

Project Title:

Mobile Unit with Imaging Devices for Retinopathy of Prematurity (ROP) screening in premature infants funded by the CSR Project of Cochin Shipyard Ltd.

Objective of this project:

Retinopathy of prematurity (ROP) is a potentially avoidable cause of blindness in children. At-risk preterm infants are examined at proper times to detect the changes of Retinopathy of Prematurity (ROP) before they become permanently destructive. This project presents the attributes on which an effective program for detecting and treating ROP could be based, including the timing of initial examination and subsequent re-examination intervals. The main aim of screening for ROP is to detect infants needing treatment for ROP.

Rationale for Retinopathy of Prematurity screening:

There is an alarming increase in the incidence of retinopathy of prematurity (ROP) in the developing countries including India today, constituting what is referred to as the third epidemic of ROP. While the incidence of ROP is on the wane in the West, thanks to the improvement in neonatal care and screening, in India we are just beginning to face the storm mainly due to increased awareness. The most important determinant of any ROP management program is an effective screening strategy.

Brief of the proposed CSR Project:

What is Retinopathy of prematurity? : Retinopathy of prematurity (ROP) is a fibro vascular proliferative disorder affecting the peripheral retinal vasculature in premature infants. It is a preventable cause of childhood blindness. With improving survival of very low birth weight infants, ROP emerged as a significant problem in India. Although the exact prevalence in India is not known, the incidence reported is between 22 and 52%. The initial signs of ROP may be detected a few weeks after birth, and the condition progresses rapidly. This means that screening has to be timely as there is only a very narrow window of opportunity for treating these babies and the condition can quickly progress to blindness.

The latest Indian screening guidelines on screening ROP by Rashtriya Balswasthyakaryakram (RSBK):

- Birth weight of <2000 grams or Gestational age at birth of <34 weeks first screening should be done before 4 weeks of birth.
- Infants born at <28 weeks and weighing <1200 g should be first screened earlier at 2-3 weeks after delivery.

The level of ROP awareness is high among pediatricians of tier one cities of India, but it is very poor in tier two cities like Ernakulum and may even be worse in tier three cities. We often see babies with advanced stage four and five ROP which were born in tier three cities and periphery. Thus, awareness among pediatricians is a must to tackle this problem. Unfortunately, this is still lacking in India. Many pediatricians refer to the ophthalmologist only when they or the parents notice white reflex, when it is too late to do anything as far as giving normal vision is concerned.These babies have never had an eye exam and come to us only after the parents notice that child is not seeing well.When enquired, these parents were never informed by the treating paediatrician about the need for an eye examination for their child. The medico-legal implications are huge and should be kept in mind by the paediatrician. The first step in reducing blindness due to ROP is recognizing that the problem exists.



Why screening for Retinopathy of Prematurity is necessary?

Jury awards for ROP malpractice have been some of the largest grants in medicine. A large proportion of litigation of cases of ROP involves failure to properly transfer care between specialists, loss to follow-up, and failure to ensure that follow-upvisits and treatment are conducted within current guidelines for follow-up and treatment. The high risk of medical liability in caring for patients with ROP has dissuaded paediatric and retina specialists from continuing to provide treatment of ROP to these patients. In addition to the legal implications, many ophthalmologists stay away from ROP screening and treatment due to the hardships often involved in these cases. They frequently require extensive travel to hospitals and clinics in underserved areas, and reimbursements for these services have declined. The fact that many premature infants often are born into a lower socio economic group presents its own set of challenges. Visual impairment is associated with reduced quality of life, loss of independence, and the reduction of potential earnings. Although children comprise only a fraction of plaintiffs in lawsuits, visual impairment is a significant disability for young patients and can thus be associated with indemnities and jury awards exceeding \$1million. As litigation in paediatric ophthalmology is distinct from adult litigation, it deserves special attention. According to a 2011 analysis of a national liability insurer covering approximately 800 ophthalmologists, less than 2% of all ophthalmology malpractice cases resulted in payment to the plaintiff.

It is also important to be aware of the emotional effect that blindness or other visual disturbances have on both the patient and parents. The child's future body image, ability to succeed in school or participate in sports, economic prospects, and parental guilt can all help to allay parents' fears.

How we are conducting screening programmes:

In our institution, we have been successful in establishing procedures and systems that significantly reduce our exposure to risk. First, we have developed multiple layers to check and confirm that patients receive examinations and follow-up treatment when required. We follow a protocol of notifying parents, guardians, hospitals, pediatricians, and if needed, social service personnel when a patient fails to show for an appointment. We visit Neonatal Intensive Care Units (NICUs) of various multi-speciality hospitals of Ernakulum and Kottayam districts of Kerala regularly /weekly for periodic screening, where with the neonatologists we keep a check on schedule ROP screening visits for all premature infants. At present we are screening 17 different NICUs in various districts of Kerala every week, and with the help of neonatologists we are treating all affected neonates in NICUs itself, that too within 48 hours of diagnosis. This immediate step can savour vision of a neonate with maximum results noted and documented in studies till now. These steps not only ensure the continuity of care but also can be provided as evidence in the case of legal investigation.

Why it is necessary to fund the Mobile ROP Unit through CSR?

This is purely a **not-for-profit** venture where trained ophthalmologists and optometrists travel from one neonatal unit to the other to examine the eye of babies, take pictures of the retina, upload it into the cloud and seek the advice of a specialist in the base hospital. The professional fee collected from the patients merely takes care of the cost of running this project i.e. salary for the manpower involved, maintenance of the equipment and running of the vehicle.

How is it superior to what is being done now?

At present the Ophthalmologists travel from one hospital to the other, carrying all the equipment and this involves lot of effort, quality of work is not good because it is a manual examination and time lost is tremendous e.g. to examine two infants in a neonatal care unit in a hospital 20 km. from here the doctor spends one day, reaching the hospital, examine the babies and coming back. In the major metro cities of our neighbouring states like Karnataka and Tamil Nadu, trained optometrists and technicians travel in a mobile unit, take pictures of the eyes of these babies and they move from one hospital to the other in the mobile unit and upload the pictures into the cloud and the ophthalmologists sitting in the base hospital visualise these images and advise the course of treatment accordingly. Therefore the advantages of the mobile ROP unit are:

a) Quality of the image is better since the high resolution camera is used to examine the babies and take pictures of the retina, so the examination is complete and most importantly lot of time is saved. b) Infants have to be examined on a weekly basis till they attain the normal weight and term and therefore the mobile unit functions very efficiently by scheduling the visits on a regular basis.

Location where the project is being proposed:

In the urban area of Ernakulam and multi-specialty hospitals in Kottayam and Alappuzha Districts. Currently we conduct ROP screening in following major hospitals:

- a) Kinder Hospital, Cherthala
- b) Bharat Hospital, Kottayam
- c) Matha Hospital, Kottayam
- d) Ernakulam Medical Centre, Ernakulam
- e) Lourdes Hospital, Ernakulam
- f) Lisie Hospital, Ernakulam
- g) Lakshmi Hospital, Ernakulam
- h) Vijayalakshmi Medical Centre, Ernakulam
- i) Welcare Hospital, Ernakulam
- j) Aster Mecity, Cheranellore, Ernakulam
- k) CIMAR Fertility Centre, Cheranellore, Ernakulam
- l) Cooperative Medical College, Thrikkakara, Ernakulam

Total Budget for the proposed ROP Mobile Unit:

ROP Mobile Unit consists of:

S.No.	Item Description	Unit	Price (Rs)
EQUIPMENT			
1	ROP Screening Camera 3nethra Neo (Wide Field Imaging Device) including accessories	1	15,63,000.00
2	Laptop for the above Device	1	37,000.00
3	Indirect Ophthalmoscope	1	1,00,000.00
4	A vehicle to carry men and material (Maruti Celerio)	1	4,00,000.00
EQUIPMENT TOTAL (Approximately)			21,00,000.00
MANPOWER			
1	Ophthalmologist	1	
2	Optometrist/Assistant	1	

Expected Outcome of the Project

India has the highest number of preterm deliveries in the world and hence, a huge burden of ROP. Staging the disease correctly, following the international treatment guidelines and timely screening could help in reducing this burden. ROP blindness is incurable and only way to avoid this is by dilated early retinal screening examination of all premature at risk babies definitely by 30 days of birth, which can reduce ROP-related ocular morbidity.

What Giridhar Eye Institute (GEI) has done till now

As a part of GEI we have screened a total of 6,048 eyes of 3,024 infants for ROP in NICUs of 14 referral hospitals in Kochi, Kerala, from July 2015 to March 2019 (45 months). Postmenstrual age ranged as low as from 24weeks to 38 weeks with a mean of 31.76 (SD \pm 2.837) weeks. The birth weight ranged as low as from 495 grams to 3000 grams with a mean of 1468.37 (SD \pm 454.50) grams. Any stage ROP was observed in 1042 eyes (521 infants) with an incidence of 17.23 of 870 eyes. Treatable or type 1 ROP was found in 322 eyes with an incidence of 5.32%. Rest 870-322 = 548 eyes had type 2 ROP or untreatable ROP which was diagnosed and followed periodically till infant retina get fully vascularized or completed normal development. Treatment in form of laser monotherapy or intravitreal injections (injections in premature infant's eye) were performed in these 322 affected eyes showing type 1 ROP and were recovered completely. However, even after appropriate laser treatment, we observed reduced treatment affect in 5 eyes (out of total 6,048 eyes), which were also recovered with surgical intervention done timely in all these 5 eyes. Thus, we recovered 6,043 eyes out of 6,048 eyes of premature infants with excellent final vision outcomes which is >99% success and a great contribution to our society which still feels ignored for this grave and unknown pathology.

Not-for-profit activities of Giridhar Eye Institute:

Giridhar Eye Institute has established a charitable trust **SSM Eye Research Foundation** in the year 2005 to take care of all the "Not-for-Profit" initiatives of this institution. **SSM Eye Research Foundation** (Operated by Giridhar Eye Institute) is a registered charitable trust established with the objective of eradication of avoidable blindness. The trust has been focusing on community centric activities since 2005 by conducting eye screening programs for the underserved. We have been working towards eradication of avoidable blindness for all these years by launching community interventions which was relevant for the society from time to time. This includes simple eye screening programs to large population based surveys and training of health care professional throughout the state. Community ophthalmic care can be encompassed into six working strata namely:

- (1) Identify the target population.
- (2) Screening
- (3) Clinical diagnosis.
- (4) Investigations.
- (5) Management.
- (6) Awareness creation.

The conventional screening programs like camps and mass awareness programs cover only 2 or 3 levels of the strata. We have been constantly **developing effective eye care screening models** for different target population by scientific outcome measurements of all our community interventions. Rotary club of Cochin has been our major partner in delivering many eye care initiatives by Giridhar Eye Institute and SSM Eye Research Foundation. Some of our community eye care interventions which were effective are given below:

- 1. SSM Eye Research Foundation Comprehensive Eye Care Screening Program
- 2. Giridhar Eye Institute School Screening program
- 3. Kusumdevi Bhalotia Low Vision and Visual Rehabilitation program
- 4. Senior citizens Eye care Initiative of Cochin
- 5. Gurudwara cataract and diabetic retinopathy screening and free treatment project
- 6. Rotary Balbhavan Comprehensive Eye screening program
- 7. Chengamanad village Diabetes and eye disease survey & awareness program.
- 8. Mulavukadu Islands 'Active case detection' initiative
- 9. Diabetic Club and Forums' support program
- 10. Kochi Metro workers eye care and occupational safety initiative
- 11.Blind football team -' Vision is Life' Awareness program
- 12. Attapadi Tribal Vision Project 'Reaching the unreached'
- 13. Orphans and Homeless' eye care program 'Lighting up lives'
- 14.Kattanam Retina screening initiative (In association with St Thomas Mission Hospital)
- 15. Mobile Retinopathy of Prematurity (ROP) screening and Laser support in Cochin
- 16. Health care workers training initiative

- 17.Kerala Comprehensive Diabetic Retinopathy Training Model (International XOVA award funding)
- 18.NPCB (National Program for Control of Blindness) cataract screening and free surgery program
- 19.Kudumbasree and Asha Workers training scheme Women's eye care initiative
- 20. Tele-ophthalmology vision program
- 21.Adoption of Chellanam Grama Panchayat for providing ophthalmic treatment to Below Poverty Line (BPL) residents free of cost for a period of one year from Oct. 2016.

These initiatives show that ours is one of the largest eye care models catering to different target population with diverse social and economic background with enormous practical feasibility. Many the above mentioned projects were executed with generous funds from various NGOs and philanthropic organizations.

- 1. Through the trust the hospitals now runs a separate community eye wing with outpatient and inpatient facilities. Over 150 cataract surgeries are performed in a month through this initiative. Apart from this the trust runs three regular free eye clinics in Ernakulam Districts which has been functioning for the last more than one decade. All these eye clinics are fully equipped to run efficient outpatient departments.
- 2. The trust is also involved in a major screening program for detection of diabetic eye diseases which is a very important cause for preventable blindness in the state of Kerala. Looking at these great initiatives the trust is now collaborating on a major project funded by Global Challenge Research Fund & UK Research and Innovation, titled the "SMART INDIA" study. We are one of the 22 odd institutions in the country which is doing the major survey covering three groups of population viz. rural, urban and industrial to understand the incidence of diabetes and diabetes related complications in the society.



3. Appreciating the various initiatives of the trust, in the year 2017, the Rotary International based in the US along with a group of Rotary Clubs in UK donated a mobile eye clinic which has been functioning efficiently for the last two years.



Sustainability of ROP Project

Screening for retinopathy of prematurity in a timely manner remains the most important initial step in the detection and management of the condition. This is of great importance as it is acknowledged that earlier treatment of the condition results in improved visual outcomes and prognosis. It is becoming increasingly recognized that retinopathy of prematurity is a disease for life and there are significant long-term sequelae. All neonatal units caring for babies at risk of retinopathy of prematurity should have a written protocol in relation to screening. During the screening examination techniques such as nesting the baby will reduce the infants stress and pain and this should be encouraged. Training of ophthalmologists in the technique of screening for retinopathy of prematurity and the recognition of the disease should not be overlooked so that a larger pool of ophthalmologists can perform screening in the peripheral hospitals. Whilst indirect ophthalmoscopy is the gold standard examination device, RetCam digital image systems are becoming increasingly important.







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