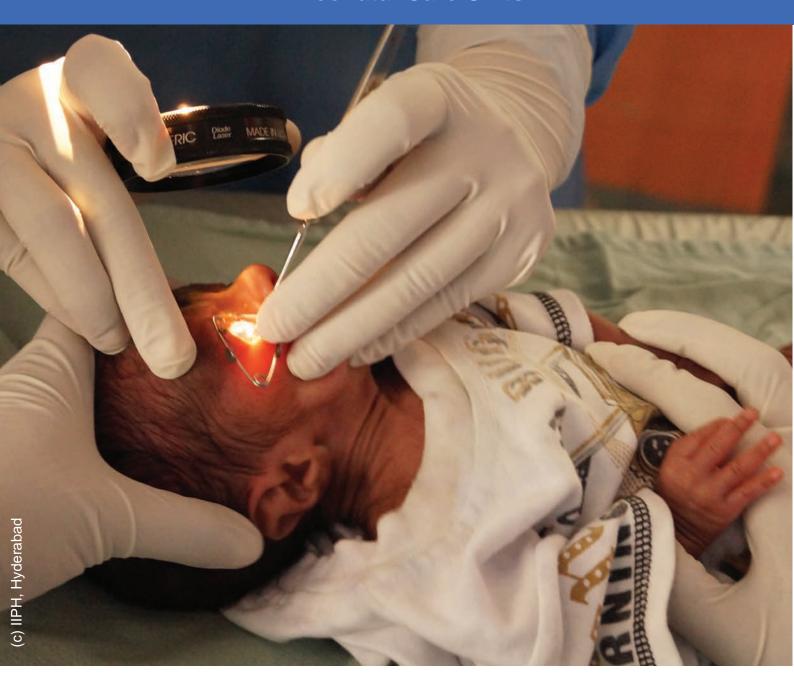






PROJECT OPERATIONAL GUIDELINES

Prevention of Blindness from Retinopathy of Prematurity in Neonatal Care Units



Screen for ROP. Save Newborn Sight







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Preface

Significant progress has been made in reducing infant mortality in India over last 10 years. To accelerate the reduction, GOI has invested to improve neonatal care. Over a quarter of world's preterm births (3.5 million) are in India. Premature birth is a major risk for infant mortality and morbidity. The survivors are also at high risk of lifelong disabilities like Retinopathy of prematurity (ROP).

Ensuring healthy survival of our infants is our current priority. The launch of Rashtriya Bal Swasthya Karyakram in 2013 was an important step in this direction. The program has identified ROP as one of the major cause of preventable childhood blindness. ROP is a potentially blinding condition of the eyes seen in approximately 10% of infants born preterm (\leq 34 weeks). Other risk factors are Septicaemia, LBW, Oxygen therapy, ventilator support, blood transfusion, failure to thrive. The incidence of ROP is rising with the improvement of the survival rates of premature infants.

Early identification through regular screening program and timely treatment can prevent more than 90% infant from becoming blind. Efforts to reduce severe ROP by improving neonatal quality of care will also help reduce neonatal morbidity. The ROP operational guidelines developed by the National ROP Taskforce, for integrating services for prevention, screening and management of ROP at the SNCU will also create a platform for availability of cross specialties services for neonates admitted in SNCU. Screening and early treatment of Sight threatening ROP is among the most cost-effective health interventions.

I congratulate the collaborative of Indian neonatal and ROP experts and LSHTM led by PHFI and funded by the Trust for developing the national ROP guidelines. The operational guidelines are designed with the aim to highlight explicitly the roles and responsibilities of all functionaries involved in providing comprehensive care for management of ROP to every new-born across all levels. This guideline will provide a framework for easy scalability of the program across the country.

Acknowledgements

Retinopathy of Prematurity is a major emerging cause of childhood blindness in India. There is a pressing need to strengthen services in SNCUs/NICUs for prevention, screening and management of ROP to ensure no infant loses sight from ROP. The operational guidelines for screening and management of ROP are a major step in facilitating units in setting up these services. I sincerely hope that the state health departments will find these guidelines helpful in scaling up ROP programs in the states.

On behalf of the Public Health foundation of India and the Indian Institute of Public Health, Hyderabad, I thank the Ministry of Health and Family welfare for their stewardship, especially the Child division, the NPCB division and RBSK unit for giving us an opportunity and guidance to contribute for preventing childhood blindness from ROP in India. I am grateful to all the people and institutions (AIIMS Delhi, PGIMER Chandigarh, LVPEI Hyderabad, Arvind Eye Care Madurai, Narayana Nethralaya Bengaluru, Sankara Nethralaya, Chennai) who have contributed in many ways to develop the guidelines, hat will have a significant sustained impact on operationalizing the Retinopathy of Prematurity program across the country.

This effort would not have been possible without the support and active involvement of Dr. Rakesh Kumar (IAS, Joint Secretary-RCH, GOI).

We gratefully recognize the cooperation and whole hearted efforts made by Dr. Ajay Khera and Dr P K Prabhakar (Deputy Commissioner, Ministry of Health and Family Welfare, Government of India). Dr Khera's approach and insights were invaluable in setting up the scope of the guideline. I also thank Professor Arun Singh (National Advisor-Rashtriya Bal Swasthya Karyakram) for very detailed inputs for integrating the activities with Newborn care and District Early Intervention Centres (DEICs).

I thank Dr N K Agarwal (DDG Ophthalmology NPCB) for critical inputs to integrate ROP eye care services in district hospitals and pivotal role of medical colleges in strengthening public health system capacity for screening and treatment of ROP. I am grateful to Dr Ajay Gambhir and the NNF ROP guidelines writing group, whose work on ROP guidelines provided the foundation stone for these operational guidelines.

I appreciate the contribution from Dr Gagan Gupta and UNICEF in integrating ROP screening and referral information in the online SNCU database. I am grateful to Prof Clare Gilbert, LSHTM whose passion and energy for preventing blindness from ROP coupled with invaluable global ROP experience has been a cohesive force in bringing all the ROP experts together in developing the guidelines. This effort would not have been possible without the funding and support in executing all activities and in providing thoughtful feedback at all stages from The Queen Elizabeth Diamond Jubilee Trust. The initiative owes much of its direction to the encouragement, inputs and guidance from Miss Indhu S, Program Manager-Rashtriya Bal Swasthya Karyakram. I also appreciate the support of the Indian Institute of Public Health, Hyderabad secretariat in drafting and coordinating to ensure a smooth process.

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Abbreviations

AIIMS All India Institute of Medical Sciences
AIOS All India Ophthalmological Society

ANC Antenatal Care

ANM Auxiliary Nurse Midwife

ALT Ask Look Test

AP – ROP Aggressive Posterior – Retinopathy of Prematurity

ASHA Accredited Social Health Activist

CPAP Continuous Positive Airway Pressure

DA Dearness/Daily Allowance

DEIC District Early Intervention Centre

DH District Hospital

FBNC Facility Based Newborn care

FOGSI Forum of Obstetrics and Gynaecological Societies of India

GA Gestational age

Gol Government of India

GMCH Government Medical College and Hospital

IANN Indian Association of Newborn Nursing

ICD 10 PCS Tenth International Classification of Diseases Procedure CodingSystem

IEC Information Education and Communication

IIPH Indian Institute of Public Health
INCU Intensive Newborn Care Unit

IV Intra venous

LBW Low Birth Weight

LSHTM London School of Hygiene and Tropical Medicine

MHT Medical Health Technician

MoHFW Ministry of Health and Family Welfare

NHM National Health Mission

NICU Neonatal Intensive Care Unit

NNF National Neonatology Forum

NPCB National Program for the Control of Blindness

PG Post Graduates

PGIMER Post Graduate Institute of Medical Education and Research

PHFI Public Health Foundation of India

PMA Post Menstrual Age

RCH Reproductive and Child Health

RBSK RashtriyaBalSwasthyaKaryakram

ROP Retinopathy of Prematurity

SNCU Special Newborn Care Unit

ST- ROP Sight Threatening ROP

TA Travel Allowance

UNICEF United Nations Children's Fund

VEGF Vascular Endothelial Growth Factor

VLBW Very Low Birth weight

WHO World Health Organization

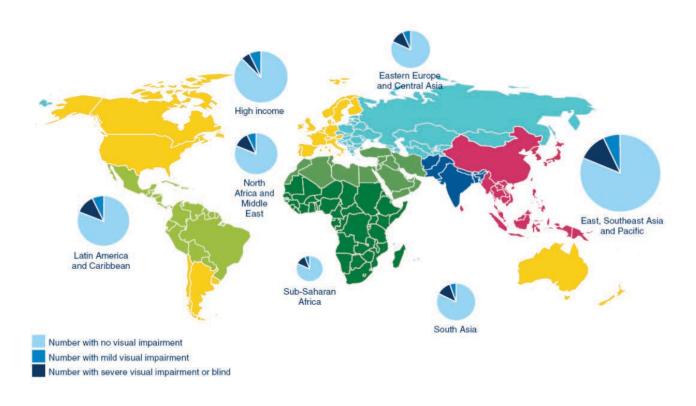
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1.Introduction and Rationale

Retinopathy of Prematurity (ROP) is a potentially blinding disease of the eye that can affect infants born four or more weeks preterm and receive intensive neonatal care. In ROP, the developing retinal blood vessels grow abnormally, which can lead to detachment of the retina and total blindness, usually in both the eyes. The risk of severe, Sight Threatening ROP, which is higher in more preterm infants, can be reduced by quality improvement measures which reduce exposure to known risk factors such as poorly administered supplemental oxygen, sepsis and poor weight gain after birth. Early detection of Sight Threatening ROP (ST-ROP), followed by urgent laser treatment, is highly effective in preserving the sight of the babies.

Recent estimates show that 32,000 infants become blind or visually impaired from ROP every year world-wide, being a far higher estimate than 10 years ago. Most of the ROP blind infants were born in countries in Asia (Blencowe, et al 2013)¹.



Distribution of ROP and its effects across the globe

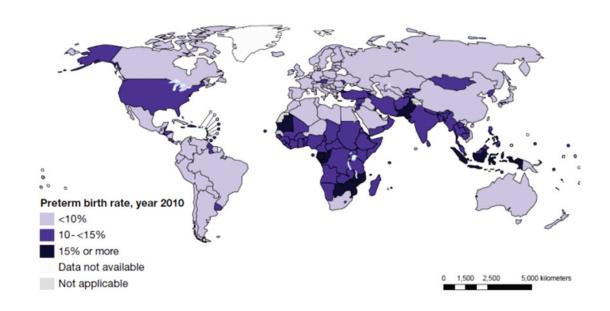
Source:Blencowe H, Lawn JE, Vazquez T, Fielder A, Gilbert C. Preterm-associated visual impairment and estimates of retinopathy of prematurity at regional and global levels for 2010.

Pediatr Res. 2013 Dec;74 Suppl 1:35-49. doi: 10.1038/pr.2013.205. Review.

Approximately 15 million babies are born preterm (<37 weeks by definition) worldwide each year and India is the country with thehighest number of preterm births (WHO 2012, Born Too Soon)².ROP is an increasingly important cause of blindness in children in low and middle income countries, including India.

According to a recent estimatein 2010, 3.5 million infants were born preterm in India (Lancet 2012)³ i.e., at less than 37 weeks gestational age (GA). Approximately one in six i.e. 600,000 were very preterm i.e. born at less than 32 weeks gestational age. Assuming 40% of these live born premature infants are admitted to Special Newborn Care Units (SNCUs) with 80% survival chances, approximately 192,000 infants are at high risk of severe ROP and need to be screened each year. Assuming 5-10% of these survivors develop ROP which needs treatment, which translates to 10-20,000 infants a year. This is a minimum estimate, as infants with a gestational age of 32-36 weeks are also at the risk of ST-ROP particularly in settings where infants receive less than optimal care. The number of infants requiring treatment for ROP is greater than the number of children with bilateral and developmental cataract, that affects nearly one in 2,500 young children (accounting to 10,000 children annually).

The escalation of services provided to the preterm infants in Special Newborn Care Units and Intensive Neonatal Care Units (INCUs/ NICUs) of Government and private sectors have increased the number of surviving preterm babies leading to an amplified risk of ST-ROP. It is estimated that more than 3000 infants become blind or visually impaired from ROP each year, due to lack of screening and treatment.



Distribution of preterm births across the globe

Source:March of Dimes, PMNCH, Save the Children, WHO. Born Too Soon: The Global Action Report on Preterm Birth. Eds CP Howson, MV Kinney, JE Lawn.

World Health Organization. Geneva, 2012

Vision is an important sense in coordinating other sensory inputs. Profound visual loss and blindness during infancy, as occurs with congenital cataract and glaucoma, some congenital defects of the eye and ROP, can have a profound impact on psychosocial, motor, and cognitive development.

ROP only affects preterm infants who receive special or intensive neonatal care. The management of this condition is different from many of the other conditions that are being addressed by Rashtriya Bal Swasthya Karyakram (RBSK) for the following reasons:

- 1. There are no community-based interventions for prevention, detection or treatment.
- 2. Screening has to take place inside the facilities caring for preterm infants within the first few weeks of life by skilled individuals, usually ophthalmologists.
- Management of ST-ROP, once detected has to be treated as an emergency and requires high levels of specialized care delivered by highly competent ophthalmologists.
- 4. The complications of ROP and preterm birth often require good quality, tertiary level pediatric ophthalmology services.



Nurse administering dilating eye drops to babies waiting to be screened before ROP in the SNCU Waiting area

Source: Niloufer Hospital, Hyderabad

See ANNEXURE I – ROP: Stage and Action Needed: Page Number 28

Retinopathy of prematurity is a dynamic, time-bound disease that is not present at birth. The condition typically starts 2-3 weeks after birth and progresses (or regresses) over the next 4-6 weeks. There is therefore, only a narrow period of time for screening and for treatment, if required. The first retinal examination usually takes place while the baby is still receiving neonatal care in the hospital or immediately after discharge. Regular retinal examination/screening needs to continue until it is safe to discontinue further screening i.e. when the retinal blood vessels have become mature, or the signs of ROP have resolved, or urgent treatment is needed.

In advanced stages of the disease the retina separates from the back of the eye (retinal detachment). The Tenth International Classification of Diseases Procedure Coding System(ICD 10 PCS) describes 5 stages of ROP (Stages 1-5) which can occur in 3 zones. Disease in Zone 1 has a worse prognosis than disease in Zones 2 or 3. Stage 4 ROP requires complex vitreoretinal surgery which can sometimes preserve useful vision. The retinal detachments seen in Stage 5 are usually inoperable.

See ANNEXURE I - ROP: Stage and Action Needed: Page Number 28

Factors that increase the risk of ROP

| Significant factors | Contributing factors |
|---|--|
| Preterm birth i.e 34 weeks/approx. 8.5 months or less gestational age Low birth weight i.e. 2000 grams or less Exposure to too much oxygen from birth | Sepsis Failure to gain weight Transfusion of blood products Respiratory Distress Small for gestational age Patent ductus arteriosus |

The number of infants at risk of ROP in India is rapidly increasing and is likely to rise dramatically further over the next few years, as services for the preterm infants continue to expand in the government and private sectors. Among the preterm infants admitted to SNCUs, all need retinal screening because nearly up to 15% develop the sight threatening stages of ROP which need urgent laser treatment by competent ophthalmologists. Laser treatment, if well applied, is highly effective at preserving sight. The massive increase in services for preterm infants in India calls for an urgent need to expand ROP programs in facilities where the majority of preterm infants are cared for.

Target Group for screening for ROP

All infants admitted to SNCUs/NICUs with the following criteria need examination by fundoscopy:

Data on gestation age are available:

- All infants born at <u>34 weeks (approx. 8.5 months) or less gestational age</u>
- All infants born of <u>more than 34 weeks/approx. 8.5 months gestational age with risk factors</u>(cardiorespiratory support; prolonged oxygen requirement; respiratory distress syndrome; chronic lung disease; fetal hemorrhage; blood transfusion; sepsis; exchange transfusion; interventricular hemorrhage; apnea; poor post-natal weight gain)

Data on gestational age are not available:

- All infants weighing 2000 grams or less at birth
- Other preterm infants based on the discretion of the pediatrician or neonatologist

Other visually impairing complications of ROP and preterm birth

Ocular complications

Preterm infants, whether they develop ROP or not, are also at increased risk of other eye conditions such as refractive errors, strabismus and cortical visual impairment, which may be associated with visual field loss and optic atrophy. Refractive errors are the commonest ocular complication, being far more common among infants born preterm than those born at term.

Myopia (short sightedness) is the commonest refractive error. Infants treated for ROP have a) very high rates of myopia, b) the myopia can be very severe and c) the myopia begins a few months after birth and can progress rapidly through early childhood.

Infants who have been treated for ROP can also develop late ocular complications such as secondary cataract, secondary glaucoma and retinal detachment. All treated infants need long term follow up by an ophthalmologist.

Infants and young children who are born preterm who are blind or severely visually impaired from ROP or from cerebral visual impairment require early visual stimulation and rehabilitation to prevent or reverse developmental delay.

| All preterm infants weighing2000g or less at birth | All preterm infants treated for ROP |
|---|--|
| From age 6 months to 7 years Refractive errors (5%), particularly myopia. May also develop squint and cortical visual impairment. | From age 6 months to 7 years Refractive errors, particularly high myopia (50%), squint and cortical visual impairment. |
| | Throughout childhood and adolescence Cataract, glaucoma and retinal detachment |



Child with cataract which can be a later complication of ROP

Source:https://consult.cybersight.org/web/ main/home



Strabismus which can be a complication of preterm birth

Source:http://www.ijo.in/viewimage.asp?i mg=IndianJOphthalmol_2011_59_6_487_ 86319_f3.jpg



Young boy wearing spectacles for high myopia which is common in children born preterm

Source: L.V.Prasad Eye Institute, Hyderabad



Young child with severe visual impairment receiving visual stimulation as part of rehabilitation

Source: L.V.Prasad Eye Institute, Hyderabad

Other complications of preterm birth

Preterm infants are also at risk of hearing impairment / deafness, cerebral palsy and learning difficulties. Allchildren born preterm should have comprehensive health assessments throughout early childhood.

See ANNEXURE II - Ocular and cortical complications of preterm infants and current follow up practice. Page Number 30

Economic impact and benefits of controlling visual loss from ROP

Several studies have demonstrated that programs for the detection and treatment of ROP are highly cost effective. For example, a study from Peru concluded that "the societal burden of blindness far exceeds the costs of treatment per child" (Dave, et al 2012)⁴ and a study from the United States of America estimated the cost per quality-adjusted life year as \$1,565, using a 3% annual discount (Dunbar, et al 2009)⁵. Another study, undertaken in Mexico and the United States of America concluded that ROP screening and treatment is highly beneficial for quality of life, cost-saving, and cost-effectiveness in both countries (Rothschild,et al 2016)⁶.In Brazil a study found that the incremental cost per at-risk baby for examination and treatment was only US\$ 80, which is less than 1% of NICU hospitalization costs in Brazil's Unified Health System (Zin, et al 2014)⁷.

2. Strategies for control of visual loss from ROP

PRIMARY PREVENTION

Prevent preterm birth

In situ transfer of threatened preterm delivery to a health facility with SNCU/NICU

Antenatal steroids for threatened preterm delivery

Prevent ROP among preterm infants by high quality neonatal care from immediately after delivery and in the SNCU/NICU:

In delivery room

Gentle resuscitation avoiding ventilation - use CPAP

Avoid unmonitored 100% supplemental oxygen - use blenders and pulse oximeters

In the SNCU/NICU

Careful oxygen delivery and monitoring. Use pulse oximeters and set saturation targets and alarms.

Prevent sepsis by effective hand hygiene, aseptic techniques, good housekeeping and antibiotic stewardship'

Promote feeding with breast milk

Avoid unnecessary transfusion of blood products

SECONDARY PREVENTION

Early detection of sight threatening ROP

Urgent treatment of sight threatening ROP

Follow up of treated infants

TERTIARY PREVENTION

Surgery for retinal detachment due to ROP

QUALITY IMPROVEMENT FOR PREVENTIVE STRATEGIES

- 1 Delivery of current best practices for neonatal care at each level
- 2 Assessment of practices on a regular basis
- 3 Analysis of outcomes in terms of survival and capacity building
- 4 Deciding target outcomes

Note: Primary prevention of Sight Threatening ROP should be emphasised in the Facilty Based Newborn Care Guidelines (FBNC) used by SNCUs.

3. Protocol for screeningfor ROP

WHICH INFANTS NEED TO BE SCREENED

Infants admitted to SNCUs/NICUs if one or more of the following apply:

- 1. Gestational age of 34 weeks or less
- Gestational age of more than 34 weeks if exposed to risk factors (see above)
- 3. If gestational age is not known, birth weight 2000 grams or less
- 4. Other preterm infants at the discretion of neonatologist or pediatrician

WHEN TO PERFORM THE FIRST SCREENING

Before discharge from the SNCU/NICU, or by 30 days of life, whichever is sooner

SCREENING METHODS

Indirect ophthalmoscopy by a trained ophthalmologist or retinal imaging using a wide-field camera (e.g. RetCam) by trained and competent personnel

Screeners must visit the SNCU/NICU on the same day of the week and time of day, so that discharged infants can be brought back for screening, if required

WHERE TO SCREEN

Preterm infants who have not been discharged from the SNCU/NICU must be examined on the unit.

Discharged infants can be followed up in the SNCU/NICU, or be seen in the ophthalmologist's clinic

MANAGEMENT DECISIONS AT EACH SCREENING

- No further screening required if retinal vessels are mature in both eyes, or ROP has regressed spontaneously
- or
- Further screening in 3-4 days, or one week, or 2 weeks as the retinal vessels are not mature, or ROP is present or
- 3. Urgent treatment is required

DOCUMENTATION AND COMMUNICATION

Findings and the management decision at each screening must be recorded in the medical records

The date for the next screening if needed must be documented in the medical records and/or discharge summary

The date for the next screening must be communicated to parents verbally and in writing

Recommendations for ROP Screening

| Who | How | When | Additional requirements |
|--|---|---|---|
| Trained ophthalmologist | Indirect ophthalmoscopy | | Ophthalmologist skilled in indirect ophthalmos copy |
| Trained ophthalmologist | Retinal imaging (e.g. using a RetCam) | Regular weekly visits to the unit on a fixed day and time of the week to examine in- | Ophthalmologist skilled in retinal imaging for ROP |
| Trained technician / DEIC optometrist | RetCam imaging of the retina | patients and infants who have been discharged | Technician / DEIC optometrist trained and accredited for ROP imaging and ophthalmologist skilled in interpreting ROP from retinal images for quality control and feedback |

If trained technicians/ DEIC optometrists screen for ROP, an ophthalmologist must be available on the same day to interpret the retinal images either sent electronically or saved on a data storage system or a tele-ROP platform so that parents know straight away if their child needs treatment, as this must be given within 48 hours.

NOTE: Regardless of the approach to screening, the pupils need to be dilated. To reduce stress, infant needs to be swaddled, tucked and given non-nutritive suckling (pacifier).

TIMING of the First ROP Screening:

Timing of the first ROP screening is very critical to retaining the best possible visual potential the baby was born with. The first ROP screening should in no circumstance go beyond the 30th day of birth. This requires concerted and focused efforts and strategies by all team members including the child care givers, eye screeners, administrators, parents and many other members of the health care team. If the baby is to be discharged early, then screening for ROP must be completed before discharge. If the baby is still in critical care, say in incubator or on ventilator, the eye screener should be called to the SNCU/NICU before Day 30th of Life so as to complete the mandatory ROP screening. If a baby is being transferred to another unit or being discharged without screening, the transfer/discharge form should clearly state the date, time and venue where ROP screening must be carried out. Awareness posters around the NICU/SNCU help generate compliance. "Tees Din Roshni Ke" or "Thirty days to Vision" should be the guiding slogan well known to all care givers and conveyed clearly to the parents.

Documenting and reporting the findings of screening:

• The findings must be clearly documented by the screener in the medical records (i.e. "no ROP in either eye", or "Right and left eye: Stage 2 in zone 2") at each examination and should be communicated to the parents clearly.

• The management decision must be clearly documented by the screener in the medical records (i.e. examine again and the date; screening can discontinue; urgent treatment is required/urgent assessment by an ophthalmologist is required). ROP screening findings and management decisions should also be recorded in the discharge summary, together with the date of the next examination, if required. All this information should be clearly conveyed to the parents.



Mother of a baby sharing her anxiety with the doctor before ROP screening.

Source: Niloufer Hospital, Hyderabad

4. Treatment – indications, methods and follow up

WHICH INFANTS NEED TO BE TREATED

Infants developing signs of sight threatening ROP in one or both eyes

WHEN SHOULD TREATMENT BE GIVEN

Within 48 hours as the disease can progress very fast to retinal detachment

WHO SHOULD TREAT

An ophthalmologist trained and competent in treating sight threatening ROP

METHOD OF TREATMENT

Laser treatment delivered by indirect ophthalmoscopy to the avascular peripheral retina

Pain control and/or sedation are required. Staff trained in neonatal resuscitation must be present

Note: Once retinal detachment has occured, complex vitreoretinal surgery by an expert can prevent blindness in some cases

WHERE TO TREAT

In the SNCU/NICU if an inpatient.

If discharged from the SNCU/NICU: in an eye department if infrastructure and personnel are available

FOLLOW UP AFTER TREATMENT

Ophthalmlogist should follow up at one week. Further laser treatment may be required

LONG TERM FOLLOW UP

Infants treated for sight threatening ROP are at high risk of refractive errors and other eye conditions. They should be followed up until at least 5 years of age

During treatment

- 1. Sedation and/or pain control are required
- 2. Staff trained in neonatal resuscitation (neonatologist/paediatrician/anaesthetist) and basic neonatal care must be present.
- 3. Everyone present while laser is being delivered must wear protective goggles to protect their eyes.

Alternative treatment:

Intraocular injections of anti-VEGF preparations for ST- ROP are recommended as "rescue" treatment only, after parental consent, when:

- a) laser treatment has failed
- b) if laser treatment is not possible e.g., the neonatologist considers the infant too sick or the pupils do not dilate adequately

Parents should be counselled about the potential for possible unknown long term complications before administering anti – VEGF preparations.



Ophthalmologist performing laser surgery on a premature baby diagnosed with ST-ROP

Source: Dr A Vinekar, Narayana Nethralaya, Bengaluru

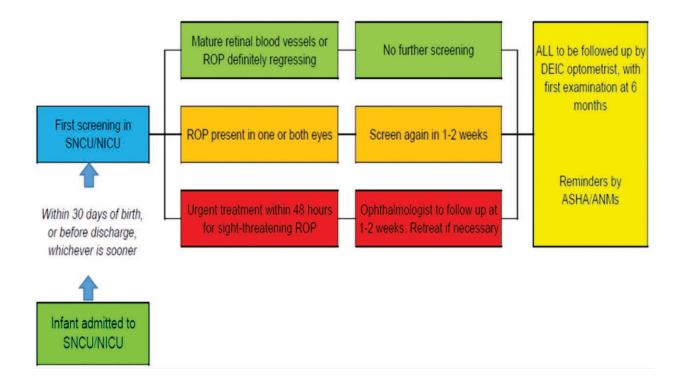
See ANNEXURE III - Indications for treating ROP: Page Number 31

See ANNEXURE IV – Equipment and consumables for screening and management of ROP: Page Number 32

Reporting the follow up after treatment:

• The date, time and place of follow up after treatment must be recorded clearly in the medical records and communicated to parents.

5. Protocol for follow up



Note: The DEIC optometrist should coordinate with SNCU/NICU staff to ensure that all infants screened for ROP are followed up at the centre.

Department of NHM Child Health

Prevention

Promot acilit as d d li r
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ns r ant natal st roids or
mot rs li I to d li r pr t rm
ns r i alit car
practic s
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Screening

S t p scr nin protocols in S C s
Id nti in ants to scr n d as p r id lin s
ns r comp t nt scr n rs isit on a r lar I asis and doc m nt t ir indin s

Treatment

Coordinat it tr atin op t almolo ist and pro id s pport d rin and a t r las r tr atm nt

Follow up

Ro tin ollo po all pr t rm in ant ntil t a o ars

National Program for the Control of Blindness (NPCB)

Screening

ns r participation o District ospital op t almolo ists in comp t nc as d mana m nt o ROP

Treatment

ns r all c ntr s it train d op t almolo ists a ipm nt orscr nin and las r tr atm nt

Follow up

Ro tin ollo po all in ants trat d orsi ttrat nin ROP

RBSK

Prevention

ns r Ms and S s pro id in ormation a o t scr nin as a mandat or pr t rm d li ri s

Screening

S C n onatolo ists pa diatricians ns r all in ants at ris ar scr n d

D IC optom trist ns r s t at all in ants scr n d ar ollo d p

Treatment

S ill d op t almolo ists cond ct las rs r r accordin to n d

Follow up

Ro tin ollo po all pr t rm in ant ntil t a o ars or ot r is all impairin complications

See ANNEXURE V – Flowchart depicting activities to be undertaken at each level: Page Number 34

7. Steps involved in implementing a program for ROP

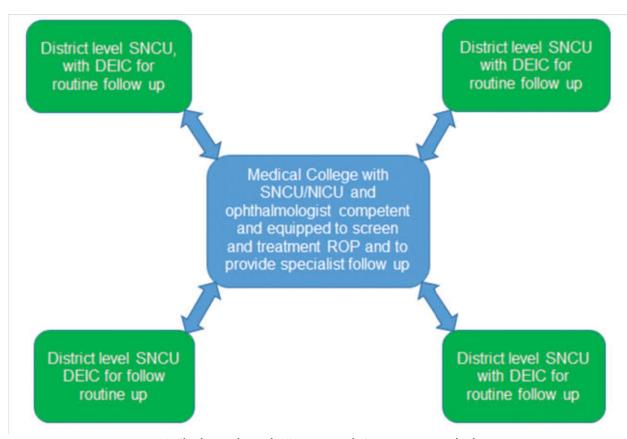
Service mapping (desk work)

- Baseline service and resource mapping should be done of available equipment, infrastructure and skills to prioritize ROP services provision in the SNCU units in a phased manner.
- SNCUs in Medical Colleges and District Hospitals:
 - O Assess the number of infants weighing 2000 g or less admitted and preterm babies of gestational age of 34 weeks/approx. 8.5 months or less(if known) who survive to discharge so as to prioritize ROP program implementation in SNCUs caring for the largest number at risk in the first instance. This information can be obtained from the Government's SNCU database.
- Eye care providers:
 - Ophthalmologists in Regional Institutes of Ophthalmology, Medical Colleges and District Hospitals and their existing skills / willingness to be trained in a) screening and b) treating ROP
 - O Ophthalmologists in the private sector and their competencies in screening and treatment
 - Equipment available for screening and treating ROP
- District Early Intervention Centres (DEICs)- location, staffing levels and equipment for eye care (as per the RBSK Guidelines)
- Prioritize 1 Medical College for mentoring 2-4 District Hospital and SNCUs

Approach recommended

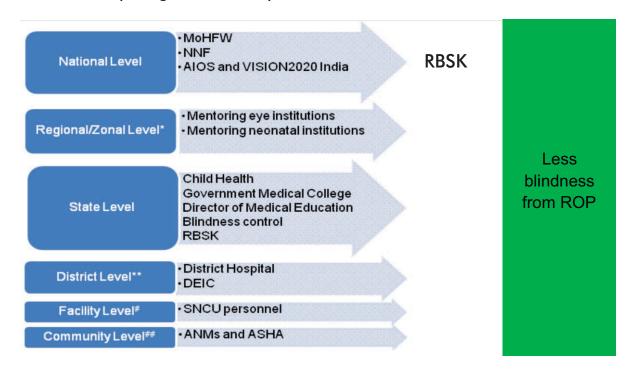
A "hub-and-spoke" approach is recommended comprising three to four District level SNCUs in the vicinity of a Medical College with an SNCU/NICU where there is an eye department with an ophthalmologist willing to be trained in screening. Ideally, this ophthalmologist would also become competent in treatment so providing screening and treatment to all the SNCUs in the locality.

The DEIC can provide routine long term follow up, with referral to the dye Department in the Medical College for more complex cases. Onward referral to a pediatric ophthalmologist may also be required.



A "hub-and-spoke" approach is recommended

Flow chart depicting roles and responsibilities at each level



Roles and responsibilities at each level

| Level | Support at different levels |
|--------------------|---|
| National | MoHFW |
| | Integrate ROP screening and treatment services with NPCB |
| | Integrate ROP prevention and screening data fields in the online SNCU database |
| | FBNC revised guidelines and training manual to incorporate ROP prevention, screening and follow-up roles and responsibilities |
| | Revised training manuals for ANM and ASHA to include roles and responsibilities for ROP awareness and follow-up |
| | RBSK |
| | Integrate follow up of all preterm infants for refractive errors etc |
| | Help coordinate with the health personnel at various levels to provide continuum of care |
| | NNF |
| | Integrate ROP service guidance National Collaborative Centre for FBNC |
| | AIOS and Vision 2020 Increase awareness and participation of eye care specialist and Vitreoretinal specialists in ROP screening and treatment |
| Regional/ Zonal | Centres of Excellence for neonatal care and eye care will provide technical support in capacity building and mentoring Establish pool of trainers for screening and management of ROP |
| State | State FBNC training centres to coordinate with the local ROP neonatal care and ophthalmic care mentoring partner to incorporate ROP prevention, screening and follow-up roles and responsibilities |
| | Identify one medical college to support 2-3 SNCUs |
| | Ophthalmology department to train ophthalmologists, PGs and DH ophthalmologist. Pediatrics department to train SNCU staffs and doctors |
| | Ophthalmologist to train two selected SNCU nurses as "ROP nurses" in each SNCU/NICU |
| | Ophthalmologist to train optometrists in DEICs in long term complications of preterm birth and other ocular conditions of childhood prioritized by RBSK Collaborate with State chapters of professional bodies |
| | Collaborate with state chapters of professional bodies |

| District | District coordinator has to report the current statistics to the State. District coordinator has to provide list of potential trainees. DEIC optometrists to screen for other visual impairments and refer to pediatric ophthalmologist. |
|-------------------------|---|
| Facility (see below) | Identify two nurses in each SNCU/NICU to be trained as "ROP nurses" Delivering screening services with appropriate referrals Recording and reporting information on screening and treatment Arrange long term follow up of all preterm infants at DEIC |
| Community | ANMs and ASHA workers generate awareness and promote antenatal steroids and facility based deliveries Ensure follow up for screening and long term follow up |



Community health worker screening for eye problems in children

Source:http://blog.operationeyesight.com/2014/08/flagship-program-recognized-asbest-practice/

See ANNEXURE VI^{*}–Hospitals to be considered as zonal mentoring institutions: Page Number 35

See ANNEXURE VII"-Baseline data collection at District Level: Page Number 35

Roles and Responsibilities of SNCU staff

| Neonatologist/ Paediatrician | ROP Nurse (nurses selected for each SNCU/NICU) |
|--|---|
| Identify infants to be screened Support ophthalmologist during treatment of ROP in SNCU Ensure findings of each screening and the management decision are documented for each baby screened at each examination Ensure receiving neonatal unit of infant referred to another neonatal unit are informed of the need for further screening, if required Ensure educational materials are easily accessible to increase awareness of ROP and the need for screening and possible treatment | Keep a diary of the date for screening of all at risk infants from the date of admission and thereafter in coordination with neonatologist Prepare equipment and child for screening Support ophthalmologist during treatment of ROP in the SNCU Ensure findings and management decisions are documented Communicate with and counsel parents about the need for further screening, and when Report statistics to the district coordinator on a monthly basis Provide ANMs and ASHAs information about the infant which needs follow up |

| DEIC Manager |
|--|
| To co-ordinate for the follow up of infants treated in medical colleges/ tertiary |
| care centre |
| Ensure availability of suitable spectacle frames for |
| infants and young children |
| Provide visual stimulation of children who are visually impaired children from all |
| causes |
| |

Roles and Responsibilities of ANMs and ASHAs

| ANMs | ASHAs |
|--|---|
| Encourage mothers at risk of preterm delivery to deliver in a facility with services for neonatal care and to take antenatal steroids | Encourage mothers of infants who require further retinal examination / screening after discharge from neonatal care to access this service |
| Ensure all preterm infants are screened | Educate mothers of infants screened for ROP to attend the DEIC for assessment after discharge from neonatal care, and to follow the recommendations regarding treatment and follow up, if indicated |
| | Provide information on care of preterm infants, including potential complications such as ROP Encourage mothers of ROP blind children to access low vision and rehabilitation services |

Training for service providers

| Health Personnel Involved | Duration and Cost of Training |
|---------------------------------|--|
| SNCU | ROP Nurse – 1 week (TA- as per actual, DA- ₹300/-day, Lodging- ₹1500/-day) Neonatologist/ Pediatrician –1 week(TA- as per actual, DA- ₹500/-day, Lodging- ₹2000/-day) |
| Eye care providers | Ophthalmologist (DH and others) – 1 to 3 months depending on their skills (TA- as per actual, DA- ₹500/-day, Lodging- ₹2000/-day) |
| | Technicians / DEIC optometrist – 1 month(TA- as per actual, DA- ₹300/-day, Lodging- ₹1500/-day) |
| Community | ANMs – 1 to 2 days (TA- as per actual, DA- ₹200/-day) ASHAs – 1 to 2 days (TA- as per actual, DA- ₹200/-day) |



Hands on training in screening by a senior ophthalmologist from LV Prasad Eye Institute, Hyderabad

Source: Niloufer Hospital, Hyderabad

See ANNEXURE VIII- Roles and responsibilities of the neonatology team and ophthalmologist (Technician/DEIC optometrist) in relation to screening for ROP in SNCU: Page Number 36

See ANNEXURE IX - Roles and responsibilities of the neonatology team and ophthalmologist in relation to treatment for ROP: Page Number 37

See ANNEXURE X - Competency based training of technician/DEIC optometrist using RetCam for ROP screening: Page Number 38

See ANNEXURE XI - Algorithm for the Management of Retinopathy of Prematurity adopted for field: Page Number 40

See ANNEXURE XII -Guidelines for frequency of screening for ROP, based on finding: Page Number 41

See ANNEXURE XIII –Recording of screening findings by an ophthalmologist: Page Number 42

See ANNEXURE XIV –Follow-up Screening for ROP for at risk Child: Page Number 43 See ANNEXURE XV - ALT form for Basic Universal Eye Screening using torch light: Page Number 44

8. Documentation and reporting

Data to be captured for screening:

| 1. | Is the infant eligible for screening: Yes No |
|----|--|
| 2. | Weight of the infant: |
| 3. | Date when the first screening was performed |
| 4. | a) Findings of first screening for Right and Left eyes: b) Retinal vessels: Mature Immature c) Stage: 1 2 3 4a 4b 5 No plus/pre-plus/ plus d) Zone: 1 2 (posterior or anterior) 3 e) Extent (clock hours – drop down of 1-12) f) AP-ROP: Yes No |
| 5. | Ocular examination: other findings |
| 6. | Management decision for each screening session a) Further screening required: Yes No b) Date of next screening c) Laser treatment in SNCU d) Laser treatment not in SNCU – refer to: e) Vitreoretinal surgery – refer to: f) Further screening required: Yes/No g) Date of next screening |
| 7. | Is the infant referred to DEIC: Yes No |

Data to be captured during management:

| | Treatment session 1: |
|----|---|
| 1. | Date of treatment: |
| 2. | Weight: |
| 3. | Right eye Left eye |
| 4. | Type: Laser Vitreoretinal surgery Anti - VEGF preparation |
| 5. | Place of treatment: SNCU Medical College Elsewhere |

Data to be captured during follow up:

| 1. | Retreatment needed: Yes No |
|----|---|
| 2. | Retreatment given: Yes No |
| | If yes: |
| | Date of retreatment: |
| | Right eye Left eye |
| | Type: Laser Vitreoretinal surgery Anti VEGF preparation |
| | Place of treatment: SNCU Medical College elsewhere |
| 3. | Final outcome of treatment: |
| | i) Structural outcome: Right eye Left eye |
| | ii) Complete regression with flat retina and no retinal folds |
| | iii) Complete regression with flat retina with folds |
| | iv) Stage: 4a 4b |
| | v) Stage: 5a 5b |
| | vi) Functional outcome: Right eye Left eye |

Data to be captured in DEIC:

| 1. | Age of the child: |
|----|--|
| 2. | Is the infant screened for ROP: Yes No |
| 3. | Is the infant referred to paediatric ophthalmologist: Yes No |
| 4. | Does the infant need follow up: Yes No If yes, when: |



Ophthalmologists recording the finding after ROP screening Source: Niloufer Hospital, Hyderabad

9. Health Communication

Communication and outreach is needed in the following areas:

- 1. To provide information regarding ROP: This will be done by
 - a) Circulating Information, Education and Communication (IEC) materials (posters, simple information sheets in relevant languages) in the SNCUs and DEICs.
 - b) Training ASHAs and ANMs to provide information to expectant mothers and those who have delivered preterm infants about the need for eye screening.
 - c) Conducting State Sensitization Meetings, involving the DEIC Manager, SNCU personnel and health officials including the Principal Secretary across all the states.
- 2. Provide information regarding the need of early identification and treatment for ROP:
 - a) The importance of early screening for identification will be shared by the ASHAs, ANMs and SNCU personnel.
 - b) Create awareness regarding the significance of early treatment for ROP through posters, campaigns, Audio-visual spots in collaboration with local champions, national icons, RBSK nodal officer and competent authorities of various medical colleges.
- 3. Increase and improve follow up of all preterm infants, including those who have been treated for ROP by creating awareness utilizing services from ASHAs, ANMs, Medical Health Technicians (MHTs), SNCU personnel and DEIC.



Sharing booklets and education materials on ROP

Source: 15th Asia Pacific Congress of Paediatrics – 2016, Hyderabad

10. Financial Guideline

In districts where the district hospital ophthalmologist is not posted or not trained in ROP screening, services of private ophthalmologist, trained in ROP screening and treatment, should be contracted.

The amount for reimbursement for screening and management will be as decided by the Central and State Governments under RBSK and NPCB programs.

Please refer to the link below for further information:

(http://nrhm.gov.in/images/pdf/programmes/RBSK/Resource_Documents/RBSK_P rocedures_and_M odel costing.pdf)

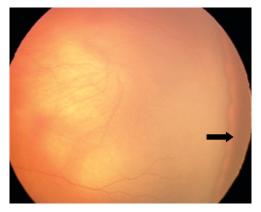
(http://npcb.nic.in/writereaddata/mainlinkfile/File310.pdf)

11. References

- Blencowe H, Lawn JE, Vazquez T, Fielder A, Gilbert C. Preterm-associated visual impairment and estimates of retinopathy of prematurity at regional and global levels for 2010.
 - Pediatr Res. 2013 Dec;74 Suppl 1:35-49. doi: 10.1038/pr.2013.205. Review.
- 2. March of Dimes, PMNCH, Save the Children, WHO. Born Too Soon: The Global Action Report on Preterm Birth. Eds CP Howson, MV Kinney, JE Lawn. World Health Organization. Geneva, 2012.
- 3. Blencowe H, Cousens S, Oestergaard MZ, Chou D, Moller AB, Narwal R, Adler A, Vera Garcia C, Rohde S, Say L, Lawn JE. National, regional, and worldwide estimates of preterm birth rates in the year 2010 with time trends since 1990 for selected countries: a systematic analysis and implications. Lancet. 2012 Jun 9;379(9832):2162-72. doi: 10.1016/S0140-6736(12)60820-4.
- 4. Dave HB, Gordillo L, Yang Z, Zhang MS, Hubbard GB 3rd, Olsen TW. The societal burden of blindness secondary to retinopathy of prematurity in Lima, Peru. Am J Ophthalmol. 2012 Oct;154(4):750-5. doi: 10.1016/j.ajo.2012.04.003. Epub 2012 Jul 24.
- 5. Dunbar JA, Hsu V, Christensen M, Black B, Williams P, Beauchamp G.Cost-utility analysis of screening and laser treatment of retinopathy of prematurity. J AAPOS. 2009 Apr;13(2):186-90. doi: 10.1016/j.jaapos.2008.10.014.
- 6. Rothschild MI, Russ R, Brennan KA, Williams CJ, Berrones D, Patel , Martinez-Castellanos MA3, Fernandes A, Hubbard GB 3rd, Chan RP, Yang Z, Olsen TW. The Economic Model of Retinopathy of Prematurity (EcROP) Screening and Treatment: Mexico and the United States. Am J Ophthalmol. 2016 Apr 26. pii: S0002-9394(16)30184-2. doi: 10.1016/j.ajo.2016.04.014. (Epub ahead of print).
- 7. Zin AA, Magluta C, Pinto MF, Entringer AP, Mendes-Gomes MA, Moreira ME, Gilbert C. Retinopathy of prematurity screening and treatment cost in Brazil. Rev Panam Salud Publica. 2014 Jul;36(1):37-43.

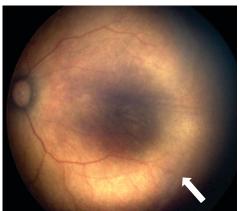
12. Annexure

ANNEXURE I- ROP: Stages and Action Needed



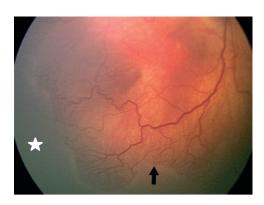
In full term infants and in more mature preterm infants the retinal blood vessels have already grown to the edge of the retina (called the oraseratta) at the time of birth or at the time of the first retinal examination.

No further screening is needed



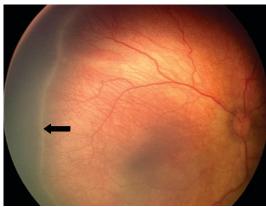
However, in preterm infants (<36 weeks) this process is not complete and the blood vessels are immature, and do not reach the edge of the retina. The arrow shows where the blood vessels have grown to. In preterm infants there is a peripheral avascular area of the retina where blood vessels are not visible at the first examination.

Further screening is needed



In early ROP the immature retinal blood vessels stop growing and a clear boundary can be seen at the junction of areas of the retina with and without blood vessels. The white star shows the area of avascular peripheral retina and the black arrow shows a clear line which indicates that the blood vessels have stopped growing (Stage 1 ROP).

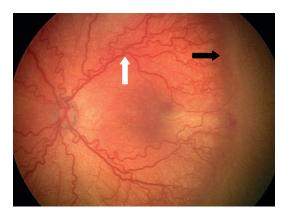
Further screening is needed



As the condition progresses the line at the boundary of vascular and avascular retina becomes raised and forms a ridge (Stage 2 ROP).

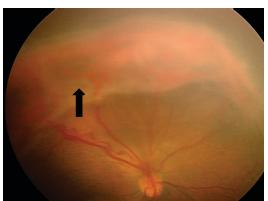
Further screening is needed

ANNEXURE I- ROP: Stages and Action Needed



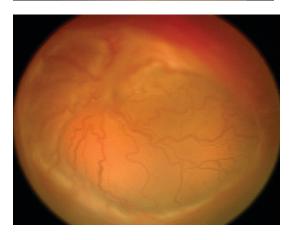
In more advanced cases abnormal blood vessels grow into the ridge, shown by the dark arrow. The blood vessels at the back of the eye can also become dilated and tortuous (white arrow), which is called "plus disease". This is a sign of acute and severe ROP which untreated has a very high risk of progressing to blinding retinal detachment (Stage 3 with plus ROP).

Urgent laser treatment is required.



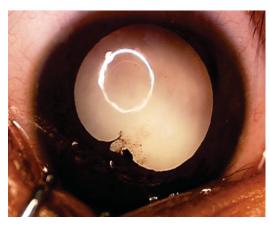
Without urgent treatment the retina can become detachment from the back of the eye. In this eye the upper part of the retina is detached and is beginning to roll up. The lower part of the retina is still attached (Stage 4 ROP).

Urgent complex surgery is required to preserve visual function



Total retinal detachment which is blinding. Complex surgery can sometimes reattach the retina, but the visual results are often disappointing (Stage 5 ROP).

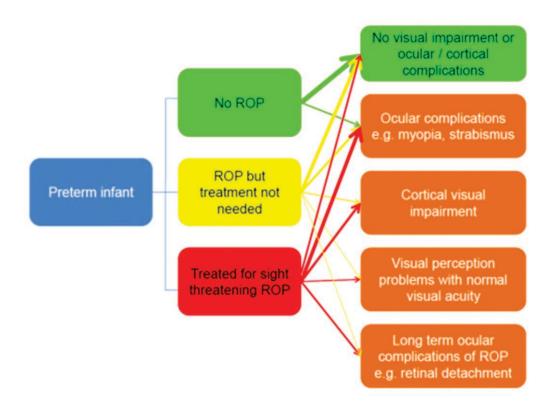
Refer for assessment for surgery. Early visual stimulation and rehabilitation can help improve a blind child's ability to function.



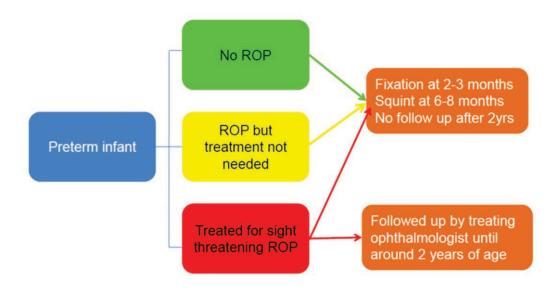
In end stage ROP the detached retina is dragged up behind the lens of the eye by scar tissue, giving rise to a white appearance inside the eye. This is often the first time carers notice a problem in their childs' eyes. Note: the bright white circle is an reflection from the camera.

Early visual stimulation and rehabilitation can help improve a blind child's ability to function.

ANNEXURE II –Ocular and cortical complications of preterm infants and current follow up practice.



Current follow up practices of preterm infants with or without ROP



ANNEXURE III - Indications for treating ROP

| Zone | Stage | Plus | No plus |
|--------------------------|-----------|--|---------|
| Zone 1 | Stage I | | |
| | Stage II | | |
| | Stage III | | |
| Zone 2 | Stage I | | |
| | Stage II | | |
| | Stage III | | |
| Zone 1/Post Zone 2 | APROP | | |
| Zone 3 | Any Stage | | |
| | Stage IV | Too late for laser. Urgent evaluation for Surgery | |
| | Stage V | Too late for laser and usually late for surgery also | |

Red: Treatment required

Green: No treatment is needed but further regular examinations are required

*Adapted from: Retinopathy of prematurity: an epidemic in the making (Chinese Medical Journal

2010;123(20):2929-2937)

ANNEXURE IV – Equipment and consumables for screening and management of ROP

| Screening |
|--|
| To be available in all SNCUs/NICUs |
| Equipment |
| Indirect ophthalmoscope (with small pupil adjustments) x1 per neonatal unit |
| Condensing lenses 20D and 28D for indirect ophthalmoscope |
| Neonatal lid speculums (Alfonso) x20 / neonatal unit (one / infant examined) |
| Scleral depressor (Schocket/wire vectis) x20 / unit (one / infant examined) |
| Consumables |
| Dilating eye drops (Tropicamide 0.5% +Phenylepherine 2.5%) |
| Local anaesthetic eye drops (Proparacaine 0.5%) |
| Artificial Tear Drops – for lubrication during procedure |
| Antibiotic drops (Moxifloxacin/Betadine) – at end of procedure (optional) |
| Clean wipes/cotton swabs – at end of procedure |
| Surgical gloves x2 – For screener and assistant |
| Hand wash (Sterillium) - for in between cases |
| Soap / Towel - for first wash |
| Coupling gel (Methlycellulose) - If Imaging Camera is used |
| Treatment |
| To be available in all SNCUs/NICUs |
| Additional Consumables |
| Sedation/IV analgesia/ Fluid support |
| Neonatal Resuscitation kit |
| Oxygen Cylinder, Oxygen mask and other delivery equipment |
| Sucrose/Dextrose – 10% solution |

Ringer lactate or balanced salt solution for corneal wetting during treatment

Additional equipment for monitoring during treatment

Pulse Oximeter

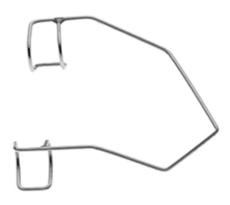
Warmer

Laser(A laser could be shared between more than one facility)

Portable diode /green laser with indirect delivery system (could be shared)

Laser Goggles x3 – Surgeon, Assistant, Paediatrician

Equipment for screening and treatment



Neonatal speculum to hold the eyelids open



Screening using a indirect ophthalmoscope and condensing lens

Source: Niloufer Hospital, Hyderabad

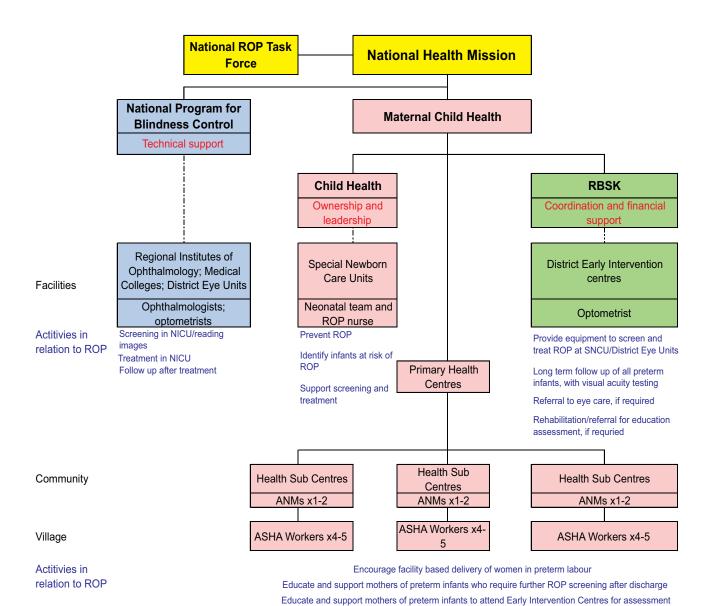


Laser unit



Baby screened for ROP using speculum and Indirect Ophthalmoscope Source: Niloufer Hospital, Hyderabad

ANNEXURE V - Flowchart depicting activities to be undertaken at each level



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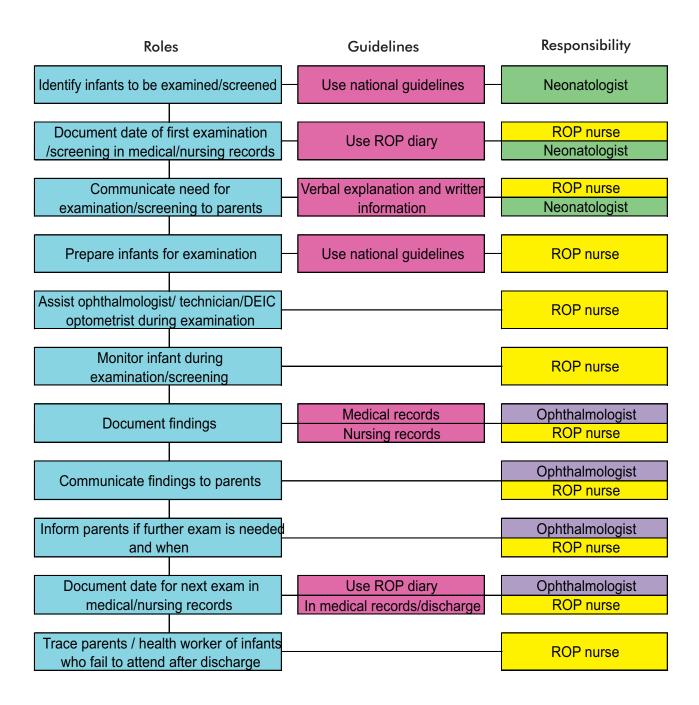
ANNEXURE VI – Suggested list of Hospitals to be considered as zonal mentoring institutions

| Zone | State | Institution | Sector | ROP expert |
|----------------------|---------------------|---|------------|-----------------------|
| East | 1.Odisha 2. West | L.V Prasad Eye Institute, Bhubaneshwar | NGO | Dr Tapas RanjanPadhi |
| | Bengal | 2. PB Aravind Eye Hospital, Kolkata | NGO | Dr Abhijit Chatterjee |
| | Maharashtra | 1.H.V. Desai Hospital, Pune | NGO | Dr SalilGadkiri |
| West | Manarashira | 2.Bombay Hospital, Mumbai | Private | Dr KarobiLahiri |
| | 1.Delhi | 1.Dr. R.P. Centre, AIIMS | Government | Dr Parijat Chandra |
| North | 2.Chandigarh | 2.PGIMER, Chandigarh | Government | Dr MangatDogra |
| 1.Karnataka South | | 1.Narayana Nethralaya, | NGO | Dr Anand Vinekar |
| | | Bengaluru | NGO | Dr MP Shanmugam |
| | | 2.Sankara Foundation Eye Hospital, Bengaluru | | |
| | 2.Tamil Nadu | 1.Aravind Eye Care System, | NGO | Dr Parag Shah |
| | | Madurai | NGO | Dr V. Narendran |
| | | 2.Aravind Eye Care System, Coimbatore | NGO | Dr PramodBhende |
| | | 3.Sankara Nethralaya, Chennai | | |
| Central | Telangana | 1.L.V Prasad Eye Institute, Hyderabad | NGO | Dr SubhadraJalali |
| | | 2.PVRI, Hyderabad | NGO | Dr Kiranmayee |

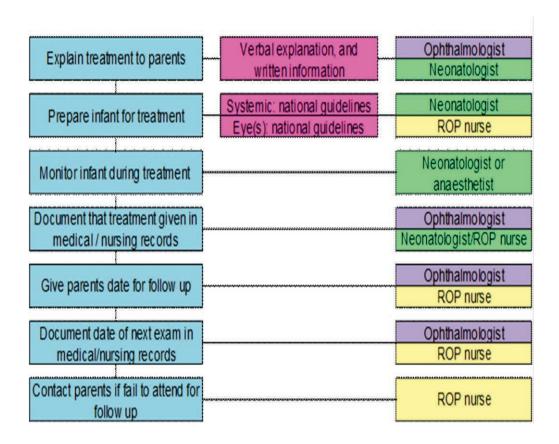
ANNEXURE VII - Baseline data collection at District Level

- Number and cadre of staff to be trained.
- Equipment needed for detection and treatment.
- Equipment needed in DEICs for long term follow up.
- Equipment required for neonatal care (from FBNC list).

ANNEXURE VIII- Roles and responsibilities of the neonatology team and ophthalmologist (or technician/DEIC optometrist) in relation to screening for ROP in the SNCU



ANNEXURE IX - Roles and responsibilities of the neonatology team and ophthalmologist in relation to treatment for ROP



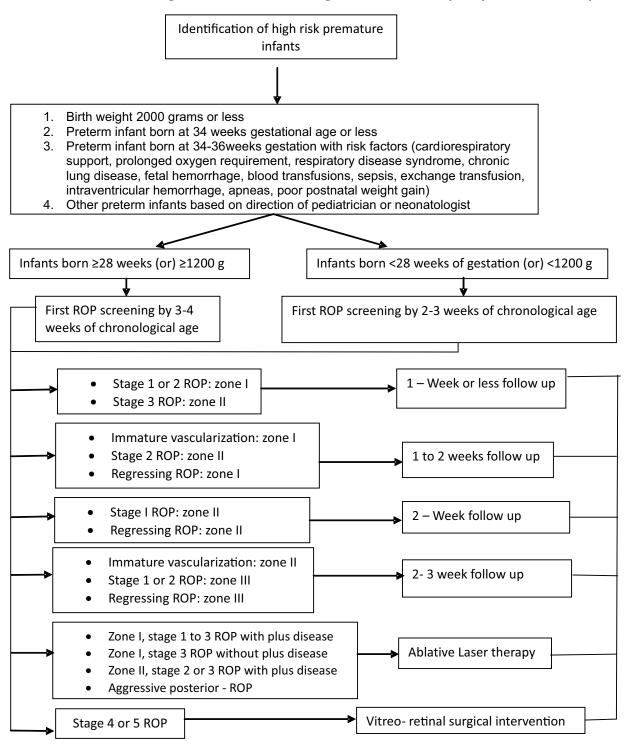
ANNEXURE X - Competency based training of technicians/DEIC optometrist using RetCam for ROP screening*

| PARAMETERS | LEVEL – I | LEVEL-II | LEVEL-III |
|-------------------------------|---|---|---|
| Basics 1.Knowledge | Basic knowledge of: 1.ROP 2. Outreach activity 3. Roles and responsibility 4. RetCam parts | 1.Details of equipment 2. Stakeholders (doctors, administrators) 3. Other common conditions (non – ROP) | 1.Comprehensive knowledge of all aspects including regional resource persons 2. Can recognize common pediatric retinal conditions |
| 2.Logistics: base hospital | Under basic checklists | Handles transportation logistics | Comprehensive care of equipment and improvisation during emergency travel |
| 3. Logistics: on site | Can perform basic sequence of events: setting up, wrapping baby, analgesia, use of speculum | Can also perform basic monitoring of the baby | Can handle all situations including performing scleral depression |
| Procedures 4.Patient record | Creates records on software. Calculation of corrected age. | Can source data from staff or local doctor | Can source information from site hospital even when missing |
| 5.Quality of image | Minimum of 70% of images are focussed | 70-90% in focus | >90% in focus |
| 6. Orientation | Minimum of 70% of images are oriented to represent the corrected quadrant/aspect | 70-90% in oriented | 90% oriented |
| 7. Quadrants | All quadrants plus temporal oraserrata in 60% of cases | Oraserrata in 75% of cases | Oraserrata>75% of cases |
| 8.Illumination | Can work in fixed illumination | Capable of dynamic changes in illumination | Adapt at changing illumination as pathology demands |
| 9. Dynamic focus | Sometimes, with difficulty | Can do in most cases | Adapt, including raised lesions and peripheral scars |
| 10. Image capture | Accomplishes video mode with difficulty | Comfortably selects stills from video | Adapt at image capture & post-processing on software |
| 11.Lenses | Can use ROP lens (13 D) | Can use high magnification with some | Can use all lenses equally well |

| 12.Speed | Completes one eye (speculum on to off) in ≤ 6 minutes | Completes one eye (speculum on to off) in ≤ 4 minutes | Completes one eye (speculum on to off) in ≤ 2 minutes |
|--|--|--|--|
| 13. Post image capture – image grading and reporting | Cannot do image processing | Can do in some cases | Adapt in highlighting features |
| 14. Disease severity | Can differentiate severe from mild ROP (plus, zone 1, stage3) | Can diagnose all stages in all zones and recognize pre plus | Adapt at diagnosing all forms of the disease including APROP |
| 15. Disease progression | Can compare between visits | Can compare between visits/eyes/other patients | Can expertly monitor progression or regression of the disease based on the images |
| 16. Decision tree | 1.Will upload all red, all orange and most green.2.Will have minimum 60% accuracy | 1.Will upload all red and most orange grades.2.Will have minimum 80% accuracy | 1.Will upload only red.2.Will have >90% accuracy |
| Post procedure | | | |
| 17. IT and image handling | Working knowledge of tele-ROP software | Comfortable with software Understands priority of uploads | 1.Exporting formats 2.Report collection and computation 3.Trouble shooting |
| 18. Records | Mother card filling hard and soft copy registers | 1.Online data maintenance | All aspects of records including reports and tabulation |
| 19. Follow – up | 1.Scheduling appointments – helps project manager 2.Follow-up score: minimum 60% compliance | Successful follow-up score: minimum 70 % | Successful follow-up score: minimum 80 % |
| Complications | | | |
| management | | | |
| 20. complications management | Not applicable | Minor aspects of equipment breakdown Parent queries in difficult situations | Can handle sick children, procedure related complications independently, parent queries, equipment breakdown |

^{*}Source: The KIDROP model of combining strategies for providing retinopathy of prematurity screening in underserved areas in India using wide-field imaging, tele-medicine, non-physician graders and smart phone reporting: Vinekar A et al, Indian Journal of Ophthalmology 2014;62(1): 41-49

ANNEXURE XI - Algorithm for the Management of Retinopathy of Prematurity



Source:NNF website:National Neonatology Forum 2010 Clinical practice Guidelines (Pejaver R, Bilagi A, Vinekar A, Jalali S, Deorari A)

ANNEXURE XII - Guidelines for frequency of screening for ROP, based on findings

| Zone of retinal findings | Stage | Follow up interval |
|--------------------------|----------------------|--------------------|
| Zone 1 | Immature vasculature | 1-2 weeks |
| | Stage 1 or 2 | 1 week or less |
| | Regressing ROP | 1-2 weeks |
| Zone 2 | Immature vasculature | 2-3 weeks |
| | Stage 1 | 2 weeks |
| | Stage 2 | 1-2 weeks |
| | Stage 3 | 1 week or less |
| | Regressing ROP | 1-2 weeks |
| Zone 2 | Stage 1 or 2 | 2-3 weeks |
| | Regressing ROP | 2-3 weeks |

Source: NNF website, National Neonatology Forum 2010 Clinical practiceGuidelines (Pejaver R, Bilagi A, Vinekar A, Jalali S, Deorari A)

Annexure XIII- Standardised Sheet for Recording Screening Results

Neonatal Ophthalmology Examination Record

| Name of facility Mothers ANC number Name of child Name of mother Name of father Mobile number SNCU database no | | | Date of birth / / (dd/mn/year) Gender M / F Gestational age weeks Birth weight grams | |
|--|------------------------|--|---|------------------|
| Document findings | at each exam | Right eye | Left eye | Signs of ROP |
| Date | 1 1 | | | - Stage 1 |
| Postmenstrual age | wks | | | Stage 2 |
| Management decision: *screen again | Circle one Yes | | | Stage 3 |
| Date of next screen *no further screening | / / dd/mn/year) Yes | | | AAA AP-ROP |
| *urgent treatment | Yes | | | •.•• Stage 4/5 |
| Examiner | | | | ×××x Laser scars |
| | | Zone (no ROP, 1-3): Stage (0-5): Pre-plus : Yes/No Plus: Yes/No | Zone (none, 1-3): Stage (0-5): Pre-plus : Yes/No Plus: Yes/No | |

For follow up visits

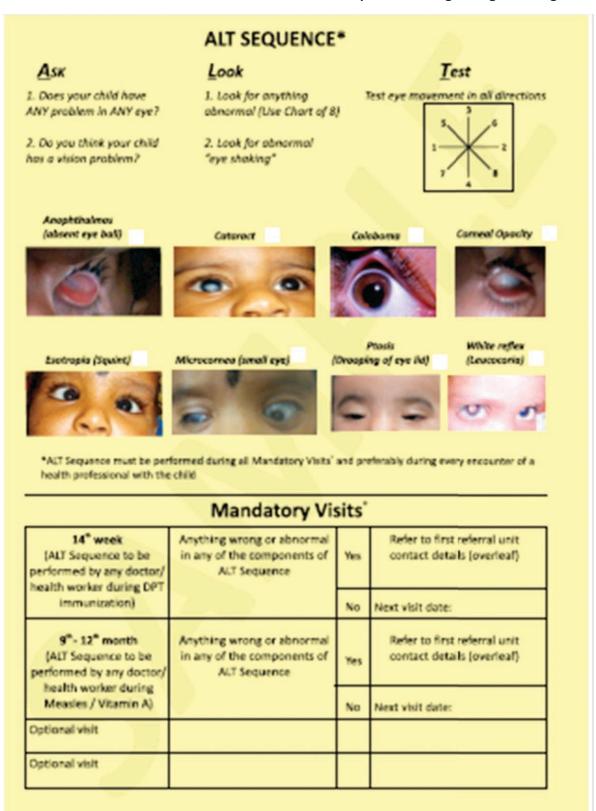
| Document findings a | at each exam | Right eye | Left eye | Signs of ROP |
|---|--|--|--|---|
| Date Postmenstrual age Management decision: *screen again Date of next screen *no further screening *urgent treatment Examiner | Wks Circle one Yes I dd/mn/year) Yes Yes | () | | Stage 1 Stage 2 Stage 3 AAA AP-ROP Stage 4/5 XXXX Laser scars |
| | | Zone (no ROP, 1-3): Stage (0-5): Pre-plus : Yes/No Plus: Yes/No | Zone (none, 1-3): Stage (0-5): Pre-plus : Yes/No Plus: Yes/No | |

Note: All preterm infants should also undergo universal screening for structural abnormalities of the eyelids and eye at birth. Findings can be recorded on the ALT form below (Annexure XVI)

ANNIEVLIDE VIV. Ealla

| ANNEXURE XIV | Follow -up Screening t | or ROP for at risk Child | | |
|--|--|---------------------------|--|--|
| ANC No: | | | | |
| BPL card: Yes No | | | | |
| Name of Father: | Name of Mother: | | | |
| Mobile No: | | | | |
| | BABY DETAILS | | | |
| Date of Birth: | | | | |
| Weight in grams: | | | | |
| Gestation (weeks): | | | | |
| Hospital of Birth: | Taluk: | | | |
| | District: | State: | | |
| | | | | |
| BABY for ROP Screening (as per | criteria specified above) | | | |
| | | | | |
| First visit (before 30 days of birth | 1) | Date: | | |
| Follow up needed: | No Yes | Date: | | |
| | | | | |
| ROP FOLLOW UP | | | | |
| Date of First follow up: | | PMA (Post menstrual age): | | |
| Date of Second follow up: | | PMA: | | |
| Date of Third follow up: | | PMA: | | |
| Date of fourth follow up: | | PMA: | | |
| Date of Fifth follow up: | PMA: | | | |
| ROP Treatment details (if any): | | | | |
| | | | | |
| BABY for UNIVERSAL Screening (Born >2000gms and/or term) | | | | |
| First visit (before 21 days of birth) date: | | | | |
| 14 weeks: | | | | |
| 9 months: | | | | |
| | | | | |
| UNIVERSAL SCREENING FOLLOW UP | | | | |
| Date of First follow up: | | | | |
| Date of Second follow up: | | | | |
| Date of Third follow up: | | | | |
| Date of fourth follow up: | | | | |

ANNEXURE XV - ALT form for Basic Universal Eye Screening using Torchlight



Source: FOREVER Card, Narayana Nethralaya (<u>F</u>ocus on <u>R</u>OP, <u>E</u>ye Care, <u>V</u>ision, <u>E</u>ye Cancer andRehabilitation Program) adapted from Dr Arun Singh, Raichak Guidelines 2012











































