Royal Cornwall Hospitals
NHS Trust

LocSSIP Guideline for Intravitreal Injections Therapy

V2.0

August 2024

Summary

This guideline outlines the process to be followed for the safe administration of Intravitreal injection therapy.

It applies to all patients undergoing intravitreal injection therapy for Wet Macular degeneration (WARM) within the RCH Ophthalmic service.

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

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1. Introduction

1.1. The Royal Cornwall Hospital Trust is committed to providing high quality patient centred care and a safe environment for all patients undergoing any invasive procedure.

1.2. This guideline has been produced in line with National Safety Standards for Invasive Procedures (NatSSIPs).

1.3. The document will provide the standards expected for the safe administration of Intravitreal Injection Therapy (IVT) by both medical and nursing staff at any of the sites within the Royal Cornwall Hospital Trust.

1.4. The aim of this document is to outline the recommended practice for managing patients from the time they enter the procedure room until they leave.

1.5. This guideline should be read in conjunction with the following documents:

- The Eye unit practice standards clinical guideline.
- The Eye Unit surgical practice standards clinical guideline.
- RCHT Five steps to safer surgery.
- RCHT CONSENT POLICY.
- Intravitreal Injection therapy (The Royal College of Ophthalmologists) May 2018 (revised August 2018).
- RCHT Infection Prevention and Control policy.

1.6. This version supersedes any previous versions of this document.

2. Background

This guideline is intended to build on the principles outlined in the RCH eye unit practice standards and to reflect the standard expected when carrying out an invasive procedure within the RCH out-patient setting.

3. Definitions

3.1. Definitions of abbreviations used in this document:

EEC - Emergency Eye Clinic.

IVT - Intravitreal Injection Therapy.

NatSSIPs - National Safety Standards for Invasive Procedures.

HCP - Health care professional.

PPE – Personal Protective Equipment.

4. Governance and Audit

The Ophthalmic governance lead will monitor the implementation of this guideline and commission a bi-annual audit of adherence. See Section 3 and Appendix 5.

5. Workforce

5.1. All patients having IVT should have a clearly documented management plan and be under the care of a named consultant ophthalmologist.

5.2. administration can be delegated by a named consultant to an appropriately trained non-medical health care professional (HCP).

5.3. The training must be fully approved locally by a trust governance committee.

5.4. Non-medical delivery of care will be supported by a local policy, with recording of training and competency measures and regular clinical audit of processes and outcomes.

5.5. The HCP giving the injection must always have immediate access to advice from an Ophthalmologist while giving injections.

5.6. In most clinics an appropriately trained clinician will be on site but if this is not the case (i.e. West Cornwall Hospital clinic) and there is a very urgent complication that requires escalation then, the HCP should:

- First contact the medical retina team at RCH.
- If none of the team can be contacted then the HCP should contact the Emergency Eye Clinic (EEC) at RCH, where appropriate action will be agreed.

5.7. For injection lists, there should be adequate nursing or healthcare assistant support to help with the procedure and to provide patient assistance.

5.8. Minimum staffing levels for each injection list is:

- 1x Registered Nurse trained in Medical Retina.

5.9. 2 x Allied Healthcare Professionals.

5.10. All members of staff involved in the delivery of LocSSIP Guideline for Intravitreal Injections Therapy must undertake local departmental specialty competency training alongside the RCHT invasive procedures training as outlined in the RCHT Safe Surgery and Interventional Procedures Policy which includes:

- WHO Checklist training (eLearning via ESR)
- Patient Safety (level 1) essentials (eLearning via ESR)
- Human Factors Training (classroom or virtual delivery booked via ESR)

6. Scheduling and List Management

These procedures will be performed as necessary when safe to do so in an appropriate environment.

7. Handovers and Information Transfer

7.1. Team Pre-Brief

This should take place at the start of the clinical session, before calling the first patient into the **procedure** room. It is a verbal discussion, led by a designated member of the team and recorded on the 'Ophthalmology injector WHO briefing form' and should be stored electronically. "Silent cockpit" principles should be observed, and all elements of the form must be considered and recorded against. These elements include.

- Staffing levels and any other relevant personnel-related factors.
- List Order and Timings.
- Available equipment.
- A brief discussion of each surgical case and the planned procedures reviewed.
- Any specific equipment or patient-related requirements should be discussed.
- All staff given the opportunity to raise any concerns of any nature.
- Any changes or alterations to the list order should be agreed and a new list printed once these have been confirmed by the team.
- The list should not proceed until any concerns have been addressed to the satisfaction of the whole team.

7.2. Pre IVT-Information

Prior to treatment all patients will have been fully counselled to include:

- Treatment options available.
- Risks.
- Benefits.
- Potential frequency and time-period.
- Who is likely to give the injection – Doctor or Allied Health Professional (AHP).
- A relevant information leaflet, in an appropriate accessible format will be provided.
- Serious and additional risks of specific products of IVT will be explained.

7.3. Consent

- Valid patient consent will be obtained prior to the first IVT procedure and will be valid for the duration of the treatment.

- As consent is taken in advance it is essential that prior to every injection the patient must be asked about any changes to their medical condition and consent should be briefly re-confirmed. These checks should be documented in the patients record.

- Consent should be obtained specifically for the AHP to give the injection, if appropriate.

7.4. Pre-Injection Preparation

General Pre-Injection Preparation

- Procedures may be carried out in a theatre, but routinely in a suitable room in an out-patient setting, with full sterile precautions.

- In an out-patient setting, a dedicated clean treatment room, with a hand-basin is required and must be approved by RCH Infection Prevention and Control Team.

- The room must be set up to include a patient couch for the procedure and staff must have access to both sides of the head of the couch.

- Ventilation must provide 10 air exchanges per hour (minimum). Where air exchanges are below 10 per hour then a local risk assessment must be undertaken and approved by RCH Infection Prevention and Control Team.

- Resuscitation facilities should be available in all settings where IVT is administered.

- All staff administering IVT must have in date Basic Life Support training and competency.

7.5. Pre-Injection Assessments and Checks

- All patients must have a visual acuity (VA) measurement (preferably LogMAR), of both eyes whether they are currently receiving injections to one or both eyes.

- If VA in either eye is reduced by more than 30 letters – the patient must be reviewed by a Doctor in EEC or clinic, prior to injection – this must be same day as attending for their injection.

- An evaluation at each appointment must be completed, to identify complications from previous injections and to review the appropriateness of the subsequent treatment recommended.

- As necessary, pupil dilatation should be checked, and a bio-microscopic examination may be undertaken prior to injection.

- Assessment for the presence of active eyelid and / or ocular surface disease which might increase the risk of endophthalmitis.
- Intraocular pressure should be measured and documented prior to first injection.
    - If IOP is above 30 mm Hg, do not give injection.
    - If IOP is above 22 mm Hg, please give G. Iopidine stat prior to the injection.
- Injection procedure **must be withheld** if there is any of the following are evident:
    - Current evidence of conjunctivitis (red eye, discharge) Patient has had a MI / heart attack (withheld injection for 3 months).
    - Patient has had a stroke (withhold injection for 1 month.)
    - Current ongoing infection ie, Ear, UTI, leg ulcers, dental abscess.
    - Previous history of loss of vision after injection. Patient should be treated in doctor-led clinics.
    - If VA in the injection eye reduced more than 30 letters - ask doctor to review (same day in EEC or clinic) before proceeding.
    - We normally do not administer IVT injections to our patients who report active infection on Nurse-led injection clinic. However, as per the criteria, if the patient has already started a course of antibiotics 48 hours prior to their appointment and patients are asymptomatic on attending for their therapy (ie.No evidence of fever/inflammation/pain), then the patient can continue with the IVT therapy. This is also the same if patients are having long-term antibiotics for conditions such UTI or COPD.
    - Increase IOP over 30 mm Hg.
- The 5 steps to safer surgery WHO for Intravitreal Injection safety checklist must be completed.

7.6. Hand Decontamination and PPE

- It is essential that appropriate hand decontamination is completed, and correct PPE worn.
- The operator must undergo surgical disinfection of their hands using either 7.5% Iodinated Povidone or 4% Chlorohexidine Gluconate surgical scrub and water or alcohol gel prior to administering IVT.

- Minimum PPE for Intravitreal injection Therapy must include:
  - Sterile latex-free surgical gloves.
  - Eye protection.
  - Non-sterile plastic apron.

7.7. Equipment Required

- Single-use topical mydriatic to achieve adequate pupillary dilation.
- Single-use topical anesthetic.
- Single-use topical povidone-iodine 5% solution or Chlorhexidine 0.1% aqueous solution
- Single use topical antibiotic.
- Single use topical eye lubricant.
- Tissues.
- An IVT surgical pack.
- 50:50 of 0.9% Sodium Chloride (NaCl) and 10% Povidone Iodine antiseptic solution or Chlorohexidine Gluconate 20% solution.
- Sterile water.
- Sterile latex-free surgical gloves.
- Small bore 30-gauge injection needles for intravitreal injection of non-colloidal clear solutions and 27 gauge for particulate preparations. Needle length should be between 12 to 15mm.

8. Procedural Verification and Site Marking

8.1. The operator must review the patients' electronic records, specifically checking:

- The planned injection procedure.
- Consent completed.
- Site marked matches site booked on electronic system.
- Specific IVT Drug to be administered.
- Once satisfied with the intended site and procedure, this should be confirmed with the patient and the assisting staff member. The patient should be asked to confirm the site.

8.2. If there is any doubt in the operator's mind as to the correct eye for injection, then they should stop the proceedings and check with the responsible consultant before proceeding.

8.3. Marking of Injection Site.

- The appropriate eye for injection should be marked above the intended eye on the forehead.
- The skin marking should be the First Letter of the drug to be administered, this supports the triangulation of safety checks – correct eye, correct drug, and correct skin mark.

9. Safety Briefing

If any issues have arisen or problems such as equipment difficulties, a debriefing is to be undertaken and recorded by the responsible practitioner in the patient note, and a Datix completed if appropriate.

10. Sign In

All members of the team must introduce themselves and observe "silent cockpit," whilst a designated member of the team performs the WHO "sign in." This includes:

- Patient identity check.
- Site to be operated on.
- Consent form checked.
- Site marked.
- Patient allergies.

11. Time Out

This stage of the WHO checklist should be performed **after** verification of the surgical site, marking and consent. A "silent cockpit" must be observed, and a designated member of the team asks the relevant questions out loud. Provided the team and patient all agree then the procedure can be performed. The practitioner administering the IVT injection should read the consent form and confirm that it has been completed in full and confirm the procedure with the IVT assistant, as part of "time out".

11.1. Injection **Administration**

- The patient should be instructed to direct gaze away from the site of injection.
- The entry site of the needle should be 3.5-4.0mm.
- The needle / syringe pouch should only be opened immediately prior to injection.

If the medication is pre-loaded, then the protective cap should be removed from the pre-prepared syringe – WITHOUT twisting or turning and then eject the air bubble at the top of the syringe. Care should be taken to not expel any medication. Do not drawback the plunger.

If the medication is not pre-loading the medication must be prepared aseptically immediately before single usage. Withdrawal is as per manufacturer's instructions. Excess medication in the syringe should be expelled through the injection needle – this is essential to ensure that the needle hub is fully primed with no air therein.

- The conjunctiva may be displaced using either a sterile cotton-tip applicator or forceps, this will ensure that there is no direct route between vitreous and ocular surface remains before or after the injection.

- Using the bud or forceps to steady the eye (if necessary), the needle is inserted perpendicular through sclera with the tip aimed toward the center of the globe (avoids any potential contact with the posterior lens). For wide bore injections entry into the pars plana may be recommended to avoid leakage.

- Inject appropriate volume (Max. 0.1ml) of medication slowly and carefully, avoiding contact between needle shaft and lid margin.

- Remove the needle carefully, it may be useful to use a sterile cotton tipped applicator to avoid reflux and steady the eye.

- Dispose of syringe and needle into the appropriate sharps bin.

- Immediately post injection, check the eye for light perception; ensuring that the central retinal artery is perfused.

- If bilateral injections are planned at the same session, each eye must be prepared separately. A different batch of instruments and medication must be used for each eye.

11.2. Post-Injection

- Instill single use antibiotic eye drop.

- Instill single use eye lubricant.

- Small volume injections (0.05ml) are unlikely to cause significant rise in intraocular pressure (IOP), post injection IOP should be carried out on any patient with a high risk of clinical concern.

- TO NOTE: Where injections volumes are administered greater than 0.05ml, or where patients have pain or reduced vision immediately post injection, there is an increased risk of longer term raised IOP in patients having regular IVT. IOP should be monitored according to the risk.

- Should high IOP occur that results in non-perfusion of the central retinal artery, indicated by no perception of light (NPL), appropriate immediate care is indicated:

- I**n a Nurse-Led Clinic**

  - The nurse should perform ocular massage for 2-3 minutes and then re-check patient's vision.

  - If no improvement then the nurse should check patient's IOP, then contact the doctor from medical retina or EEC for further advise and management.

  - 'If still no improvement, repeat the above procedure for 2 more minutes and recheck the vision.

  - If still no improvement, give oral Diamox 250 mg stat and contact the Eye doctor in the same hospital.

  - If no ophthalmology doctor available (i.e. in WCH), contact Eye Casualty and dial 999 for urgent transfer to Treliske sit.

- **In a Doctor-Led Clinic lead**

  - The Doctor should perform ocular massage and administer Acetazolamide. If all measures fail, the doctor should perform anterior chamber paracentesis.

    - Following IVT clear printed instruction leaflet to be provided to the patient, which includes 24/7 emergency contact details

    - Patients are informed of common symptoms immediately post injection (e.g. blurring and floaters).

    - Patients are instructed to Contact the RCH Emergency Eye Casualty clinic in working hours and out of hours they should contact 111 or the Urgent Care Services, if they have any symptoms indicating a serious complication.

11.3. Clinical Record Post-Injection

- The following should be recorded onto the current electronic platform:

  - All clinical details relating to the current episode of IVT.

  - Batch number of drugs injected.

  - Proposed follow up arrangements (this will depend on drug administered and patient's condition).

12. Prosthesis Verification

Not applicable for this procedure

13. Prevention of Retained Foreign Objects

Not applicable for this procedure

14. Sign Out

14.1. This final part of the WHO checklist should be performed by a designated member of the team at the end of the procedure, before the patient or anyone leaves the procedure room. “Silent cockpit” must be observed.

14.2. Sign out includes:

- Verbal confirmation that the name and site of the procedure have been accurately recorded.
- Any variations to standard discharge.

15. Debriefing

This should take place at end of the session before any member of staff leaves the procedure room and recorded on the relevant specialty WHO briefing form. “Silent cockpit” should be observed. All members of the procedure room team should be involved in the discussion, which aims to identify factors which went well during the session and any safety or efficiency issues which came to light which might require attention.

16. Dissemination and Implementation

16.1. The document is available on the document library. Significant updates will be communicated via Trust wide email.

16.2. Implementation of the policy will be via Trust wide communication and supported by appropriate training for the relevant members of staff.

17. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Intravitreal Injection Procedure Room.
Lead	CNS Lead for IVT, Eye Unit Sister, Ophthalmology Governance Lead.
Tool	Trust wide WHO Audit Tool.
Frequency	Monthly Audit.
Reporting arrangements	WHO auditing feeds into the Safer Surgery Committee, that informs the Care Group.
Acting on recommendations and Lead(s)	CNS Lead for IVT, Eye Unit Sister, Ophthalmology Governance Lead. Required actions will be identified and completed in a specified timeframe.

Information Category	Detail of process and methodology for monitoring compliance
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within appropriate. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

18. Updating and Review

18.1. The document review process is managed via the document library. Document review will be every three years unless best practice dictates otherwise. The author remains responsible for the policy document review. Should they no longer work in the organisation or in the relevant practice area then an appropriate practitioner will be nominated to undertake the document review by the designed director.

18.2. Revision activity will be recorded in the versions control table to ensure robust document control measures are maintained.

19. Equality and Diversity

19.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion and Human Rights Policy' or the Equality and Diversity website.

19.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	LocSSIP Guideline for Intravitreal Injections Therapy V2.0
This document replaces (exact title of previous version):	Local Safety Standards (LocSSIPs) for Intravitreal Injection Therapy Clinical Guideline V1.0.
Date Issued/Approved:	May 2024.
Date Valid From:	August 2024.
Date Valid To:	August 2027.
Directorate/Department responsible (author/owner):	Clinical Matron for Specialist surgery, CNS lead for IVT, WARM Clinical Lead.
Contact details:	ellen.daquioag@nhs.net a.patwardhan@nhs.net
Brief summary of contents:	Intravitreal Injection Procedure Room Standards.
Suggested Keywords:	Intravitreal Injection Therapy, standards, LocSSIPs.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer.
Approval route for consultation and ratification:	Ophthalmology Specialty Tri, Ophthalmology Business and Governance members, Care Group Governance Meeting, Care Board Meeting.
General Manager confirming approval processes:	Roz Davies, General Manager, Specialist Services and Surgery.
Name of Governance Lead confirming approval by specialty and care group management meetings:	Maria Lane, Governance Manager, Specialist Services and Surgery.
Links to key external standards:	None.
Related Documents:	Eye Unit Practice Standards Clinical guideline V1.0.
Training Need Identified?	No.

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical/Ophthalmology.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
May 2021.	V1.0.	Initial Issue.	Paulette Hunkin Clinical Matron for Specialist Surgery. Ellen Daquioag CNS lead for IVT. Ashish Patwardhan Eye Unit Clinical lead.
August 2024.	V2.0.	Partial Update 2.5.2.4 section added 'Current ongoing infection i.e., Ear, UTI, leg ulcers, dental abscess'.	Clinical Matron for Specialist surgery Paulette Hunkin, CNS lead for IVT Ellen Daquioag, Eye Unit clinical lead Ashish Patwardhan.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy/policy/proposal/service function to be assessed:	Local Safety Standards (LocSSIPs) for Intravitreal Injection Therapy V2.0.
Directorate and service area:	Ophthalmology, Specialist Services and Surgery.
Is this a new or existing Policy?	Existing.
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Paulette Hunkin – Clinical Matron for Specialist Surgery.
Contact details:	01872 253416.

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	This guideline is written for members of the RCHT Ophthalmology Eye unit who are responsible for managing patients undergoing Intravitreal Injection Therapy as an out-patient.
2. Policy Objectives	To Standardise Practice.
3. Policy Intended Outcomes	All staff to reflect the Policy Standards in Practice.
4. How will you measure each outcome?	WHO Audit.
5. Who is intended to benefit from the policy?	Staff and Patients.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/visitors: No • Local groups/system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/groups:** Safer Surgery Group.
6c. What was the outcome of the consultation?	Approved.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No**.**

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Paulette Hunkin – Clinical Matron for Specialist Surgery.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis