Karnataka Internet Assisted Diagnosis of Retinopathy of Prematurity (KIDROP)

Program Evaluation Based On CDC Guidelines

An Interim Report

NHMRC Preterm Infants Centre of Research Excellence
Disclaimer

This interim report is the result of an evaluation conducted by the NHMRC (National Health and Medical Research Council) Preterm Infants Centre of Research Excellence, University of Western Australia. Global shortage of workforce needed for Retinopathy of Prematurity (ROP) services has fuelled interest in tele-medicine. The KIDROP tele-ROP program provides screening and treatment for ROP in under-served areas of Karnataka, a state in south western part of India. We chose to study the KIDROP model to evaluate the effectiveness of tele-imaging and contribute to a rigorous evidence base.

The views and opinions expressed in this publication are those of the authors and they are based on visits to the screening sites, engaging with different stakeholders, personal experiences of working in both developing and developed economies and literature review. KIDROP program director’s views were taken on the functioning and logistics of the program operation. While adequate efforts have been made to ensure that the contents of this publication are accurate, we shall not be liable for any loss or damage that may be caused directly or indirectly through the use of, or reliance on, the contents of this publication.
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# Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acronyms</td>
<td>1</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>2</td>
</tr>
<tr>
<td>Executive Summary</td>
<td>3</td>
</tr>
<tr>
<td>Retinopathy of Prematurity - Background Information</td>
<td>5</td>
</tr>
<tr>
<td>KIDROP - Why evaluate?</td>
<td>10</td>
</tr>
<tr>
<td>Evaluation methods and Findings</td>
<td>11</td>
</tr>
<tr>
<td>Discussion and Limitations</td>
<td>29</td>
</tr>
<tr>
<td>Recommendations and Conclusions</td>
<td>42</td>
</tr>
<tr>
<td>References</td>
<td>46</td>
</tr>
<tr>
<td>Bibliography of Documents Reviewed</td>
<td>48</td>
</tr>
</tbody>
</table>
## Acronyms & Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IAP</td>
<td>Indian Academy of Pediatrics</td>
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<tr>
<td>INAP</td>
<td>India Newborn Action Plan</td>
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<td>KIDROP</td>
<td>Karnataka Internet Assisted Diagnosis of Retinopathy of Prematurity</td>
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<td>NHM</td>
<td>National Health Mission</td>
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<td>NICU</td>
<td>Neonatal Intensive Care Unit</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<td>NMR</td>
<td>Neonatal Mortality Rate</td>
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<td>NN</td>
<td>Narayana Nethralaya</td>
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<td>NNF</td>
<td>National Neonatology Forum</td>
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<td>NNPD</td>
<td>National Neonatal Perinatal Database</td>
</tr>
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<td>RBSK</td>
<td>Rashtriya Bal Swasthya Karyakram</td>
</tr>
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<td>ROP</td>
<td>Retinopathy Of Prematurity</td>
</tr>
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<td>SNCU</td>
<td>Special Newborn Care Units</td>
</tr>
<tr>
<td>SRS</td>
<td>Sample Registration System</td>
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<td>VIIO</td>
<td>Vittala International Institute of Ophthalmology</td>
</tr>
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</table>
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The field visit to Bangalore, India was partly funded by the NHMRC Preterm Infants Centre of Research Excellence, University of Western Australia.
Executive summary

Retinopathy of prematurity (ROP) is a serious vision threatening disorder affecting preterm infants. Timely screening and treatment is indicated for severe ROP to prevent blindness. With increasing survival of preterm infants, the number needed to be screened for ROP in India has increased substantially in recent years. However, ROP workforce to care for these vulnerable infants in India is very limited.

The shortage of pediatric ophthalmologists, pediatric retina or ROP specialists is a global phenomenon. Limited workforce in this field has fuelled an interest in tele-imaging as an alternate to ophthalmologist-led screening. Though it has not been accepted as a standard screening method, tele-imaging is replacing indirect ophthalmoscopy in many parts of the world out of sheer necessity. One major advantage of the tele-imaging is that the trained imaging staff could be used for screening.

Karnataka Internet Assisted Diagnosis of Retinopathy of Prematurity Program (KIDROP) is one such tele-imaging ROP program. It was first initiated in Bangalore in 2008. In collaboration with the National Health Mission and the Karnataka state Government the services were gradually expanded to other parts of the state in the last seven years. The trained image technicians are efficiently utilised for ROP surveillance under the supervision of an Ophthalmologist. In addition to the ROP services, the program renders training for imaging staff and liaises with other health care providers including pediatricians and obstetricians.

The aim of this evaluation is to examine the process of functioning of KIDROP and to gather evidence for tele-imaging. We have followed a systematic approach using CDC (Centers for Disease Control and Prevention) guidelines for program evaluation.
It is evident from our review and other publications that KIDROP has filled the ‘service delivery gap’ by improving the access to ROP screening and increasing the participation of neonatal units. From our evaluation we can confidently say that KIDROP Tele-ROP surveillance is functioning as per the objectives of the program and is reaching to those infants who are in need. Cost effectiveness of the program and long term outcomes are worth evaluating and will be done in a phased manner.

One of the main challenges KIDROP program currently facing is the Government’s decision to probably change to an ophthalmologist-led model instead of tele-medicine. It is a serious concern, given the limited ROP work force available in the state. Globally, even in developed nations many units are transitioning to tele-imaging screening model which reaffirms our belief that tele-imaging is the answer to tackle the enormous burden of screening for ROP in India. We have discussed the pros and cons of the different models in this report.

At this juncture, since KIDROP is serving as an effective ROP screening model, priority should be given to expand the program and promote primary prevention. More efforts are needed to increase the awareness of ROP among service providers and to place an evidence based oxygen management practice for preterm babies in the neonatal units. In a country like India which has implemented the polio campaigns successfully, ROP care can achieve quick gains if appropriate actions are taken. The action framework for effective ROP care in India should be ‘Scale up what works well while filling knowledge and action Gaps’.

We have also highlighted the future research needs in our discussion. As per our original plan a final report with complete analysis is scheduled to be delivered in late 2016.
BACKGROUND

Retinopathy of Prematurity and importance of screening

Retinopathy of prematurity (ROP) is a disease of the developing eye, which affects the retinal vessels of premature infants. Failure to detect and treat severe ROP during the neonatal period will lead to ‘permanent loss of vision’. Hence, screening for ROP is an important component of preterm care. ROP can only be diagnosed through direct visualization of the retina. Optimal treatment outcomes are achieved with early detection of disease, laser treatment when indicated and serial follow-up.

Global burden of ROP

The incidence of ROP in premature infants is inversely proportional to their birth weight and gestational age. In the last two decades, the survival rate of preterm infants has increased significantly across the globe both in developed and developing economies. In countries like India, China, Brazil and Mexico, this survival pattern is likely to increase even further, as the preterm care improves. The recently published data from the neonatal centers in US showed an incidence of 15% of stage ≥ 3 (severe ROP) in infants born <28 weeks of gestational age \( (\text{Stoll et al, 2015}). \) The incidence of severe ROP in middle income countries varies between 4.4 to 44.9 \% \( (\text{Table 2 - Zin & Cole 2013}). \)
Changing epidemic over the last 60 years

ROP was causing blindness in the West, when preterm infants were treated with unrestricted 100% oxygen. This resulted in the ‘first epidemic’ in the 50’s. Once the role of oxygen was identified, strict guidelines for oxygen usage were implemented and this guideline introduction was associated with decreased incidence. The second epidemic happened in the 80’s-90, when advances in neonatal intensive care resulted in increased survival of extremely preterm infants.

Third epidemic of ROP

Currently “Developing economies are experiencing a mixture of ROP first epidemic pattern (poor or no control of supplemental oxygen) and second epidemic pattern (evolving but uneven care of very preterm infants) where larger and more mature infants are also affected” (Darlow et al, 2013). Darlow in his article states that “the main reason for this third epidemic is not the lack of knowledge but translating that knowledge into practice which is a challenge”.

“The main reason for this third epidemic is not the lack of knowledge but translating that knowledge into practice which is a challenge”  
Brian Darlow
ROP burden in India

The annual burden of neonatal deaths decreased significantly from 1.35 million in 1990 to 0.76 million in 2012 (INAP, 2014). Approximately 35% of neonatal deaths are caused by prematurity. As the preterm care improves the NMR (Neonatal Mortality Rate) is likely to come down even further. Governments and other organisations are working towards the single digit NMR by 2030. The national neonatal perinatal database from 18 centres across India (NNPD Data, 2002-2003) showed that approximately 8.7% of newborn had a birth weight of less than 2kg. There are approximately two million babies born annually in India who are in need of ROP screening service.

The recent increasing survival pattern together with poorly monitored oxygen therapy has put the number of babies needed to be screened at significantly higher in India as compared to other developed and developing nations. The assumptive model based on birth rate, prematurity rate, survival rate of those preterm infants, and incidence of severe ROP among those survivors and 50% unfavourable outcome among the untreated group, puts the estimate of “17, 564 blind infants each year in India alone” (Zin and Cole et al, 2013). This will be the difference between offering and not offering ROP screening and laser treatment in India.

“Based on vital statistics and mortality rate there are 17,564 blind infants each year in India alone”
Zin and Cole
Screening guidelines for ROP in India

The national task force on ROP, National Neonatology Forum (NNF) have published consensus guidelines for screening and treatment of ROP \textbf{(NNF ROP Guidelines, 2010)}. However, this has not been translated into daily clinical practice. There are many reasons for this patchy adaptation of guidelines. There are only few centers in India that undertake ROP management and they are mainly concentrated around the cities. The ‘shortage of trained ophthalmologists’ who are able and willing to give complete ROP care is global but middle income countries including India are feeling the crisis most acutely. Other reasons like ‘lack of awareness among treating pediatricians’ is also a significant factor contributing to the poor progress of ROP screening services. A pilot survey using telephonic interview among 241 pediatricians of six states showed at least 34% of them were not referring for ROP screening \textbf{(Patwardhan et al, 2011)}.

Screening guidelines for ROP in developed world

Countries such as the USA, UK, and Australia have strict guidelines for oxygen use and screening for ROP, in preterm infants who are at risk. In most of the units ROP screening currently is done by ophthalmologists by a hand held \textbf{Binocular Indirect Ophthalmoscope (BIO)}. This has been considered as a standard diagnostic examination for ROP \textbf{(Quinn, G. E., et al 2014: e-ROP study)}
Change in choice of screening

Over the last decade, the ROP workload and medico legal risks on ophthalmologists have increased enormously in the developed nations. The situation is expected to get worse considering the increasing survival of extreme preterm infants, and the limited number of ophthalmologists who can handle ROP management. In certain countries like USA, Australia and New Zealand, BIO has been replaced by digital retinal photography (DRP) where non-ophthalmologists (nurses, technicians) take the images using a hand held camera. These images are later interpreted by ophthalmologists who are based far away from the field. Laser treatment is undertaken on the minority of infants-screened when indicated by an ophthalmologist (Wang, S. K. et al, 2015, Athikarisamy S.E et al 2014).

The change in the choice of screening is due to a combination of factors including lack of trained personnel, medical liability and reimbursement issues. These factors have fuelled interest in telemedicine based ROP screening (Fierson, W. M., et al 2015). In Australia and New Zealand many large NICU’s have implemented tele imaging. In USA, Stanford University Network for Diagnosis of Retinopathy of Prematurity (SUNDROP) has implemented the tele imaging in the state of California and the program has been operational since 2005 (Wang, S. K. et al, 2015)
Situation in developing world and India

In developing economies like India, the use of a standard BIO examination by an ophthalmologist has presented many challenges because of the limited expertise and large patient population. Since countries like India are very much in need of an alternate screening method appropriate to the ‘increased number of infants’. KIDROP (Karnataka Internet Assisted Diagnosis of ROP) is one such screening program proposed as an alternative to standard BIO which could be used in a large population. KIDROP uses trained staff (non-physicians, non-ophthalmologists) to acquire images.

Need for evaluation of existing ROP programs

The joint technical report (USA) published in 2015 stated that tele-imaging “does not supplant BIO for ROP evaluation”; however it acknowledged that tele-imaging has the “potential to allow the diagnosis and monitoring of ROP to occur in lieu of the necessity for some repeated on-site examinations in NICU” (Fierson, W. M., et al, 2015). The same report suggested that future research should include evaluating satisfactory performance standard for ROP programs, access to care, and cost effectiveness.

Community health programs of importance need to be justified in low resource settings. This can be done by evaluating the aim, objectives, operations and outcomes systematically. Program evaluation helps to identify practices that are successful and worth funding, and also helps in finding out areas in need of improvement.
KIDROP PROGRAM EVALUATION

Aim and objectives of this evaluation

Systematic evaluation of the KIDROP project using the “program evaluation guidelines by CDC” is aimed to provide an insight to the day to day functioning of the program operation, the immediate and short term outcomes and scope for any further improvement.

Evaluation Methods

We used CDC framework for program evaluation in public health (Milstein & Wetterhall1999) which consists of six steps (Figure 1).

![Figure 1. Six steps of CDC evaluation framework](image-url)
Engagement of stakeholders

We first approached the KIDROP program director for consent of program evaluation. The KIDROP team and the evaluating team together identified the various partners who are involved in the program and the stakeholders (Figure 2) for whom the program is beneficial.

Figure 2. Key stakeholders of the KIDROP program
We have used the logic model (Figure 3) to describe the links between activities and outcomes. First three steps of logic model will form the process evaluation and the next three steps form the outcome evaluation (*CDC, 2013*). Our intention is to monitor the program longitudinally completing all six steps. This interim report is based primarily on the ‘process evaluation’ which is intended to highlight the development, implementation, challenges and some early outcomes for the KIDROP.

**Logic model (Process Evaluation + Outcome evaluation)**

**Process Evaluation focus**

1. Inputs  
2. Activities  
3. Outputs

**Outcome evaluation focus**

4. Short-term outcomes  
5. Intermediate Outcomes  
6. Long-term outcomes

*Figure 3. Logic Model*

This evaluation focused on the following key areas

1. The perceived need that motivated the introduction of the ROP screening
2. Implementation of KIDROP program
3. Training component (Training of imaging staff and program coordinator)
4. Implementation challenges
5. Successes of the program
6. Opportunities for improvement and enhancement of the program
We formed an evaluation plan methods grid (Figure 4) to enhance the clarity of our reporting.

<table>
<thead>
<tr>
<th>Evaluation Question</th>
<th>Indicator or Performance Measure</th>
<th>Methods</th>
<th>Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>What processes lead to implementation of program?</td>
<td>Description of process steps, actions and strategies</td>
<td>Interviews and document reviews</td>
<td>Site visits, publications and interviews</td>
</tr>
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</table>

**Figure 4. Evaluation Plan Method Grid**

The current report is based on the information gathered through following methods.

1. Interviews with a range of program stakeholders

2. Analysis of program data from KIDROP database

3. Thematic analysis of consumer and practitioner experiences and perceptions, provided to the evaluator by various stakeholders

4. Review of KIDROP program related documents including MOU with the government and reports from other organizations like UNDP (United Nations Development program)

5. Review of various journal articles and reports published by KIDROP

6. Field visits and informal interviews at the screening sites

7. Review of published literature from other similar programs and expert opinions (for comparative analysis)
The principal evaluator (SA) visited the KIDROP headquarters that is located in Bangalore and from there travelled across the state to different sites where the KIDROP screening program has been implemented. The evaluator was able to get first-hand information, covering a variety of locations including private hospital NICUs, Government special care units (SNCU) and neonatal intensive care units that are caring for preterm infants in a remote location. There was sufficient variation across the sites, in terms of patient population, the pediatric practices including oxygen therapy to allow comparison between rural and urban centers.

A sample group of screening locations were chosen randomly from each zone to represent different parts of Karnataka. The chosen locations (Figure 5) were Bangalore, Hassan (South Karnataka), Davengere (Central Karnataka) and Bijapur and Bagalkot (North Karnataka). Principal evaluator also visited the sites which are serviced by the Vittala ROP team which is currently doing the ROP screening service in the South Karnataka Zone.

Figure 5. Sites visited by the principal evaluator
As well as providing a description of the implementation of the KIDROP at each zone, this report provides brief information on the role of program coordinator and imaging staff, training of the program staff, and the experience of the paediatricians and nursing staff about the program and some indication of the outcomes achieved.

DESCRIPTION of KIDROP PROGRAM

Perceived need that motivated the introduction of the KIDROP

Keeping in mind the growing need for a comprehensive approach to tackle ROP in India, the Karnataka Internet Assisted Diagnosis of Retinopathy of Prematurity (KIDROP) was initiated by the Narayana Nethralaya (NN) post-graduate institute of ophthalmology in the year 2008. KIDROP director stated that many unscreened infants presenting with advanced stages of ROP and blindness to the institution prompted the initiation of KIDROP. In the beginning, KIDROP was implemented in urban and rural Bangalore. A pilot program covering private and public hospitals in the immediate vicinity of Bangalore was undertaken over a period of 18 months. The data from the pilot project convinced the state government regarding the need for an expansion to other parts of the state (Retina Today, 2014). In 2009, in collaboration with the state government under the auspices of National Health Mission (NHM), KIDROP was expanded to other parts of the state. NHM provided the logistic support including the RetCam (Imaging Camera), Vehicle (A tempo Traveller) and a portable laser unit with laser indirect ophthalmoscopy (ILO) delivery.
NHM continues to support the day to day running cost of the screening services, including the staff salary and fuel and vehicle related expenses. NN continues to provide the technical and screening services through imaging technicians, program coordinator and ophthalmologists. Under the current Public Private Partnership (Figure 6), NHM and NN provide screening at no additional cost. Currently the SNCUs and NICUs of the government sector and private neonatal intensive care units across the state are serviced through the KIDROP screening program. In 2013, the South Zone area screening was handed over to the Vittala ROP team (Run by Vittala International Institute of Ophthalmology) through a tender process.
This collaborative public-private-partnership approach from the government (under NHM) and the private (Narayana Nethralaya) is aims screen and treat for retinopathy of prematurity and thereby preventing blindness in a significant number of infants.

**KIDROP program implementation in the four Zones**

The program coverage area is divided into four zones (Figure 7) namely the South, Central, North and West Coast. South Karnataka HQ is located in Bangalore where NN is located. Central Zone team is located in Davangere and North Zone is stationed at Raichur. West coast Karnataka team is located in Mangalore. The team travelled to different districts on a specified day of every week. The team travel as far as 200-250 km just to reach one location and at certain towns are required to stay overnight.

Every zone has a team which consists of a program coordinator, imaging staff, and a Driver. Every team has a vehicle (Tempo Traveller), a RetCam (portable imaging camera), a mobile data plan, and a log book each for imaging and for the vehicle.
KIDROP uses the ‘triple T’ philosophy (Figure 8) which stands for telemedicine, training of peripheral ophthalmologists, and talking to neonatologists, pediatricians and gynaecologists for their day to day functioning.

**Figure 8 Triple T philosophy**

<table>
<thead>
<tr>
<th>Telemedicine</th>
<th>Training</th>
<th>Talking to</th>
</tr>
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<tr>
<td>• RetCam shuttle images taken by trained imaging staff</td>
<td>• Of peripheral ophthalmologists</td>
<td>• Neonatologists, pediatricians and Obstetricians</td>
</tr>
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**KIDROP Team**
- North Karnataka
- Central Karnataka
- Western Karnataka

**Vittala ROP Team**
- South Karnataka
Telemedicine

NNF clinical practice guidelines states that “screening for ROP should be performed in all preterm neonates who are born < 34 weeks gestation and/or < 1750 grams birth weight; as well as in babies 34-36^{+6} weeks gestation or 1750-2000 grams birth weight if they have risk factors for ROP” (NNF ROP Guidelines, 2010). KIDROP relies on birth weight for enrolling and all infants weighing less than 2000 g are included in the screening as Gestational age estimation is unreliable especially in rural population. The SNCUs have a registry of infants who are fulfilling the criteria. Centres that are not served by the KIDROP team regularly are using the REDROP strategy where a REDCARD given to mothers whose babies are <2000 grams and they are called on their mobile phones to schedule appointments at a nearby screening center (Retina Today, 2014).

The program coordinator contacts the parents of the infants who need the screening the previous day. The nursery staffs both in government and private nurseries prepare these infants for screening with medication to dilate the pupil. Once the team arrives at the neonatal unit trained imaging staffs using the RetCam Shuttle screen the eligible infants. Trained staffs are capable of triaging these images based on the principle of “pattern recognition”. The triage system follows a colour-coded protocol (Figure 9). The imaging staff if needed upload these images from the rural centers for reporting by the ophthalmologist. The imaging staff are quite adept in identifying the ROP that requires immediate treatment from the ones not requiring treatment (Vinekar, 2014).
**Work flow**

1. **Driver**
2. **Imaging staff**
3. **Program Coordinator**

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**Figure 9. Work flow of screening & Colour-coded protocols**
Those infants who need laser treatment are given the laser within 24-48 hours of diagnosis through one of the following options (Figure 10). If the Ophthalmologist is unable to travel to the patient’s NICU, KIDROP arranges for a local expert to visit and treat the patient. Funding is provided by the KIDROP for the parents to travel to Bangalore if the procedure cannot be provided at the rural centre. The zonal team schedules a follow-up appointment with the parents to acquire post treatment images.

![Figure 10. Treatment Options](image)

**Training component (Training of imaging staff and program coordinator)**

Vinekar et al’s paper (2014) gives a comprehensive overview of several aspects of the training program. During the training of imaging staff, working methodology and the ability to image and decide for follow-up based on a ‘three-way algorithm’ were assessed. One important aspect of the training is that of an indigenously developed 20-point score (STAT score) which grades the overall ability of image technicians (Level I to III). It takes
approximately 90 days to train a level III technician. Approximately 15 teams have been trained to undertake screening and have been placed in remote areas of Karnataka.

The KIDROP team has also trained ophthalmologists, ophthalmic and non-ophthalmic technicians, and program coordinators to become familiar with ROP care. The training has also been extended to inter-state staff from Maharashtra, Gujarat, Rajasthan, Andhra Pradesh, Odisha and Uttar Pradesh. All teams that trained in KIDROP are using RetCam and KIDROP model of screening except Rajasthan. KIDROP has also trained staff from other countries including South Africa, UAE, Lebanon, Indonesia, Saudi Arabia and recently Bangladesh.

In addition, this program has generated interest among the post graduate students in both pediatric and ophthalmology disciplines. It has created opportunities for the same students to do research projects on ROP related topics leading to postgraduate thesis and dissertations. In tertiary hospitals, ophthalmology Post Graduate students attend the screening session which is a huge learning experience for them.

Figure 11. Imaging session being attended by post-graduates and house officers.
The work flow of ‘Vittala ROP screening program’ is described by Murthy et al (2013) in their study methodology.

Program challenges

The KIDROP program has many organizational challenges. The list of problems includes low awareness, technological problems (maintenance of equipment), financial sustainability issues, and problems related to the ongoing agreement with the Government of Karnataka. However, repeated engagement and dialogue between different stakeholders has helped run the screening program effectively.

One of the main challenges this program currently facing is the Government’s decision to probably change the existing model. There was discussion among the officials regarding an alternate ‘ophthalmologist-led screening program’ in local SNCUs. The principal evaluator met with the NHM officials and they were of the opinion that ROP services should be transferred to ophthalmologists in the Government hospital. One of the main reasons the officials stated was the operational cost of tele-screening and the high cost of the RetCam. They also stated that this will allow them to build capacity for the future.

When specifically asked about the very high workload of ophthalmologist-led screening, especially involving preterm babies, the doctors in the Government sector stated that an incentive model for the ophthalmologists may be able to overcome the issue. The health service is already planning to up-skill the ophthalmologists to undertake ROP services.
Integration of ROP services

In the current surveillance area, pediatricians’ general knowledge about ROP and the need for screening have improved, as has their confidence in working with the ROP screening team. Timely screening, laser treatment for at risk infants and regular follow-up (post laser) has helped the team to get more confidence from parents and pediatricians. It was pleasing to see that ROP screening services have been integrated with other routine programs like immunization and well-baby services (Figure 12).

Figure 12. Both private and Government SNCU’s have designated areas for ROP screening
At present, no limit has been set for the potential expansion of the program. There has been limited reach in western Karnataka partly due to the distance between the major towns and because of the difficult terrain. Non-coverage of the screening services at taluk levels, even within zones where the program operates is an issue. The fear among the few pediatricians whom we met is that there are some infants being missed for ROP screening especially in taluk and sub taluk levels.

**Crucial role of program coordinator**

The KIDROP experience shows clear benefits of having a program coordinator. In addition to day to day functioning of screening program, they play a pivotal role in linking the private nurseries to be a part of the screening services. Program coordinator’s roles are to contact the nurseries providing care for preterm infants and to enrol them for screening, contribute to care planning, provide a direct service to infants and their families, and most importantly, coordinate various aspects of the ROP care such as treatment and follow up with the ophthalmologist, pediatricians and parents.

**Successes of the program**

Neonatologists, pediatricians, nurses, and parents reported that the service is working well and screening for ROP is a welcome addition to the other newborn services. Pediatricians especially those who are in private practice reported that because of the KIDROP, many more infants were receiving a vision-saving screening which is convenient and is conducted in their own setting. One advantage with the trained image technicians is that they were able to interpret the image finding and were able to give the outcome decision at the end of examination itself. This is very helpful particularly for those parents who often travel 50-100 km using public transport.
Outcome data

Since the inception of the program in 2008, KIDROP has screened 18,290 infants (as of July 2015). During these eight years, 1319 infants received laser treatment for severe ROP. A significantly greater burden of ROP was seen in private nurseries. This may be due to the smaller and sicker infants being cared at private nursing homes. The table (1) below gives the ROP incidence in various zones according to the place they were cared.

<table>
<thead>
<tr>
<th>Zone</th>
<th>Infant cared at</th>
<th>Total number screened (n)</th>
<th>No ROP (n)</th>
<th>ROP requiring only follow up (n)</th>
<th>ROP requiring Treatment (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Karnataka</td>
<td>Public Hospitals</td>
<td>1824</td>
<td>1272</td>
<td>442</td>
<td>110</td>
</tr>
<tr>
<td></td>
<td>Private Units</td>
<td>7481</td>
<td>4922</td>
<td>1655</td>
<td>904</td>
</tr>
<tr>
<td>Central Karnataka</td>
<td>Public Hospitals</td>
<td>2992</td>
<td>2371</td>
<td>574</td>
<td>47</td>
</tr>
<tr>
<td></td>
<td>Private Units</td>
<td>619</td>
<td>390</td>
<td>181</td>
<td>48</td>
</tr>
<tr>
<td>North Karnataka</td>
<td>Public Hospitals</td>
<td>2436</td>
<td>2055</td>
<td>335</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td>Private Units</td>
<td>2240</td>
<td>1489</td>
<td>596</td>
<td>155</td>
</tr>
<tr>
<td>West coast Karnataka</td>
<td>Public Hospitals</td>
<td>303</td>
<td>190</td>
<td>106</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Private Units</td>
<td>395</td>
<td>215</td>
<td>178</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>18290</td>
<td>12904</td>
<td>4067</td>
<td>1319</td>
</tr>
</tbody>
</table>

Vinekar et al have published many peer reviewed articles periodically highlighting the quantitative outcome of the program. The most recent one *(Vinekar et al, 2015)* published in Seminars in Fetal & Neonatal medicine gives a comprehensive overview of the program impact for the North Karnataka and Central Karnataka zones. We have summarised the key facts from the publication in the following table (2).

Some information gaps still remain. This is particularly true in relation to the number of eligible infants who are needed to be screened. This will be part of our ongoing evaluation and we have highlighted this in our discussion.
### Program highlights

<table>
<thead>
<tr>
<th>Training &amp; accreditation for imaging staff</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field work started</td>
<td>2011 in North Karnataka, 2012 in Central Karnataka</td>
</tr>
<tr>
<td>Number of districts</td>
<td>13</td>
</tr>
<tr>
<td>Number of NICUs</td>
<td>36 (Government 14, Private 22)</td>
</tr>
<tr>
<td>Total number of babies screened</td>
<td>7106</td>
</tr>
<tr>
<td>Imaging sessions</td>
<td>20,214</td>
</tr>
<tr>
<td>Any stage ROP</td>
<td>1591 (22.39%)</td>
</tr>
<tr>
<td>ROP Requiring treatment</td>
<td>254 (3.57%)</td>
</tr>
<tr>
<td>Level 111 technician’s ability to diagnose</td>
<td>94.3 % agreement with ROP specialist finding</td>
</tr>
<tr>
<td>% of Treatment warranting infants missed</td>
<td>0.4 %</td>
</tr>
</tbody>
</table>

*Table 2. Data for Central and North Karnataka (Vinekar, A et al, 2015)*
DISCUSSION

We were pleased to note that the KIDROP program is providing an excellent service to the community in the state of Karnataka. The overall objective of this systematic evaluation was to provide evidence for future policy direction and for implementation of ROP screening program on a larger scale. This exercise will also put in place ‘a comprehensive framework’ for evaluation of similar programs. This evaluation is a combined work of the evaluating team and the KIDROP.

As we have stated in our methodology, this evaluation is a ‘process evaluation’ and not an ‘outcome evaluation’. Process Evaluation also known as implementation or formative evaluation, “are designed to investigate program integrity (Nixon 1997) by determining the extent to which a program is operating as intended via the assessment of ongoing program elements and the extent to which the target population is being served” {as quoted in Tomison, A. M. (2000)}.

Our key questions were, 1. Whether the KIDROP program has been implemented as planned? 2. Has the target infants been accessed effectively? In the process of our evaluation we have found that KIDROP program is facing certain challenges. Hence our discussion mainly focuses on the best suitable ROP service model for India. When knowledge and action gap on a health issue increases, the need for service delivery also increases. An ideal health service model should ensure high coverage, providing quality care (doing right thing at right time) and providing equity care (ensuring all section of the population is served).
Primary Preventive approaches (Filling Knowledge & action gaps)

Though the pathogenesis leading to ROP are multifactorial, the main reasons for current increased burden in India are due to the ‘uneven-expanded neonatal care’ in recent years and the current practice of ‘unblended oxygen for preterm infants’. Hence there is a need for a primary preventive approach. This approach needs to focus on new programs and initiatives to address prevention of preterm birth, and optimal care of prematurity including an evidence based guideline for oxygen delivery. We need both top down and bottom up approaches to educate and promote a safe practice among paediatricians and create more awareness about the need for timely ROP screening and treatment. While it is very important to focus on the primary preventive approaches, the current epidemic proportion of ROP in India warrants an immediate radical secondary prevention approach.

Secondary prevention approach – Overcoming shortage of ROP workforce

Task Shifting

Evidence around the globe suggests and recognizes shortage of trained ophthalmologists as one of the key factor for the increased burden of blindness from ROP. One way of overcoming the shortage of work force is to delegate the task from physicians to other health care professionals. The strategy of ‘task shifting’, delegating the tasks to the lower category that can perform them successfully has been shown as an effective model in many community health programs especially in communicable diseases like HIV. (WHO, Task Shifting)
The KIDROP program has adopted a very similar approach of task shifting where the trained image staff has taken over the major work of screening. Achieving this on a larger scale, especially in resource-constrained settings, demands a departure from conventional models that depend on highly specialized professionals, is challenging.

**Challenges of task shifting**

Nevertheless, if this model has to be adopted nationwide on a large scale it needs to overcome significant challenges. It needs to protect both the imaging technicians and the infants receiving care. The professional bodies like the NNF and other ophthalmological societies should work towards an administrative regulation/legislative framework, which will enable the imaging technicians to learn to take the images under the supervision of ophthalmologists.

Credentialing can include a range of quality assurance mechanisms such as license to image, registration, certification or accreditation. These bring benefits to image technicians as well as to service users. Greater confidence, increased job satisfaction, increased involvement in work and rapid career progression can all result from forms of credentialing. Task shifting must be implemented such that it improves the overall quality of care *(WHO, Task Shifting)*.

The National Task Force for ROP has already begun steps in this regard. Having accepted the KIDROP’s STAT score as a validated score to train imagers, certification for different levels of technicians would be one of the methods to provide a regulatory sanctity to this cadre.
What works well in community?

Ideally this model of Tele-imaging should be compared with other program alternatives. However, the absence of a successful alternative operational model in a larger scale has impeded the comparison of this approach. One of the major drawbacks of this Tele-model is the cost of the imaging camera, which costs from USD 70,000.00 -130,000.00. There is also an ongoing operational cost which involves salary and travel. We found from direct interaction with various stakeholders and from the published reports that the current community-based Tele-ROP in Karnataka appears to be **responsive and serving the local need** and saving infants from potential blindness. Direct engagement of the NHM in this project was one of the strengths of the screening program, and that commitment from NHM through logistics and financial support has helped the expansion of KIDROP to other parts of state.

Ophthalmologist-led screening. Is it the right alternative model?

The Government is considering implementing the ‘Ophthalmologist-led screening’ using Indirect Ophthalmoscope at the local SNCU’s instead of the existing KIDROP model. Ophthalmologist-led screening may be cost effective, but there are not enough ROP trained ophthalmologists in the current government SNCUs. Feedback from KIDROP team is that even within the existing model the agreed participation of Government doctors at the time of imaging has been poor. Hence a transition of allowing only Government doctors to screen for ROP using indirect ophthalmoscopy without monitoring or surveillance is not without peril and may not be possible. This has been the model used in developed countries and has been found to be unsustainable in many centers.
A recent review of the Mexican system where the health system are very similar to the Indian setup has shown that the ophthalmologist lead Indirect Ophthalmoscope model provided compliant ROP services in only 31.2% of NICUs. In 34.4% of NICUs the program was non-compliant and in the other 34.4% there was no program at all (Zepeda-Romero, L. C., & Gilbert, C, 2015).

**ROP workforce and training**

Waiting for enough new ophthalmologists to train through the system will mean lengthy delays in providing the urgently needed services. The current ROP workforce in India are either trained abroad or trained in the major referral hospital across India and it involves significant training period and good exposure to ROP care. Short term courses and workshops may not be able to give adequate training/exposure which is needed to run a standalone ROP practice confidently. Keeping the future in mind, more ophthalmologists will need to be trained through the system and the ROP training should be incorporated into the post-graduate curriculum for ophthalmology.

Government health services of developing countries can no longer fulfil all the health programs by themselves, especially, ROP screening which needs expertise to diagnose and treat. In their quest for greater cost-effectiveness, Governments must have the correct alternative plan before changing the existing model. Government should be willing to take the active support of and a greater contribution from, the private sectors that are willing to partner with the government to reduce the burden. Governments are in a position to seek new and perhaps unfamiliar partners, ranging from private eye institutions to technological partners and variety of non-governmental organizations.
Pediatrician-led model: Another proposed model

Pediatric practice based ophthalmology screening using a low cost camera seems like a promising option for the future. Gilbert et al, (2015) reported a potential for a paradigm change with neonatologists taking the lead in running the ROP screening program in their respective intensive care units using a low-cost fundus imaging camera. The options for imaging staff could include neonatologists, trained nurses or trained imaging technicians. In this model the ophthalmologists are utilised only for consultation in difficult image interpretations and management of potential infants needing laser.

In India, the newborn care is predominantly serviced by a specialist Pediatrician with an interest in neonatology rather than a sub-specialist neonatologist. Hence, the Pediatrician-led model may be practical in those intensive care units where neonatologists are available. Our interaction with pediatricians and neonatologists across the state showed a very similar trend. The larger intensive care units of teaching hospitals where neonatologists were leading the care were welcoming such a move. Neonatologist-led model has the potential to be a future of ROP screening in India especially with many qualified neonatologists coming out from Indian institutions and significant number of neonatal trained doctors returning from overseas training. As pointed out in the paper by Gilbert et al, (2015) this model needs to overcome certain challenges which include change in mindset and a framework for both ophthalmologists and neonatologists to work together with clearly defined roles.
<table>
<thead>
<tr>
<th>Option</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tele-Imaging model</strong></td>
<td>Works well for large number of at risk population (KIDROP)</td>
<td>Camera Cost</td>
</tr>
<tr>
<td></td>
<td>Imaging (screening) is possible with non-physicians (Athikarisamy et al, 2014 Systematic review, SUNDROP experience, e-ROP study)</td>
<td>Technological constraints</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Administrative framework needed to protect the imaging staff and infant</td>
</tr>
<tr>
<td><strong>Ophthalmologist-led model in SNCU</strong></td>
<td>Been the standard examination for many years</td>
<td>Not enough workforce who are trained in ROP care</td>
</tr>
<tr>
<td></td>
<td>Cost – effective?</td>
<td>Evidence to show that it works well in large population is limited</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mexican study demonstrated that it is not a compliant model</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>(Zepeda-Romero,L.C., 2015)</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Private nurseries may not be able to access the service</td>
</tr>
<tr>
<td><strong>Pediatrician-led model</strong></td>
<td>Images can be taken by nurses/doctors</td>
<td>Every neonatal unit will need an imaging camera and a leader who can take charge</td>
</tr>
<tr>
<td><em>(A proposed model for future)</em></td>
<td>Ensures all infants are screened</td>
<td>Need multidisciplinary co-ordination</td>
</tr>
</tbody>
</table>

*Table 3. Comparison of the three ROP screening models*
Tele-imaging: The future of ROP screening

Even in countries such as New Zealand and Australia, where the number of screening infants are much lower than the Indian Setup are shifting away from professional ophthalmologist lead screening. Trained nurses take the images, to overcome the shortage of limited workforce and ophthalmologists are utilized for treatment and follow up. This imaging also gives the opportunity for storage of pictures for future references. Especially with increasing litigations related to ROP care, there is an increased need for proper documentation. In the United States, the SUNDROP model has used trained nurses to take images and it has been successful for the past 8 years.

Imminent challenges

1. Workforce planning

The recent Supreme Court judgment against a state health system has created more awareness of ROP among health service providers. This has resulted in more number of pediatricians and health services seeking for ROP screening services. The recently introduced Rashtriya Bal Swasthya Karyakram (RBSK) is an initiative aimed at screening over 27 crore children from 0 to 18 years, has listed ROP as one of the condition. Hence there is support from central Government in terms of funding and logistics. NGO’s like ‘Public Health Foundation of India’ through Queen’s Diamond Jubilee trust, London, UK; working on preventable blindness, is also willing to partner with Governments. So currently the scenario in India is close to a stage where the demand for ROP service will increase but the health services may not be ready in terms of workforce that can care for ROP (both screening and treatment) on a larger scale.
2. **Cost of cameras**

In the near future low cost cameras that are capable of wide filed imaging of infants are likely to be available. The primary evaluator of this report met with some potential developers. This could facilitate widespread access of the technology and help bridge the gap between the demand and supply of ROP services especially at sub district level neonatal centers. Any new camera would be more successful if in addition to being low cost, is more portable, easy to use and integrated with a tele-medicine platform that allows a short turnaround time between imaging the baby and receiving the report from a ROP specialist with additional features of data management, storage, archiving and data mining.

**Strength of KIDROP program**

This Evaluation, studied the most extensively implemented model of tele-ROP surveillance in a rural set up. **Key strength of this program success is the demonstration that, public private partnership can bring a radical change.** The success of the program provides the Government with a solid foundation upon which to base future program-related decisions. Data derived from the KIDROP and the publications has been particularly valuable in this regard.

**Limitation of this evaluation**

**Under-coverage:** There was no data available on the number of infants who are in need of screening (total number of at risk infants). Hence it was not possible to calculate the percentage of under-coverage. It is measured as “the number of infants who received screening divided by the number of infants who are in need of screening” (Issel, L. M, and 2004 Page 326).
**Type of evaluation**: There is a subtle difference between the three levels of ‘intervention effect evaluations’ as described by Issel, L. M, (2004). The current report is based on outcome documentation from the KIDROP data collection. More rigorous form of data is needed for outcome evaluation. We need pre-intervention or baseline data as well to compare the effect of the program.

**Need for further studies**

The evaluation of KIDROP program is an ongoing process and the impact of this program on long term outcomes, and cost effectiveness will be evaluated in a phased manner. From our evaluation we have identified three questions which need to be answered and we believe they can be answered by conducting a pilot study in a given geographical area.

1. **What is the number of infants who are in need of ROP screening in a given District or Zone?**

   This is possible in the current coverage area of KIDROP by linking all the private nurseries and government hospitals and tracking all the infants who are fulfilling the criteria for screening.

2. **What is the prevalence of ROP related blindness in an unscreened area?**

   This study can be undertaken in one or two districts of the neighbouring states with similar demographic profile where ROP screening services are not available. Following up all the infants discharged from SNCU who fulfilled the criteria for ROP screening will help us better understand the natural history of ROP in Indian cohorts.
3. Whether proposed ophthalmology-led model is as effective as tele-imaging?

Since the Government is considering implementing this model, doing feasibility and validity study will be valuable in one of the western Karnataka district where currently no ROP screening service is available.
### Summary of opportunities to improve the program and increase participation

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Government/ NHM</strong></td>
<td>Develop a strategy to support the future expansion of the screening program including the nurseries in the taluk levels</td>
</tr>
<tr>
<td></td>
<td>A reporting system very similar to the AFP surveillance where the onus is on the paediatricians to contact the screening service</td>
</tr>
<tr>
<td></td>
<td>Develop Key Performance Indicators and targets for participation and outcomes to enhance program monitoring and continuous improvement.</td>
</tr>
<tr>
<td><strong>Private Partner</strong></td>
<td>Develop a quality management plan and periodic audit of images and image interpretation by imaging staff</td>
</tr>
<tr>
<td></td>
<td>Ongoing mentorship and continuing education for the program staff including exposing them to basic neonatal resuscitation skills.</td>
</tr>
<tr>
<td><strong>Professional Bodies like IAP, IMA and NNF</strong></td>
<td>Promote awareness among the service delivery partners like neonatologists and paediatricians, including consideration of conducting workshops for ROP during conferences and regional meets.</td>
</tr>
<tr>
<td></td>
<td>Information packages to primary health care practitioners, nurses in PHC and obstetricians as they are the first contact. This will help to create more awareness during antenatal visits</td>
</tr>
</tbody>
</table>
**Recommendations**

ROP screening and treatment for at risk infants is not only a medical requirement but the health systems are legally bound as well. Hence **ROP screening is not a choice anymore and it is mandatory.**

The importance of setting up a low cost, efficient ROP screening and treatment program cannot be overemphasized considering that the incidence of ROP is expected to increase exponentially.

Reversing the current ROP epidemic requires **a comprehensive approach that targets both prevention and treatment interventions.**

While the Government is bound to **provide a screening service in public hospitals,** Government also should be in a position to **regulate screening in private institutions.** Those private institutions that have the expertise should be allowed to conduct their own screening; however private institutions/nurseries **should give the Government the minimum data set for surveillance.** If the private nurseries do not have the facility to screen or treat they should use the services provided by the Government.

There is a need for a ROP screening program which is effective in controlling blindness and equipped with adequate work force which can cater to a wider group. In a country like India which has implemented many effective public health programs successfully, **ROP care can achieve quick gains if appropriate actions are taken now.**
The worldwide picture of future ROP screening is going to be telemedicine based. Karnataka tele
ROP (KIDROP) program has proven that a community based approach is possible for a disease like
ROP, by using human resource skill appropriately (task shifting).

Telemedicine based imaging has proven to be successful for diabetic retinopathy on a large scale
in India. Hence such a model is feasible for ROP and this has been demonstrated by the KIDROP
statistics.

Unfortunately the major ROP experts in India are mainly in the private sector and few major
teaching hospitals of public system. Hence the Government should not hesitate to avail their
services, especially those who are volunteering to manage the ROP burden. Programs like polio
eradication campaign have utilized this model of Public-Private-Partnership effectively.

As part of the primary preventive approach the pediatric and neonatal professional bodies should
bring forth strict guidelines with regards to administration of oxygen. SNCU’s will need oxygen
blenders to minimize the exposure to 100% oxygen. An approach of oxygen targeting (evidence
based guidelines), oxygen monitoring (pulse oximeter) and oxygen titrating (blenders) will help
in curtailing the incidence.

ROP surveillance systems should be strengthened and integrated into existing national health
information systems. The components of surveillance should include risk factors, screening
outcome, treatment and follow-up data.

To carry out their tasks successfully, the program coordinators, image technicians need regular
ongoing mentorship, supervision and reliable logistical support.
Final Conclusions

Karnataka tele-imaging program is playing a crucial role in broadening the access and coverage of ROP screening services in remote areas of Karnataka.

Prompt identification of infants and optimal treatment with laser is preventing blindness in a significant number of infants. The KIDROP model has shown the importance of photo documentation in ROP screening.

Recent evidence of effective screening on a larger scale is summarized in our evaluation and from the review of the literature.

A deviation from the current model of tele-imaging and regressing back to indirect ophthalmoscopy performed by inadequately trained ophthalmologists could be fraught with the danger of sub-optimal management of ROP.

ROP screening and treatment is now a mandate and any sub-optimal management could expose the government to medico-legal liability. The recent Supreme Court of India judgment against the health system should be an eye opener both for the health providers and policy makers.
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**Supreme Court Judgment**

**UNDP Report**
National Health and Medical Research Council (NHMRC - Australia), Preterm Centre of Research Excellence is a multi-institutional research and education collaboration focused on improving outcomes for the 15 million babies born prematurely around the world each year. The Centre, administered by The University of Western Australia, employs a holistic approach to solving problems faced by infants born preterm.
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