

Evidence Based Guideline for Screening of Retinopathy of Prematurity - Scope

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1. Guidance title

Evidence Based Guideline for Screening of Retinopathy of Prematurity

1.1 Short title

ROP Screening Guideline

2. Background

- a) Retinopathy of prematurity (ROP) is a potentially blinding condition. First described in the 1940's as retrolental fibroplasia, ROP is a condition confined to the immature retinal vascular system (1). The likelihood of developing ROP is related to the stage of vascular development, which in turn relates to the postmenstrual age (or maturity) of the baby. With no effective therapeutic measures, screening was not considered a priority in the UK until the development of an internationally agreed classification for ROP in 1984 (1) and the demonstration of the efficacy of treatment for severe disease (2).
- b) Using Data from the Office of National Statistics of England and Wales and an estimation for Scotland and Northern Ireland there are thought to be approximately 8112 live births < 1500g in the UK (3). Retinopathy of prematurity develops in 60% of infants weighing <1500g at birth and 65% in infants <1250g. Severe ROP is uncommon (4). In countries with high-quality neonatal care, sight-threatening ROP is largely confined to babies with birth weight (BW) <1000g and is very uncommon in babies with BW >1250g (5). Although most extremely preterm babies develop some degree of ROP, severe disease is relatively infrequent; in one multicentre study 66% of babies with BW <1251g developed ROP but only 18% reached stage 3 (using the international classification) and 6% required treatment (6).
- c) The RCPCH National Neonatal Audit Programme assessed whether the number of babies born weighing <1501g, or at gestational age of <32 weeks, undergo the first retinopathy of prematurity (ROP) screening in accordance with the NNAP interpretation of the current guideline recommendations (7). Within the 179 neonatal units included in the final analysis there were 8999 babies eligible for ROP screening. Their findings show that including post-discharge screenings, 98.1% of eligible babies had at least one screening for ROP recorded. There were 94.4% of babies were screened on-time in accordance with current NNAP criteria and of the remaining babies, 3.1% were first screened after the closure of the screening window, and <1% were screened before the screening window opened (7).
- d) A national guideline for identifying which babies are at risk of ROP, describing a screening protocol and identifying criteria for treatment was first drawn up in the UK

in 1990 by a working party of the Royal College of Ophthalmologists (RCOphth) and the British Association for Perinatal Medicine (BAPM) and was reviewed in 1996. The latest update in 2008 was led by RCPCH with RCOphth, BAPM and BLISS (Guideline for the Screening and Treatment of Retinopathy of Prematurity) (9, 10) and after 10 years an update is needed.

- e) The guideline to which this scope relates will be a revision of the 2008 guideline and will involve members of the Royal College of Paediatrics & Child Health (RCPCH) and representatives from relevant organisations.

3. Clinical need for updating the guideline

- a) The current guideline was published in 2008 and since then, new research might be available. The clinical recommendations proposed in 2008 are now due to be reviewed to ensure they are in line with any new evidence and any current clinical practices.
- b) Since publication of the 2008 guideline we know that babies are at greater risk of missing initial screening and follow up due to babies being discharged earlier than in the past. Research has found that extremely premature babies can expect to stay in hospital for some time beyond their due date, however babies born at 30 and 31 weeks of gestation are often discharged home sooner, at a median of around 30 days prior to their due date (11). The guideline aims to address this situation.
- c) Screening is acknowledged to be stressful for both patients and their parents and with only approximately 4% of screened babies requiring treatment under the current guidelines (1); the question is raised as to whether too many babies are being unnecessarily screened. The production of this guideline should allow a critical appraisal of the indications for screening.
- d) The organisation of services has changed since the production of the latest guideline with the establishment of regional neonatal networks and babies more commonly moved between neonatal units. Specifically, the most preterm babies should be moved to regional NICUs for their early care, and moved to a LNU or SCU nearer home as their condition stabilises. The production of an updated guideline would allow these changes to be reflected.

4. Guideline Methodology

The guideline update will be developed according to the NICE accredited RCPCH guideline process manual, titled: 'Setting Standards for Development of Clinical Guidelines in Clinical Guidelines in Paediatrics and Child Health, 2016' (available [here](#)).

The methodology will be fully documented in the final guideline and complemented by relevant detailed appendices.

The guideline update will follow standard guideline developmental stages, from agreeing the scope, to carrying out an evidence review based on systematic review methods and with the full involvement of a multidisciplinary guideline development group and the engagement of relevant key stakeholders at different stages, including a formal external consultation.

Clinical recommendations will be proposed in key areas of clinical practice; and will be developed taking into consideration the findings of the evidence review and the consensus of clinical and lay representation expertise. The wording of the clinical recommendations will reflect the strength of the recommendation.

5. Guideline Contents

This section defines exactly what the guideline will and will not examine, and what the developers will consider.

5.1 Audience

The guideline will primarily be aimed at the neonatal and ophthalmic teams but will also provide a resource for all healthcare professionals involved in the screening and treatment of ROP. The guideline will be produced for use within the UK healthcare environment.

Although the guideline will not be directly aimed at parents of infants with ROP, their needs will be considered both within the main document and in a separate parent information leaflet.

5.2 Population

Groups that will be covered:

- a) All babies at risk of developing sight-threatening ROP.

5.3 Healthcare setting and services

- a) Primary, secondary and tertiary healthcare settings in which the screening and diagnosis of babies at risk of ROP takes place.

5.4 Key areas of management

The guideline will contain a background section which will include the historical perspective, epidemiology, clinical features and a summary of the aetiology and risk factors for ROP. This section is for reference and will not include evidence-based recommendations.

The evidence-based guidance will include the following key areas of management:

a) Screening

Recommendations in this section will consider the following areas:

- Criteria for entry into the screening programme (based on birth weight and gestational age).
- Timing of the 1st screening examination.
- Ophthalmic criteria for frequency of screening examinations.
- Ophthalmic criteria for termination of the screening programme.
- Arrangements for continuing first screening or continuing screening for babies who have been transferred or discharged home.
- Training and expertise of ROP screeners.
- What information should be provided for parents and when.

Other recommendations are likely to include the risks associated with screening and the impact of these risks with regards to the screening location, management of the baby prior, during and after screening, and the associated resources e.g. equipment, competencies of staff.

b) Information for Parents

Throughout the guideline the issues around communicating with parents will be considered. If it seems appropriate a separate section in the main guideline on how the healthcare team should communicate with parents may be included to address the process of providing information to parents regarding screening and diagnosis.

Information will also be included on parental consent, parental information, and support and counselling, and screening and treatment outcomes.

c) Recommendations for further research: The guideline will also include suggestions for further research.

5.5 Clinical management – areas that will not be covered

- a) Detailed discussion of the aetiology and risk factors for ROP (this area was also outside the scope for the current 2008 guideline).

- b) Methods for preventing or reducing incidence of ROP (this area was also outside the scope for the current 2008 guideline).
- c) Management of babies with ROP (this area was also outside the scope for the current 2008 guideline).
- d) The follow up of preterm babies in general (this area was also outside the scope for the current 2008 guideline).
- e) First ROP treatment and long-term management of ROP (this area is excluded from this scope as the review of ROP treatment is being led by the RCOphth-with close collaboration with RCPCH).
- f) Health economist assessment including the cost effectiveness of ROP screening in the guideline (this area was also outside the scope for the current 2008 guideline).
- g) Evidence for organisational issues will not be reviewed directly, however recommendations may be developed where appropriate (this area was also outside the scope for the current 2008 guideline).

5.6 Audit support within the guidance

The guidance aims to review existing key criteria for audit, which will enable objective measurements to be made of the extent and nature of local implementation of this guidance. Key recommendations for implementation will be highlighted and tools for implementation of the guideline may also be included.

6. Clinical questions

Topic area	Evidence Questions	Recommendations to address
1. Purpose and benefits of ROP Screening	<ul style="list-style-type: none"> • What is the evidence that screening for ROP identifies babies at risk of developing sight threatening ROP? • What is the evidence that treatment of babies identified as having sight-threatening ROP as part of a screening programme prevents visual morbidity? • What is the prevalence of visual morbidity in unscreened populations? 	None
2. Screening Criteria	<ul style="list-style-type: none"> • Below what birth weight is a baby at risk of developing sight-threatening ROP? • Below what gestational age is a baby at risk of developing sight-threatening ROP? • How effective is a risk model analysis in identifying babies that should be entered into a screening programme? 	Which babies should be screened for ROP

Topic area	Evidence Questions	Recommendations to address
3. ROP screening protocol	<ul style="list-style-type: none"> • What is the earliest postnatal/postmenstrual age that an ophthalmic examination gives a clear view of the retina? • What is the earliest postnatal/postmenstrual age that ROP can develop? • What is the earliest and latest postnatal/postmenstrual age that sight threatening ROP (stage 3) develops? • What is the relationship between gestation/birthweight and the rate of retinal vascularisation? 	<p>The range of postnatal/postmenstrual ages within which the first screening for ROP should take place</p> <p>In which (if any) groups of babies can the first screen be safely postponed and for how long</p> <p>Maximum postnatal/postmenstrual age by which first screen has been completed</p>
4. Sub Topic Area - Continued Screening:	<ul style="list-style-type: none"> • What stages of ROP, location and extent of ROP have the potential to become sight threatening? • What are the ophthalmic criteria that the baby is no longer at risk of sight threatening ROP? 	<p>The ophthalmic criteria that a subsequent screening examination is required</p>
5. Sub Topic Area - Interval between screening examinations	<ul style="list-style-type: none"> • What are the factors affecting the rate of ROP progression? • How long can it take for ROP defined as non-sight threatening to become sight threatening? • Are there any groups of babies at risk of rapid progression of ROP? 	<p>Interval between screening examinations</p>

Topic area	Evidence Questions	Recommendations to address
6 ROP screening examinations	<ul style="list-style-type: none"> • What clinical adverse events have been reported in association with ROP screening (including adverse drug reactions (ADR's) to eye drops)? • In which group of babies have adverse clinical events during or shortly after ROP screening been reported? 	<p>The document will provide general principles for:</p> <ul style="list-style-type: none"> Requirements for the location for screening babies Facilities in the immediate screening environment Neonatal unit staff present at the screening examination Clinical circumstances (if any) in which an ROP screening examination is not advised at the time indicated Screening babies with life-limiting illness /major congenital abnormalities/previous cardiac arrest Any non-clinical reasons for postponing screening (e.g. no parental presence) Neonatal management prior to screening e.g. withholding feeds, pre-oxygenation etc. How the baby should be prepared for screening e.g. which drops, how many, when etc.

Topic area	Evidence Questions	Recommendations to address
7. Training and expertise for ROP screeners	<ul style="list-style-type: none"> • What training & experience should be gained prior to starting screening? • What training & experience is needed for the continuation of screening • How should training for ROP screening be conducted? 	<p>Number of babies/screening exams/year required to maintain expertise</p> <p>Competencies required in ROP screeners</p> <p>CPD for ROP screeners</p> <p>Recognition of ROP screening in consultant's job plans</p> <p>Leave cover/ avoiding occasional practice</p> <p>Opportunities for teaching</p>
8. Screening technique	<ul style="list-style-type: none"> • What are the benefits/risks for each screening technique with regards to view of retina, ease of use etc? • What evidence is there that suggests that screening causes distress & if so what measures can be taken to prevent it? • What are the risks/benefits of using a lid speculum and scleral indenter • How should the results of the screening examination best be recorded? 	<p>Use of different screening equipment</p> <p>Use of lid speculum and scleral indenter</p> <p>Use of disposable equipment/cleansing equipment</p> <p>Measures that can be used to calm the baby</p> <p>Recording the results of the screening examination by stage and zone/ Use of eye diagrams in notes</p> <p>Value of ROP book or diary</p>

Topic area	Evidence Questions	Recommendations to address
9. Responsibilities and organisation of services	<ul style="list-style-type: none"> • What are the elements of a successful screening programme? • How should the screening programme be organised? • What skills and expertise should those responsible for the screening programme have? 	<p>Who has responsibility for deciding which infants to enroll in the screening programme?</p> <p>Which member of the neonatal team has responsibility for informing the ophthalmologist of an infant to screen?</p> <p>Who is responsible for making sure the 'window of opportunity' is not missed?</p> <p>Who has responsibility for ensuring screening is completed whilst as an inpatient?</p>
10. Screening in babies transferred or discharged home before screening is complete	<ul style="list-style-type: none"> • What is the prevalence of ROP related visual morbidity in babies discharged home or transferred to another hospital compared to other groups? • What information should be handed over during transfer of babies and who should be responsible for ensuring this occurs? • What is the did not attend (DNA) rate at follow up ROP screening appointments post hospital discharge? • What family and infant factors are associated with ROP clinic non-attendance? • Are there any interventions to improve clinic attendance by families with premature babies? 	<p>What information about ROP screening and treatment should be given to new hospital and how should this information be transferred?</p> <p>Who should take responsibility for ensuring screening is complete?</p> <p>Which babies/families should be targeted to improve clinic attendance?</p> <p>What effective interventions have been identified for improving clinic attendance post discharge?</p> <p>What information relating to ROP should be handed over to the receiving hospital during the transfer of the baby?</p> <p>Who should take responsibility for handing over patient ROP screening information during transfer of the baby between hospitals?</p>

Topic area	Evidence Questions	Recommendations to address
11. Information for Parents about screening	<ul style="list-style-type: none"> • What information should hospital staff give to parents and carers before screening? • When should parents and carers receive information about screening? • Is informed consent required for screening? • Should parents be invited to attend screening examinations? 	<p>When parents should be informed that their baby is at risk of ROP</p> <p>The information parents should be given, how and by whom</p> <p>Whether parents should be invited to attend screening examinations</p> <p>Whether informed consent is required in relation to eye examinations</p> <p>Informing parents about outcome of screening exam</p>

7. Dissemination

The information will be presented in four formats:

- An electronic, web-based guideline document
- A parent information leaflet
- A quick reference document or poster outlining the major findings
- The guideline either in summary, in sections or as a whole will be submitted to journals prior to wider dissemination.

8. Further Information

Further information is available from the Royal College of Paediatrics and Child Health.

8.1 Scope Version

This is the first draft of the scope.

8.2 Guideline

The update of the guideline will begin in September 2019. The final guideline publication date is estimated to be Autumn/Winter 2020.

9. References

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