{Insert} Name of Trust

Clinical Policy for the Administration of Intravitreal Injections of Anti-VEGF Medication for Macular Disease by Non Medical Practitioners

Summary
This policy describes the processes required for non-medical healthcare professionals to carry out intravitreal injections of anti-VEGF medication.

Version: X.0
Status: xxx
Approved: X.X.20XX
Ratified: X.X.20XX

Clinical Unit or Department:	
Name of author(s)	
Name of responsible individual	
Approved by:	
Ratified by :	
Date issued:	
Review date	
CQC relevant domains	
Target audience:	Nursing, orthoptists, optometrists, ophthalmic photographers, ophthalmologists, ophthalmology managers

Version History

Version	Date Issued	Brief Summary of Change	Author

1. Introduction

In recent years, the involvement of non-medical healthcare professionals (HCP) in delivering an extended scope of practice assessing and managing patients and/or performing procedures has become widely accepted practice to cope with significantly rising demand for eye care and to support the expansion of non-medical roles, and is supported by the Royal College of Ophthalmologists (RCOphth) and other HCP professional organisations as well as the NHS England National Elective Care High Impact Intervention and GIRFT.

2. Purpose

This policy sets out the process required for designated HCP to train for and to deliver intravitreal injections as independent non-medical injectors to the standards required by NICE and the RCOphth. This will contribute to the efficient delivery of the ophthalmology 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 the ophthalmology service. 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).

3. Scope

This policy applies to all trust sites where intravitreal injections are carried out and is relevant to 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
- Sharps policy
- Consent policy
- Clinical governance/risk management policy
- Local safety standards for invasive procedures (LocSSIPs).

To be eligible for undertaking the procedure staff must have a minimum time of 1 year's post registration ophthalmic experience and be:

- Registered nurse (RN) at band 6 or above who must either hold an ophthalmic nursing qualification or have sufficient ophthalmic experience to be judged by their manager and lead retinal nurse/consultant ophthalmologist as competent to commence training,

- Registered orthoptist at band 6 or above who has sufficient ophthalmic experience to be judged by their manager and lead retinal nurse/consultant ophthalmologist as competent to commence training;
- Registered optometrist at band 6 or above who have sufficient ophthalmic experience to be judged by their manager and lead retinal nurse/consultant ophthalmologist as competent to commence training.

Suitable staff members from a nursing or orthoptic background at band 5 level may commence training for an extended role in botulinum clinics and progress to band 6 on completion of their training.

4.0 Duties and responsibilities

4.1 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:

- British and Irish Orthoptic Society (BIOS)
- Health and Care Professions Council (HCPC)
- General Optical Council (GOC)
- College of Optometrists
- Nursing and Midwifery Council (NMC)

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, the HCP is required to regularly audit their patient records and care as part of their annual appraisal / individual performance review. HCPs must attend regular clinical update sessions on intravitreal injections and the relevant conditions.

From the point of registration, each practitioner must adhere to their professional body/regulatory code of conduct and is accountable for his/her practice.

4.2 Consultant ophthalmologist's, lead nurse's and trainer's responsibilities

The consultant and the lead nurse must ensure the HCP has achieved a satisfactory knowledge base and competencies with which to perform this enhanced role. The consultant and lead nurse 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 consultant and lead nurse 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.

4.3 Manager's 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.

Managers must also ensure that staff in a dedicated injection clinic are not interrupted or asked to cover other tasks.

4.4 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.

5.0 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 appendices. 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 with competencies recorded and will 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.

6 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. More time may be required if patients require extra support. 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.

7. Outcome measures

Data to be collected:

- Record of all cases to be kept by HCPs for activity levels
- Data capture/audit from electronic patient record if available .
- Regular updates of portfolio including any learning materials
- Regular audit of adherence to protocol, case management and record keeping in conjunction with trainer
- Regular documented reflective practice on cases of interest or with learning opportunities
- 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.

8.0 Stakeholder engagement and communication

This guideline was developed by the medical retina medical team with other ophthalmic medical staff, orthoptic, optometrist, nursing staff and the management team.

Stakeholder engagement with consultants and other relevant staff has been through insert name of appropriate meetings and other methods e.g. emails or team meetings.

9.0 Approval and ratification

This policy was approved by the insert name of committee and ratified by the insert name of committee.

10.0 Dissemination and implementation

This policy will be implemented and disseminated to all staff involved in the administration of intravitreal injections or medical retinal care, and will be communicated to key stakeholders and policy users via email, and highlighted at team meetings and insert name of other meetings or insert other methods of dissemination.

This policy will be published on the trust intranet site.

11.0 Review and revision arrangements

This document will be reviewed on a 3 year basis by the Policy Owner/Authors.
Changes to the legislation or national guidelines of the administration of intravitreal injections by non-medical personal, or any trust serious incidents will trigger a review of this document.

12.0 Document Control and Archiving

Insert standard trust information of document storage and removal old versions/archiving

13.0 Monitoring compliance with this policy

Element to be Monitored	**Staff conducting**	**Tool for Monitoring**	**Frequency**	**Responsible Individual/Group/ Committee for review of results**	**Responsible individual/ group/ committee for 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	All staff	Incident reporting	ongoing	Lead consultants Risk team	Ophthalmology CG
Complaints	Complaints team	Complaints process	ongoing	Lead consultant Ophthalmology manager PALS	Ophthalmology CG

14.0 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
Ophthalmic Common Clinical Competency Framework (OCCCF). RCOphth, BIOS, RCN, College of Optometrists. https://www.rcophth.ac.uk/professional-resources/new-common-clinical-competency-framework-to-standardise-competences-for-ophthalmic-non-medical-healthcare-professionals/
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
Sharps policy
Clinical record keeping policy
Clinical governance policy
Risk management policy
WHO checklist/Surgical Safety/Local SSIPs Policy
Mental capacity policy

{Insert} Name of Trust

Add other relevant trust document names

Appendix 1 : 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.

Baseline competencies for training

Orthoptists, optometrists and nurses will have had differing training and experience in a number of baseline skills or knowledge in terms of:

- Assessing patients with ophthalmic conditions
- Slit lamp
- Tonometry
- Handling of medicines, delivering injections
- Basic knowledge of ophthalmic disease.

For these baseline skills and knowledge/experience, the trainer / ophthalmologist and line manager will need to agree if there is any basic training required to bring the HCP to a level where the intravitreal training can commence and make a plan to train and evidence competencies for any areas which are not covered as part of core training before embarking on the advanced practice training.

Note that if the HCP will be consenting for this procedure, they must fulfil the trust requirements / training for non-medical consenting.

Who can provide workplace based 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 three 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.

Note that, in due course, the planned Royal College of Ophthalmologists OCCCF training programme to competency level 3 should deliver a nationally recognised training pathway.

The HCP will maintain a portfolio of their training and continued learning and performance. As they progress, further records of their cases and experience, a log of discussions and unfamiliar conditions, reflective learning on a smaller number of cases, further reading, written summaries of key conditions or areas of care and workplace based assessments, and discuss with the trainer and their appraiser as part of their annual performance review.

Theoretical training

This may 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
- E-learning for health RCOphth approved modules
- Access to .wet lab to practice the technique on an artificial eye with saline.

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
- Reflective practice.

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.

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.

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
- Draping of the patient if draping used
- Insertion of the speculum if used
- Use of injection device e.g. Invitrea if used

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.

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 six months or 100 cases, the HCP should undertake an audit, document reflective practice and undergo a review of their independent practice with a trainer or consultant. Thereafter performance will be assessed as part of the annual performance review.

Appendix 2. Competencies.

For **New Practitioners** who are:

- undertaking intravitreal injection as a new skill or,
- unable to present their manager with proof of continuing competency.

You must complete all relevant training specific to the extended role requirements and then ensure all competencies signed off not only by your trainer, but also by the ophthalmology consultant before you practice independently. You must 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 but have had a gap in service (≥6months).
- Completed training from another provider/trust previously and have proof of continuing competency in the form of a completed and signed recent (within the last two years) competency document.

You must be assessed as competent at the discretion of the supervising consultant ophthalmologist or experienced HCP trainer. This can include:

- HCP observing in clinic
- Open discussion to ensure theoretical competence
- Observed practice
- Case discussion
- Successful completion of 1-2 wpBA's.

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.

{Insert} Name of Trust

Intravitreal injections: Competency checklist - knowledge

Successful completion of this competency will enable the HCP to move onto practical training.

Aims and Objectives	The HCP is able to demonstrate supporting knowledge, understanding underpinning intravitreal injections. In the ophthalmology service
Training Prerequisite	Prior to this assessment the practitioner has successfully completed the following: **Theoretical knowledge via courses, e-learning or local training** **Background reading, learning and theory portfolio produced for intravitreal injections**
Your Responsibility	All staff should ensure they keep their knowledge and skills up to date through local policies, standard operating procedures and guidance. It is the responsibility of the individual to work within their own scope of competence relevant to their job role and follow their professional bodies Code of Conduct.
Employee signature/print name: …….. Assessor signature print name: …… Date: ……..	
Policies, Guidelines and Protocols:	**Date policy read by clinician and initials**
Intravitreal injection non medical policy	
Trust intravitreal/AMD/ophthalmology guideline s	
RCOphth and NICE AMD guidelines	
Infection control policy	
Consent policy	

	Underpinning knowledge and understanding demonstrated for	**Date and assessor initials**
Local clinical policies or guidelines	• AMD/intravitreal/ophthalmology guidelines and policy • Infection control policy • Consent policy • Mental capacity policy • List other relevant trust policies	
National policies and guidelines	• RCOphth and NICE AMD/intravitreal guidelines •	

Knowledge specific to injection practice	Demonstrates knowledge of: • Anatomy and physiology of the eye and the retina • Classification of macular disease • OCT images (relevant to macular disease) • Infection control and intravitreal injections • Pharmacology (to include all drugs administered during injection visits • Latest clinical information on treatment and treatment delivery and up to date evidence underpinning this practice • Risks and benefits of treatment and how to counsel and consent patients for intravitreal injections • Set up (drugs, equipment, patient preparation) • Process of giving intravitreal injection, including the practicalities and placement of injections • Recognition of complications and what actions to take	
Professionalism	• Demonstrates a working knowledge of own responsibilities and accountability in relation to current policies and procedures as well as national standards of professionalism such as HCPC, BIOS, GOC and NMC standards. • Demonstrates an in depth understanding of their duty to maintain professional and ethical standards of confidentiality • Risk and legal issues around extended role development • How to audit HCP practice • Reflective practice	
Performance Criteria	**Date of assessment and assessor initials**	
WpBA undertaken and passed		
WpBA for undertaken and passed		

{Insert} Name of Trust

Record of supervised practice: observation/preparation/injection*

Ward / Department ……Name ……

Date	Pt record Number	Comments	Signature of practitioner	Signature of Supervisor

***delete as appropriate, only use one sheet for each type of supervised task**

{Insert} Name of Trust

Record of independent intravitreal injections

Ward / Department ……Name …….

Date	Pt record Number	Comments	Signature of practitioner	Signature of Supervisor* record if supervised or observed

{Insert} Name of Trust

Intravitreal injecting – Workplace based assessment

Brief description of case:		
Expectations:	**Achieved** (or not applicable)	**Not Achieved**
Prepares room and equipment: • Checks room and equipment is clean and suitable • Ensures all equipment present and suitable • Ensures all drugs are present and not expired		
Checks **notes** • Checks notes and ensures completed consent, clinical notes with up to date examination, no contraindications or concerns, drug prescribed • Ensures correct drug available		
Correct **counselling**, advice, risk, benefits, information provision, consenting		
Correct **management plan**		
Patient preparation and comfort • Identifies patient, checks allergies, checks medical history changes • Checks patient understands procedure and can explain procedure • Undertakes consent if relevant • Positions patient • Ensure patient comfort and advice how to say if not comfortable • Completes miniWHo checklist and marks eye		
Uses appropriate **equipment and** understands the preparation for injection • Assembles equipment and drugs as required • Cleans trolley if not done • Perform hand hygiene • Draws up and prepares drug as required • Opens any pack, syringes and needles, drops and arranges appropriately. • Dons sterile gloves • Instils anaesthetic • Instils iodine • Cleans skin (if appropriate)		
Delivers injection • Apply drape or lash tape if used and inserts speculum • Or inserts injection device carefully under upper, then lower, eyelid. • Marks site • Administer the injections • Remove injection needle • Delivers pressure to prevent bleeding. • Dispose of needle in appropriate sharp bin • Disposes of drug appropriately.		
Able to identify **successful/unsuccessful injection** • Minimum discomfort to the patient (during and after procedure). • No pain • No significant bleeding/bruising		

• Clear injection site no vitreous wick • Patient calm • Patient can detect hand movement vision • Seeks medical care if issues.		
Safe **discharge** • Check IOP if required according to protocol • Provide and advise on any prescription • Check and organise next appointment date • Advice on symptoms of concern and contact if problems		
Documentation Complete documentation correctly side, sites, drug, drug amount, batch number, name etc and any GP letter		

Areas of particularly good practice:	Areas for improvement:
Discussion:	
Actions: **Outcome: Pass/ Fail**	

{Insert} Name of Trust

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:	
Has completed knowledge competency sign off:	
Has observed 20 injection pathways	
Has undertaken 20 supervised preparations	
Has undertaken 30/50 supervised injections	
Has successfully undertaken 2 wpBA for preparation and injections	
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: ……	

Appendix 3. 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 4 Guidance on the measurement of Intra Ocular Pressure (IOP) following Intravitreal injection of anti-VEGF medication for macular disease.

Loading doses: Following injection numbers 1, 2, 3 the IOP should be measured pre and post injection to see if patient is prone to pressure rises.

After loading doses have been administered, the patient's IOP should be measured every 6 months in the clinic unless the practitioner feels that more frequent IOP measurement is indicated. Reasons for this must be discussed with the supervising doctor and documented in the patient's health records

Patients with glaucoma or identified as at risk for raised IOP after injections by the ophthalmology:
Glaucoma patients or other patients at high risk of raised IOP or IOP-related harm require IOP measurement pre and post injection every visit.

{Insert} Name of Trust

Appendix 5 SOP

Standard Operating Procedure

Title Administration of Intravitreal Injections of anti-VEGF medication for macular disease by non medical health care professionals

Department: Ophthalmology

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

Version: X.X
Approved: *x.x.20xx*
R*atified: *x.x.20xx

*X*Clinical Unit or Department:	
Name of author(s)	
Name of responsible individual	
Approved by:	
Ratified by :	
Date issued:	
Review date	
CQC relevant domains	
Target audience:	Nursing, orthoptists, optometrists, ophthalmologists, ophthalmology managers

Version	Date Issued	Brief Summary of Change	Author

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 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

Also note the exemptions of administrating Ozurdex injections

- *OZURDEX should not be used in patients with any infection in or around the eyes*
- *OZURDEX should not be used in patients with glaucoma that has progressed to a cup-to-disc ratio of greater than 0.8.*
- *OZURDEX should not be used if the patient has a posterior lens capsule that is torn or ruptured.*
- *OZURDEX should not be used in patients with AC IOLs or Aphakic patients*

- 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% and Cetrimide 0.1%) 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

- Disposable plastic apron
- 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.
- Ensure that the patient knows how to communicate if they are suffering any discomfort during the procedure e.g. asking HCP to pause procedure.
- Open pack:
  - The assisting practitioner must decontaminate hands prior to opening out the pack
  - 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 and a disposable plastic apron.
- 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 Tisept solution (Chlorhexidine gluconate 0.015% and Cetrimide 0.1%).
- Apply sterile drape over patient's eye (in units which drape) or use and large-blade lid speculum +/- lash tape if used
- Insert lid speculum OR insert injection device
- Instil additional drop of 0.4% oxybuprocaine or promymetacainas outlined in PGD
- Mark the injection site by measuring 4.0mm from limbus for phakic eyes and 3.5mm from the limbus in pseudophakic eyes if not using injection device.
- Disinfect the bung on the medicine vial with an alcohol steret, allow it to dry prior to inserting the needle and then drawn up your medication.

- Administer drug by injection at marked site.
- Establish that patient can see hand movements (to ensure no significant change in vision).
- Remove eyelid speculum and skin drape / injection device and wash off iodine from skin with sterile saline solution
- Remove used AMD pack and ensure that the needle and any other sharps are disposed of directly in to the sharps container.
- Used sterile gloves, surgical mask and plastic apron 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
- Designated nurse to check patient's IOP post procedure as required (See Appendix 4 of policy)
- 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 Documentation

- 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 amount of the drug injected, batch number, expiry date, the eye injected date, time, name, signature and designation .
- 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.

4.8 Drugs Used for Procedure

4.8.1 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

4.8.2 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

4.8.3 Povidone Iodine 5% Eye Drops
Legal status: Prescription only medicine. Must be prescribed by a doctor as this is unlicensed

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.

4.8.4 Anti-VEGF medication
This may be Lucentis (Ranibizumab) or Eylea (Aflibercept).
4.8.5 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.

4.8.6 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.

4.8.7 Carmellose Sodium 0.5% 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 four times a day or as needed

Side Effects

Eye irritation

Contraindications

Pregnant or lactating women

Children under 16 years of age

Patient refuses consent

4.9 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 if no doctor on site

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. If the IOP is not controlled and if there is not a doctor on site, the patient should be transported via an ambulance to a site where a doctor is available. 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 and urgent blue light patient transport arranged to the relevant site if pressure has not decreased and vision resolved

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. Approval

This SOP is part of the HCP policy and was approved by the insert committee name committee and ratified by the committee name.

6. 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 and highlighted at insert name of meetings or other methods.
This SOP will be published on the intranet site.

7, 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.

Previously approved versions of this SOP will be removed from the intranet by the insert details of archiving

9. Monitoring compliance with this SOP

Monitoring requirement	Monitoring frequency	Monitoring lead	Monitoring reported to…
This SOP will be reviewed by the authors annually to ensure that its content remains valid and in date	History	SOP Author	Service meeting review
Adverse events- incident reporting	Ongoing	Risk Team Retinal consultants	Clinical lead

10 Related Documents

Insert any related trust documents

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 7 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 • Insert any others here or amend the above •
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.

{Insert} Name of Trust

Initial Risk Score i.e. with existing controls in place	Consequence (1-5)		
	Likelihood (1–5)		
	Risk Score (1 – 25)		
Actions to reduce the risk to an acceptable level			
Description of actions	Cost	Responsibility (Job title)	Completion Date
Register risk on DATIX (for all risks > 3) if appropriate	nil		
Existence of Policy complaint with NICE and College guidance			
HCP to follow professional codes of conduct and guidance			
Trainers and trainees given enough time in job plan to train and learn			
Clear detailed training programme and competency recording led by retinal consultants.			
Regular audit of practice and log books			
Doctor on site at all times OR immediate access to named doctor for advice and pathway to send patient			
HCPs trained and competent to diagnose and/or provide immediate treatment for complications			
Insert details of any staffing number or availability adaptations or other mitigations			
Maximum number of patients on HCP at 15			
Target Risk Score i.e. after **full** implementation of action plan	Consequence (1-5)		
	Likelihood (1–5)		
	Risk Score (1 – 25)		
	Date for completion		

Assessment undertaken by: Name		Job title	
Lead:			
Date of assessment		Date of next review	

{Insert} Name of Trust