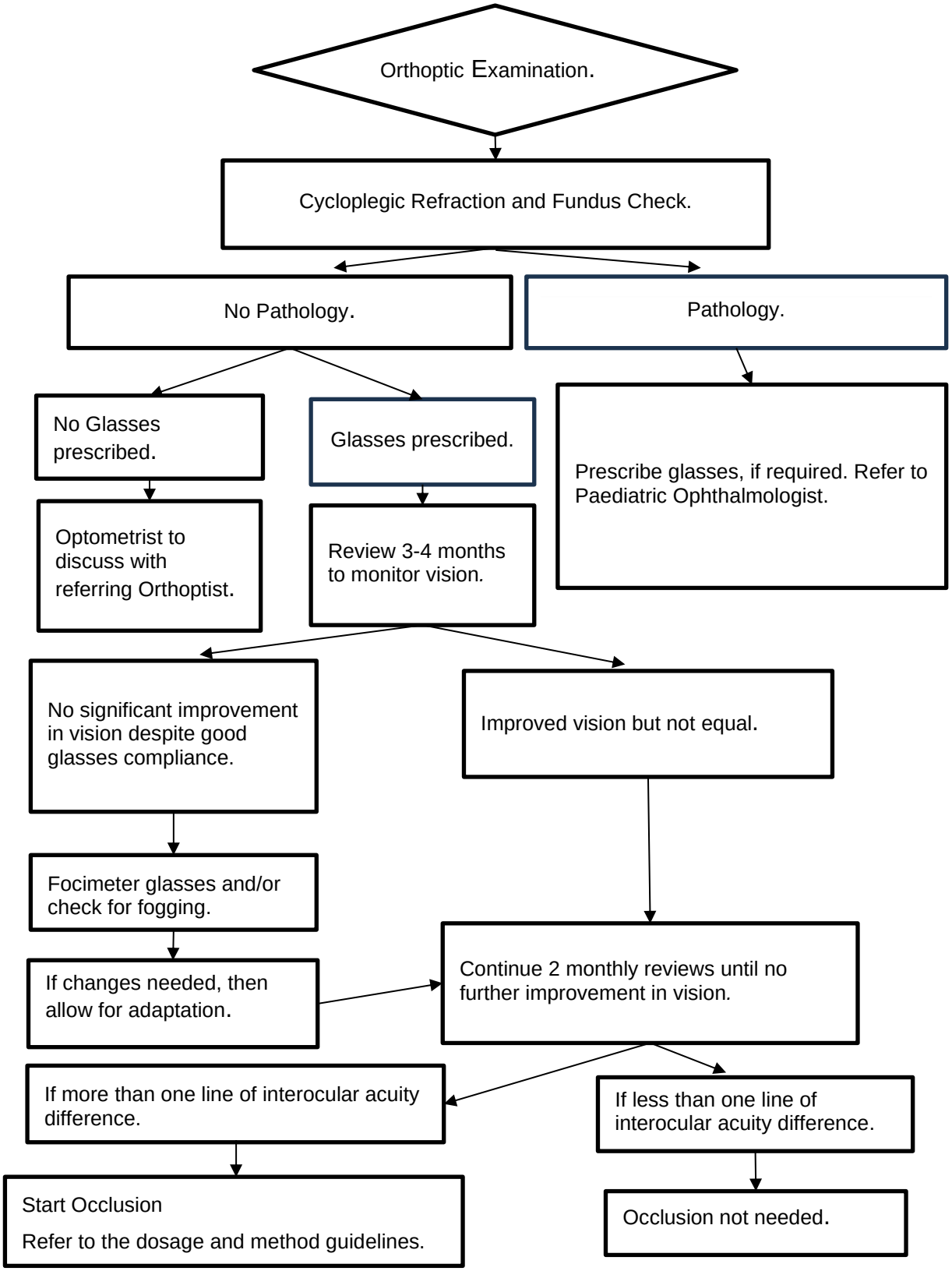
Royal Cornwall Hospitals
NHS Trust

Management of Amblyopia in Children under the care of the Orthoptic Service Clinical Guideline

V1.0

August 2024

Summary - Amblyopia Guidelines



The aim of this document is to guide Orthoptists involved by **outlining** a consistent management plan for children with amblyopia.

This is a guideline and does not override clinical judgement in individual cases.

1. Aim/Purpose of this Guideline

1.1. This guideline has been developed in line with evidence-based research to provide a consistent approach to the assessment and management of children undergoing occlusion therapy for amblyopia.

1.2. The orthoptist may decide, within their professional clinical judgement, to deviate from the following guidelines so that treatment may be tailored to the specific needs of an individual patient.

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.

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2. The Guidance

Amblyopia is defined as a reduction in visual acuity which remains after refractive error has been corrected and after the removal of any pathology obstructing vision[1].

The overall aim of amblyopia management is to achieve maximum visual acuity in the affected eye when it is below the age-related normal range.

2.1. Principal Method

2.1.1. All patients must have a pupil check and a cycloplegic refraction, fundus and media examination prior to the commencement of the amblyopia treatment. This must be repeated at least annually after commencement of treatment but should be rechecked earlier if concerned [2].

2.1.2. A full orthoptic investigation, including IMAR visual acuity (VA) cover test and assessment of binocular functions should be undertaken wherever possible.

2.1.3. In those children where acuity cannot be quantified, e.g. pre-verbal infants or children with additional needs, the presence of a unilateral strabismus and the quality of the fixation in the non-fixing eye should be used as an indicator of the presence of amblyopia [2]. A functional vision

assessment (e.g. Bradford Vision Box [3]) should be recorded in these cases to allow comparability during treatment.

2.1.4. In cases of stimulus deprivation amblyopia (SDA) the causative factor e.g. cataract may need to be dealt with before amblyopia treatment can be initiated. However, lamellar or partial cataracts, or partial corneal opacities are often managed conservatively by accurate refraction and occlusion alone [4.5].

2.1.5. Patients/Parents can be offered the choice of conventional occlusion or atropine penalisation as a first-line treatment (if the child meets the inclusion criteria for atropine penalisation within this guideline).

2.1.6. Where there are concerns regarding an increase in the amplitude of nystagmus on occlusion, optical and pharmacological penalisation may be most appropriate [6].

2.1.7. Improvement in visual acuity following refractive correction (spectacle adaptation) should be allowed prior to amblyopia treatment. This may take up to 16 to22[7-9] weeks in cases of ametropia or anisometropia. However, this may not be suitable for all patients and clinical judgement may override this decision and amblyopia therapy started sooner.

2.1.8. Patients with eccentric fixation would typically initially be treated with conventional occlusion. Inverse occlusion can be considered when appropriate [10].

2.1.9. Although there is less robust evidence of the effectiveness of occlusion in cases of stimulus deprivation amblyopia, patients with this usually need more aggressive occlusion regardless of age therefore will not follow the dosage guideline in this document. Despite rigorous occlusion being recognised as necessary, this should be balanced with increased chances of developing binocularity with less rigorous dosages [4].

2.2. Conventional Occlusion

2.2.1 Conventional occlusion is the use of a patch to cover the better-seeing eye. If glasses are worn the patch should be worn under the glasses.

2.2.2 Normally a dose of 2 to 6 hours per day is effective and the treatment effect is greatest within the first 400 hours or 6 months of occlusion wear [11,12].

2.2.3 Most children need between 150 and 250 hours of amblyopia treatment for a 2 line gain, with older children needing higher dosages [13,14].

2.2.4 The addition of near activities to a portion of the occlusion time does not significantly improve visual outcomes [15].

2.2.4 Recommended doses for occlusion.

- <0.3 llogMAR Maximum of 2 hours per day [2].
- 0.3-0.6 llogMAR 2-4 hours per day [2].

- >0.6 llogMAR maximum 6 hours per day [2].

2.2.5 If the VA fails to improve by at least 4 letters/pictures (on a crowded test) after each visit, the occlusion dose may need to be increased.

2.2.6 Patients should be reviewed every 6-8 weeks after commencement of occlusion.

2.2.7 Older patients (>6 years) with no/poor fusion should be evaluated with the Sbisa bar/ Bagolini filter bar prior and during occlusion.

2.2.8 There is no conclusive evidence to define the age at which testing should commence or the specific density of suppression that indicates treatment should be stopped.

2.2.9 Assessment and interpretation of risk of intractable diplopia remains unclear, but in UK clinical practice, assessment most commonly commences from age 6 and filter 7 is most often used as the point at which treatment is stopped [16].

2.2.10 If diplopia occurs, then treatment should be stopped immediately. It should be noted that the Bagolini filter bar (filters 0-16) and Sbisa bar (filters 1-17) are not equivalent. Monitoring of suppression should be undertaken using the same bar at each visit [17].

2.2.11 Young strabismic patients who demonstrate constant uniocular preference may need part-time total occlusion in the absence of linear/ multiple optotype VA. Patients that have ptosis where one pupil is occluded at times, may need part-time total occlusion to prevent the development of amblyopia. It is important to note the visual behaviour responses and document these:

- Assess fixation and record (central/ steady/ maintained/ alternation/ eccentric/ nil demonstrable).
- Visual interest – use of Bradford Vision Box.
- Alternation to a 10-dioptre vertical prism.
- Record presence and clinical features of nystagmus.

2.2.12 Continue occlusion until no significant improvement despite increasing the occlusion dosage over 2 visits or if vision equalizes. Significant improvement is defined as 0.100 IMAR or better. The same VA test needs to be repeated for consistency in addition to progressing to a harder test.

Once optimum VA has been achieved, occlusion should be tapered to reduce the risk or recurrence.

2.2.13 Continued failure to improve VA (or deterioration of VA), despite good compliance, within 4-6 months of starting treatment should prompt re-refraction, repeated fundus/media examination and possible further investigations.

2.2.14 Parents or Guardians will be given the departmental patient information leaflet 'Poor vision in one eye (Amblyopia)' RCHT 319, which includes the instructions for patching, name of the orthoptist and departmental contact details.

2.3. Atropine Occlusion

2.3.1. Penalisation with 1% atropine has been shown to be as effective as occlusion in moderate (0.3-0.7 IMAR) and severe (0.8-1.30 IMAR) amblyopia in children aged 3-7[18-24].

2.3.2. Atropine can only be prescribed by a doctor or non-medical prescriber. Orthoptist can supply and administer atropine according to either an agreed Trust Patient Group Direction (PGD) or following the completion of a Health and Care Professions Council (HCPC) approved training program.

2.3.3. Weekend only atropine is comparable in effect to daily instillation [22,23]. The combination of atropine and optical penalization should be considered for use in patients with severe amblyopia (0.8 -1.3) [25].

This should be done following discussion with the consultant responsible for the patient's care as there is an increased risk of reverse amblyopia when combining atropine penalization with optical penalization. See appendix I for optical penalisation table for guidance on reducing or increasing prescription.

2.3.4. Patients/Parents or Guardians should be given the choice of total occlusion or atropine penalisation (if the child meets the inclusion criteria within this guideline) as a first line treatment.

2.3.5. Inclusion Criteria:

- Must be able to perform a pin-hole VA assessment.
- Greater than 3 years old.
- Good attendance.
- Able to do a LogMAR crowded vision test.
- Up to date refraction.
- Normal level of VA in the non-amblyopic eye.
- Has been in full time glasses for a minimum of 16-18 weeks to allow refractive adaptation.
- Patient had a refraction, fundus & media examination within the past 12 months.

2.3.6. Unsuitability for Atropine Penalization.

- Aphakic/ pseudophakic eyes.

- Patients with Down's syndrome.
- Patients with a history of cardiac disorders.
- Raised intraocular pressure, glaucoma, narrow angles.
- Known hypersensitivity to any component of the atropine preparation.

2.3.7. Commencing Treatment:

- Atropine 1% w/v preservative- free eyedrops in unit dose vials (Minims) can be prescribed by an Ophthalmologist, non-medical prescriber, supplied under a PGD or Human Medicines Regulations (2012) exemption. The patient's GP can also be asked to prescribe this medication via letter but is under no obligation to do so.
- The instructions for atropine should specify that it should be administered to the non-amblyopic eye once daily on Saturdays and Sundays only, as this has been shown to be the most effective treatment regime[23].
- The patient's GP should be informed in writing when atropine is commenced.
- All parents/guardians should be informed of possible side effects, which can include pupil enlargement, transient eye stinging on instilling drops, sensitivity to light, possible swap of fixation with regards to strabismus. Other possible side effects include dryness of mouth and skin, flushing of the face or irritability. If any of these side effects occur parents/guardian should be advised to contact the Orthoptic Department.
- Systemic absorption (and therefore side-effects) can be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the atropine eye drop.
- Parents or guardians should be issued with the leaflet 'Information for parents about the treatment of Amblyopia using Atropine' RCHT 713 with a copy of the leaflet for the parent's school if appropriate. The leaflet should specific which eye is being treated and the required frequency for administering atropine.

  Please refer to the current edition of the British National Formulary (BNF- https://bnf.nice.org.uk or the Summary of Product Characteristics (SPC- www.medicines.org.uk) for a full list of possible interactions. Advice should be sought from an appropriate healthcare professional if required.

2.3.8. Documentation

The following should be documented on Medisight:

- Name and strength of drug, eg. Atropine 1% w/v.

- Pharmaceutical form (i.e. preservative-free eyedrops in unit dose vials).

- Dose, which eye, and frequency of administration.

- Advice regarding the potential side effects

- Any suspected adverse drug reaction must be recorded on MediSIGHT and in any other hospital patient records with a letter to the GP. Incidents should be reported via Datix as per local reporting policy. Any reaction (allergy or sensitivity) should also be recorded on the Wellsky EPMA system. Atropine 1% w/v eyedrops are an established medicine with a long history of use. Therefore only suspected reactions that are serious, medically significant, or result in harm need to be reported to the MHRA via the Yellow Card scheme. These reactions should be reported even if it is not certain that it was caused by atropine, or if the reaction is well recognized, or if other medicines.

  Refer to the current version of the “Allergies or Sensitivities to Medicines Procedure”, available in the intranet Document Library, for further guidance.

2.3.9. Duration of treatment.

- Patients should be reviewed every 6-8 weeks.

- Atropine treatment can be repeated for up to 3 cycles of 6-8 weeks in normal circumstances.

- After 3 cycles, the patient should have a period without atropine for 1 month. During this break, they should try to undertake 2 hours of total occlusion to reduce the risk of amblyopia recurrence.

- If the patient’s VA has improved with atropine penalisation but has not reached optimum VA, then a further 3 cycles can be repeated.

- Continue with atropine until no significant improvement over 2 visits or vision equalizes. Significant improvement is defined as 0.100 LogMAR or better (using the same VA test).

- Fixation swap does not need to occur for atropine therapy to be effective.

- Testing at each visit.

- Check compliance with treatment and any side effects.

- Check pupil of the non-amblyopic eye is fully dilated, and the pupil of the amblyopic eye is not dilated.

- Test near and distance VA of each eye.

- Test the visual acuity of the non-amblyopic eye with a pin-hole.

- If strabismus is present, note which eye is fixing for near and distance.
- A full orthoptic assessment at each follow-up appointment will not be appropriate or required whilst the patient is on atropine.
- Indications to accept VA and cease treatment.
- Less than 1 line interocular difference in VA.
- No significant improvement in VA on 2 consecutive visits despite good compliance.
- Distance VA in normal eye reduces to worse than 0.3 (assessed with pin-hole also). For those children on optical penalisation, the VA should be tested with the child's full glasses prescription.
- Allergic reaction or hypersensitivity to atropine.
- Manifest deviation develops which was not previously present.
- Onset of binocular diplopia.

2.4. References

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3. Monitoring Compliance and Effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored.	Start VA level and final VA level.
Lead.	Faye Gibson.
Tool.	Data collection from Medisoft.
Frequency.	Every 2 years.
Reporting arrangements.	Head Orthoptist to receive the report. Report to be discussed at the Orthoptic staff meeting.
Acting on. recommendations and Lead(s).	Faye Gibson.
Change in practice and lessons to be shared.	Discussion at the orthoptic staff meeting. Any changes required will be identified and actioned.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

4.2. Equality Impact Assessment

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

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Management of Amblyopia in Children under the Care of the Orthoptic Service Clinical Guideline V1.0
This document replaces (exact title of previous version):	New document
Date Issued/Approved:	May 2024
Date Valid From:	August 2024
Date Valid To:	August 2027
Directorate/Department responsible (author/owner):	Faye Gibson, Head Orthoptist
Contact details:	01872 253287
Brief summary of contents:	This guideline sets out the process for the Orthoptist to use when managing amblyopia in children under the care of the Orthoptic Service.
Suggested Keywords:	Amblyopia, Occlusion, Atropine, Orthoptic.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Orthoptic Staff Meeting
Manager confirming approval processes:	Roz Davies
Name of Governance Lead confirming consultation and ratification:	Maria Lane
Links to key external standards:	British Orthoptic Society Amblyopia guidelines.
Related Documents:	Orthoptists Medical Exemptions. Clinical Guideline (V1, May 2023). Medicines Policy, Chapters 2 (V5, June 2023), 3 (V4, May 2022), 4 (V4, May 2023), 5 (V6, June 2023), 6 (V4, Sep 2023).

Information Category	Detailed Information
	Developing, Implementing and Reviewing Patient Group Directions Policy (V5, Mar 22).
Training Need Identified?	No.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet.
Document Library Folder/Sub Folder:	Orthoptic / Orthoptics.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
August 2024	V1.0	Initial issue.	Faye Gibson, Head Orthoptist.

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:	Management of Amblyopia in Children under the Care of the Orthoptic Service Clinical Guideline V1.0
Directorate and service area:	Ophthalmology, Specialist Surgery.
Is this a new or existing Policy?	New.
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Faye Gibson Head Orthoptist.
Contact details:	01872 253287.

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)	Orthoptists and Optometrists working within Royal Cornwall Hospital NHS Trust.
2. Policy Objectives	To provide guidelines to the Orthoptists and Optometrists working within Royal Cornwall Hospital NHS Trust when managing children with amblyopia.
3. Policy Intended Outcomes	To Achieve maximum visual acuity in the affected eye when it is below the age-related normal range.
4. How will you measure each outcome?	Audit of outcomes.
5. Who is intended to benefit from the policy?	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:** The British and Irish Orthoptic Society and PEDIG study group were both used and referenced during the writing of this document.
6c. What was the outcome of the consultation?	The workforce was happy with the document as it was felt it was in line with national guidance and studies.
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	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
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: Faye Gibson Head Orthoptist.

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

Appendix 3. Optical Penalisation

See the table below as a guide for the amount to penalise the lens in the non-amblyopic eye.

LogMAR VA. (Amblyopic eye).	Snellen Equivalent.	Reduce plus/ increase minus in the non-amblyopic eye by:
0.3.	6/12.	-2.00.
0.4.	6/15.	-2.50.
0.5.	6/19.	-3.00.
0.6.	6/24.	-3.50.
0.7.	6/30.	-4.00.
0.8.	6/38.	-4.50.
0.9.	6/48.	-5.00.
1.0.	6/60.	-5.50.
<1.0.	<6/60.	-7.00.

Appendix 4. Atropine Occlusion Checklist

Please ensure the following checklist is completed and filed in the patient record:

Documented fundus, media, disc.	
Refractive adaptation completed.	
Management options discussed with parent/guardian.	
Risks & benefits of atropine discussed.	
Patient information leaflet provided.	
Greater than 3 years old.	
Crowded logMAR vision achieved.	
Near VA recorded.	
Not on antihistamines.	
Not on ADHD/ASD medication (including tricylics).	
Not a poor attender.	
No ocular pathology other than amblyopia.	
No communication barrier.	
No cardiac problems (including children with Down's syndrome).	
No glaucoma.	
Review appointment made.	
GP informed by letter re: commencement of atropine treatment	