

Thames Valley & Wessex Operational Delivery Networks (Hosted by University Hospital Southampton NHS Foundation Trust)

Thames Valley & Wessex Retinopathy of Screening and Treatment Guidance

Description	Network clinical guideline		
Target audience	Thames Valley and Wessex ODN Neonatal Network		
Related documents / policies	UK screening of Retinopathy of Prematurity Guidelines RCPCH March 2022		
	Retinopathy of prematurity Examinati	on recording fron	n
	Screening for retinopathy of prematurity: Information for parents and carers		
	UK Treating Retinopathy of Prematurity in the UK Clinical Guidelines Summary RCOphth March 2022		
	Treatment for Retinopathy of Prematurity: Information Leaflet for Parents		
	TV & Wessex Retinopathy of Prematurity Care Pathway January 2023		
Author(s)	Please see individual documents for Author and version		
Policy sponsor	No		
Is there any non- compliance with NICE guidance?	No		
First Consultation	Thames Valley and Wessex ODN NICU Medical Leads		
Second Consultation	Thames Valley and Wessex ODN Governance Forum		
Approval committee		Approval date	
Thames Valley and We	essex ODN Governance Forum		
TVW ODN reference	Version	Publication date	Next review due
	, and the second	March 2023	March 2026

1 Version control

Date	Consultation / Comments	Version created	Page	Key changes
Nov 22		Please see individual documents for Author and version		New guidance based on RCOpth 2022 guidance.
Jan 23	P McEwan			No changes made

2	Index	
1	Version control	1
2	Index	2
3	Executive Summary / Introduction	3
4	Scope and purpose	3
5	Details of guideline to be followed	4
6	Roles and responsibilities	15
	Communication and training plans	
8	Process for monitoring compliance	15
9	Document review	15

3 Executive Summary / Introduction

Retinopathy of prematurity (ROP) is one of the few causes of childhood visual disability which is largely preventable. Many extremely preterm infants will develop some degree of ROP, although the majority of cases this never progresses beyond mild disease which resolves spontaneously without treatment. A small proportion develop potentially severe ROP, which can be detected through retinal screening. If untreated, severe disease can result in visual impairment, consequently all infants at risk of sight- threatening ROP (ST-ROP) should be screened.

All babies less than 31 weeks (i.e., up to and including 30weeks and 6 days) or birth weight less than 1501gms should have ROP screening (gestational threshold change since RCPCH 2008 Guidance). The RCPCH Guidance 2022 includes evidence-based recommendations and good practise points for ROP screening.

All neonatal units within TV & Wessex Neonatal ODN should comply with the RCPCH and RCOphth Guidance 2022 for the screening and treatment of Retinopathy of prematurity.

4 Scope and purpose

The guideline applies to all neonatal units covered by Thames Valley and Wessex Neonatal Operational Delivery Network. This includes the following hospitals:

Thames Valley		
TRUST	Hospital	Designation
Oxford University Hospitals NHS Foundation Trust	- John Radcliffe Hospital, Oxford	NICU Cardiac
Buckinghamshire Healthcare NHS Trust	 Stoke Mandeville Hospital, Aylesbury 	LNU
Frimley Health NHS Foundation Trust	- Wexham Park Hospital, Slough	LNU
Milton Keynes University Hospital NHS Foundation Trust	- Milton Keynes General Hospital	LNU
Royal Berkshire NHS Foundation Trust	- Reading	LNU

Wessex		
TRUST	Hospital	Designation
University Hospital Southampton NHS	- Princess Anne Hospital	NICU
Foundation Trust		Cardiac
		Surgical
Portsmouth Hospitals University NHS Trust	- Queen Alexandra Hospital	NICU
Dorset County Hospital NHS Foundation	- Dorset County Hospital,	SCU
Trust	Dorchester	
Hampshire Hospitals NHS Foundation Trust	- Basingstoke and North	LNU
	Hampshire Hospital	
Hampshire Hospitals NHS Foundation Trust	- Royal Hampshire County	LNU
	Hospital, Winchester	
Isle of Wight NHS Trust	- St Mary's Hospital	SCU
University Hospitals Dorset NHS Foundation	- Poole Hospital	LNU
Trust	·	
Salisbury NHS Foundation Trust	- Salisbury District Hospital	LNU
University Hospitals Sussex NHS Foundation	- St Richard's Hospital,	SCU
Trust	Chichester	

5 Details of guideline to be followed Summary of ROP Screening Guideline recommendations

ROP Screening Recommendations

Screening criteria

All infants less than 31 weeks' gestational age (up to and including 30 weeks and 6 days) OR less than 1501g birth weight should be examined to screen for the presence of ROP (one criterion to be met for inclusion). [Evidence level: High (Grade: B)]

Time of first examination

For infants born before 31+0 weeks' gestational age, the first ROP examination should be performed between 31+0 and 31+6 weeks' postmenstrual age, or at 4 completed weeks' postnatal age (28–34 days), whichever is later. [Evidence level: High (Grade: B)]

For infants born at and after 31+0 weeks' gestational age with birthweight less than 1501g, the first ROP examination should be performed at 36 weeks' postmenstrual age or 4 completed weeks' postnatal age (28–34 days), whichever is sooner. [Evidence level: High (Grade: B)]

When to consider referral

Refer infants for treatment when the following criteria have been met:

- · zone I with plus disease and with any stage of ROP
- zone I without plus disease but with stage 3 ROP
- zone II with plus disease and with stage 3 ROP (zone II stage 2 with plus disease is borderline for treatment and may be treated or re-examined in one week or less).
 (note: plus disease should be present in at least two quadrants).

Discuss with treating ophthalmologist when referral-warranted ROP is present:

- · any pre-plus or plus disease in two or more quadrants in any zone
- · any zone I or posterior zone II disease
- · any stage 3 disease in any zone. [Evidence level: High (Grade: B)]

Subsequent examinations

After the first ROP screening, if treatment is not required, re-examine at least weekly when:

- · the vessels end in zone I or posterior zone II with or without any stage of ROP; OR
- · there is any plus or pre-plus disease; OR
- · there is stage 3 ROP in zone II or III

until the criteria for treatment or two weekly examination or termination of screening have been reached. [Evidence level: High (Grade: B)]

After the first ROP screening, if treatment is not required and criteria for weekly examination are not present, re-examine at least every two weeks when:

- · the vessels end in mid or anterior zone II or in zone III; AND
- · there is no plus or pre-plus disease; AND
- · there is no ROP or stage 1 or 2 ROP

until the criteria for treatment or weekly examination or termination of screening have been reached. [Evidence level: High (Grade: B)]

Delayed examination

Only in rare circumstances, consider postponing the examination or performing a limited examination without an eyelid speculum and scleral indentor, when an infant is exceptionally unstable.

- This decision should be made at consultant/senior level, and the rationale, its
 implications, and next steps in screening should be discussed with parents/carers and
 recorded in the infant's medical records.
- Reschedule the next examination no later than one week beyond the intended examination. [Evidence level: Low (Grade: D)]

Termination of screening

For infants without ROP, continue examinations until vascularisation has extended into zone III – as a guide, this is unlikely to have occurred prior to 36 completed weeks' postmenstrual age (36+0 weeks). If there is uncertainty about the zone, consider a further confirmatory examination two weeks later. [Evidence level: High (Grade: B)]

For infants with any stage ROP, consider discontinuing screening examinations when any of the following characteristics of regression are detected on at least two consecutive examinations:

- · partial resolution progressing towards complete resolution
- · change in colour of the ridge from salmon pink to white
- · growth of vessels through the demarcation line. [Evidence level: High (Grade: B)]

Preparation for examination

Preparation of the eye

Use a mydriatic combination of phenylephrine 2.5% and cyclopentolate 0.5%. Instil one drop of each drug in two doses, five minutes apart, one hour prior to examination to achieve effective mydriasis in preparation for ROP screening.

Tropicamide 0.5% may be used as an alternative to cyclopentolate 0.5%, noting that it has a shorter duration of action. [Evidence level: High (Grade: B)]

Pain relief

Use proxymetacaine 0.5% or oxybuprocaine 0.4% as topical anaesthesia just prior to examination when an eyelid speculum is to be used. [Evidence level: High (Grade: B)]

Comfort care during examination

Consider using a combination of care techniques to comfort the infant during eye examination, as per local guidance. These may include the use of nesting or swaddling, non-nutritive sucking, administration of expressed breast milk, and/or oral sucrose solution. [Evidence level: Moderate (Grade: B)]

Parents/carers should be offered the opportunity to be present during the examination and to facilitate comfort care. [Evidence level: Moderate (Grade: B)]

Considerations during examination

Keep ROP screening examinations as short as possible as they have short-term effects on an infant's blood pressure, heart rate and respiratory function.

For examinations undertaken as an outpatient, ensure appropriate neonatal resuscitation equipment and a health professional trained in paediatric basic life support are available in the examination area.

If infants are unstable during an outpatient examination a period of observation is necessary before discharge home.

Discuss with parents/carers the results of the screening, the next steps and that their baby may be unsettled after the examination. [Evidence level: Moderate (Grade: D)]

Screening examination techniques

Binocular indirect ophthalmoscopy (BIO) and wide-field digital retinal imaging (WFDRI) can be used as examination techniques to screen for ROP.

As examination of the peripheral retina may be limited using WFDRI, either the final screening examination should be performed using BIO or screening should be continued for a longer period until the criteria for termination have been met (WFDRI only). [Evidence level: Moderate (Grade: B)]

Use of eyelid speculum and scleral indentor

The periphery of the retina should be adequately examined. When using binocular indirect ophthalmoscopy, this may be facilitated using an eyelid speculum and scleral indentor. Be aware the indentor is used to gently rotate the eye, not to indent the sclera. [Evidence level: High (Grade: B)]

Equipment sterilisation

Sterilise all reusable instruments and disinfect lenses as per hospital policy and manufacturers' guidance or use single-use instruments. [Evidence level: High (Grade: B)]

Recording the results of a screening examination

Record ophthalmological findings of each ROP examination in the infant's medical records, including detailed information on:

- · extent of vascularisation by zone in the absence of ROP
- · zone and stage of ROP
- · extent of ROP stage in clock hours
- · presence and extent in quadrants of any pre-plus or plus disease
- · name of the examiner
- · date of the next examination or discharge from screening. [Evidence level: Low (Grade: D)]

Informing parents/carers about screening

Discuss with parents/carers the need for ROP screening and provide parents/carers with access to written information (the Parent/Carer Information Leaflet) with enough time before the examination to allow for questions. [Evidence level: Low (Grade: D)]

Record in the infant's medical records that this information has been given and by whom.

When screening is not complete at the time of discharge, ensure parents/carers are given an outpatient appointment prior to hospital discharge and inform them about the risk of not detecting progression of ROP if appointments are missed.

When screening is complete, ensure parents/carers are informed about the potential for development of refractive errors and/or strabismus later in childhood. [Evidence level: Low (Grade: D)]

Long-term follow-up after screening or treatment

Monitor all infants with treated ROP at a frequency dictated by the clinical condition (see ROP Treatment Guideline). [Evidence level: Low (Grade: D)]

Service Configuration Recommendations

Workforce

Each neonatal Operational Delivery Network (ODN) should ensure, in liaison with local ophthalmology services, that robust arrangements are in place for competent screening and treatment of infants at risk of ROP. Arrangements for ophthalmology cover during planned and unplanned leave should be in place to ensure an uninterrupted service. [GDG consensus (GPP)]

Each neonatal unit should have an identified consultant ophthalmologist with responsibility for screening and deputy/deputies with appropriate knowledge, skill, and competency. [GDG consensus (GPP)]

Each neonatal ODN should a standard operating procedure for arranging safe and timely treatment, either on-site or transfer to another unit when required. [GDG consensus (GPP)]

Protocol

All units providing care for infants at risk of ROP should have a written protocol on ROP screening, treatment and the management of infants who need to be transferred to another neonatal unit for treatment. [GDG consensus (GPP)]

The protocol should use the National Screening and Treatment Guidelines as the foundation for local practice and should include:

- roles and responsibilities of key personnel involved in scheduling ROP first screening examinations and follow-up appointments, in particular for those transferred or discharged from the unit before screening has commenced
- roles and responsibilities of those personnel involved in ROP treatment (including the consultant neonatologist, ROP coordinator and screening/treating ophthalmologist)
- · contact details for key personnel involved in the ROP service
- · record-keeping, use of information leaflets, stores, equipment and its maintenance
- standard operating procedures and audit recommendations for assessment of the quality of service. [GDG consensus (GPP)]

Responsibility for transfers, home discharge and arranging outpatient screening

For infants transferred to another neonatal unit either before ROP screening begins or when screening has been started but not completed, it is the responsibility of the referring neonatal team to ensure that the receiving unit is aware of the need to start or continue ROP screening. [GDG consensus (GPP)]

For infants discharged home before screening is complete, the first follow-up outpatient appointment should be confirmed, and the details of the location and timing provided to parents/carers before hospital discharge. The importance of attending outpatient appointments should be explained and attendance facilitated as appropriate. [GDG consensus (GPP)]

Communications on failure to attend outpatient screening

For missed outpatient appointments, parents/carers should be contacted by telephone and then by letter to rearrange the appointment which should be within one to two weeks, depending on clinical concerns. When necessary, community support should be explored to assist parents/carers in attending appointments. [GDG consensus (GPP)]

Telephone and written communications should be recorded in the infant's medical records. [GDG consensus (GPP)]

Responsibilities for record-keeping for inpatient examination

Neonatal units should keep a record of all infants that require ROP review and the arrangements for their follow-up. [GDG consensus (GPP)]

Screening status and the need for further examinations should be recorded and highlighted in all transfer letters so that screening can continue. [GDG consensus (GPP)]

Recording of the status of ROP should be documented on a form (paper or electronic) that is compatible with the International Classification of ROP and there should be ready access to past records showing the previous status of ROP. [GDG consensus (GPP)]

Facilities and equipment

Provision and maintenance of an appropriate venue and equipment required for the safe delivery of ROP screening (both inpatient and outpatient), including monitoring and resuscitation, is the responsibility of the department in which the activity occurs. [GDG consensus (GPP)]

Ophthalmologists' work commitment

Ophthalmologists undertaking regular ROP screening, and their deputies, should have this work included in their job plan. [GDG consensus (GPP)]

Ophthalmologists' expertise and training

Consultant ophthalmologists who undertake ROP screening must have the appropriate knowledge, skill and competency to perform the examination and be able to identify ROP disease that requires treatment and must ensure that their skills are current and maintained. [GDG consensus (GPP)]

Summary of Treatment of ROP recommendations

The following recommendations and GPPs, with their evidence levels have been made:

What are the indications for treatment of ROP?

Evidence Grade A

Treat infants in whom a screening examination has detected:

- Zone I any stage ROP with plus disease
- Zone I stage 3 ROP without plus disease
- Zone II stage 2 or 3 with plus disease
- A-ROP

Plus disease should be present in at least two quadrants. Vessel changes should be assessed within Zone I. GPP: Zone II stage 2 with Plus ROP, is borderline for treatment and close watching is an acceptable alternative approach.

Closely monitor infants (weekly review and if concerned discuss with the network treating ophthalmologist) in whom a screening examination has detected:

- Zone I stage 1 or 2 without plus disease
- Zone II stage 3 without plus disease

How urgently should treatment for ROP be given?

Evidence Grade B

Infants with A-ROP or zone I stage 3 with plus ROP should be treated as soon as possible and within 48 hours. Infants with zone I stage 1 or 2 ROP with plus disease, zone I stage 3 ROP without plus disease, or zone II stage 2 or 3 with plus disease should be treated within 48-72 hours.

What information should be provided to parents of infants with ROP?

GPP

The treating ophthalmologist should have a consent discussion with the parents/carers of an infant requiring treatment for ROP and should gain informed explicit consent prior to the procedure taking place.

Treating discharged infants

GPP

Infants who require treatment for ROP after discharge from hospital should be admitted to a suitable neonatal or paediatric unit with facilities and experience of caring for infants after neonatal surgery.

How should ROP be treated?

Evidence Grade A

Zone I and Posterior Zone II

Treatment-requiring A-ROP and ROP in zone I should be treated with an intravitreous injection of an anti-VEGF agent. Anti-VEGF agents must NOT be administered if there are any signs of periocular infection.

In the view of the GDG, posterior Zone II (2 disc diameters anterior to the junction of Zone I and Zone II) or any "notch" of ROP that encroaches backwards into Zone I, may behave in a similar way to Zone I and may be treated accordingly.

Zone II (except posterior zone II)

Treatment-requiring ROP in zone II should be treated with transpupillary laser, to produce near-confluent ablation of the entire avascular retina.

Anti-VEGF treatment results in fewer eyes with high myopia, but requires more intensive follow up and carries a higher rate of retreatment. Anti-VEGF agents must NOT be administered if there are any signs of periocular infection.

When should infants treated for ROP be reviewed and what are the indications for retreatment of ROP?

Post-treatment review is important to detect and treat adverse events, monitor disease regression, detect disease reactivation and determine if retreatment is necessary.

Laser

The first examination should take place 5-9 days after treatment and should initially continue weekly to assess for signs of regression or for any signs that re-treatment may be required. From 7-14 days start to consider re-treatment with laser if disease regression is inadequate and untreated retinal areas are identified. Rescue treatment with an anti-VEGF agent should be considered from 14 days if disease regression is inadequate and laser treatment has been optimal.

Anti-VEGF

The first examinations should take place 1-2 days and 5-7 days after treatment to detect adverse effects of treatment. Following partial or complete disease regression, regular examinations should be maintained to detect disease reactivation: weekly for 4 weeks, 2 weekly for a further 12 weeks and then 4-weekly for at least a further 8 weeks (total of 24 weeks) and up to 32 weeks in eyes treated for A-ROP with bevacizumab).

Disease reactivation in the form of plus disease and / or extraretinal new vessels should be treated with transpupillary laser, to produce near-confluent ablation of the entire avascular retina.

Anti-VEGF agents may be used for retreatment but require more intensive follow up and carry a higher rate of further disease reactivation, requiring further retreatment. Anti-VEGF agents differ. The above follow up schedule was used in the RAINBOW trial of ranibizumab. Longer follow up may be needed following bevacizumab (follow up to 65 weeks PMA has been recommended).

GPP



Following initial Anti-VEGF treatment consider EUA / Examination under sedation with possible transpupillary laser to produce near-confluent ablation of the entire avascular retina IF the retina has not fully vascularised (or this is uncertain) AND:

- Regular follow-up is becoming unsustainable for social and / or geographic reasons.
- The growing child's limited cooperation precludes adequate examination of the peripheral retina.
- There is uncertainty about the presence of signs of disease reactivation.

OR:

 During longer term follow-up a significant area of Persistent Avascular Retina is seen or suspected.

What are the indications for vitreo-retinal surgery?

Evidence Grade B

As soon as any significant peripheral retinal traction is detected, the case should be discussed with a specialist paediatric VR surgery centre, with a view to possible transfer for early vitreoretinal surgery.

What skills and training are required for those who treat ROP?

Evidence Grade C

Any ophthalmologist undertaking treatment or making treatment decisions must be skilled in examining premature retinae to identify the type of ROP and which treatment modality is most appropriate for the patient. Ophthalmologists in treating centres should have experience in undertaking both laser and anti-VEGF injection in preterm infants so they can offer the most appropriate treatment for each patient. Some local ophthalmologists may be competent in anti-VEGF injections but will refer for laser therapy. When this expertise is not available within the local unit, formal network arrangements must be in place with good communications for prompt transfer to the treating centre.



RCPCH UK screening of Retinopathy of Prematurity Guidelines Summary of recommendations



RCPCH Screening of retinopathy of prematurity guideline

Retinopathy of prematurity Examination recording from



ROP-examination-record.pdf (rcpch.ac.uk)

<u>Screening for retinopathy of prematurity: Information for parents and carers</u>



UK-screening-retinopathy-prematurity-information-parents-carers.pdf (rcpch.ac.uk)

RCOphth UK Treating Retinopathy of Prematurity in the UK Clinical Guidelines

Executive summary



<u>Treating-Retinopathy-of-Prematurity-in-the-UK-Guideline-Exec-Summary.pdf (rcophth.ac.uk)</u>

RCOphth UK Treatment for Retinopathy of Prematurity: Information Leaflet for Parents



ROP_Information_Leaflet.pdf (rcophth.ac.uk)

Link to the TV & Wessex Retinopathy of Prematurity Care Pathway

ROP Care Pathway_v1.3 (piernetwork.org)

6 Roles and responsibilities

This guideline applies to all clinical staff working within the Thames Valley and Wessex Neonatal ODN. Staff have a responsibility to ensure that they are aware of this guideline and its contents. They should clearly document their rationale if they have not complied with the recommendations detailed in this guideline. It is the responsibility of department managers, consultants, team leaders and education leaders to ensure staff are aware of this guideline.

7 Communication and training plans

The guideline will be displayed on the Thames Valley and Wessex Neonatal ODN website and sent to the relevant Care Group clinical teams. The team leaders will be expected to cascade to all relevant staff groups. All medical, nursing staff caring for newborns should have support and training in implementing the contents of the guideline. In addition, the guidelines will be included in local induction programs for all new staff members.

8 Process for monitoring compliance

The purpose of monitoring is to provide assurance that the agreed approach is being followed. This ensures that we get things right for patients, use resources well and protect our reputation. Our monitoring will therefore be proportionate, achievable and deal with specifics that can be assessed or measured.

Key aspects of this policy will be monitored:

Element to be	RCPCH ROP Guidance
monitored	
Lead (name/job title)	TVW Neonatal ODN
Frequency	3 yearly
Reporting	Updates shared to all Clinical and Nurse Leads to disseminate.
arrangements	

Where monitoring identifies deficiencies, actions plans will be developed to address them.

9 Document review

Guideline to be reviewed after three years or sooner as a result of audit findings or as any changes to practice occurs.