.

Governance and Audit:

A safety incident is the injection of the wrong medicine, the injection of the wrong eye and the treatment of the wrong patient. All safety incidents are to be reported on Datix, and the latter two are Never Events. Review of the notes, the scans, the documentation on the theatre register and written reports from all involved sites will be part of the investigation following a safety incident. The Consultant in charge of the list is informed and has the responsibility to disseminate the information to all members of the team. The safety event must be reported and discussed at the Departmental M&M meeting, to communicate the learning from the incident to the whole Department. The HCPs working under this SOP have to audit their outcomes and present their annual audits at the Departmental Audit Meeting.

Element to be Monitored	**Staff conducting**	**Tool for Monitoring**	**Frequency**	**Responsible Individual/Group/ Committee for review of results/report**	**Responsible individual/ group/ committee for acting on recommendations/action plan**
Service delivery and unit outcomes	Lead Retinal Consultant	Audit	Every 12 months	Ophthalmic clinical governance/audit meetings	Ophthalmic or MR clinical lead
HCPs	Lead Retinal Consultant and Lead Nurse	Audit and patient satisfaction survey	For the first 100 patients then annually	Lead Consultant and Lead Nurse	Retinal Team
Complications or adverse events to be recorded	All staff	Incident reporting	ongoing	Lead consultants Risk team	Ophthalmology CG
Complaints	Complaints team	Complaints process	ongoing	Lead consultant Ophthalmology manager PALS	Ophthalmology CG

To submit monthly Safe Surgery Audit and WHOBARS assessment as per Safe Surgery Quality Assurance & Accreditation programme.

Training:

The HCPs starting their training must familiarise themselves with this SPO before they start practicing their role. The training will be followed by theoretical background knowledge, as well as provision of practical skills.

Documentation:

The consultation with the decision making for the treatment and the consenting process is documented either on the patient's paper notes or Medisight (electronic medical records). Accordingly, the provision of the intravitreal treatment is documented on the notes, and all the accompanying documets (prescription, checklist). A record of the patients details, the treating clinician, the drug injected and the

batch number are recorded in the procedure's book kept in the Clean Room (at UHL or the community treatment hubs).

References to other standards, alerts and procedures:

Supporting References / Evidence Base National documents

Intravitreal Injection Therapy, Ophthalmic Service Guidance, Royal College of Ophthalmologists, https://curriculum.rcophth.ac.uk/wp-content/uploads/2018/02/Intravitreal-Injection-Therapy-August-2018-2.pdf

British Medical Association (2015) British National Formulary, British Medical Association and the Royal Pharmaceutical Society of Great Britain.

Nursing and Midwifery Council (2015) code of professional conduct, NMC London http://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/revised-new-nmc- code.pdf.

The British & Irish Orthoptic Society Code of Ethics

https://orthoptics.org.uk/Resources/Documents/Standards/BIOS_Code_of_Ethics.pdf The Health & Care Professions Council (HCPC) Standards of Conduct, performance & ethics

http://www.hpcuk.org/aboutregistration/standards/standardsofconductperformanceandethics/BIOS – Intravitreal therapy standards of practice 2016.

General Optical Council. Standards of Practice. https://www.optical.org/en/Standards/ College of Optometrists Guidance for Professional practice. https://guidance.college- optometrists.org/home/

Royal College of Ophthalmologists (2018) Guidance intravitreal injections https://www.rcophth.ac.uk/wp-content/uploads/2018/02/Intravitreal-Injection-Therapy.pdf Royal College of Ophthalmologists (2013) College Statement on intra-ocular injections by non-medical health care professionals

http://www.rcophth.ac.uk/news.asp?itemid=1363&itemTitle=College+Statement+on+intra%2Docular+injections+by+non%2Dmedical+health+care+professionals&section=24&sectionTitle=News May 2013

Royal National Institute of Blind People. Future Sight Loss UK 1: Economic Impact of Partial Sight and Blindness in the UK Adult Population. London: RNIB; 2009. Available from: http://www.rnib.org.uk/aboutus/research/reports/otherresearch/pages/fsluk1.aspx. Accessed February 12, 2014.

Varma D, Lunt D, Johnson P, Stanley S. A novel approach to expanding the role of nurses to deliver intravitreal injections for patients with age related macular degeneration. Int J Ophthalmic Pract.

2013;4 (2):68–74. 10
RCOphth Quality Standards for medical retina services. RCOphth 2018. NICE guidance for AMD. https://www.nice.org.uk/guidance/ng82

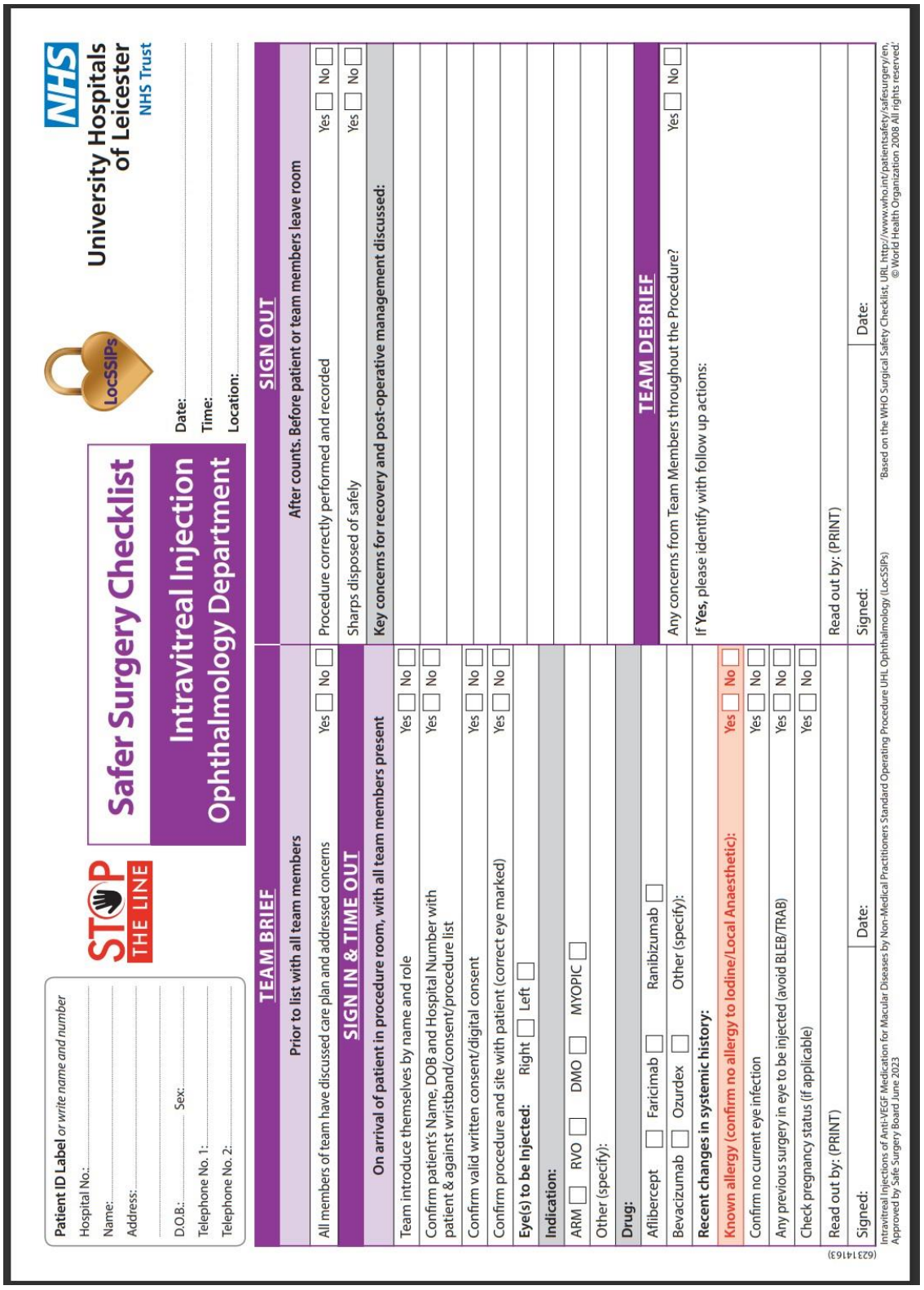
Local documents
Infection control policy Ophthalmology department guidelines Consent policy
Clinical record keeping policy Clinical governance policy Risk management policy
WHO checklist/Surgical Safety Policy Mental capacity policy

National Safety Standards for Invasive Procedures, NHS England 2015: https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/09/natssips-safety-standards.pdf

UHL Safer Surgery Policy: B40/2010
Other relevant UHL policies that may need to be cited:
UHL Sedation Policy: Safety and Sedation of Patients Undergoing Diagnostic and Therapeutic Procedures B10/2005
UHL Consent to Treatment or Examination Policy A16/2002
UHL Delegated Consent Policy B10/2013
UHL Patient Identification Band Policy B43/2007
UHL Guideline: Anticoagulation management ("bridging") at the time of elective surgery and invasive procedures (adult) B30/2016
UHL Guideline: Management of adult patients with diabetes undergoing elective surgery and procedures B3/2013
UHL Guideline: Venous thromboembolism risk assessment B9/2016
UHL Guideline: Antibiotic guide for surgical prophylaxis in adults B14/2007 (or other relevant guideline)
Shared decision making for doctors: Decision making and consent (gmc-uk.org)
COVID and PPE: UHL PPE for Transmission Based Precautions - A Visual Guide
COVID and PPE: UHL PPE for Aerosol Generating Procedures (AGPs) - A Visual Guide

END

Appendix 1: UHL Safer Surgery *Department* Checklist



Patient ID Label *or write name and number*
Hospital No.:
Name:
Address:
D.O.B.: Sex:
Telephone No. 1:
Telephone No. 2:

STOP THE LINE

Safer Surgery Checklist

Intravitreal Injection Ophthalmology Department

LocSSIPs

Date:
Time:
Location:

University Hospitals of Leicester NHS Trust

TEAM BRIEF

Prior to list with all team members

All members of team have discussed care plan and addressed concerns — Yes ☐ No ☐

SIGN IN & TIME OUT

On arrival of patient in procedure room, with all team members present

Team introduce themselves by name and role — Yes ☐ No ☐

Confirm patient's Name, DOB and Hospital Number with patient & against wristband/consent/procedure list — Yes ☐ No ☐

Confirm valid written consent/digital consent — Yes ☐ No ☐

Confirm procedure and site with patient (correct eye marked) — Yes ☐ No ☐

Eye(s) to be Injected: Right ☐ Left ☐

Indication:

ARM ☐ RVO ☐ DMO ☐ MYOPIC ☐

Other (specify):

Drug:

Aflibercept ☐ Faricimab ☐ Ranibizumab ☐

Bevacizumab ☐ Ozurdex ☐ Other (specify):

Recent changes in systemic history:

Known allergy (confirm no allergy to Iodine/Local Anaesthetic): Yes ☐ No ☐

Confirm no current eye infection — Yes ☐ No ☐

Any previous surgery in eye to be injected (avoid BLEB/TRAB) — Yes ☐ No ☐

Check pregnancy status (if applicable) — Yes ☐ No ☐

Read out by: (PRINT)

Signed: Date:

SIGN OUT

After counts. Before patient or team members leave room

Procedure correctly performed and recorded — Yes ☐ No ☐

Sharps disposed of safely — Yes ☐ No ☐

Key concerns for recovery and post-operative management discussed:

TEAM DEBRIEF

Any concerns from Team Members throughout the Procedure? — Yes ☐ No ☐

If **Yes**, please identify with follow up actions:

Read out by: (PRINT)

Signed: Date:

(6231463)

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Approved by Safe Surgery Board June 2023

'Based on the WHO Surgical Safety Checklist, URL http://www.who.int/patientsafety/safesurgery/en/,
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STOP THE LINE

Safer Surgery Checklist

Intravitreal Injection Ophthalmology Department

LocSSIPs

NHS University Hospitals of Leicester NHS Trust

Named Consultant:

Injector:

Clinician:

Date:

This checklist MUST be filed in the patient's folder

INJECTION DETAILS:

		ROUTE	PRESCRIBER PRINT NAME	PRESCRIBER SIGNED	GIVEN BY	TIME
Minims Proxymetacaine 0.5%	Left ☐ Right ☐ Bilateral ☐	Topical				
Minims Tetracaine 1.0%	Left ☐ Right ☐ Bilateral ☐	Topical				
Minims Povidone Iodine 5%	Left ☐ Right ☐ Bilateral ☐	Topical				
Minims Oxybuprocaine 0.4%	Left ☐ Right ☐ Bilateral ☐	Topical				
Minims Chloramphenicol 0.5%	Left ☐ Right ☐ Bilateral ☐	Topical				
Aflibercept Injection 0.05ml	Left ☐ Right ☐ Bilateral ☐	Intravitreal				
Faricimab Injection 0.05ml	Left ☐ Right ☐ Bilateral ☐	Intravitreal				
Ranibizumab Injection 0.05ml	Left ☐ Right ☐ Bilateral ☐	Intravitreal				

PROCEDURE RECORD (Tick or circle)

Eye: Left ☐ Right ☐ Bilateral ☐ Aflibercept ☐ Faricimab ☐ Ranibizumab ☐ Ozurdex ☐ Avastin ☐	Injection Site	ST/ IT Quadrant	3.5mm/4mmLimbus
Prep: Povidone Iodine 5% ☐ 10% ☐ UNICEPT ☐	VA post IVI	HM/ CF	
Minims Chloramphenicol 0.5% / Minims Oxybupracaine 0.4% ☐			
Comments:			
Given by (sign):			

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'Based on the WHO Surgical Safety Checklist. URL http://www.who.int/patientsafety/safesurgery/en.

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(623 14163)

Appendix 2: Patient Information Leaflet for *Intravitreal Injections of Antti-VEGF Medication for Macular Diseases* Available at:

Having an OCT scan of your eye (optical coherence tomography) (leicestershospitals.nhs.uk)
Treatment of diabetic macular oedema (leicestershospitals.nhs.uk)
Treatment of age-related macular degeneration (leicestershospitals.nhs.uk)
Aftercare for an intravitreal injection in your eye (leicestershospitals.nhs.uk)

Appendix 3: Policy on Intravitreal injections of anti-VEGF medication non-medical

Duties and responsibilities

Practitioners responsibilities

Practitioners undertaking the training are responsible for compliance with trust policies; engaging actively with the training, keeping up to date, accurate training records; ensuring they act within their sphere of competence; completing accurately the relevant parts of the medical records; following SOPs; reporting adverse events and safety concerns to their supervisor, consultant or their line manager.

Practitioners are accountable for their own practice and must adhere to their relevant Professional Body and Regulatory Body requirements, guidelines and codes of practice / conduct.

Failure to do so could result in the loss of protection from the trust's liability cover and individual professional indemnity cover, could result in investigation and formal action in line with disciplinary procedures and may put the practitioner's registration at risk if concerns are raised about fitness to practice.

Once signed off as competent to practice independently, the HCP is required to audit their patient records after the first 6 months or first 100 cases and then yearly as part of their annual appraisal / individual performance review.

HCPs must attend a mandatory annual peer review and clinical update session on intravitreal injections.

Consultant ophthalmologist's and trainer's responsibilities

The consultants must ensure the HCP has achieved a satisfactory knowledge base and competencies with which to perform this enhanced role. The consultant can undertake this directly or can delegate some or all parts to a senior colleague with appropriate experience, knowledge and training who is a named intravitreal injection trainer that is an HCP with more than 2 years' independent intravitreal injection experience, or a fellow or ST 6 and above ophthalmic trainee. However, the consultants retain responsibility for the training and sign off before the HCP begins independent practice.

The trainer will:

- Formally examine the HCP to ensure she/he has the knowledge base required
- Ensure the HCP only progresses to each stage of training once they are sure that prior training is complete/competency has been achieved and the practitioner is ready to progress.
- Provide adequate time for the HCP to observe intravitreal injection technique and to subsequently supervise and assess the HCP's procedural skills.

The consultant will arrange that they or a suitably other ophthalmologist is immediately available to support the HCP during an intravitreal injection clinic. The doctor should either be present in the clinical area or, if the HCP is competent to manage immediate emergencies (see below), by phone with a pathway in place to see a doctor urgently with the appropriate safe timescale if required, once the HCP has undertaken initial treatment.

The patient remains under the care of a named consultant ophthalmologist at all times.

Managers responsibility

The manager(s) [lead nurse, lead orthoptist, lead optometrist or ophthalmology department manager] will keep a record of all competencies and a register or list of named trainers and HCPs eligible to perform independent injecting.

Managers must only endorse skills if such development is in line with the practitioner`s job description and existing trust policies and service requirements.

Managers must ensure that the practitioner is supported in skills development in the form of:

- Opportunities for supervised practice
- Assessment of competency and sign off.

Employer's responsibilities

The employer will ensure that the HCP's training and supervision is provided in a timely manner, ensuring trainers and supervisors are supported to deliver the time required. Employers will ensure HCPs are appropriately banded for the work they undertake and are given the time to undertake the training and audit during their current role.

The employers will ensure that, subject to following trust policy, HCPs have suitable indemnity for this scope of practice.

Training

HCPs can only commence training after identification as suitable by the Lead Nurse and approval by their line manager. Training will be carried out as detailed in appendix 1. Practitioners will receive theoretical training initially and, when completed, will undertake observational training and, when this is completed, will undertake practice supervised by a consultant or nominated trainer. At each stage, the practitioner can proceed to the next stage of training only if their trainer considers he /she is ready. They will require assessment as competent by their trainer and competencies recorded as detailed in appendix 2 and have undertaken and evidenced reflective practice. The practitioner must be satisfied with his/her own level of competence in accordance with the guidelines and codes of conduct from their relevant regulator and professional body.

The HCP will undergo an informal review of practice with their trainer and/or the medical retinal consultant and/or lead nurse after three months of independent injecting.

Frequency of practice

HCP led intravitreal injection clinics will be carried out according to service need. Once a practitioner has been signed off as competent, they should be performing injections regularly to maintain skills. In injection only clinics (not one stop) usually no more than 15 injections should be carried out per morning/afternoon session unless there are exceptional circumstances such as an increased number of bilateral cases. Additional patients can only be added to each list with the confirmed agreement of the HCP and the consultant/senior doctor in charge of the session. HCPs will be expected to deliver a maximum number of three sessions per week and will only exceed this number with their express agreement.

Outcome measures

Data to be collected is:

- Record of all cases to be kept by HCPs for activity levels
- Data capture/audit.
- Post-operative endophthalmitis level comparable to doctor endophthalmitis level and in line with RCOphth guidance and evidence from literature. Any cases identified need to be reported as incidents and medical retina consultants should undertake with managers and inflectional control team a root cause analysis (RCA) investigation.
- Number of cases presenting as emergencies post injection comparable to rates experienced by medical practitioners and within normal limits.
- Any incidents or serious incidents or patient complaints, including the result for the patient or of any investigation, with appropriate reflective practice and learning recorded
- Patient experience / satisfaction survey at discretion of HCP and line manager.

The HCP will undertake an audit of their first 100 cases or first 6 months practice, and on an annual basis thereafter as part of their annual appraisal and individual performance review.

Supporting References / Evidence Base national documents

British Medical Association (2015) British National Formulary, British Medical Association and the Royal Pharmaceutical Society of Great Britain.

Nursing and Midwifery Council (2015) code of professional conduct, NMC London http://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/revised-new-nmc-code.pdf.

The British & Irish Orthoptic Society Code of Ethics. https://orthoptics.org.uk/Resources/Documents/Standards/BIOS_Code_of_Ethics.pdf

The Health & Care Professions Council (HCPC) Standards of Conduct,

performance & ethics
http://www.hpcuk.
org/aboutregistration/standards/standardsofconductperformanceandethics/
BIOS – Intravitreal therapy standards of practice 2016.

General Optical Council. Standards of Practice. https://www.optical.org/en/Standards/
College of Optometrists Guidance for Professional practice. https://guidance.college-optometrists.org/home/
Royal College of Ophthalmologists (2018) Guidance intravitreal injections https://www.rcophth.ac.uk/wp-content/uploads/2018/02/Intravitreal-Injection-Therapy.pdf
Royal College of Ophthalmologists (2013) College Statement on intra-ocular injections by non-medical health care professionals http://www.rcophth.ac.uk/news.asp?itemid=1363&itemTitle=College+Statement+on+intra%2Docular+injections+by+non%2Dmedical+health+care+professionals&section=24&sectionTitle=News May 2013
Royal National Institute of Blind People. Future Sight Loss UK 1: Economic Impact of Partial Sight and Blindness in the UK Adult Population. London: RNIB; 2009. Available from: http://www.rnib.org.uk/aboutus/research/reports/otherresearch/pages/fsluk1.aspx. Accessed February 12, 2014.
Varma D, Lunt D, Johnson P, Stanley S. A novel approach to expanding the role of nurses to deliver intravitreal injections for patients with age related macular degeneration. *Int J Ophthalmic Pract*. 2013;4 (2):68–74. 10
RCOphth Quality Standards for medical retina services. RCOphth 2018.
NICE guidance for AMD. https://www.nice.org.uk/guidance/ng82

Local documents

Infection control policy
Ophthalmology department guidelines
Consent policy
Clinical record keeping policy
Clinical governance policy
Risk management policy
WHO checklist/Surgical Safety Policy
Mental capacity policy

Appendix 4: Training programme for non-medical clinical professionals administering intravitreal injections

Eligibility: Practitioners must fulfil the requirements of the policy in terms of qualifications and experience and have approval by the Lead Nurse and their line manager before undertaking training. Practitioners must ensure that all training in development is in line with scope of practice and job description and must submit any application for training to their manager for endorsement.

Who can provide training?

Medical retinal consultants can provide training alongside the retinal or ophthalmology Lead Nurse. Part or all of the training can also be provided by the following staff, if approval has been granted by the medical retinal lead consultant or other retinal consultant:

- Consultant injectors
- SAS doctors
- Fellows
- Trainees of ST6 and above
- HCPs with more than 2 years continuous (or equivalent) of independent injecting experience in the NHS.

The training programme

There are two main parts to the training programme, and the practical training comprises 3 aspects:

- Theoretical training
- Practical training
    - Observation of practice
    - Supervised practice:
        - preparation of patient
        - administration of injection

The member of staff must have completed the intravitreal training course including both theoretical and practical components and have been assessed as competent by their supervising consultant or trainer. All training completion must be approved by a medical retinal consultant if it has been delivered by other trainers before independent practice commences.

1. Theoretical training

To be delivered in a number of ways:

- Attendance at a recognised external intravitreal training day e.g. Moorfields course
- Locally delivered half to one day training course run by local medical retinal consultants and non-medical health care professionals.
- One to one sessions with medical retina consultant to informally cover key knowledge.
- Educational DVD or online video training

Topics which must be covered through these routes are as follows:

- Anatomy and physiology of the eye and the retina
- Classification of macular disease
- OCT images (relevant to macular disease)
- Issues around infection control and intravitreal injections
- Pharmacology update (to include all drugs administered during injection visits
- Risk and legal issues around extended role development
- Latest clinical information on treatment and treatment delivery and up to date evidence underpinning this practice
- How to audit HCP injections
- Consenting for intravitreal injections
- Process of giving intravitreal injection, including the practicalities
- Recognition of complications and what actions to take.

The practitioner needs to undergo an assessment with a trainer to record their knowledge competencies and understanding of key trust policies and national requirements and obtain sign off.

2.1 Practical Training: Observation of practice

On satisfactory completion of the theory training, HCPs in training can commence their period of observation whereby they shadow their assigned trainer(s) and follow each patient from assessment through to discharge. Once the treatment of twenty patients has been observed, recorded on the competency assessment log sheet which is countersigned by the trainer, the next stage can begin.

2.2 Practical training: Supervised Practice: Preparation of the patient

The next step of the training pathway is to prepare the patient for the intravitreal injection. The practitioner will need to be able to demonstrate the following:

- Checks room and equipment and drugs including emergency equipment
- Confirmation patient identity
- Suitable assessment key factors and consent in the records
- Checks patient history
- Explanation of the procedure to the patient
- Explanation HCP led procedure
- Checks allergies
- Confirms which eye to be injected
- Positioning of the patient and discussion on comfort
- Hand hygiene
- Skin and eye cleansing
- Insertion of the speculum

On completion of twenty preparations with completion of the signed competency sheet, the trainer will decide if the practitioner can proceed to the next stage or whether further practice is required.

2.3 Practical training: Supervised Practice: Administration of the injection

The final step of the training pathway will be for the practitioner to administer the intravitreal injection. The practitioner will, under strict supervision, administer at least 30-50 injections before the trainer will assess whether the practitioner is safe to proceed independently.

If at this stage the practitioner is not yet ready to practice unsupervised they must continue supervised practice until the trainer feels they are ready for a further assessment. The trainer must also be happy that the practitioner can undertake lists to the required safety and efficiency to practice independently a whole list.

All the competencies must be completed and signed off and audit of practice must occur at this stage and be approved by a medical retinal consultant before undertaking independent practice. In addition, there should be evidence of reflective practice.

At all stages, The HCP trainee must not be signed off as a competent practitioner unless the trainer and consultant are fully confident in the practitioner's ability to run independent lists.

The first 3 lists/clinics should occur with experienced injectors nearby with some degree of supervision to ensure support is nearby and practitioners have gained the confidence to practice independently.

After three months, the HCP should undergo a review of their independent practice with a trainer or consultant and should then undertake the required audit after the first 6 months or 100 cases and thereafter every year and regular reflective practice.

Appendix: 5 Competencies

For **New Practitioners** who are undertaking intravitreal injection as a new skill:

You must complete the training and then ensure all competencies signed off not only by your trainer, but also by the medical retina consultant before you practice independently. You must be reassessed against the competency standard every year or after a break of six months of more where the skills have not be undertaken. You must also be confident you are performing within your sphere of competency.

For **Current Practitioners** who have:

- Completed the HCP training programme previously and have been assessed and signed off as competent against the HCP competencies.

You must be assessed as competent using this competency standard by a competent trainer before continuing to undertake the skill independently. You must be reassessed against the competency standard every year or after a break of six months of more where the skills have not be undertaken. You must also be confident you are performing within your sphere of competency.

All practitioners must ensure that successful completion of the competencies occur on time and that this is fully discussed and signed off by the trainer. Practitioners must ensure that copies of the signed competency are sent to their manager, and they should retain a copy for their own portfolio.

The assessor

The assessor must be a competent medical injector or HCP who is on the list of approved trainer/assessors. The assessor must only sign the competency when all aspects of the competency standards have been demonstrated by the practitioner.

Competency recording forms

Intravitreal injections: Competency checklist - knowledge

Ward / Department ……Name ……

	Competency	Competency Checklist	Assessor's / Self Assessor's Signature
1	Demonstrate familiarity with and understanding of the principles of the Trust Framework for Enhancing the Scope for Clinical Practice	**States key aspects of Trust Framework for Enhancing the Scope for Clinical Practice/Intravitreal injection policy:-** • Competence to be assessed via Trust ratified competencies. • Competency development must be appropriate and safe. • Vicarious liability. • On-going competency-Trust requirements • Evidenced based practice.	

	Competency	**Competency Checklist**	**Assessor's / Self Assessor's Signature**
2	Demonstrate familiarity with Trust Infection Control Policy	**Under observation and where appropriate can state and demonstrate:** • Correct use of Personal Protective Equipment. • Safe handling of sharps. • Safe handling of clinical waste and spillage. • Decontamination of equipment. • Decontamination of environment. **Under observation and where appropriate can state and demonstrate:** • The importance of correct hand hygiene.	
3	Demonstrate familiarity with Trust policy and Profession specific guidelines on records and record keeping	**State and discuss:** • The key points in the Trust for Records and Record keeping. • The importance of accurate documentation. • Individual accountability and confidentiality. **Under observation:** • Can document the appropriate information accurately and according to Trust Policy in the notes.	

	Competency	**Competency Checklist**	**Assessor's / Self Assessor's Signature**

4	Demonstrate familiarity with the Trust Consent to Policy	**State and discuss:-**
		• The key principles of the Trusts Consent Policy with respect to consenting for care and treatment.
		• Staff responsibility and accountability for ensuring that they act in accordance with the policy when consenting patients for treatment including recognising when they are not permitted to take consent.
		• For consent to be valid, the patient must:
		  ○ Be competent to take the particular decision;
		  ○ Have received sufficient information to take it;
		  ○ Not be acting under duress.
		• Patient's agreement to the intervention and the discussions which led up to that agreement.
		• Process to follow when a patient does not have capacity to consent and in emergency situations.
		• Process to follow when a patient refuses treatment or changes their mind about consenting to a procedure when they have already signed the consent form
		• Documentation – either through the use of a consent form or through documenting in the patient's health records that they have given verbal consent.	

	Competency	**Competency Checklist**	**Assessor's / Self Assessor's Signature**
5	Uphold the Nursing & Midwifery Council: The Code Professional Standards of practice and behaviour for nurses (2015) or similar professional standards Health Care Professions Council Standards of Conduct, Performance and Ethics	**State and discuss key aspects of the NMC or similar Code:-** • Exists to safeguard the health and wellbeing of the public. • Sets the standards of education, training and conduct that Nurses and Midwives need to deliver high quality healthcare consistently throughout their careers. • Ensures that Nurses and Midwives keep their skills and knowledge up to date and uphold the standards of their professional code. • Ensures that Midwives are safe to practise by setting rules for their practice and supervision. • Fair processes to investigate allegations made against Nurses and Midwives who may not have followed the code. **State and discuss key aspects of the Health Care Professions Council Standards of Conduct, Performance and Ethics:- You must** • Act in the best interests of service users. • Respect the confidentiality of service users. • Keep high standards of personal conduct. • Provide any important information about your conduct and competence. • Keep your professional knowledge and skills up to date. • Act within the limits of own knowledge, skills and experience and if necessary refer the matter to another practitioner. • Communicate properly and effectively with service users and other practitioners. • Keep accurate records. • Obtain informed consent to provide care or services (so far as possible).	

	Competency	**Competency Checklist**	**Assessor's / Self Assessor's Signature**
6	Demonstrate familiarity with the legal and professional implications of intravitreal injection	**State & discuss:** • Individual legal responsibility. • Implications for the practitioner. • Accountability. • Duty of care/reasonable care. • Vicarious liability. • Informed /valid consent. • Mental capacity. • Local policies and procedures. • Negligence. • Registered practitioner understands that an ophthalmologist must be available on the phone and, if cannot manage immediate complications themselves, doctor must be in the department and available to assist with complications, whilst clinic is progress • The competency does **not** cover the injection to pregnant patients. • The competency does not cover intravitreal injections of Avastin (Bevacizumab)	
7	Demonstrate knowledge of the anatomy and physiology of the eye.	**State & discuss:** • Appropriate patients for intravitreal injection. • The anatomy of the eye. • Areas of the eye to avoid. • Individual patient factors.	
8	Demonstrate knowledge of the procedure for intravitreal injection	**State & discuss:** • Is able to access relevant trust policies and procedures. • Is up to date with current practice.	

	Competency	**Competency Checklist**	**Assessor's / Self Assessor's Signature**
9	Is able to identify appropriate equipment and drugs and understands the process for delivering an intravitreal injection	**State & discuss:** • Describes the equipment used and demonstrates understanding of its use. • Rationale for the cleaning of the trolley prior to use. • Describes drugs used, how to use and how they work • Describes requirements for prescribers.	
10	Discuss patient preparation prior to intravitreal injection insertion	**State & discuss:** • Informed / valid consent (as appropriate). • Limits of practice and patient selection. • Reassurance and explanation. • Previous injection history. • Correct area for injection selection • Any requirement to check IOP.	
11	Demonstrate knowledge of the infection control issues relating to intravitreal injections.	**State & discuss:** • Main sources of bacteria for intravitreal injections associated infections. • Standard precautions for infection control. • Appropriate single use equipment. • Aseptic non-touch technique. • Hand hygiene and bare below the elbow. • Eye preparation. • Sharps safety including disposal care and maintenance. • Issues of iodine "allergy" and use of chlorhexidine.	

	Competency	Competency Checklist	Assessor's / Self Assessor's Signature
12	Demonstrate knowledge of risk management issues relating to intravitreal injection and trust sharps and incident policies	**State & discuss:** • Needle stick injuries: ○ Incidence. ○ Reasons for. ○ Cost to the practitioner/organisation. ○ Trust's policy. • Best and safe practice to reduce risks • The Trust's incident reporting procedure. • Awareness of clinical governance processes and audit, e.g. Safety Thermometer Data Collection Tool.	
13	Demonstrate knowledge of the potential complications of intravitreal injection and how to reduce the risk	**State & discuss:** Signs and symptoms, management of the following: • Wrong eye injected. • Iodine administered in iodine allergic patient. • Sub-conjunctival haemorrhage. • Corneal abrasion. • Cataract. • Retinal tears/detachment. • Air bubbles. • Raised intraocular pressure. • Vitreous wicks. • Endophthalmitis. • Post procedure infection.	

Record of observation of intravitreal injections

Ward / Department ……Name ……

Date	Pt record Number	Comments	Signature of practitioner	Signature of Supervisor

Record of supervised practice of preparation for intravitreal injections

Date	Pt record Number	Comments	Signature of practitioner	Signature of Supervisor
**W a r d / **				

Department ……Name ……

Record of supervised practice of administering intravitreal injections

Date	Pt record Number	Comments	Signature of practitioner	Signature of Supervisor

Ward / Department ……Name …….

Record of independent intravitreal injections

Date	Pt record Number	Comments	Signature of practitioner	Signature of Supervisor

Ward / Department ……..……Name ……..……..…….

Intravitreal injecting - Competency Checklist – Skills

Ward / Department ……Name ……

	Competency	Competency Checklist	Assessor's / Self Assessor's Signature
1	Has observed 20 injection pathways	**Provide evidence** • That 20 injections pathways have been observed. • That trainer happy for them to proceed	
2	Has undertaken 20 injection preparations	**Provide evidence** • That 20 injections have been prepared. • That trainer happy for them to proceed	
3	Has undertaken 30/50 observed or supervised injections	**Provide evidence** • That 30-50 injections have been performed under supervision. • That trainer happy for them to proceed. • They have observed a number of different practitioners to observe differing techniques. • Kept a record of all patients and audited patients for outcome.	
4	Prepares room and equipment	**Under observation:** • Checks room and equipment is clean and suitable • Ensures all equipment present and suitable • Ensures all drugs are present and not expired	
5	Checks notes	**Under observation:** • Checks notes and ensures completed consent, clinical notes with up to date examination, no contraindications or concerns, drug prescribed • Ensures correct drug	

	Competency	**Competency Checklist**	**Assessor's / Self Assessor's Signature**
6	Patient discussion and comfort	**Under observation:** • Identifies patient, checks allergies, checks medical history changes • Checks patient understands procedure • Checks patient understands HCP • Positions patient • Ensure patient comfort and advice how to say if not comfortable • Completes miniWHo checklist and marks eye	
7	Is able to identify appropriate equipment and understands the process for delivering an intravitreal injection	**Under observation:** • Assembles equipment as identified in procedure and in accordance with manufacturer's instructions. • Cleans trolley if not done • Sterile gloves, packs, syringes and needles, drops opened onto sterile field. • Sterile gallipot/tray filled with 5ml normal saline 0.9% and approximately 5mls Iodine solution. • Instils anaesthetic and iodine drops	
8	Demonstrate procedure for intravitreal injection.	**Under observation can:** • Perform hand hygiene and on sterile gloves • Draws up and prepares drug as required • Reconfirms eye • Clean skin with iodine • Instil anaesthetic/iodine drops	
8	Continued	**<u>Procedure continued:</u>** • Inserts speculum • Marks site • Administer the injection • Remove speculum • Dispose of needle in appropriate sharp bin	

	Competency	**Competency Checklist**	**Assessor's / Self Assessor's Signature**
9	Is able to identify successful/unsuccessful intravitreal injection.	**Under observation can demonstrate:** • Signs of successful injection. ○ Minimum discomfort to the patient (during and after procedure). ○ No pain. ○ No significant sub-conj bleeding ○ Clear injection site/no vitreous wick. ○ Patient can detect hand movement vision ○ Seeks urgent medical care if issues.	
10	Safe discharge	**Under observation can:** • Provide and advise on any postop prescription • Check next appointment date • Advice on symptoms of concern and contact if problems	
11	Documentation	**Under observation can:** • Complete documentation correctly side, drug, prescription of post-op drops, name and any GP letter	

Competency sign off form: Non-Medical Intravitreal Injecting

This form must be completed and returned to your line manager once you have gathered all your evidence to support your claim of competence and been assessed in practice.

Name:	
Designation:	
Ward / Department:	
Date of study day:	
Date of original sign off as independent injector	
Date of last Assessment:	

I feel competent in this procedure and understand the competency statement, action and outcome. Having received appropriate training, I accept responsibility for my own competence and have discussed this role as part of my job description with the person to whom I am managerially accountable.

Your signature: ……

I have assessed ……. in this competency and feel that both practice and knowledge meet the required standard.

Assessor's signature: ……

I confirm that the above named person has provided appropriate evidence to support a claim of competence and has been assessed in practice.

Manager's name: ……

Manager's signature: ……

This competency is due for reassessment on (date) …… and also complete an independent audit on at least 50 cases each year.

Appendix: 6 Reflective practice template

Ward / Department ……Name …….

O/S/I*	Date	Brief description of episode and comments or reflections by practitioner	Trainer/assessor comments and constructive feedback	HCP sign	Trainer print and sign

*O/S/I = Observed/supervised/independent

Appendix 7: SOP

Standard Operating Procedure

Title Administration of Intravitreal Injections of anti-VEGF medication for macular disease by non-medical injectors

Department: Ophthalmology

SOP Summary

This SOP describes the equipment and procedure required for the administration of medication via Intravitreal injection.

Version: 1.0
Approved:
Ratified:

Clinical Unit or Department:	Leicester Royal Infirmary
Name of author(s)	Ms Rossella Anzidei (Consultant Ophthalmologist) Mr Vasileios Konidaris (Consultant Ophthalmologist)
Name of responsible individual	
Approved by:	
Ratified by :	
Date issued:	
Review date	
CQC relevant domains	
Target audience:	Non-health care Practitioners, Nursing, orthoptists, optometrists, ophthalmologists, ophthalmology managers

1. Introduction

This standard operating procedure (SOP) is for all non-medical injector health care professionals (HCPs) whether nursing, orthoptist or optometrist, who have been allocated to carry out intravitreal injections for patients with macular disease.

2. Scope

The purpose of this SOP is to describe the preparation and process for carrying out intravitreal injections in the ophthalmology service.

3. Process

3.1 Consent, prescribing and documentation

The plan for treatment is discussed with the patient in the consultant led clinics; this includes treatment modality, course of treatment, consent for treatment, any commissioner therapy application and provision of the intravitreal injection patient information leaflet.

Before starting the procedure the HCP must ensure that the patient has been given the relevant information and written consent for the procedure has been obtained prior to the first injection taking place. The HCP should also check the consent for the course of treatment is up to date. This process will ensure that the patient is aware of the rationale for the procedure and of all potential complications.

The HCP must ensure that the drug has been prescribed by a doctor or independent prescriber and that this is documented correctly.

4.2 Exemptions to treatment by the HCP

The intravitreal injection procedure should not be performed by the HCP if:

- The patient will not provide valid consent or refuses treatment by the HCP
- The HCP does not feel it is safe to proceed or has concerns performing the injection
- The HCP does not have immediate access to medical support (ie the doctor should either be present on site or, if the HCP is competent to manage immediate emergencies,

by phone with a pathway in place to see a doctor urgently with the appropriate safe timescale if required, once the HCP has undertaken first treatment).

- The consultant or senior fellow decides that the patient requires a member of the medical team to perform the procedure
- A patient has had repeated previous complications such as central retinal artery occlusion and required paracentesis.
- Active eyelid and/or ocular surface disease such as blepharitis
- Other high risk ocular comorbidity e.g. retinal detachment
- Other medical conditions making the administration difficult e.g Parkinson's disease, difficult positioning or ocular fixation problem such as nystagmus

4.3 Prior to intravitreal injection commencing

The HCP will:

- Review the patient's notes and:
  - Ensure the patient has been referred for treatment by the consultant or trained assessor in charge of the clinic.
  - Ensure that the drug has been prescribed correctly.
  - Confirm that a recent retinal and macular examination has been taken place and details of the examination are recorded in the notes. If not, a review must be obtained before intravitreal injection taking place.
  - Confirm that the patient has undergone all the relevant checks and tests in accordance with clinic protocols
  - Check if the patient has any allergies and if the patient has a definite allergy to povidone iodine ensure that this has been be verified by the consultant so an alternative preparation can be used. When patients are allergic to povidone iodine, chlorohexidine gluconate can be used.
  - Check a recent visual acuity test has been performed
  - Ensure the patient shows no signs of infection such as conjunctivitis and blepharitis, if there possible signs of infection this must be discussed with the doctor and a clear treatment plan put in place.
  - Check the patient's medical history as HCPs must not inject the patient if the patient is suffering from:-

  Unstable angina
  Uncontrolled hypertension
  Any evidence of infection
  Ocular infection

Recent MI or CVA
Pregnancy
Previous allergy to the drugs
Too high INR

- Check that the consultant or fellow in charge of the injection session is available in the injection service. The injection list must not commence until the senior doctor in charge of the session is available. If the HCP is trained to instigate initial management of complications, check there is a senior doctor available on the phone and someone who can receive any urgent complications.
- Review the injection room facilities, ensuring it is clean and safe for use.
- Check all equipment is ready for the session.
- Ensure all drugs are present and in date
- Ensure that a designated nurse or healthcare assistant/technician is present in the treatment room to assist with the procedure.
- Ensure that the assistant has followed the correct hygiene precautions and aseptic technique in preparing the patient for the injection.

4.4 Preparation of the patient

- The HCP should introduce themselves to the patient and confirm the patient's identity in accordance with the trust policy, ensuring that the patient states their name and date of birth.
- The HCP should explain to the patient that they will be administering the intravitreal injection prescribed by the doctor or independent prescriber.
- The HCP should again verbally confirm with the patient their allergy status and past medical history including checking for hypertension and whether they have suffered a recent heart attack or stroke or attended hospital since their last injection. This will prevent any untoward side effects from medications used during this procedure.
- The patient consent form should be checked and the HCP should confirm with the patient which eye(s) is to be treated. The patient's eye(s) to be treated must be marked according to trust policy, if there is a discrepancy between the notes and patient the consultant or fellow in charge of the clinic should be consulted.

- The abbreviated surgical safety checklist should be completed and both the injecting practitioner and assistant must check and verbally confirm.
- The Correct Identity of the patient.
- The Correct Eye to be injected and eye is marked.
- The drug to be injected.
- The HCP should check if the eye to be treated is phakic or pseudophakic. Document this in the patient's clinical record as this will influence the choice of injection site.
- If the patient has a history of glaucoma and/ or previous complications from an injection procedure this should be noted
- The procedure should be fully explained, allowing time for the patient to ask questions.

4.5 Equipment required to perform Intravitreal Injection

- Proxymetacaine or Oxybuprocaine hydrochloride eye drops
- Iodine skin scrub (10% aqueous solution) or Tisept solution (Chlorhexidine gluconate 0.015%) if patient has skin sensitivity or allergy to Povidone Iodine.
- Povidone Iodine 5% eye drops, if the patient is allergic to Iodine the use of Chlorhexidine 0.02% must be confirmed with the doctor.
- Tissues
- Injection pack
- Injection drug
- Dressing trolley cleaned thoroughly with detergent, followed by 70% isopropyl alcohol.
- Surgical face mask
- Sterile gloves
- Hand antiseptic (4% Chlorhexidine Gluconate or 7.5% Iodine)
- Sharps container
- Clinical Waste bin

All eye drops and equipment must be checked before use in accordance with trust policy. All eye drops must be instilled in accordance with the policy and procedure guidelines and the relevant patient group directions (PGDs)

4.6 Procedure

- Ensure that the patient is positioned comfortably on the couch or wheel chair.
- Used sterile gloves, surgical mask to be discarded in clinical waste bag together with all other clinical waste.

- Hand decontamination to be undertaken prior to continued patient care and documentation of procedure
- Dressing trolley to be wiped down with 70% alcohol wipes between patients
- Give patient written after care advice and a contact telephone number in case they have any cause for concern. Concerns would include severe pain, a significant drop in visual acuity. Inform patient where they can call or return to if they experience any problems.
- Ensure patient has a follow up appointment.
- Give discharge medications as per PGD

4.7 Drugs Used for Procedure

4.7.1 Proxymetacaine hydrochloride 0.5% eye drops minims.

Legal status: Prescription only medicine.

Dose: Once only

Method and route of administration:

Follow standard eye drop instillation procedure. Instil two drops to the outer aspect of the lower fornix of the affected eye.

Advice to patients

- Drop may sting
- Patients should refrain from touching or rubbing their eyes due to loss of corneal sensation
- Advise the hospital of any unwanted effects.

Adverse drug reactions

- Burning and stinging
- Transient blurring of vision on instillation
- Acute, intense and diffused corneal epithelial keratitis
- Iritis with descemetitis
- Local anaesthetic eye drops cause a temporary (approximately half an hour from administration) elimination of the blink reflex

Record keeping

The administration of proxymetacaine hydrochloride 0.5% eye drops will be recorded in the patient's case notes, recording date, time and signature of HCP.

Information to be documented:

- Name, form and strength of medicine to be documented in full

- Date, which eye time and dosage administered

4.7.2 Oxybuprocaine hydrochloride 0.4% eye drops (benoxinate) minims.
Legal status: Prescription only medicine.
Dose: Once only
Method and route of administration:
Follow standard eye drop instillation procedure. Instil two drops to the outer aspect of the lower fornix of the affected eye.
Advice to patients

- Drop may sting
- Patients should refrain from touching or rubbing their eyes due to loss of corneal sensation
- Advise the hospital of any unwanted effects.

Adverse drug reactions

- Transient stinging, local irritation
- Superficial punctuate keratitis or oedema
- Ineffective tearing due to temporary elimination of the blink reflex
- Hyperaemia
- Oedema

Record keeping

The administration of oxybuprocaine hydrochloride 0.4% eye drops will be recorded in the patient's case notes, recording date, time and signature of HCP.
Information to be documented:

- Name, form and strength of medicine to be documented in full
- Date, which eye time and dosage administered
- Signature of HCP

4.7.3 Povidone Iodine 5% Eye Drops
Legal status: Prescription only medicine.
Dose: One drop into the lower conjunctival sac and onto lid margins 3 minutes prior to administration of intravitreal injection.
Method and route of administration:
One drop into the lower conjunctival sac.
Advice to patient
Drop may sting
Route of administration
Topically to the lower conjunctival sac and lid margins
Frequency of administration and maximum dosage

Instil one drop in to lower conjunctival sac and onto lid margins prior to administration of intravitreal injection.

Record keeping

The administration of Povidine iodine 5% eye drops will be recorded in the patient's case notes, recording date and time of administration and signature and designation of HCP following prescription by a doctor.

4.7.4 Anti-VEGF medication

This may be Lucentis (Ranibizumab), Eylea (Aflibercept), Beovu (Brolucizumab) or Vabysmo (Faricimab).

4.7.5 Lucentis (Ranibizumab)

Legal status: Prescription only medicine.

Dose: Supplied as an injection 10mg/ml, dose is once only 500mcg once a month for three months with further injections as needed

Method and route of administration:

By intravitreal injection, for supply of treatment:

Advice to patient

- Advise if any loss of vision immediately
- Advise the hospital of any unwanted effects.

Adverse drug reactions

- Nausea
- Headache
- Eye pain
- Conjunctival and retinal haemorrhage
- Oedema
- Vitreous detachment
- Retinal Detachment
- Endophthalmitis

Record keeping

The administration of Anti-VEGF medication must be recorded in the patient's records including date and time of administration and signature and designation of HCP.

4.7.6 Eylea (Aflibercept)

Legal status: Prescription only medicine.

Dose: Supplied as an injection 40mg/ml, dose is 2mg aflibercept (50 microlitres-0.05ml)) once a month for three months followed by one injection every two months. After 12 months of treatment the treatment interval may be extended depending on the patient's condition

Method and route of administration:
By intravitreal injection, for supply of treatment

Advice to patient

- Advise if any loss of vision immediately
- Advise the hospital of any unwanted effects.

Adverse drug reactions

- Nausea
- Headache
- Eye pain
- Conjunctival and retinal haemorrhage
- Oedema
- Vitreous detachment
- Blindness
- Hypopyon
- Endophthalmitis,
- Uveitis,
- Retinal detachment
- Raised intraocular pressure
- Conjunctival and retinal haemorrhage

Record keeping

The administration of Eylea medication 0.05ml will be recorded in the patient's case notes, including date, time of administration and signature and designation of HCP.

4.7.7. Beovu (brolucizumab)

Legal status: Prescription only medicine

Dose: The recommended dose is 6 mg brolucizumab (0.05 ml solution) administered by intravitreal injection every 4 weeks (monthly) for the first 3 doses. Thereafter, the physician may individualise treatment intervals based on disease activity as assessed by visual acuity and/or anatomical parameters. A disease activity assessment is suggested 16 weeks (4 months) after treatment start. In patients without disease activity, treatment every 12 weeks (3 months) should be considered. In patients with disease activity, treatment every 8 weeks (2 months) should be considered. The physician may further individualise treatment intervals based on disease activity.

Method and route of administration: By intravitreal injection, for supply of treatment

Advice to patient

Advise if any loss of vision immediately

Advise the hospital of any unwanted effects

Adverse drug reactions

- Nausea

- Headache
- Eye pain
- Conjunctival and retinal haemorrhage
- Oedema
- Vitreous detachment
- Blindness
- Hypopyon
- Endophthalmitis
- Uveitis, Intraocular inflammation
- Retinal detachment
- Raised intraocular pressure
- Conjunctival and retinal haemorrhage

Record keeping

The administration of brolucizumab 0.05 ml solution will be recorded in the patient's case notes, including date, time of administration and signature and designation of HCP.

4.7.8 Vabysmo (faricimab)

Legal status: Prescription only medicine

Posology

nAMD

The recommended dose for Vabysmo is 6 mg (0.05 mL solution) administered by intravitreal injection every 4 weeks for the first 4 doses. Thereafter, an assessment of disease activity based on anatomic and/or visual outcomes is recommended 20 and/or 24 weeks after treatment initiation so treatment can be individualised. In patients without disease activity, administration of Vabysmo every 16 weeks should be considered. In patients with disease activity, treatment every 8 weeks or 12 weeks should be considered. Monitoring between the dosing visits should be scheduled based on the patient's status and at the physician's discretion, but there is no requirement for monthly monitoring between injections.

DMO

The recommended dose for Vabysmo is 6 mg (0.05 mL solution) administered by intravitreal injection every 4 weeks for the first 4 doses. Thereafter, treatment may be individualised using a treat-and-extend approach following an assessment of the individual patient's anatomic and visual outcomes. The dosing interval may be extended from every 4 to every 16 weeks, with extensions in increments of up to 4 weeks, based on the physician's judgement of the individual patient's anatomic and/or visual outcomes. If anatomic and/or visual outcomes change, the treatment interval should be adjusted accordingly, and interval reductions of up to 8 weeks may be implemented if deemed necessary. Monitoring between the dosing visits should be scheduled based on the patient's status and at the physician's discretion, but there is no requirement for monthly monitoring between injections.

4.7.9 Chloramphenicol 0.5% Eye Drops

Legal status prescription only medicine **Route of administration**

Topically to the lower conjunctival sac

Frequency of administration and maximum dosage

To instill one drop in the conjunctival sac after the intravitreal injection

Side effects

Transient irritation, burning, stinging and sensitivity reactions such as itching and dermatitis

Contraindications

Hypersensitivity to the active substance chloramphenicol or to any of the excipients, myelosuppression during previous exposure to chloramphenicol, known personal or family history of blood dyscrasias including aplastic anaemia.

4.7.10 Hypromellose 0.3% Eye Drops

Supplied to the patient to take home **Legal status**: CE marked medical device**Route of administration**

Topically to the lower conjunctival sac unless Doctor requests otherwise

Frequency of administration and maximum dosage

One drop as needed

Side Effects

Eye irritation

Contraindications

Children <3 years old

Breastfeeding

Contact lenses

4.8 Potential risks of Intravitreal injection

The risks of intravitreal injections include:

- Pain
- Bleeding (subconjunctival, vitreous haemorrhage)
- Retinal tear / detachment
- Cataract (from inadvertently hitting the lens)
- Infection (endophthalmitis)
- Loss of vision (from any of above)

- Loss of the eye (from a severe infection)
- Raised intra ocular eye pressure

Also risk of needlestick injury to staff.

4.9 Managing complications immediately

Intravitreal injections carry risks and one potential risk is if the intraocular pressure (IOP) rises to a very high level which then occludes the central retinal artery. This could result in permanent irreversible vision loss if the IOP is not reduced within a short period of time. It is not always possibly for a doctor has been present in the eye department to provide assistance and to continue to deliver a safe level of capacity of care to avoid unsafe delays to injections. Delays to injection care could result in increased vision loss from macular conditions. The risk of central retinal artery occlusion (CRAO) is very rare, less than 1 in 1000 injections.

After an intravitreal injection, each patient is asked to count fingers or detect whether a hand is moving in front of the patient, to ascertain whether the patients' central retinal artery is adequately perfused. If the IOP has elevated to a critical level, then the CRA could be occluded by this raised IOP and the patient could lose vision permanently without intervention. The recommended intervention is to administer 500mg acetazolamide tablets orally and one drop of apraclonidine 1% STAT in the affected eye. The incident should be fully documented in the electronic patient record system and in the patients' notes.

Post injection vision check: if unable to CF or see HM then senior assessor will need to examine the patient and determine why the vision has been lost. Variety of reasons exists such as vitreous haemorrhage, lens trauma or raised IOP occluding CRA.
In case of the latter the following steps should be followed:

1) administer one drop of apraclonidine 1% STAT to the affected eye
2) administer 500mg po acetazolamide STAT
3) doctor called

Any complications or untoward incidents must be reported immediately to the supervising consultant or senior fellow and then via the trusts incident reporting system. All cases of endophthalmitis must be reported as an incident and involve the local infection control team.

5. Dissemination and Implementation

This SOP will be disseminated following ratification, to all staff involved in the administration of intravitreal injections, and will be communicated to key stakeholders via email.
This SOP will be published on the intranet site.

6. Review and Revision Arrangements

This document will initially be reviewed on an annual basis by the SOP Owner/Authors, for two years (if practice new) and then every three years after.
Changes to the legislation of the administration of intravitreal injections by non-medical personal will trigger a review of this SOP.

8. Document Control and Archiving

The current and approved version of this document can be found on the Trust's intranet site. Should this not be the case, please contact the SOP owner / author.

Glossary

Term	**Definition**
Cataract	Opacity of the lens
Endophthalmitis	An inflammatory condition of the intraocular cavities
Intravitreal Injection	The route of administration of a drug inside the eye
Retinal detachment	Separation of the neurosensory retina from the pigment epithelium
Hypopyon	Pus in the anterior chamber
Oedema	Swelling
Intraocular eye pressure	The fluid pressure inside the eye
Anti-VEGF medication	Anti-vascular endothelial growth factor

Appendix 8: Risk Assessment

Department / Directorate	Ophthalmology
Description of risk	**This risk assessment is to assess any risks associated with non-medical practitioners expanding their role and undertaking Intravitreal injections for patients in the medical retina service.** Intravitreal injections are associated possible complications such as : • Infection (endophthalmitis) • Retinal Detachment • Cataract • Raised intra ocular pressure The above complications could occur for all competent practitioners whether medical or non-medical professional. These complications are rare. However some are sight threatening, especially if the complication is not spotted or some immediate treatment is not performed. Risks associated with a non-medical HCP carrying out this procedure include:- • Perception by patient/family that complication was due to injection not performed by doctor • Failure of HCP to detect complication • Having the experience and ability to manage complications which may occur; • Non enough staff or time to undergo training • Not enough senior staff or consultant time to supervise and sign off training • Capacity issues creating pressure to have excessive numbers on injection clinics
Existing controls in place when risk was identified	• The guidelines from the Royal College of Ophthalmologists are followed. • Compliance with Consent Policy • Aseptic technique used. • The procedure would be done in a clean environment compliant with national guidance. • Medical consultant leadership and supervision of service. • An Incident Reporting process in place for adverse events. • Records are kept of procedures carried out and complications noted. • An audit of the service is regularly carried out. • Regular patient feedback is sought. • Process in place for reporting cases of endophthalmitis.

	• Governance structures in place where issues / concerns can be raised. • A complaints system is in place where these are reviewed and lessons are learned and shared. • Regular follow up of patients are performed post treatment in the eye clinic.

Appendix 9: PATIENT SATISFACTION QUESTIONNAIRE

1. The Practitioner introduced herself and was friendly and approachable

Strongly Agree **Agree** **Uncertain** **Disagree** **Strongly Disagree**

2. When I attended for injection the practitioner carefully checked everything before treating me

Strongly Agree **Agree** **Uncertain** **Disagree** **Strongly Disagree**

3. I was happy with my time taken for my visit today

Strongly Agree **Agree** **Uncertain** **Disagree** **Strongly Disagree**

4. The procedure for having my injection was explained clearly to me

Strongly Agree **Agree** **Uncertain** **Disagree** **Strongly Disagree**

5. The Practitioner answered all my questions and discussed any concerns I had

Strongly Agree **Agree** **Uncertain** **Disagree** **Strongly Disagree**

6. The practitioner seemed knowledgeable and competent

Strongly Agree **Agree** **Uncertain** **Disagree** **Strongly Disagree**

7. The Practitioner made sure I was comfortable during my injection

Strongly Agree **Agree** **Uncertain** **Disagree** **Strongly Disagree**

8. If I have further injections I would be happy for the practitioner to do this

Strongly Agree **Agree** **Uncertain** **Disagree** **Strongly Disagree**

9. Overall how would you rate your care and treatment during your appointment today?

Excellent **Good** **Fair** **Poor** **Very Poor**

10. Any further comments

Appendix 10: OCT Competency

OCT COMPETENCY BOOKLET
FOR CLINICAL SETTING

As part of the new role for non-medical Practitioners lays the ability to assess patients in the medical retina clinics, before delivering them intravitreal injections.

Aim: To be able to safely and competently assess a patients OCT making a clinical decision on the patient's treatment pathway, ensuring protocol is adhered to at all times.

Key Staff: Non-medical Practitioners

Reports to: Consultant Ophthalmologist

Key Criteria:

- To have a good knowledge and understanding of the anatomy and physiology of the eye, in particular the retina
- To have a good knowledge and understanding of various eye conditions, in particular retinal vein occlusions, Diabetes and AMD.
- To be able to assess the patients OCT scan and ensure the correct treatment outcome is chosen and within the appropriate timescale for each individual case
- To be able to work autonomously
- To be able to accurately record findings in the patient's notes
- To be able to complete any other paperwork required and dictate letters so patients are informed of the outcome.

Evidence Portfolio

Alongside completing this competency booklet a portfolio of each individuals work should also be completed, with a minimum of fifty completed records enclosed, whilst ensuring patient confidentiality is adhered to, and to be shown to the assessor if required to do so.

Diabetic retinopathy

Diabetic retinopathy is the leading cause of legal blindness in the working age population in industrialised countries. This loss of vision occurs as a result of several mechanisms, the most common cause to date being attributed to diabetic macular oedema (DMO).

Management of patients with DMO has evolved over the last few decades from the use of laser as the old gold standard to much newer therapies. Recent innovative research focusing on the use of anti-vascular endothelial growth factor (anti-VEGF) therapy to treat DMO has shown particular promise due to overall efficacy. Ranibizumab, the first anti-VEGF agent to gain approval for the treatment of DMO in 2013, was based on multiple studies including the RISE and RIDE studies. Aflibercept later obtained licence for treating DMO in 2014 based on the VIVID-DME and VISTA-DME studies. Despite similarities of the two anti-VEGF agents, the pharmacodynamics of aflibercept and ranibizumab differ greatly.

Retinal vascular occlusion

Central Retinal Vein Occlusion (CRVO) is the second most common retinal vascular disease after diabetic retinopathy and is known to affect one person per 1000 at any one time. CRVO is classified into two types: ischemic and non-ischemic. Ischemic CRVO, clinically more

severe of the two, accounts for 20% of acute presentations and results in a significant increase in vascular endothelial growth factor A. Non-ischemic CRVO is known to convert to ischemic CRVO in approximately a third of the cases. CRVO commonly affects one eye; however in approximately 10% of the cases it may be bilateral. There is also an associated 1% risk per year of known CRVO patients to develop RVO in the second eye.

Macular oedema, a well-known complication of CRVO, is characterized by hypoxic retinal tissue release of vascular endothelial growth factor (VEGF) and inflammatory mediators such as interleukin (IL)-8, angiopoietin (ANG)-2 and intercellular adhesion molecule (ICAM)-1. Both these VEGF dependent and inflammatory pathways result in fluid accumulation within the retina and reduced visual acuity. Self-resolution of the intraretinal fluid is noticed in approximately a third of cases with non-ischemic CRVO and associated macular oedema. A plethora of therapeutic modalities have been introduced within the last years regarding the treatment of macular oedema related to CRVO when self-absorption of the intraretinal fluid does not occur. Treatment options include laser photocoagulation, intravitreal steroid use, and newer therapies with anti-VEGF.

Multiple anti-VEGF therapies have been used in the treatment of CRVO related macular oedema including bevacizumab, ranibizumab, and aflibercept. The efficacy of these anti-VEGF agents was demonstrated by numerous studies, notably the CRUISE study for ranibizumab, and the extension studies HORIZON and RETAINS, COPERNICUS and GALILEO study for aflibercept, and numerous studies with level 2 and 3 evidences for bevacizumab. Most of them investigated the anatomical and functional response to treatment with anti-VEGF through changes in central retinal thickness (CRT) and visual acuity.

Branch retinal vein occlusion (BRVO) is a relatively common vascular retinal condition with an incidence of 0.5% to 1.2%. Macular oedema secondary to a BRVO typically causes significant visual loss with little propensity to improve without treatment. This loss of vision occurs as a result of several mechanisms, the most common cause being attributed to macular oedema.

Much like DMO, management of patients with MO secondary to BRVO has evolved over the last few decades from the use of laser, to anti-VEGF therapy. For BRVO with MO, there are robust clinical trial data for the clinical effectiveness of ranibizumab and aflibercept. Ranibizumab was the first anti-VEGF agent to gain approval in the United Kingdom for the treatment of MO secondary to BRVO in 2013. Its approval was based on the BRAVO study, which showed that the mean gain in BCVA at 6 months was 18.3 letters with 0.5mg ranibizumab compared to 7.3 letters with the sham injection. Aflibercept obtained licence for treating MO secondary to BRVO in 2016 based on the VIBRANT study.

Optical Coherence Tomography

Optical coherence tomography (OCT) technology allows the acquisition of cross-sectional images of the retina with semi-histologic resolution. It permits to define the location and nature of the changes in the retina and adjacent structures and objectively evaluates the thickness of the retina and surrounding structures. These capabilities allow detection of newly emerging fluid and/or intraretinal or subretinal tissue and tissue below the retinal pigment epithelium (RPE) and assess the response to anti-vascular endothelial growth factor (VEGF) drugs.

The images are presented in a colour (or gray) scale based on the different reflectivity of the tissue structures. More concisely, tissues that reflect more light or disperse more light are shown in red and white, respectively, while the ones that reflect or disperse less light are shown in blue and black. Tissues that moderately reflect light are shown as green or yellow. It should be noted that the colour shown in the images represents the optical properties of the tissues and not the tissues themselves. Therefore, the image is not real but represents the true dimensions of the measured structures

Normal eye

The vitreous transmits light without reflecting it and is depicted in black in OCT images (Figure 1). The posterior hyaloid usually is indistinguishable from the retinal surface except when the posterior vitreous is detached and appears as a weakly reflective band. The choriocapillaris and choroid are highly reflective layers, because they are vascular and limit light penetration into the deeper layers. Blood vessels are identified by their high reflectivity and the masking effect generated on adjacent tissues (Table 1).

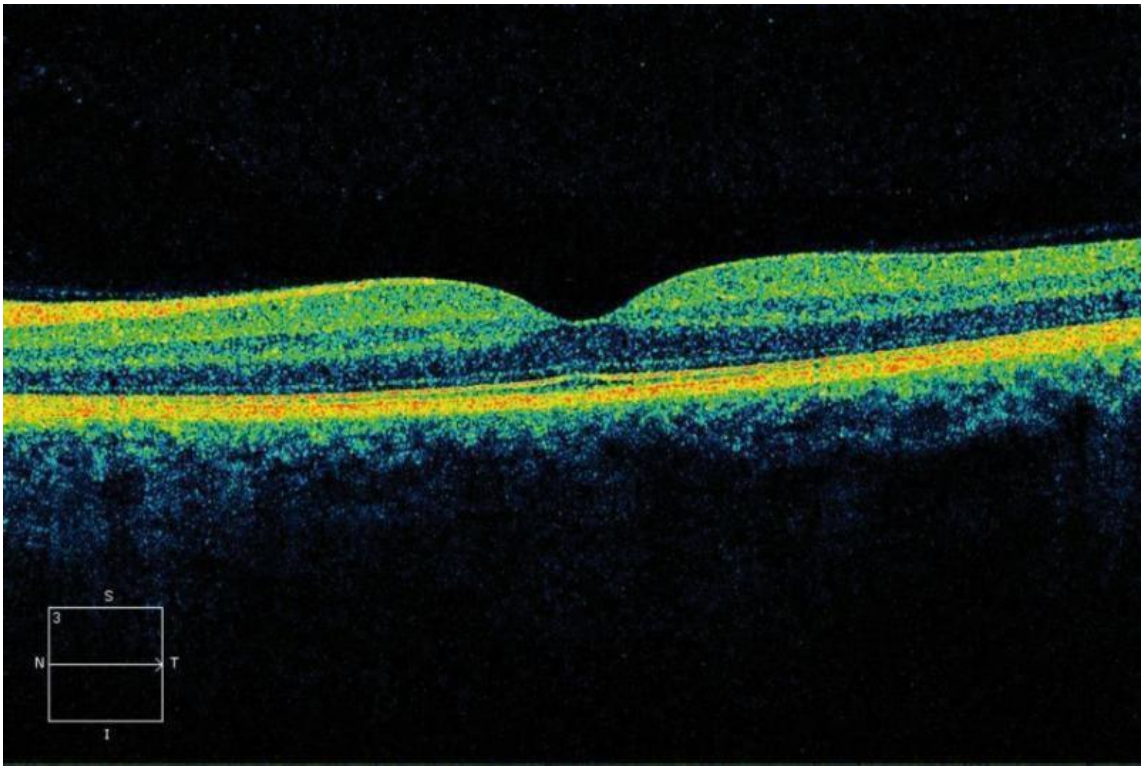


Figure 1. OCT of a normal eye.

Table 1. Reflectivity Patterns of the Retinal Structures in Normal Eyes	
Hyperreflectivity pattern	Nerve fiber layer, thicker in the nasal portion (red), RPE and choriocapillaris (red)
Normal reflectivity pattern	Inner and outer plexiform layer (yellow-green), inner and outer nuclear layers (blue)
Hyporeflectivity pattern	Photoreceptor layer

Intraretinal and Subretinal Fluid

Intraretinal fluid can occur either diffusely; creating increased retinal thickness and reduced retinal reflectivity, or appear localized in non-reflective well-defined cysts (cystic macular oedema). Subretinal fluid corresponds to the accumulation of a clear or lipid-rich exudate (serous fluid) in the subretinal space, i.e., between the neurosensory retina and the underlying RPE (Figure 2).

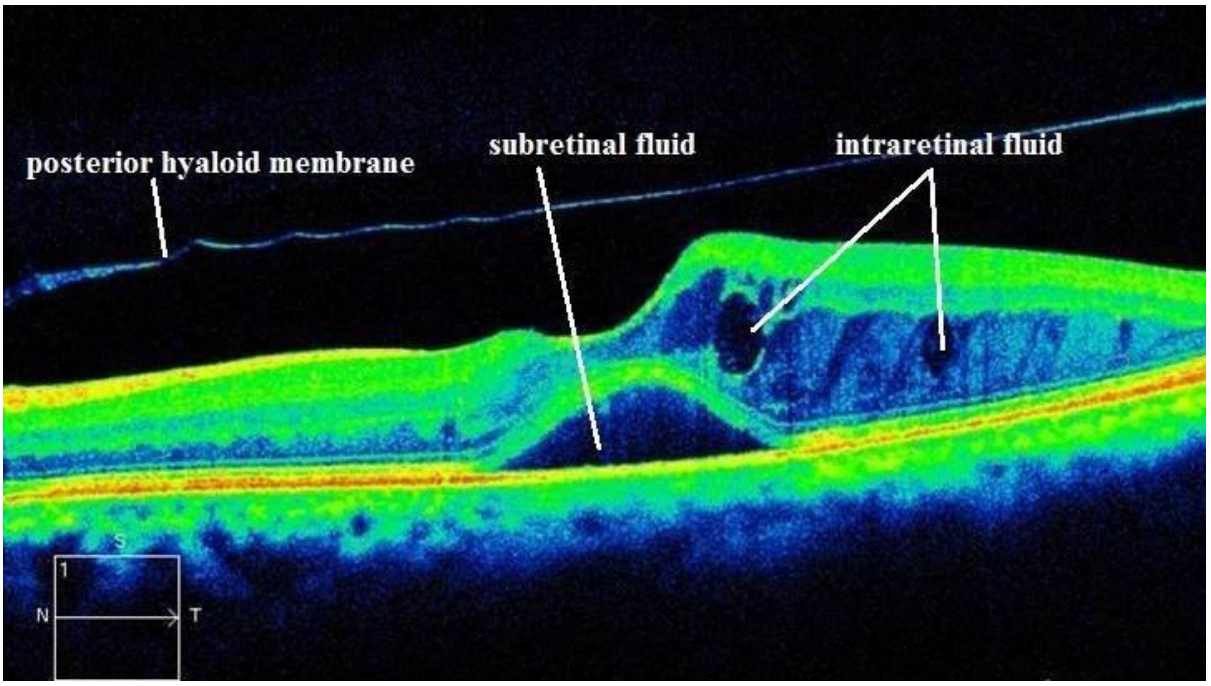


Figure 2. Intraretinal and subretinal fluid

Spectral-Domain OCT

The spectral-domain (SD) OCT devices include a spectrometer in the receiver that analyzes the spectrum of reflected light on the retina and transforms it into information about the depth of the structures according to the Fourier principle. This technology eliminates the need to

mechanically move the reference arm with the consequent increase in the speed with which images are received and axial resolution in time-domain (TD) OCT.

Vascular endothelial growth factor (VEGF)

VEGF-A is an important permeability inducer and is about 50,000 times more potent than histamine. It is also a potent mitogen in endothelial cells and may have an important role in maturing of new blood vessels through pericytes. VEGF-A is involved in physiological angiogenesis in adults, for example, in the female reproduction cycle. In addition, VEGF-A mRNA is expressed in various healthy human adult tissues that do not show angiogenesis, such as the epithelium of the choroid plexus in the brain, the glomerular epithelium in the kidney, the gastrointestinal mucosa and hair follicles. It has been suggested that VEGF-A maintains the integrity of endothelial cells via anti-apoptotic signalling. VEGF-A has been recognised as an important neuroprotectant in the central nervous system.

Although mechanistic studies have suggested that VEGF-induced volumetric blood flow to the retina may be partially responsible for neuroprotection, ex vivo retinal cultures have revealed a direct neuroprotective effect for VEGF-A. VEGF receptor-2 expression has been detected in several neuronal cell layers of the retina, and functional analyses have shown that VEGFR-2 is involved in retinal neuroprotection. It has been shown that VEGF-A is secreted by RPE cells, on their basal side, i.e. the side adjacent to the choriocapillaris, and the 3 VEGFRs are expressed in choriocapillaris endothelial cells, on the side facing retinal pigment epithelial cells. It has long been known that loss of RPE cells in the human eye causes atrophy of the choriocapillaris. Since VEGF is highly regulated by hypoxia, a feedback mechanism must exist in these epithelia to promote physiological formation of new blood vessels when tissue oxygenation is low.

VEGF and pathology

The predominant role of VEGF-A in the development of pathological angiogenesis, such as that occurring in tumours and ischemic and inflammatory processes was widely demonstrated in the last decade. In hypoxic states, VEGF is secreted by RPE cells. This factor induces endothelial cell proliferation and increases vascular permeability. It has been shown in several models that VEGF-A is required and sufficient for development of new blood vessels in the retina and the iris. As already mentioned, VEGF-A has been identified as a primordial factor in the neovascular response induced by retinal ischemia. Therefore, VEGF-A levels are increased in the vitreous and retina of patients with neovascularisation secondary to proliferative diabetic retinopathy, venous occlusion or retinopathy of

prematurity. Vascular endothelial growth factor A (VEGF-A) regulates angiogenesis and vascular permeability in the eye, both in physiological and pathological processes.

It is possible to inhibit every step of the angiogenesis cascade induced by VEGF: VEGF synthesis may be inhibited by inhibiting the synthesis of the corresponding mRNA or by inhibiting transcription. The effect of VEGF may also be directly inhibited, by inhibiting protein action. This is the mechanism used in anti-VEGF therapies. Treatment of AMD, DMO and MO secondary to RVOs with anti-VEGFs is thus considered to be a turning point since its emergence has allowed a more direct approach to its selective inhibition.

Three drugs in this class are currently used: ranibizumab (Lucentis®), aflibercept (Eylea®) and bevacizumab (Avastin®), of which only the first two have been approved for this therapeutic indication.

Ranibizumab (Lucentis®)

Ranibizumab is a Fab fragment of a recombinant humanized monoclonal antibody with high affinity for VEGF-A. Ranibizumab has a solid clinical development program for this therapeutic indication, involving over 7,000 patients. Ranibizumab binds to an amino acid chain common to all VEGF-A isoforms, thus rendering them inactive, reducing retinal and choroidal angiogenesis and halting the increase in capillary permeability.

It has been shown in animal models that ranibizumab effectively penetrates the retina and the subretinal space after intravitreal injection. Its systemic half-life is short (2-3 hours, following intravitreal administration) and systemic clearance is fast, which makes its administration safe. The average vitreous elimination half-life is approximately10 days. The recommended dose is 0.5 mg.

Treatment includes a loading phase, consisting of 3 monthly injections, in the first 3 months, and a maintenance phase, where retreatment is decided according to disease progression, mostly evaluated in monthly visits through VA and OCT criteria, at least during the initial stage or recent activity.

Results from numerous multicentre studies indicate that individual treatment criteria should be adopted during the maintenance stage, allowing an effective approach to maintaining visual gains, as well as allowing follow-up in clinical practice, with maximum systemic and ocular safety.

Vision is expected to be maintained in 90-95% of patients; a minimum gain of 3 lines should be observed in 30-40% of patients treated with ranibizumab.

Aflibercept (Eylea®)

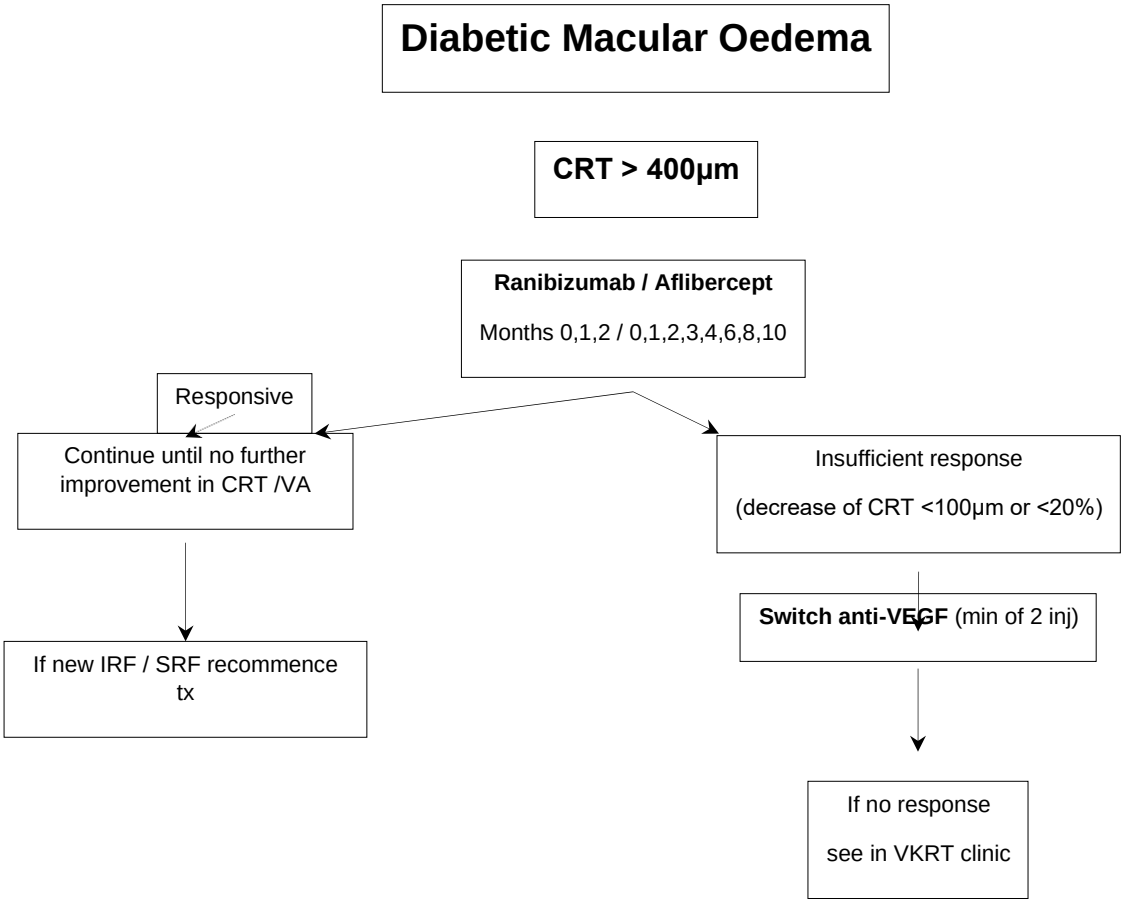
Aflibercept is a recombinant fusion protein consisting of the natural (all human) extracellular ligand binding sequences of VEGFR1 and VEGFR2 attached to the Fc portion of an IgG molecule. Aflibercept is approved for the treatment of nAMD, DMO and macular oedema due to RVO.

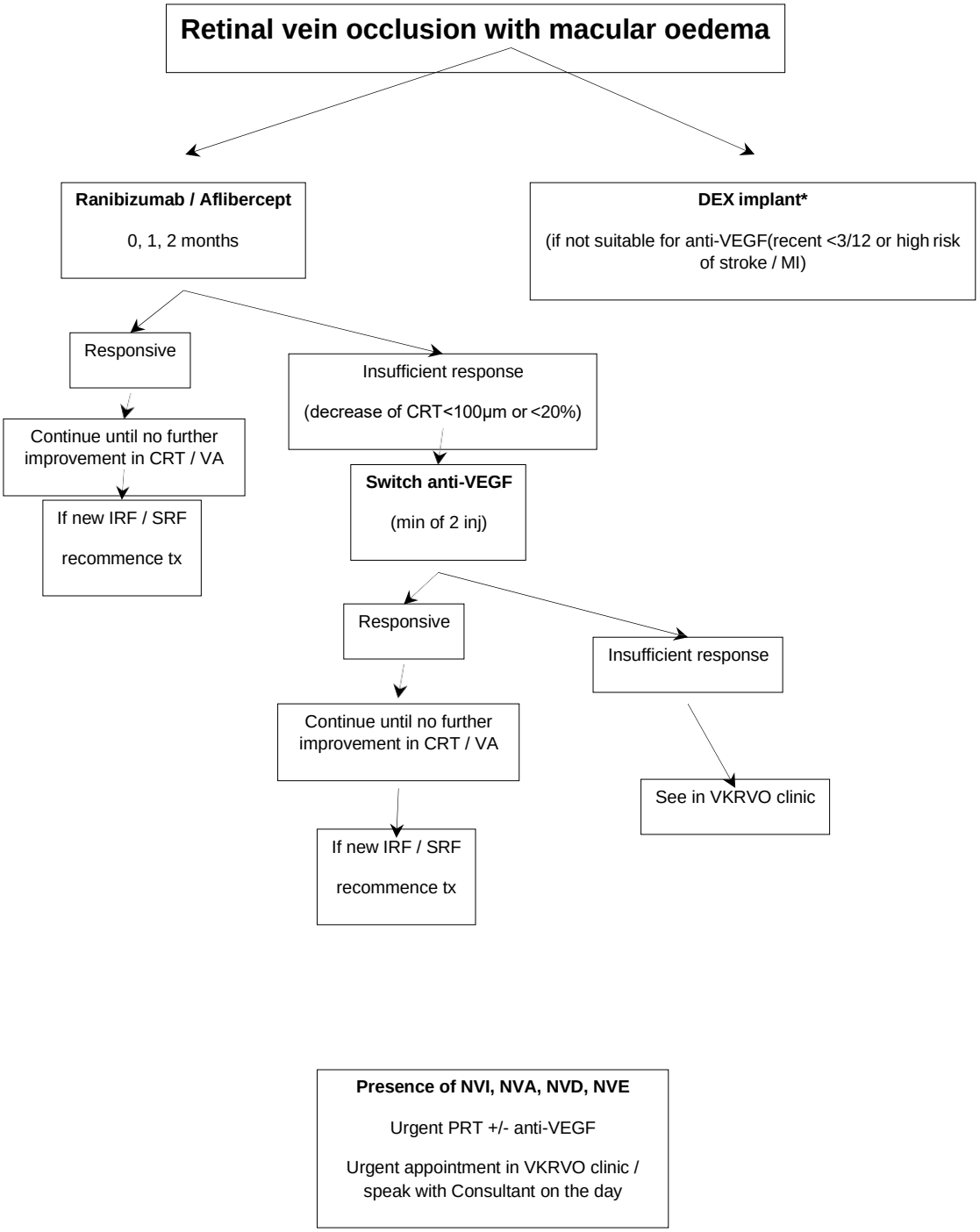
The three-dimensional configuration of aflibercept enables it to simultaneously bind both sides of the VEGF dimer in a "two-fisted grasp". This results in a higher binding affinity for $VEGF_{165}$ compared to ranibizumab and bevacizumab, which confers the advantage of the potential for less frequent dosing of aflibercept, with substantial saving in cost and treatment burden to patients. Peak efficacy of aflibercept in patients with nAMD is similar to that of ranibizumab but the duration of action is slightly longer.

Brolucizumab (Beovu)

Brolucizumab is a specifically engineered anti-VEGF. It is a single-chain antibody fragment aims to facilitate deeper penetration of active molecules than larger molecules within tissue. Brolucizumab has a high affinity to VEGF-A isoforms1 and can inhibit VEGF through prevention of the ligand-receptor interaction. The recommended dose is 6 mg brolucizumab (0.05 ml solution) administered by intravitreal injection every 4 weeks (monthly) for the first 3 doses. Thereafter, the physician may individualise treatment intervals based on disease activity as assessed by visual acuity and/or anatomical parameters. A disease activity assessment is suggested 16 weeks (4 months) after treatment start. In patients without disease activity, treatment every 12 weeks (3 months) should be considered. In patients with disease activity, treatment every 8 weeks (2 months) should be considered. The physician may further individualise treatment intervals based on disease activity.

Up to now >1,000 patients were treated with Beovu in two Phase III trials.Uncommon adverse reactions (<1%) included endophthalmitis, blindness, retinal artery occlusion, retinal detachment, conjunctival hyperaemia, lacrimation increased and vitreous haemorrhage. Most serious adverse reactions included blindness (0.8%), endophthalmitis (0.7%), retinal artery occlusion (0.8%) and retinal detachment (0.7%). The proportion of eyes with ≥15-letter loss at Week 48 was balanced across both treatments.


Diabetic Macular Oedema
CRT > 400µm
Ranibizumab / Aflibercept
Months 0,1,2 / 0,1,2,3,4,6,8,10
Responsive
Continue until no further improvement in CRT /VA
If new IRF / SRF recommence tx
Insufficient response
(decrease of CRT <100µm or <20%)
Switch anti-VEGF (min of 2 inj)
If no response
see in VKRT clinic


Retinal vein occlusion with macular oedema
Ranibizumab / Aflibercept
0, 1, 2 months
DEX implant*
(if not suitable for anti-VEGF(recent <3/12 or high risk of stroke / MI)
Responsive
Insufficient response
(decrease of CRT<100µm or <20%)
Continue until no further improvement in CRT / VA
If new IRF / SRF
recommence tx
Switch anti-VEGF
(min of 2 inj)
Responsive
Insufficient response
Continue until no further improvement in CRT / VA
See in VKRVO clinic
If new IRF / SRF
recommence tx
Presence of NVI, NVA, NVD, NVE
Urgent PRT +/- anti-VEGF
Urgent appointment in VKRVO clinic / speak with Consultant on the day

After shadowing the medical retina consultants in clinic for a period of four weeks, the non- medical practitioner will start assessing patients independently but under supervision, discussing a number of 20 cases with the Consultant trainer. Each patient discussed will be recorded in the portfolio and once the non-medical Practitioner has been assessed as competent by the supervisor then he/she will proceed assessing patients unsupervised. A consultant trainer or another responsible doctor will be available at all times for any doubts concerning clinical decisions.

In the following page the assessment appendix.

Competence category	Positive features	Opportunities for improvement	Performance level / score
Communication and working with the patient and / or family	-Explanation of procedure to patient and ensuring patient -Ongoing reassurance to patient -Explanation of main aspects of retinal condition and management options		
Safety	-Checking patient identification on notes and computer database		
Procedural competence	-Assess features of Optical Coherence Tomography (OCT) -Decide about appropriate management based on current and previous OCT images, visual acuity results and previous notes -Record outcomes on the patients' notes -Fill-in appropriate forms for treatment / clinic review -Appropriately seek for advice when in doubt	-Read relevant literature (book / online sources)	
Team working			

Assessors Recording Form

Trainee's name: **Date:**

ASSESSMENT PRACTICE LOG

	Date	**Assessor's name**	**Assessor's signature**	**Your signature**	**Score**
Communication and working with the patient					
Checking patient identification on notes and computer database					
Assess features of Optical Coherence Tomography (OCT)					
Decide about appropriate management					
Record outcomes on the patients' notes					
Fill-in appropriate forms for treatment / clinic review					