

Operational guidelines for ROP in India: A Summary

Rajan Shukla¹, G V S Murthy^{1,2}, Clare Gilbert², Bala Vidyadhar¹, Sridivya Mukpalkar¹

Retinopathy of Prematurity (ROP) is a potentially blinding disease of the eye that can affect infants born four or more weeks preterm and have received intensive neonatal care. ROP is a dynamic, time-bound disease that is not present at birth. Preventing visual loss from ROP in India requires scaling up services for screening and treatment for ROP to match the exponential growth in neonatal intensive care in India and other low- and middle-income countries. Operational guidelines for prevention of visual loss from ROP will facilitate rapid scale up of services, by identifying key players and their roles and responsibility in the Indian context. The guidelines recommend broad eligibility criteria for screening (gestational age ≤ 34 weeks, birth weight ≤ 2000 gms) as the special newborn care unit (SNCU) have varying quality of neonatal care. Treatment is based on the early treatment for retinopathy of prematurity (ET-ROP) study treatment criteria. The screening criteria could be revisited when more contextual evidence on the risk of ROP is available in India.

Key words: India, operational guidelines, preterm infants, retinopathy of prematurity

Retinopathy of Prematurity (ROP) is a potentially blinding disease of the eye that could affect infants born four or more weeks preterm and have received intensive neonatal care.^[1,2] ROP is a dynamic, time-bound disease that is not present at birth. The risk of severe, sight-threatening ROP (ST-ROP), which is higher in more preterm infants, can be reduced by quality improvement measures that reduce exposure to known risk factors such as poorly administered supplemental oxygen, sepsis and poor weight gain after birth. Early detection of ST-ROP, followed by urgent laser treatment, is highly effective in preserving the sight of the babies.^[3]

ROP is emerging as a leading cause of avoidable childhood blindness in India and other low- and middle-income countries (LMIC).^[2,4] Strengthening of efforts by Ministries of Health over the last two decades to reduce neonatal mortality as part of the millennium development goals (MDG) and the sustainable development goals (SDG) have not only improved survival of the preterm babies, but has also increased the number of babies at risk of blindness from ROP.^[5,6] It is imperative to integrate ROP services with newborn and child health services to ensure healthy survival of preterm infants. This requires that all neonatal intensive care units have a system in place to screen and treat ROP to save sight. If detected late or untreated, severe sequelae can result in irreversible blindness and all the psychosocial, educational and economic

implications.^[7] The minimum necessity is that all babies at risk of ST-ROP are screened and treated.

All eligible preterm infants admitted to special newborn care units (SNCUs) need retina screening because up to 15% develop ST-ROP^[8] and these babies need urgent laser treatment by an ophthalmologists trained in the procedure. Laser treatment if applied well and in time is highly effective at preserving sight. The exponential 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 receive care.^[9] Three major programs cover the range of services for prevention of blindness from ROP in India. They are Child Health, Ministry of Health and Family Welfare; Rashtriya Bal Swasth Karyakram^[10] (RBSK) and National Programme for Control of Blindness and Visual Impairment^[11] (NPCB and VI). SNCUs under child health are accountable for healthy survival of all preterm children under their care and follow them for a period of two years to ensure healthy development. RBSK, launched in 2013, covers early detection and management of 4 'D's'- defects at birth, diseases of childhood, deficiencies and developmental delays- covering 29 conditions including ROP. NPCB and VI is responsible for strengthening the public eye health system for screening and treatment of ROP.

The operational guidelines were developed to facilitate scaling up of services for screening and treatment of ROP

¹Associate Professor, Health Policy and Management, India ROP Partners Implementation Consortium, Indian Institute of Public Health, Hyderabad, India, ²International Centre for Eye Health, Department of Clinical Research, London School Hygiene & Tropical Medicine, London, UK

Correspondence to: Dr. Rajan Shukla, Indian Institute of Public Health Hyderabad, Plot # 1, A N V Arcade, Amar Co-operative Society, Kavuri Hills, Madhapur, Hyderabad - 500 033, Telangana, India. E-mail: rajan.shukla@iiph.org

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in public and private sectors. Adherence to the guidelines will also strengthen existing ROP screening services. The salient features of the guidelines are presented in this paper. Complete ROP screening operational guidelines are available at <https://drropindia.org/retinopathy-of-prematurity/policy-makers-rop/#operationalguidelines>.

Process

A national group of experts representing neonatal care, eye care, public health experts and program managers (Child health, RBSK, NPCB and VI), were commissioned by the National ROP Task Force to develop the ROP operational guidelines. The group met multiple times and interacted through emails to undertake multiple revisions to finalize the guidelines. The national expert group considered several factors in preparing the guidelines such as reviewing guidelines from other countries, integration of ROP services into the existing child care programs, the variation in the quality of neonatal care in different levels/regions and evidence of bigger babies presenting with Stage 4 or stage 5 ROP in tertiary eye care centers across India.^[12,13]

Factors that increase the risk of ROP

In addition to preterm birth, exposure to excessive oxygen is major risk factor for ST-ROP. Other risk factors include sepsis, intra-ventricular hemorrhage, respiratory distress, failure to gain weight and blood transfusions, while breast feeding and kangaroo mother care reduce the risk of STROP. Interventions which reduce the risk of ST-ROP are also key components of high quality neonatal care and are covered under facility based newborn care guidelines.^[14] Indeed, the incidence of ST-ROP can be a good indicator to monitor the overall quality of neonatal care in addition to mortality rates, which has been recognized by WHO.^[14]

Results

The guideline development group developed India-specific strategies [Fig. 1] and protocols to implement ROP services in the country. These guidelines define the roles and responsibilities [Table 1] of the three major national programs at national, state [Fig. 2] and health facility level [Table 2] to improve coordination for efficient service delivery. The guidelines also emphasize the need to generate greater

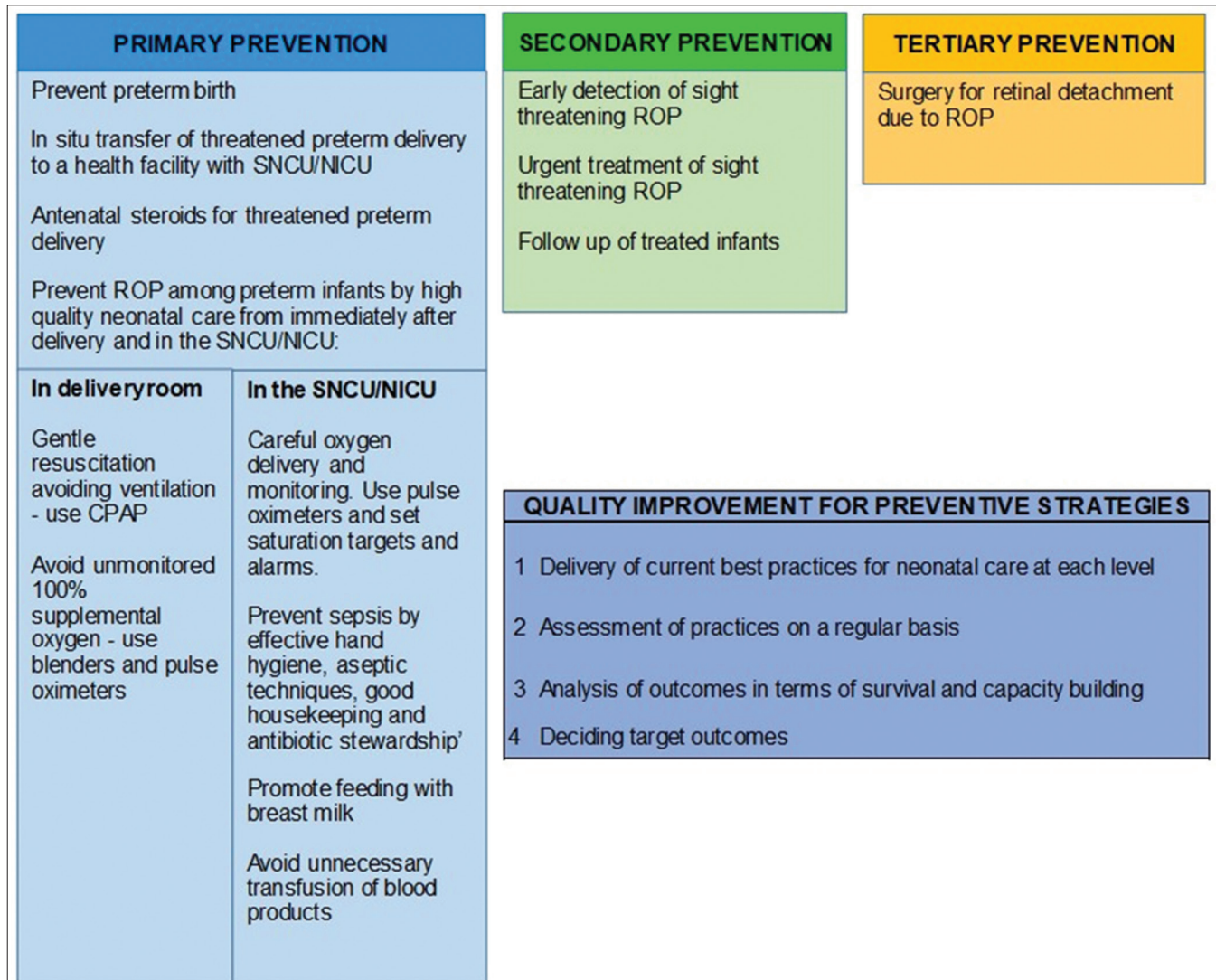


Figure 1: Strategies for control of visual loss from ROP

Table 1: Roles and responsibilities at each level of the health system

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

Table 2: Roles and responsibilities of different personnel at health facilities in the system

At SNCU level (DH/Medical Colleges)		At the District Early Intervention Centres		At the lower levels of the health systems (block/villages)	
Neonatologist/ Paediatrician	ROP Nurse (nurses selected for each SNCU/NICU)	Optometrist	DEIC Manager	ANMs	ASHAs
<ul style="list-style-type: none"> -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 	<ul style="list-style-type: none"> -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 	<ul style="list-style-type: none"> -Screening for structural eye defects or universal eye screening and identifying babies who will need ROP screening, in SNCU everyday -Identifying and counselling for follow up children at DEIC: based on any stage of ROP, any family history of early vision impairment, all preterm children or low birth weight children -Follow up for refractive errors, strabismus, acuity of vision etc., and referral for any surgical or medical intervention for eye i.e., if any way vision impairment affects the child's education -Refer complex cases to an ophthalmologist experienced in paediatric ophthalmology 	<ul style="list-style-type: none"> -To co-ordinate for the follow up of infants treated in medical colleges/ tertiary care center -Ensure availability of suitable spectacle frames for infants and young children -Provide visual stimulation of children who are visually impaired children from all causes 	<ul style="list-style-type: none"> -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 -Provide information on care of preterm infants, including potential complications such as ROP 	<ul style="list-style-type: none"> -Encourage mothers of infants who require further retinal examination/screening after discharge from neonatal care to access this service -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 -Encourage mothers of ROP blind children to access low vision and rehabilitation services

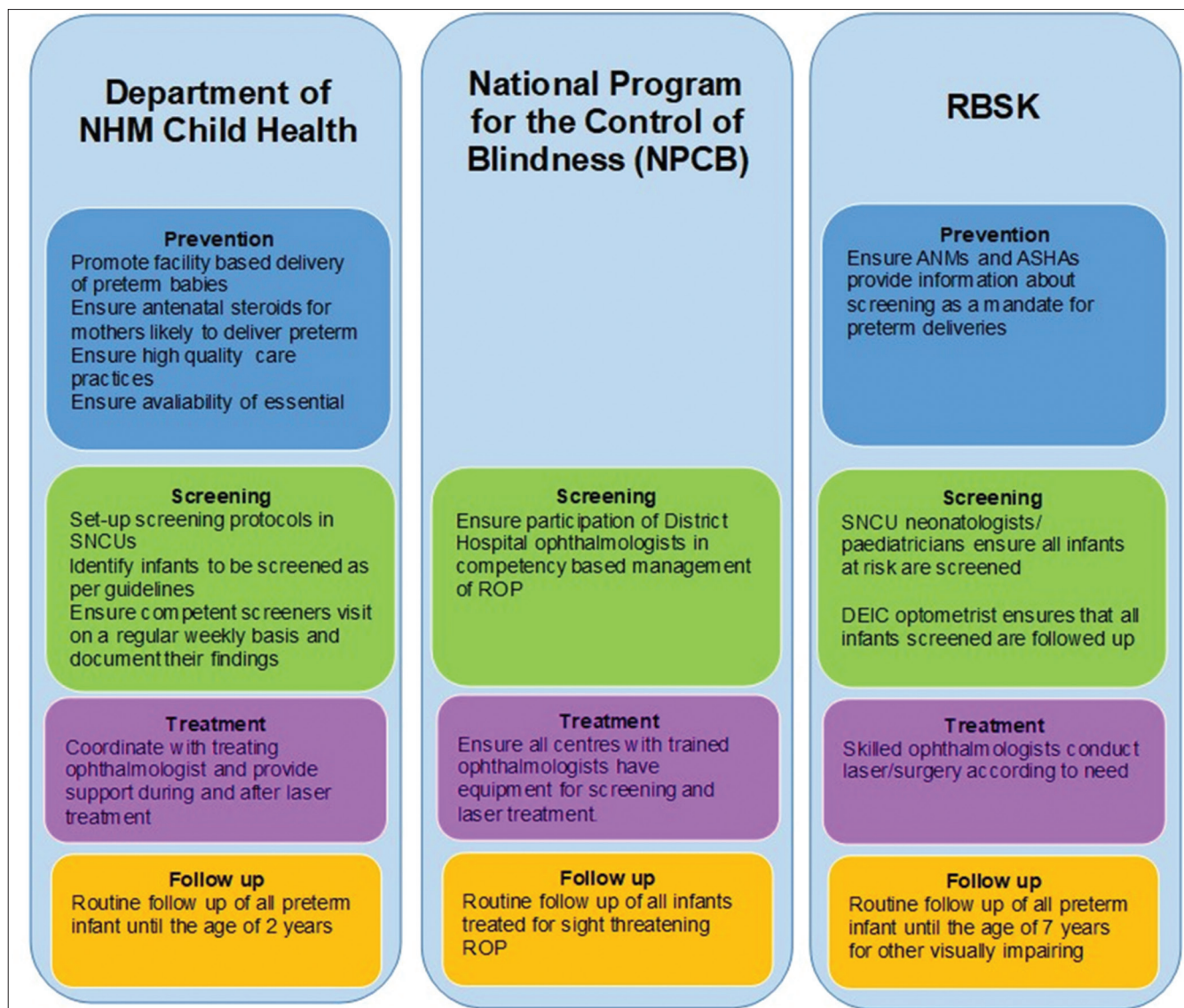


Figure 2: Roles of NHM Child Health, NPCB and RBSK in the management of ROP

awareness about ROP and its risk factors among a wide range of stakeholders. The guidelines also identify the need to build the capacity of several different cadres for screening and treatment of ROP. The key recommendations in the ROP operational guidelines are shown below [Figs. 3-5].

Criteria for ROP screening

The ROP screening criteria of gestational age and birth weight are lower in the developed world.^[15] In order to accommodate and allow the variable quality of care in India, and in view of the increased risk of ST-ROP, the screening criteria have been kept broad.^[8,12,13] All infants admitted to SNCUs/NICUs with the following criteria need examination by funduscopy [Fig. 3]: (1) all infants born at 34 weeks or less gestational age; (2) all infants weighing 2000 g or less at birth, (3) all infants born at more than 34 weeks gestational age with associated risk factors (cardiorespiratory support; prolonged oxygen requirement; respiratory distress syndrome; chronic lung disease; fetal hemorrhage; blood transfusion; sepsis; exchange transfusion; intraventricular hemorrhage; apnea;

poor post-natal weight gain), (4) other preterm infants based on the discretion of the pediatrician or neonatologist.

The first step for ROP screening is identification of infants eligible for screening. This is facilitated by maintaining ROP screening diary in which infants are listed as per screening schedule based on eligibility criteria (gestational age, birth weight) at the time of admission and the recommendation of pediatricians while an inpatient. The first ROP screening should take place by 25-30 days of life. This is possible with a coordinated effort of all health care personnel involved in childcare. All eligible babies should also be screened before discharge even if this is early.^[9,16] Screening should take place in the SNCU/NICU for inpatients. Outpatients can be examined in the unit or in eye departments.

The findings and management decision must be clearly documented by the screener in the medical records at each screening episode, for example "no ROP in either eye, immature retinal vessels", or "right and left eye: Stage 2 in zone 2" as well as the date and name of the screener. If further screening is

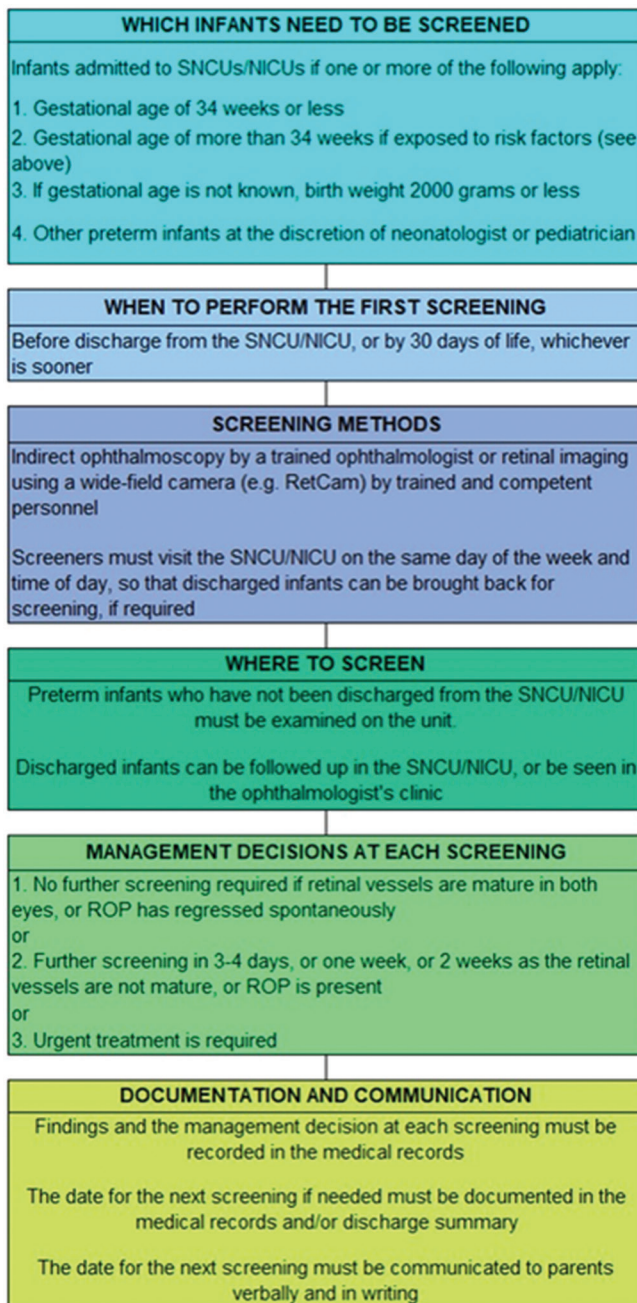


Figure 3: Protocol for screening for ROP

required, the date and place must also be clearly documented and communicated. This is particularly important before discharge or transfer to another unit.

Approaches for ROP screening

The details of different approaches for ROP screening are shown Table 3. If trained technicians/District Early Intervention Center (DEIC) optometrists screen for ROP using wide-field retinal imaging systems, an ophthalmologist should interpret the retinal images as soon as possible on-or off-line so that treatment can be instituted within 48 hours if needed. Regardless of the approach, take informed consent from parents, the pupils should be dilated with tropicamide 0.5%-1% with phenylephrine 2.5% dilating drops, and the

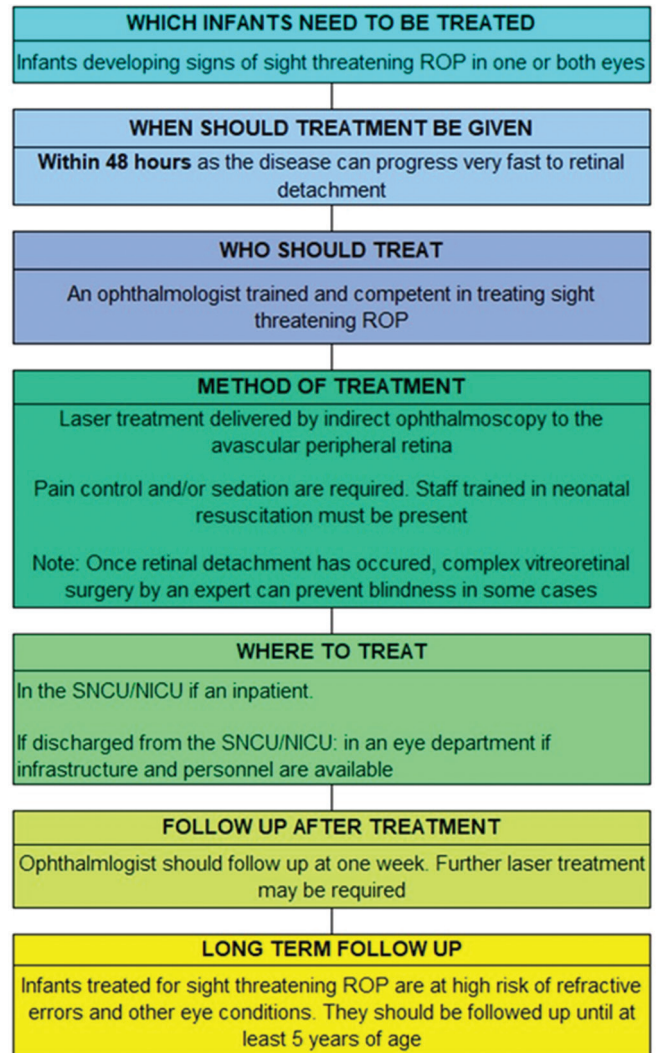


Figure 4: ROP treatment protocol

infants fed at least an hour before screening. To reduce stress, infants should be swaddled, tucked and given non-nutritive suckling (pacifier). A trained nurse should assist the screener and monitor the baby's vitals during screening.

ROP Treatment protocol [Fig. 4]

The indications for treatment are based on the ETROP criteria.^[3] The gold standard treatment is peripheral retinal ablation, and the guidelines recommend that this be undertaken in the unit for inpatients, or in tertiary eye care centers or medical colleges with capacity to manage preterm babies. An appropriate referral system integrated into referral mechanism of the child health program is very important. Alternate, less evidence-based treatment consists of intravitreal anti-vascular endothelial growth factor (anti VEGF), usually bevacizumab;^[17] babies with Stage 4 ROP require vitreoretinal surgery.

Discussion

There is a small window of opportunity for effective management of ROP. Hence it requires a very targeted approach. A "hub and spoke" approach is recommended comprising three to four district level SNCUs in the vicinity of a medical college

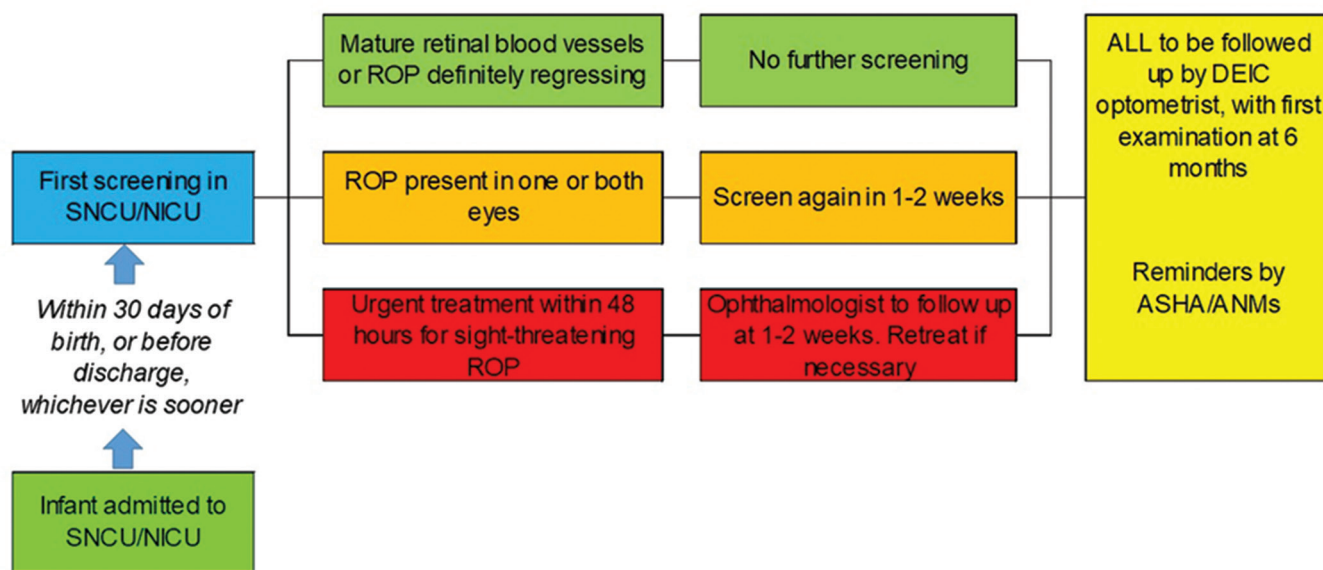


Figure 5: Protocol for follow up. **Note:** The DEIC Optometrist should coordinate with SNCU/NICU staff to ensure that all infants screened for ROP are followed up in the DEIC

Table 3: ROP screening - by whom, how and when

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

with an SNCU/NICU capable of laser treatment for ROP. The guidelines differentiate the roles and responsibilities of different cadre delivering services for prevention of blindness from ROP, allowing better coordination between the relevant programs. Generating awareness about ROP and capacity building for screening and treatment will be key to implementation of the guidelines. Ensuring quality screening services is of vital importance for the timely identification of babies with ST-ROP. The guidelines will facilitate audit of ROP programs to improve the quality of ROP screening and treatment services, and the guidelines should be revised in 3-5 years as further evidence is generated. The operational guidelines for prevention of visual loss from ROP would facilitate rapid scale-up of ROP services in public and private sector NICU/SNCUs. Ensuring every eligible preterm infant receiving neonatal intensive care receives a timely screening and treatment for ROP is important for the healthy survival of preterm babies.

Conclusion

Protocol based services for prevention of blindness from ROP will ensure standardization of services, rapid identification of capacity building needs and scale-up of ROP services. The evidence generated through a large scale ROP programs will not only help refine the operational and technical guidelines, but also facilitate monitoring the quality of neonatal care.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

References

1. Quinn GE, Gilbert C, Darlow BA, Zin A. Retinopathy of prematurity: An epidemic in the making. *Chin Med J* 2010;123:2929-37.
2. 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;74(S1):35.
3. Early Treatment For Retinopathy Of Prematurity Cooperative Group. Revised indications for the treatment of retinopathy of prematurity: Results of the early treatment for retinopathy of prematurity randomized trial. *Arch Ophthalmol* 2003;121:1684-94.
4. Blencowe H, Moxon S, Gilbert C. Update on blindness due to retinopathy of prematurity globally and in India. *Indian Pediatr* 2016;53:S89-92.
5. Moxon SG, Lawn JE, Dickson KE, Simen-Kapeu A, Gupta G, Deorari A, *et al.* Inpatient care of small and sick newborns: A multi-country analysis of health system bottlenecks and potential solutions. *BMC Pregnancy Childbirth* 2015;15:S7.
6. Neogi S, Khanna R, Chauhan M, Sharma J, Gupta G, Srivastava R, *et al.* Inpatient care of small and sick newborns in healthcare facilities. *J Perinatol* 2016;36:S18.
7. Kulkarni S, Gilbert C, Zuurmond M, Agashe S, Deshpande M. Blinding retinopathy of prematurity in Western India: Characteristics of children, reasons for late presentation and impact on families. *Indian Pediatr* 2018;55:665-70.
8. Meraz-Gutiérrez MP, Olguín-Manríquez FJ, Arriola-López AE, Berrones-Medina D, Price KW, Morales-Canton V, *et al.* Evidence to modify guidelines for routine retinopathy of prematurity screening to avoid childhood blindness in middle-income countries. *Rev Mex de Oftalmol* 2016;90:167-73.
9. Vinekar A, Jayadev C, Dogra M, Shetty B. Improving follow-up of infants during retinopathy of prematurity screening in rural areas. *Indian Pediatr* 2016;53 Suppl 2:S151-4.
10. <https://rbsk.gov.in/RBSKLive/>. Rashtriya Bal Swasthya Karyakram. c2019.
11. <https://npcbvi.gov.in/>. National program for blindness and visual impairment. c2019.
12. Jalali S, Anand R, Rani PK, Balakrishnan D. Impact of the day-30 screening strategy on the disease presentation and outcome of retinopathy of prematurity. The Indian twin cities retinopathy of prematurity report number 3. *Indian J Ophthalmol* 2014;62:610-4.
13. Shah PK, Narendran V, Kalpana N. Aggressive posterior retinopathy of prematurity in large preterm babies in South India. *Arch Dis Child Fetal Neonatal Ed* 2012;97:F371-5.
14. Available from: <https://www.newbornwhocc.org/Facility-Based-Care-of-Preterm-Infant.html>. Facility-Based Care of Preterm Infant (Eliminating retinopathy of prematurity by improving quality of care). Web resource. 2018-19.
15. Gilbert CE. Screening for Retinopathy of Prematurity: Does One Size Fit All? *BMJ Publishing Group. Arch Dis Child Fetal Neonatal Ed* 2016;101:F280-1.
16. Vinekar A, Jayadev C, Mangalesh S, Kurian M, Dogra M, Bauer N, *et al.* Initiating retinopathy of prematurity screening before discharge from the neonatal care unit: Effect on enrolment in rural India. *Indian Pediatr* 2016;53 Suppl 2:S107-11.
17. Hartnett ME. Advances in understanding and management of retinopathy of prematurity. *Surv Ophthalmol* 2017;62:257-76.