# Clinical practice pack for non-medical practitioners: Administration of Intravitreal Injections for Macular Disease

## Document 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:** Final  
**Approved:** X.X.20XX  
**Ratified:** X.X.20XX

<table>
<thead>
<tr>
<th>Clinical Unit or Department:</th>
<th>Name of author(s)</th>
<th>Name of responsible individual</th>
<th>Approved by:</th>
<th>Ratified by:</th>
<th>Date issued:</th>
<th>Review date</th>
<th>CQC relevant domains</th>
<th>Target audience:</th>
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<tr>
<th>Version</th>
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<th>Brief Summary of Change</th>
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UKOA Intravitreal injection non-medical practice pack OCT 2019. FINAL
Clinical practice pack for non-medical practitioners.

UKOA clinical practice packs are based on already developed documents used in hospital trusts and health boards across the UK for advanced practice and extended roles for health care professionals (HCP), combined with expert consensus views from UKOA professional members.

They are **not** designed to be used without any change but are designed to be a starting point for hospitals and professionals to create their own documents to support HCPs in this role. These packs should be reviewed, edited and changed as required to fit the provider’s and professionals’ particular service requirements and the organisation’s processes. Areas which are particularly likely to need consideration as to local needs are in grey text.

Queries, comments or feedback to the UKOA on this document are very welcome.

Authors:

Mary Freeman, Consultant Nurse, Sheffield
Robin Hamilton, Consultant Ophthalmology, Moorfields Eye Hospital
Adam Mapani, Lead Intravitreal Nurse, Moorfields Eye Hospital
Melanie Hingorani, Consultant Moorfields, Chair UKOA
UKOA Multidisciplinary Group

Please delete this page before use in trusts and health boards.
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. There is a growing need for greater diversity of knowledge and skills within the ophthalmology workforce in order to cope with significantly rising demand for eye care. This 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/EyesWise and Getting it Right First Time (GIRFT). The development of allied and non-medical health professionals to deliver more multidisciplinary care is a key objective of the NHS long-term plan and interim people plan.

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.

3. Scope
This policy applies to all hospital 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 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
{Insert} Name of Trust

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 at band 5 level may commence training for an extended role in intravitreal injection clinics and progress to higher banding on completion of their training.

4.0 Duties and responsibilities

4.1 Practitioners Advanced/extended practice HCP responsibilities

HCP’s undertaking the training are responsible for:

- Compliance with hospital policies
- Engaging actively with the training
- Keeping up to date
- Keeping accurate training records
- Ensuring they act within their sphere of competence
- Completing accurately the relevant parts of the medical records
- Following Standard operating Procedures (SOPs)
- Reporting adverse events and safety concerns to their supervisor, consultant or their line manager.

Once signed off as competent to practice, the HCP is required to:

- keep a record of their competency sign off
- undertake regular clinical update sessions or CPD on medical retinal conditions and intravitreal injections
- regularly audit their patient records and care
- maintain and update their portfolio
- review these as part of their annual appraisal / individual performance review.

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

It is the trainer’s responsibility to 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.

Appropriate delegated trainers include:

- HCP with more than 2 years’ experience as a intravitreal injecting advanced practitioner
- A fellow or ST 6 and above ophthalmic trainee
- SAS doctor experienced in intravitreal injecting.

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However the consultant retains responsibility for the training and sign off of the HCP before they begin independent practice.

The trainer will:
- Examine the HCP to ensure she/he has the knowledge base required
- Provide adequate time for the HCP to observe care and to subsequently supervise and assess the HCP’s knowledge, skills and procedural technique.

The consultant will arrange that they or another suitably qualified ophthalmologist are available to support the HCP during clinics whilst training and also once qualified. The doctor should either be present on site or by phone with a pathway in place for the patient to see a doctor urgently with the appropriate safe timescale if required once the HCP has undertaken any initial urgent or unplanned treatment.

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

4.3 Manager’s responsibilities
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 hospital policy, HCPs have suitable indemnity for this scope of practice.

5.0 Training
HCPs can only commence training after approval by their line manager.

5.1 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
• Fundus examination with a slit lamp lens
• Understanding of retinal disease and ophthalmic procedures and ophthalmic/systemic disease which may be relevant to intravitreal injections
• Experience in advanced practice in ophthalmology clinics.
• Undertaking invasive procedures
• Consent ing.

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 advanced 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 intravitreal advanced practice training. Staff wishing to undertake consent for intravitreal injections must complete the hospital consent training requirements

5.2 Intravitreal advanced practice training
The HCP will gain the appropriate theoretical knowledge of anatomy and physiology, assessment and examination, disease, investigations and management from a combination of the following:
• Attending local, regional or national courses
• Informal in house training or sessions with the consultant or other trainer
• Additional reading around the subject area in books and journals
• Reading of local and national retinal and injecting care guidelines
• E-learning modules e.g. RCOphth medical retina modules on E-Learning for Health.

The HCP will maintain a portfolio of the above. As they progress, the portfolio will incorporate 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 (symptoms, assessment and signs, investigations, management, red flags, complications see appendix) and workplace based assessments, and this will be discussed with the trainer as part of their competency assessment. Training may be undertaken as part of the AMD RCOphth OCCCF competency framework.

The HCP will need to know:
• 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

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Process of giving intravitreal injection, including the practicalities
Recognition of complications and what actions to take
Reflective practice.

The HCP will gain **practical knowledge** as follows:

- This period will usually last at least 3 months
- 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 and signed off on the log sheet, the next stage can begin.
- 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 sheet, the trainer will decide if the practitioner can proceed to the next stage or whether further practice is required
- 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 to be recorded on the logbook sheets before the trainer will assess whether the practitioner is safe to proceed independently. This will be done through at least 2 successfully completed work based assessments.

  **Workplace based assessment may be carried out by the trainer, however where possible it would be best practice for the assessor to be different from the trainer. These are pre-identified cases in which the assessor observes the HCP from start to completion of two cases. The assessment should analyse all aspects of assessment, preparation, and treatment including soft skills such as communication as well as technical skills such as injection technique.**

- If 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.

Note if the HCP wishes to consent for the procedure, they must additionally have completed the hospital consent training requirements.

The HCP will maintain a portfolio of their learning, experience and performance, and will add to this as they progress. The portfolio will contain:

- Evidence of theoretical training, courses, teaching and CPD
- Records of their cases and experience
- A log of discussions and unfamiliar conditions seen
- Reflective learning on a small number of cases
- Further reading e.g. books, review articles, research papers
- Written summaries of key conditions (symptoms, assessment and signs, investigations, management, red flags, complications
- Workplace based assessments
- Competency sign off documents.

At sign off, the HCP will discuss the knowledge and experience gained and the workplace based assessments in their portfolio with their consultant / trainer. The consultant / trainer will, if satisfied, record the HCP as competent using the final competency checklist form.

Once signed off:

- The HCP must practice in accordance with the protocol.
- 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 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
- The HCP will undergo an informal review of practice with their trainer and/or the consultant ophthalmologist after three to six months of independent practice.
- The HCP will undergo review of practice and the portfolio as part of their annual appraisal / individual performance review.

5.3 Sign off for current or experienced practitioners

For Current Practitioners who have:

- Completed the HCP training programme or equivalent previously and are currently practicing in this area (eg. specialist injecting extended-role optometrists)
- 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 or HCP trainer. This should include:

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Open discussion of relevant diseases to ensure theoretical competence
- Successful completion of at least 1 workplace based assessment;
- Creation / update and review of a portfolio
- Sign off of the competency assessment form.

For staff who have had a Gap in Service (≥6months):
Competence can be reassessed at the discretion of the supervising consultant or trainer; this may involve some of the following:
- Case discussion
- Observed practice
- The HCP observing in clinic and lasers
- Work placed based assessment

The portfolio must be updated and reviewed and a competency assessment form must be signed off.

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 infectional 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

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• 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 document was developed by the medical retina 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 document was approved by the insert name of committee and ratified by the insert name of committee.

10.0 Dissemination and implementation
This document 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 document will be published on the hospital intranet site.

11.0 Review and revision arrangements
This document will be reviewed on a 3 year basis by the Document 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 information of document storage and removal old versions/archiving

13.0 Monitoring compliance with this document

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<th>Element to be Monitored</th>
<th>Staff conducting</th>
<th>Tool for Monitoring</th>
<th>Frequency</th>
<th>Responsible Individual/Group/Committee for review of results</th>
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<td>Lead Retinal Consultant</td>
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<td>For the first 100 patients then annually</td>
<td>Lead Consultant and Lead Nurse</td>
<td>Retinal Team</td>
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14.0 Supporting References / Evidence Base

National documents


RCOphth Quality Standards for medical retina services.


NICE guidance for AMD. https://www.nice.org.uk/guidance/ng82

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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

Add other relevant trust document names
Appendix 1: Intravitreal Injections: Competency checklist

Successful completion of this competency will enable the HCP to undertake independent intravitreal injecting.

Aims and Objectives

The HCP is able to demonstrate supporting knowledge, understanding and competency in 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:

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<td>RCOphth and NICE AMD guidelines</td>
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<td>Consent policy</td>
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**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

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Record of supervised practice: observation/preparation/injection

Name, designation and signature

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<th>Signature of Supervisor</th>
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Record of independent intravitreal injections

Name, designation and signature

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<th>Date</th>
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<th>Comments</th>
<th>Signature of practitioner</th>
<th>Signature of Supervisor* record if supervised or observed</th>
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Intravitreal injecting – Workplace based assessment

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

- 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
<table>
<thead>
<tr>
<th>Name:</th>
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<tbody>
<tr>
<td>Designation:</td>
</tr>
<tr>
<td>Ward / Department:</td>
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</table>

**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 wp8A 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:**

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### Appendix 2. Reflective practice template

**Name, designation and signature**

<table>
<thead>
<tr>
<th>O/S/I*</th>
<th>Date</th>
<th>Brief description of episode and comments or reflections by practitioner</th>
<th>Trainer/assessor comments and constructive feedback</th>
<th>HCP sign</th>
<th>Trainer print and sign</th>
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<tbody>
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</table>
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.
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
Ratified: X.x.20xx

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<tbody>
<tr>
<td>Name of author(s)</td>
</tr>
<tr>
<td>Name of responsible individual</td>
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<tr>
<td>Approved by:</td>
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<tr>
<td>Ratified by:</td>
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<tr>
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</tr>
<tr>
<td>Review date</td>
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<tr>
<td>CQC relevant domains</td>
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<td>Target audience:</td>
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<table>
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<th>Brief Summary of Change</th>
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UKOA Intravitreal injection non-medical practice pack OCT 2019. FINAL
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
Name of Trust

- 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 wheelchair.
- 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% Povidone 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.

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Name of Trust

- 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 into 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

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• Burning and stinging
• Transient blurring of vision on instillation
• Acute, intense and diffused corneal epithelial keratitis
• Iritis with descemetis
• 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 into 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:

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• 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

<table>
<thead>
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<th>Monitoring lead</th>
<th>Monitoring reported to…</th>
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<td>History</td>
<td>SOP Author</td>
<td>Service meeting review</td>
</tr>
<tr>
<td>Adverse events - incident reporting</td>
<td>Ongoing</td>
<td>Risk Team Retinal consultants</td>
<td>Clinical lead</td>
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10 Related Documents
Insert any related trust documents

Glossary

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<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Cataract</td>
<td>Opacity of the lens</td>
</tr>
<tr>
<td>Endophthalmitis</td>
<td>An inflammatory condition of the intraocular cavities</td>
</tr>
<tr>
<td>Intravitreal Injection</td>
<td>The route of administration of a drug inside the eye</td>
</tr>
<tr>
<td>Retinal detachment</td>
<td>Separation of the neurosensory retina from the pigment epithelium</td>
</tr>
<tr>
<td>Hypopyon</td>
<td>Pus in the anterior chamber</td>
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<tr>
<td>Oedema</td>
<td>Swelling</td>
</tr>
<tr>
<td>Intraocular eye pressure</td>
<td>The fluid pressure inside the eye</td>
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<tr>
<td>Anti-VEGF medication</td>
<td>Anti-vascular endothelial growth factor</td>
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# Appendix 6 Risk Assessment

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<th>Ophthalmology</th>
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<td><strong>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.</strong></td>
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<tr>
<td>Intravitreal injections are associated possible complications such as :-</td>
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<tr>
<td>• Infection (endophthalmitis)</td>
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<tr>
<td>• Retinal Detachment</td>
<td></td>
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<tr>
<td>• Cataract</td>
<td></td>
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<tr>
<td>• Raised intra ocular pressure</td>
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<tr>
<td>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.</td>
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<tr>
<td>Risks associated with a non medical HCP carrying out this procedure include:-</td>
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<tr>
<td>• Perception by patient/family that complication was due to injection not performed by doctor</td>
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</tr>
<tr>
<td>• Failure of HCP to detect complication</td>
<td></td>
</tr>
<tr>
<td>• Having the experience and ability to manage complications which may occur;</td>
<td></td>
</tr>
<tr>
<td>• Non enough staff or time to undergo training</td>
<td></td>
</tr>
<tr>
<td>• Not enough senior staff or consultant time to supervise and sign off training</td>
<td></td>
</tr>
<tr>
<td>• Capacity issues creating pressure to have excessive numbers on injection clinics</td>
<td></td>
</tr>
<tr>
<td>• Insert any others here or amend the above</td>
<td></td>
</tr>
<tr>
<td>• The guidelines from the Royal College of Ophthalmologists are followed..</td>
<td></td>
</tr>
<tr>
<td>• Compliance with Consent Policy</td>
<td></td>
</tr>
<tr>
<td>• Aseptic technique used.</td>
<td></td>
</tr>
<tr>
<td>• The procedure would be done in a clean environment compliant with national guidance.</td>
<td></td>
</tr>
<tr>
<td>• Medical consultant leadership and supervision of service.</td>
<td></td>
</tr>
<tr>
<td>• An Incident Reporting process in place for adverse events.</td>
<td></td>
</tr>
<tr>
<td>• Records are kept of procedures carried out and complications noted.</td>
<td></td>
</tr>
<tr>
<td>• An audit of the service is regularly carried out.</td>
<td></td>
</tr>
<tr>
<td>• Regular patient feedback is sought.</td>
<td></td>
</tr>
<tr>
<td>• Process in place for reporting cases of endophthalmitis.</td>
<td></td>
</tr>
<tr>
<td>• Governance structures in place where issues / concerns can be raised.</td>
<td></td>
</tr>
<tr>
<td>• A complaints system is in place where these are reviewed and lessons are learned and shared.</td>
<td></td>
</tr>
<tr>
<td>• Regular follow up of patients are performed post treatment in the eye clinic.</td>
<td></td>
</tr>
</tbody>
</table>
## Name of Trust

<table>
<thead>
<tr>
<th>Initial Risk Score i.e. with existing controls in place</th>
<th>Consequence (1-5)</th>
<th>Likelihood (1-5)</th>
<th>Risk Score (1 – 25)</th>
</tr>
</thead>
</table>

### Actions to reduce the risk to an acceptable level

<table>
<thead>
<tr>
<th>Description of actions</th>
<th>Cost</th>
<th>Responsibility (Job title)</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Register risk on <a href="#">DATIX</a> (for all risks &gt; 3) if appropriate</td>
<td>nil</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Existence of Policy complaint with NICE and College guidance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCP to follow professional codes of conduct and guidance</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Trainers and trainees given enough time in job plan to train and learn</td>
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<tr>
<td>Clear detailed training programme and competency recording led by retinal consultants.</td>
<td></td>
<td></td>
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<tr>
<td>Regular audit of practice and log books</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doctor on site at all times OR immediate access to named doctor for advice and pathway to send patient</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCPs trained and competent to diagnose and/or provide immediate treatment for complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insert details of any staffing number or availability adaptations or other mitigations</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Maximum number of patients on HCP at 15

<table>
<thead>
<tr>
<th>Target Risk Score i.e. after full implementation of action plan</th>
<th>Consequence (1-5)</th>
<th>Likelihood (1-5)</th>
<th>Risk Score (1 – 25)</th>
</tr>
</thead>
</table>

### Assessment undertaken by:

<table>
<thead>
<tr>
<th>Name</th>
<th>Job title</th>
</tr>
</thead>
</table>

### Lead:

<table>
<thead>
<tr>
<th>Date of assessment</th>
<th>Date of next review</th>
</tr>
</thead>
</table>

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