International Journal of Neonatology
Open Access - Peer-Reviewed - ISSN 2998-4785

Portico Archived | Crossref DOI | CC BY 4.0 Licensed

Research Article

Abnormal Red Reflex Among Neonates Born at Moi Teaching and Referral Hospital Eldoret, Kenya: Proportion, Causes, and Accuracy of the Red Reflex in Identification of Ocular Pathologies

Njie Albertine Enjema [1*], Winstone M Nyandiko [1,2*], Eric Ngetich [3], Richard Mugo [1], Maureen Chepkoech [1], Ernest Ollando [5,6], Claudio Owino [4,5]

[1] Academic Model Providing Access to Healthcare, Eldoret, Kenya

[2] Department of Child Health and Paediatrics, Moi University School of Medicine, Eldoret, Kenya

[3] Directorate of Paediatrics and Child Health, Moi Teaching and Referral Hospital Eldoret, Kenya

[4] Department of Surgery and Anesthesiology, Moi University School of Medicine Eldoret, Kenya

[5] Department of Ophthalmology, Moi Teaching and Referral Hospital Eldoret, Kenya,

[6] Department of Ophthalmology, Aga Khan University, Nairobi, Kenya

*** Correspondence:** Njie Albertine Enjema, Academic Model Providing Access to Healthcare, Eldoret, Kenya

*** Correspondence:** Winstone M Nyandiko, Department of Child Health and Paediatrics, Moi University School of Medicine, Eldoret, Kenya, Academic Model Providing Access to Healthcare, Eldoret, Kenya.

Published citation: Njie Albertine Enjema, Winstone M Nyandiko, Eric Ngetich, Richard Mugo, Maureen Chepkoech, et al. **Abnormal Red Reflex Among Neonates Born at Moi Teaching and Referral Hospital Eldoret, Kenya: Proportion, Causes, and Accuracy of the Red Reflex in Identification of Ocular Pathologies**. International Journal of Neonatology. 1(2):15-30.

Article DOI: 10.14302/issn.2998-4785.ijne-26-6416

Abstract

Background

The red reflex is an integral component of routine newborn screening in high-income countries. It is a non-invasive screening test using an ophthalmoscope to check for a normal red or orange glow from a newborn's pupils. However, this is yet to be adopted as a routine examination in many low- and middle- income countries. Pursuant to the asymptomatic nature of many congenital and acquired ocular diseases, it is imperative to have contextual data to facilitate upscaling of the use of this simple examination method for identification of ocular pathologies.

Objective

To determine the proportion and causes of abnormal red reflex in neonates born at Moi Teaching and Referral Hospital (MTRH), and the accuracy of the red reflex in identifying these neonates.

Methods

This was a cross-sectional hospital-based study of 552 consecutively sampled neonates between February 2024 and September 2025 at the newborn unit of Moi Teaching and Referral Hospital in western Kenya. Initial screening of the red reflex was done using a direct ophthalmoscope. The reference test was dilatation and indirect ophthalmoscopy (gold standard) done by a specialist ophthalmologist. The red reflex was classified as normal or white or abnormal with abnormal defined as dull or absent. Sensitivity, specificity, positive and negative predictive values determined the accuracy of this reflex.

Results

A total of 552 neonates were enrolled; 45.8 % female and 54.2% were male. About two thirds (66.8%) of the neonates had a birthweight >2.5kgs and 22.3% weighed lower than 1.5kgs. More than half (56%) were borne at ≥ 39 week' gestation, while a 5.6% were born at <28 weeks. The red reflex was performed on 1104 eyes of the 552 enrolled neonates. An abnormal red reflex was identified in 124 neonates (22.5%) of whom 95(76.6%) had a confirmed abnormality on ophthalmoscopy. The most common identified causes were retinal haemorrhage (11.9%), physiologic retinal immaturity (9.2%) and retinopathy of prematurity (4.0%). Overall diagnostic accuracy of the red reflex examination was 83.7% with a sensitivity of 60.9%, specificity of 92.7%, positive predictive value of 76.6%, and negative predictive value of 85.7%. Gestational age (<28 weeks, aOR 4.1(95% CI,1.4-12.5), and birth weight (<1.5kgs, aOR 6.29(95% CI,3.0-14.5)) were significantly associated with an abnormal red reflex.

Conclusion

The red reflex has high accuracy and specificity and good sensitivity. The findings of this study affirm the utility of the red reflex in identifying neonates with ocular pathologies in a low resource setting. Integrating this test as a screening tool for comprehensive eye care will lead to prompt referral for specialist care, a reduction in blindness from neonatal ocular pathologies and improved outcomes.

Keywords:
red reflex; ocular pathologies; eye care; morbidity; accuracy

Article Information	
Academic Editor	Anubha Bajaj[1] [1] Consultant Histopathologist, A.B. Diagnostics, Delhi, India.
Received Date	22 July 2026
Accepted Date	8 October 2026
Published Date	3 November 2026
Online	3 November 2026
Publication	Volume 1; Issue 2; Pages 15–30
Copyright	© 2026 Njie Albertine Enjema, et al.
Licence	This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited. https://creativecommons.org/licenses/by/4.0/

Introduction

Newborn screening has steadily become an integral part of fostering neonatal care in the developed world. However, many low- and middle- income countries are yet to incorporate the full range of

newborn screening tests when compared with higher income countries that are able to screen for about fifty diseases at birth [1]. Implementation of newborn screening programs is challenging in developing economies, notably those in Africa [2]. More specifically, majority of newborns with ocular disorders are usually missed at delivery, as these conditions tend to be asymptomatic at birth, necessitating routine screening for identification [3].

Globally, childhood blindness has been shown to have a linear relationship with under-five mortalities [4]. Children who are visually impaired tend to have a lower quality of life than children without visual impairment as this group is more likely to be socio-economically deprived and die in childhood [5]. Childhood blindness has also been demonstrated to occur with other conditions such as intellectual disability and autism spectrum disability [6]. In Kenya, limited attention has been directed towards child eye care and the various aetiologies of vision impairment [7].

The red reflex, an examination of pupil reflections, can help identify avoidable causes of blindness such as congenital cataract, retinoblastoma, retinal detachment, and vitreous opacities [8]. This reflex can also identify comorbid ocular conditions such as retinopathy of prematurity whose prevalence is on the rise in many African countries [9]. In a study by Subhi et al, the red reflex was comparable to wide-field digital retinal imaging system in detecting ocular diseases that necessitated urgent care as regards cost effectiveness of both methods.

Visual impairment has a huge impact on a child's academic and career opportunities, social life including stigmatization, functionality, and overall health [10]. The dire implications of loss of vision necessitate upscaling of measures to curb its prevalence by early detection of reversible and correctable aetiology. This study therefore aims at determining the proportion and causes of abnormal red reflex as well as assessing the accuracy of a simple newborn eye examination method - the red reflex, in identifying ocular diseases among neonates born at Moi Teaching and Referral Hospital (MTRH) Kenya.

Materials and Methods

This was a cross-sectional hospital-based single-blinded study of 552 neonates in the newborn unit of the Riley Mother and Baby section of Moi Teaching and Referral Hospital. On average 150 babies are managed at the newborn unit every month. The newborn unit comprises of the following departments: a neonatal intensive care, acute prematurity, stable prematurity, stable term, high-dependency care and surgical. It is managed by 4 neonatologists, 2 consultant pediatricians and a variable number of neonatology fellows, pediatric residents, medical officers, medical officer interns, nurses, nutritionist and clinical officers. We enrolled 552 neonates consecutively between February 2024 to September 2025. Sample size estimation was done using the Burderer's formula imputing : 23% as a sensitivity, 98% as specificity, [3], and an assumed proportion of 50% given that the prevalence of congenital ocular diseases is unknown in Kenya (Taksande et, 2021).

Ethical approval from Institutional Review and Ethics Committee (IREC) of Moi University and Moi Teaching and Referral Hospital (approval number: 0004553) and administrative approval from the CEO of MTRH were obtained. Codes were assigned to the enrolled neonates for utilization in this study and for enhancement of confidentiality. Written informed consent was obtained from parents or guardians of neonates for ocular examinations to be done. Consent was done in English or Kiswahili as preferred by parent/guardian of neonates. Assent was not applicable in this study. Prior to use, the consent form was translated from English to Kiswahili and back translated from Kiswahili to English for ease of understanding by parents/guardians of neonates. Term neonates and pre-term neonates who had attained at least one month of age were enrolled in this study. Enrolment was done at one month of age for the pre-term neonates to eliminate the bias of high false negative screening in retinopathy of prematurity at one month. Six neonates were not enrolled as a result of refusal of consent and three neonates were excluded due to anophthalmia.

All neonates enrolled in this study underwent red reflex assessment using a direct ophthalmoscope by a research assistant in a dark room at time of discharge from the hospital or after one month of age for preterm neonates admitted to the newborn unit. The research assistant was a qualified registered

degree level nurse who underwent training by a certified ophthalmologist on conducting of the red reflex. The color, brightness and equality of the reflex in both eyes of each participant was observed and documented. The reflex results were subsequently categorized as normal, white or abnormal (dull or absent)reflex. The outcome of red reflex was categorized as dichotomous normal or abnormal (dull or absent) for inclusion in the 2x2 table for estimation of accuracy. The standard operating procedure for conduction of the red reflex was adopted from Volume 27 of the Community Eye Health Journal guidelines on how to test for the red reflex in a child (Community Eye Health Journal, 2014). The red reflex by direct ophthalmoscope was considered as the primary test. Additionally, the Hawthorne effect on the user of the initial test was minimized by the fact that all neonates were screened (were asymptomatic) and thus, there were no ocular symptoms or signs to influence the initial test user on if the red reflex should be reported as normal or absent/abnormal on the basis of clinical presentation.

The confirmatory test was dilatation and indirect ophthalmoscopy (reference test) by an experienced specialist ophthalmologist using an ophthalmoscope. All neonates, irrespective of initial test (red reflex assessment) results, underwent the reference standard test (dilatation and indirect ophthalmoscopy). Dilatation was done using Tropicamide–phenylephrine a maximum of two drops was instilled in each eye, with a 5-minute interval between drops, resulting in adequate pupil dilation within 15–30 minutes, which persisted for up to 3 hours. During the eye examination, proparacaine eye drops were administered to provide topical anaesthesia, thereby reducing pain and discomfort and improving tolerance of the procedure in neonates. Following completion of the eye examination, moxifloxacin eye drops were administered as prophylaxis. Moxifloxacin eye drops were used as an infection prevention method given that the study was conducted on neonates including premature neonates, who consist of a vulnerable population. In addition, the speculums used were not disposable speculums and had to be sterilized before utilisation on each neonate. Sterilization however does not guarantee 100% infection prevention and thus the need for ocular antibiotic prophylaxis. Futhermore, moxifloxacin is abroad spectrum antibiotic and thus was a great choice for prophylaxis in the current study.

The identification of an ocular pathology was also documented as dichotomous (present or absent) to complete the 2X2 contingency table for assessment of diagnostic accuracy of the red reflex test. This was a single-blinded study, as the ophthalmologists carrying out the reference test were unaware of the results of the primary test. In addition, the study participants consisted of a non -enriched sample due to the lack of heterogeneity in assessment of the neonates, i.e., only one index test and one reference standard test was done.

Data management and Analysis

All study data were captured using Redcap, a secure web-based application for managing research data. Regular quality checks were conducted throughout the data collection period to ensure completeness, accuracy, and consistency of the data. Following these checks, a clean Comma-Separated Values (CSV) file was exported from Redcap for subsequent analysis. Descriptive statistics were generated to summarize neonates' characteristics. Categorical variables were presented as frequencies and proportions with corresponding 95% confidence intervals estimated using binomial exact methods. Continuous variables were summarized using means and standard deviations or medians and interquartile ranges (IQR), depending on variable distribution. Group comparisons were conducted using Pearson's Chi-square test for categorical variables and analysis of variance (ANOVA) for continuous variables, with simulation-based p-value correction applied when expected cell counts were small. The primary outcome for inferential analysis was the presence of abnormal red reflex (binary: abnormal vs. normal).

To assess associations between neonatal and clinical characteristics and the primary outcome, univariable and multivariable logistic regression models were fitted. Crude odds ratios (ORs) and adjusted (aORs) with 95% confidence intervals were reported. All variable in consideration that were

deemed to be clinically relevant were included in the multivariable logistic regression model to estimate aORs. Model diagnostics were performed to assess overall model adequacy. Diagnostic accuracy of the initial red reflex test was evaluated using the ophthalmologist-confirmed assessment as the reference standard. A 2×2 confusion matrix was constructed to compare results from the initial screening with those from the confirmatory ophthalmologic examination.

The analysis of accuracy of the red reflex in comparison to the reference test was done at neonate level and not at individual eye level. Therefore, the results from the two eyes of each neonate were considered together, and each neonate contributed one observation to the comparison between the red reflex test and the reference standard. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were calculated along with their corresponding 95% confidence intervals. Sensitivity was defined as the proportion of true abnormal cases correctly identified by the screening test (TP/(TP+FN)), while specificity represented the proportion of true normal cases correctly identified (TN/(TN+FP)). Positive and negative predictive values were calculated as the probability that positive and negative screening outcomes, respectively, reflected true findings based on the reference standard. Overall diagnostic accuracy was defined as the proportion of correctly classified observations (TP+TN) out of the total screened population. Wilson score confidence intervals were applied to all diagnostic accuracy metrics to account for binomial distribution characteristics and improve interval coverage over the Wald method, particularly for proportions near 0 or 1 or small cell counts. All analyses were conducted using the caret and binom statistical packages in R version 4.4.1

Results

The proportion of neonates with abnormal red reflex

We recruited 552 neonates between February 2024 to September 2025. The red reflex was assessed in 1104 eyes of the 552 enrolled neonates using a direct ophthalmoscope, with slightly more than half of the population being male(54.2%)and females being(45.8%). About two thirds (66.8%) of the neonates had a birthweight >2.5kgs and 22.3% weighed lower than 1.5kgs. More than half (56%) were born at ≥ 39 week' gestation, while a 5.6% were born at <28 weeks.

An abnormal red reflex was identified in 124 neonates, resulting in a prevalence of 22.5% (95% Confidence Interval: 19.0% to 26.2%). Consequently, 428 neonates (77.6%, 95% CI: 73.8% to 81.0%) presented with a normal red reflex.

Test for bivariate association between abnormal red reflex vs demographics

Bivariate analysis (Table 1) revealed a significant association ($p < 0.001$) between an abnormal red reflex and key neonatal characteristics, including gestational age, day of life at examination, and birth weight. For instance, the proportion of abnormal red reflexes was highest among neonates born at <28 weeks of gestation (77.4%), those examined after 7 days of life (28.3%), and those with a birth weight <1.5 kg (51.2%). In contrast, sex of the baby showed no significant association with red reflex findings ($p = 0.916$).

Table 1. Demographic characteristic of neonates with abnormal red reflex

	Abnormal Red reflex (N=124)	Normal Red reflex (N=428)	Total (N=552)	p value
Gestational Age (LNMP)				
<28	24 (77.4%)	7 (22.6%)	31 (100.0%)	< 0.001

Table 1 (continued)

	Abnormal Red reflex (N=124)	Normal Red reflex (N=428)	Total (N=552)	p value
28-34	30 (31.2%)	66 (68.8%)	96 (100.0%)	
35-38	16 (11.9%)	119 (88.1%)	135 (100.0%)	
39+	54 (18.6%)	236 (81.4%)	290 (100.0%)	
Sex of the baby				
Male	68 (22.7%)	231 (77.3%)	299 (100.0%)	0.916
Female	56 (22.1%)	197 (77.9%)	253 (100.0%)	
Day of life				
1-7 days	39 (15.5%)	213 (84.5%)	252 (100.0%)	< 0.001
After 7 days	85 (28.3%)	215 (71.7%)	300 (100.0%)	
Birth weight (g)				
<1.5kg	63 (51.2%)	60 (48.8%)	123 (100.0%)	< 0.001
1.5-2.5kgs	6 (10.0%)	54 (90.0%)	60 (100.0%)	
>2.5kgs	55 (14.9%)	314 (85.1%)	369 (100.0%)	
Confirmatory reference test				
Abnormal	95 (60.9%)	61 (39.1%)	156 (100.0%)	< 0.001
Normal	29 (7.3%)	367 (92.7%)	396 (100.0%)	

Multivariable Logistic Regression

Using multivariable logistic regression analysis (Table 2), two factors remained independent predictors of an abnormal red reflex after adjustment. Neonates born at a gestational age of less than 28 weeks had four times the odds of an abnormal reflex compared to those born at 39 weeks or later (aOR = 4.01, 95% CI: 1.37–12.54, p = 0.013). Furthermore, neonates with a birth weight below 1.5 kg had six times the odds of an abnormal reflex compared to those weighing more than 2.5 kg (aOR = 6.29, 95% CI: 2.80–14.54, p < 0.001). In the adjusted model, sex and day of life at examination were no longer significantly associated with red reflex status.

Table 2. Odd ratios comparing neonates identified by red reflex to have abnormal vs normal eyes

Dependent:		OR (univariable)	OR (multivariable)
Gestational Age (LNMP)	39+	-	-
	35-38	0.59 (0.31-1.05, p=0.082)	0.70 (0.37-1.29, p=0.273)

Table 2 (continued)

Dependent:		OR (univariable)	OR (multivariable)
	28-34	1.99 (1.17-3.34, p=0.010)	0.74 (0.33-1.64, p=0.466)
	<28	14.98 (6.44-39.32, p<0.001)	4.01 (1.37-12.54, p=0.013)
Sex of the baby	Male	-	-
	Female	0.97 (0.64-1.44, p=0.865)	0.65 (0.41-1.04, p=0.075)
Day of life	1-7 days	-	-
	After 7 days	2.16 (1.42-3.33, p<0.001)	0.79 (0.43-1.40, p=0.427)
Birth weight (g)	>2.5kgs	-	-
	1.5-2.5kgs	0.63 (0.24-1.44, p=0.317)	0.86 (0.30-2.11, p=0.759)
	<1.5kg	5.99 (3.82-9.49, p<0.001)	6.29 (2.80-14.54, p<0.001)

Ocular Disorders Identified by Confirmatory Examination

Following confirmatory examination with dilatation and indirect ophthalmoscopy (the reference standard), several ocular pathologies were identified (Table 3). The most common pathologic conditions were retinal hemorrhage, found in 66 neonates (11.9%), and retinopathy of prematurity in 22 neonates (4.0%). However, 9.2% with abnormal red reflex had physiologic immature retina. A variety of other significant but less frequent pathologies were also diagnosed, including congenital cataract and retinal detachment (each 0.2%), collectively representing 2.0% of the screened population.

Table 3. Ocular disorders identified by the reference test

Ocular Condition	Count (%)
Retina haemorrhages	66 (11.9%)
Retinopathy of prematurity	22 (4.0%)
Failed dilatation of unspecified etiology	12 (2.2%)
Vitreous opacity	6 (1.1%)
Persistent fetal vasculature	5 (0.9%)
Engorged vessels	3 (0.5%)
Pale atrophic disc	3 (0.5%)
Large macula breed	2 (0.4%)
Tigroid fundus	2 (0.4%)

Table 3 (continued)

Ocular Condition	Count (%)
Congenital cataract	1 (0.2%)
Retinal detachment	1 (0.2%)
Disc pallor	1 (0.2%)
Radial posterior synechiae	1 (0.2%)
Perforated central cornea with fibrinous exudate	1 (0.2%)
Immature retina (physiologic)	51 (9.2%)

Diagnostic Accuracy of the Red Reflex Test

The diagnostic performance of the initial red reflex test, using ophthalmologist-confirmed findings as the reference standard, is presented in Table 4a. The test demonstrated a sensitivity of 60.9% (53.1–68.2), correctly identifying about two-thirds of neonates with true ocular pathology. It also showed a high specificity of 92.7% (89.7–94.9)) and a strong negative predictive value of 85.7% (82.1–88.7, indicating that a normal red reflex was highly reliable in ruling out disease. The positive predictive value was 76.6% (95% CI: 68.4–83.2), and the overall diagnostic accuracy was 83.7% (80.4–86.5).

Table 4a. Confusion Matrix: Red reflex both eyes vs Confirmatory Test

Red reflex findings	Reference test: Yes	Reference test: No
Yes	95 (76.6%)	29 (23.4%)
No	61 (14.3%)	367 (85.7%)
Total	156	396

Yes means pathology identified and no refers to normal ocular findings

Based on these results, the diagnostic accuracy of the Red reflex test was as follows: sensitivity 60.9% (95% CI: 53.1–68.2), specificity 92.7% (95% CI: 89.7–94.9), positive predictive value76.6% (95% CI: 68.4–83.2), negative predictive value 85.7% (95% CI: 82.1–88.7), and overall accuracy 83.7% (95% CI: 80.4–86.5) (Table 4b).

Table 4b. Diagnostic Accuracy of Red Reflex Initial Test Compared with Ophthalmologist Reference Standard

Measure	CI
Sensitivity	60.9% (53.1–68.2)
Specificity	92.7% (89.7–94.9)
Positive Predictive Value	76.6% (68.4–83.2)

Table 4b (continued)

Measure	CI
Negative Predictive Value	85.7% (82.1–88.7)
Accuracy	83.7% (80.4–86.5)

Sub analysis on a sample of neonates

In a subsample of 211 neonates (100 normal, 111 abnormal by reference test), the neonate's history and relevant covariates were examined for their association with confirmed ocular disorders (Table 5). Mode of delivery was significantly associated with abnormal findings ($p < 0.001$), with the highest proportion observed in assisted vaginal deliveries (87.5%). Oxygen administration was also strongly linked to ocular pathology, with 61.8% of neonates who received oxygen having abnormal eyes compared to 36.0% who did not ($p < 0.001$). Maternal parity and APGAR score patterns were not significantly associated with the presence of ocular disorders.

Table 5. Birth history from a sample of those found with normal and abnormal eyes based on reference test

	Abnormal (N=111)	Normal (N=100)	Total (N=211)	p value
Mode of delivery				
AVD	14 (87.5%)	2 (12.5%)	16 (100.0%)	< 0.001
C/S	29 (36.7%)	50 (63.3%)	79 (100.0%)	
SVD	68 (58.6%)	48 (41.4%)	116 (100.0%)	
Parity				
0	48 (43.2%)	15 (15.0%)	63 (29.9%)	0.135
1	33 (29.7%)	48 (48.0%)	81 (38.4%)	
2	16 (14.4%)	22 (22.0%)	38 (18.0%)	
3	7 (6.3%)	12 (12.0%)	19 (9.0%)	
4+	7 (6.3%)	3 (3.0%)	10 (4.7%)	
APGAR				
E-E-E	63 (50.4%)	62 (49.6%)	125 (100.0%)	0.216
E-E-M	1 (50.0%)	1 (50.0%)	2 (100.0%)	
M-E-E	21 (67.7%)	10 (32.3%)	31 (100.0%)	
M-E-M	1 (100.0%)	0 (0.0%)	1 (100.0%)	
M-M-E	9 (56.2%)	7 (43.8%)	16 (100.0%)	
M-M-M	10 (55.6%)	8 (44.4%)	18 (100.0%)	
S-E-E	1 (50.0%)	1 (50.0%)	2 (100.0%)	

Table 5 (continued)

	Abnormal (N=111)	Normal (N=100)	Total (N=211)	p value
S-M-E	1 (50.0%)	1 (50.0%)	2 (100.0%)	
S-M-M	2 (100.0%)	0 (0.0%)	2 (100.0%)	
S-S-M	0 (0.0%)	1 (100.0%)	1 (100.0%)	
NA	2 (18.2%)	9 (81.8%)	11 (100.0%)	
Oxygen				
No	27 (36.0%)	48 (64.0%)	75 (100.0%)	< 0.001
Yes	84 (61.8%)	52 (38.2%)	136 (100.0%)	
Follow up 1 outcome for neonates with Abnormal reference test done by ophthalmologist				
Awaits Cataract Surgery	1 (100.0%)	0 (0.0%)	1 (100.0%)	
Bilateral blindness secondary to ROP stage 5-	1 (100.0%)	0 (0.0%)	1 (100.0%)	
Died	3 (100.0%)	0 (0.0%)	3 (100.0%)	
Missed appointment	10 (100.0%)	0 (0.0%)	10 (100.0%)	
Normal	86 (100.0%)	0 (0.0%)	86 (100.0%)	
Ongoing ROP regress on the R.E, LE-Blindness	1 (100.0%)	0 (0.0%)	1 (100.0%)	
Ongoing ROP regression	6 (100.0%)	0 (0.0%)	6 (100.0%)	
Ongoing ROP regression, later baby died	1 (100.0%)	0 (0.0%)	1 (100.0%)	
Ongoing ROP regression.	1 (100.0%)	0 (0.0%)	1 (100.0%)	
R.E-Normal. L.E - Blindness	1 (100.0%)	0 (0.0%)	1 (100.0%)	

Among the 111 neonates with a confirmed ocular disorder who were followed up, the majority (n=86, 77.5%) had a normal outcome at their first follow-up visit, indicating resolution or regression of the initial finding. However, significant adverse outcomes were also noted: three neonates (2.7%) died, two (1.8%) developed bilateral blindness secondary to advanced retinopathy of prematurity, and nine (8.1%) had ongoing ROP requiring monitoring. An additional 10 neonates (9.0%) missed their scheduled follow-up appointments.

Assessing differences in other diagnoses between the normal vs non normal neonates based on reference test.

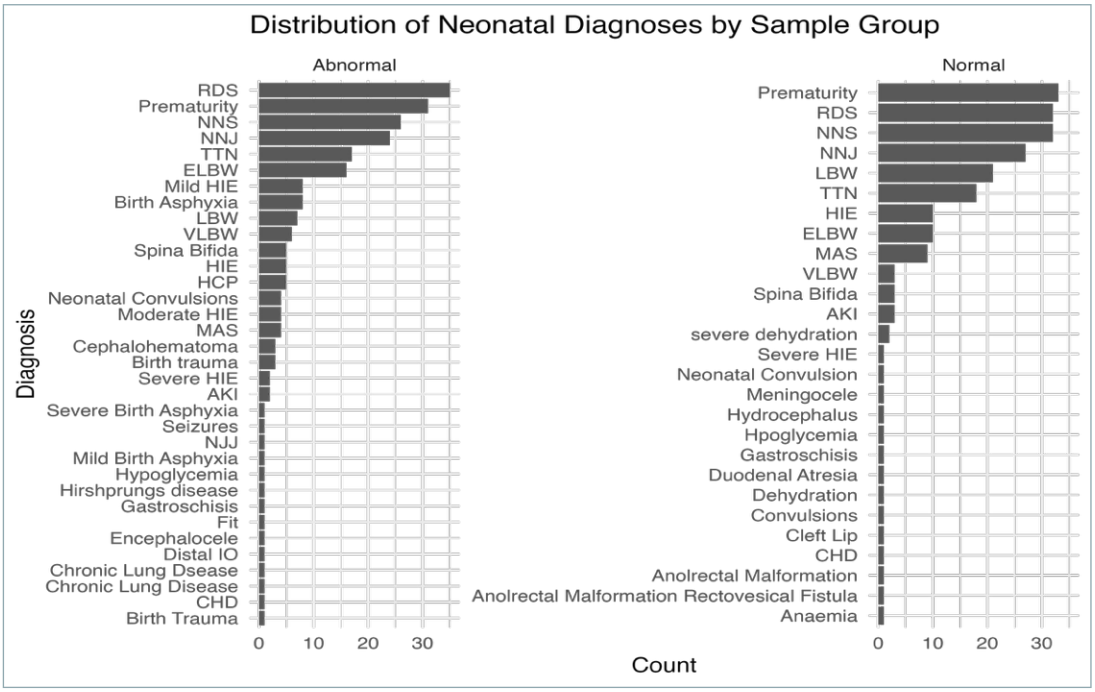


Figure 1. illustrates the spectrum of secondary diagnoses in neonates stratified by the reference test outcome.

Neonates with confirmed ocular pathology most frequently carried secondary diagnoses of respiratory distress syndrome (RDS), Prematurity, Neonatal sepsis (NNS), Transient Tachypnea of the Newborn (TTN) and Extremely Low Birth Weight (ELBW). Notable comorbidities also included Hypoxic-Ischemic Encephalopathy (HIE), very low birth weight (VLBW), and neonatal seizures. In contrast, neonates without ocular pathology exhibited a similar, broad range of secondary diagnoses, prominently featuring Prematurity, RDS, and NNS/NNU-related care, along with diagnoses like Meconium Aspiration Syndrome (MAS), congenital anomalies (e.g., Spina Bifida), and congenital heart disease (CHD). This overlap underscores that both groups were drawn from a high-risk neonatal population with substantial comorbidity burdens.

Discussion

This study was conducted to determine the proportion, causes, and diagnostic accuracy of the red reflex test among neonates at MTRH. The proportion of neonates with abnormal red reflex was 22.5%, and 28.3% of neonates were confirmed to have ocular pathology on reference examination. The most common abnormalities were retinal hemorrhage (11.9%) and immature retina (9.2%). Extreme prematurity (<28 weeks of gestation) and very low birth weight (<1.5 kg) were strong independent predictors of abnormal reflex. The red reflex test demonstrated moderate sensitivity (76.6%), high specificity (85.7%), and an excellent negative predictive value (92.7%). These metrics confirmed its value as a screening tool in this setting, consistent with existing studies [8,11,12].

Interpretation of Proportion and Spectrum of Ocular Pathology

In our study, 22.5% of neonates had an abnormal red reflex. Other studies have reported lower proportions between 0.5% and 5%. [13,14,15]. This difference may be as a result of the fact that the current study was hospital-based while the other studies were community-based. In addition, the difference may have resulted from differences in study population as the current study included preterm neonates. Retinal hemorrhage was the leading abnormality, consistent with other global studies that linked hemorrhagic lesions to vaginal delivery, birth trauma, and neonatal distress [16,17]. Immature retina was also common. The high diagnosis of retinal hemorrhage is reflective of the enrolment of preterm neonates in our study. In addition, retinopathy of prematurity was also a significant finding. This is consistent with meta-analyses of studies on NICU populations in low-resource settings[18,19].

Congenital cataract and retinoblastoma were rare in our study, but their detection is critical. Given that these conditions can hamper the quality of life and have negative outcomes, even isolated cases of these conditions carry lifelong consequences, and their rarity highlight the need for routine newborn ocular screening. Other studies have reported higher detection of congenital cataract beyond the neonatal period such as by Singh et al who reported 77.9% of their study population with bilateral cataract at a mean age of 4.1 months [±2.6 months] [20].

Evidence-based data on the diagnosis of ocular pathologies emphasize the fact that rare but severe causes of leukocoria are often missed without structured screening programs [8,11]. The limited identification of such conditions in hospital-based studies highlight the need for expansion of diagnosis beyond hospital settings. Mobile applications and community-based screening tools have been shown to be relevant in upscaling the diagnosis of ocular pathologies [12,15]. A study in Tanzania used enhanced mobile application in a bid to improve the diagnosis of ocular pathologies by the red reflex. The study demonstrated highest sensitivity with red reflex assessment using Catcam (97.6%), an infra-red based camera, followed by Arclight (92.7%), PEEK retina (90.2%) and torchlight (7.3%) [9]

Predictors of Abnormal Red Reflex

Extreme prematurity and very low birth weight were the strongest independent predictors of an abnormal red reflex. Neonates born before 28 weeks of gestation were four times more likely to have an abnormal reflex, while those weighing less than 1.5 kg had six times the odds. These findings can be explained by the fact that this group of neonates are more likely to have an underdeveloped retinal vasculature. In addition, an underdeveloped retina poses a higher risk of development of retinopathy of prematurity[21,22]. Sakaria et al., and Chen et al., in their studies had similar findings, demonstrating that prematurity and low birth weight were significant predictors of an abnormal red reflex. [11,23,13]. The afore mentioned studies are from mixed settings and we can thus conclude that the red reflex remains relevant in both high- and low-income countries. In addition to the setting, the nature of the abnormality may also play a role as the red reflex has demonstrated superiority in identifying anterior segment abnormalities [24].

Gender and day of life at examination were not significant predictors of an abnormal red reflex in the multivariable analyses. This may probably suggest that intrinsic neonatal maturity outweighed demographic or temporal factors. Similar findings were observed by Blazon et al., and Chen et al., who reported that sex and age at screening were not significant factors that affected identification of ocular pathologies by the red reflex test. [14,23]. These results reinforce the importance of prioritizing clinical susceptibility over socio-demographic characteristics in neonatal ocular screening.

Diagnostic Accuracy of the Red Reflex Test

The red reflex test had moderate sensitivity and high specificity. Sensitivity of 60.9% indicated that approximately one in three true cases were missed, while specificity of 92.7% showed that most normal neonates were correctly identified as not having an ocular pathology by the red reflex. The negative predictive value of 85.7% confirmed that a normal reflex was highly reliable in ruling out disease. The positive predictive value of 76.6% highlighted the risk of false positives, which may cause parental anxiety but ensured that fewer true cases were missed.

Existing literature affirm the findings of the current study, revealing strong specificity but variable sensitivity of the red reflex test [8,3,11]. Recent quality of care improvement initiatives in Neonatal Intensive Care Units (NICUs) in the United States also had similar findings and recommended the need for structured referral pathways for screen-positive neonates [12,11].

Our results confirmed that the red reflex test was a valuable screening tool but not a definitive diagnostic test, and confirmatory ophthalmologic examination remained essential.

Birth History and Follow-up Outcomes

Assisted vaginal delivery was strongly associated with ocular pathology. This finding was consistent with studies that linked mechanical birth trauma to retinal hemorrhage [13,23]. Oxygen therapy was

also significantly associated with abnormal findings, potentiating the established link between supplemental oxygen and retinopathy of prematurity [15,25].

Most abnormalities resolved spontaneously, with 77.5% of neonates showing normal outcomes at follow-up. This can be explained by the fact that most pathologies identified, (retinal hemorrhages and transient immaturity in neonates) are known to spontaneously resolve over time [26]. We also found dire outcomes, including blindness and death. Irrespective of the fact that these complications were noted in few neonates, these findings emphasized the need for systematic follow-up and highlighted that screening programs must include mechanisms to track and manage screen-positive neonates to improve their outcome.

Clinical and Policy Implications

Our findings support the integration of red reflex screening into routine newborn care in Kenya. This test is simple, inexpensive, and feasible for healthcare providers and it has great reliability in ruling out disease. Policy frameworks such as the Kenya National Eye Health Strategic Plan (2020–2025) emphasized early detection of childhood blindness but had limited implementation (Kenya Ministry of Health, 2020; PolicyVault [27]; PATH Early Childhood [28]). Routine red reflex screening, particularly for preterm and very low birth weight neonates, should be prioritized within Reproductive, Maternal, Newborn, and Child Health (RMNCH) programs implemented in Kenya and similar settings in East Africa [29,30].

The limited detection of rare but severe conditions such as congenital cataract and retinoblastoma highlight the need for innovative approaches [31]. Mobile applications and community-based screening tools could extend detection beyond tertiary centers, enabling parents and primary care providers to identify abnormalities early and seek referral for prompt management [12,11,23]. Such innovations would complement hospital-based screening and improve outcomes.

Strengths and Limitations

This study had several strengths. It included a large consecutive sample from a busy referral center, enhancing generalizability to similar African settings. Screening was systematic, and confirmatory testing was conducted using gold-standard indirect ophthalmoscopy in a single-blinded design. The analysis was comprehensive, incorporating proportion, predictors, diagnostic accuracy, and follow-up outcomes.

The hospital-based design is a limitation which could have caused inflation of proportion compared to community populations. Spectrum bias was possible given the high proportion of preterm neonates, which may have affected diagnostic accuracy estimates. Follow-up was incomplete for some neonates, limiting assessment of long-term visual outcomes. These limitations were consistent with challenges reported in other NICU-based studies in Africa and Asia [18,15,13]. Despite these challenges the above- mentioned strengths highlight the significance of our study. Additionally, preterm neonates were screened at one month and beyond to reduce the risk of an erroneously high false negative predictive value.

Conclusion

The red reflex test is a valuable and practical screening tool in a high-risk neonatal population. It demonstrated high accuracy and specificity and moderate sensitivity. Its high negative predictive value of 85.7% made it an excellent rule-out test, while its moderate positive predictive value necessitated confirmatory ophthalmologic evaluation. We advocate for the systematic adoption of red reflex screening in Kenyan neonatal units as a first step toward preventing avoidable childhood blindness through early detection of ocular pathologies and referral.

Future implications

Visual impairment has a huge impact on a child's academic and career opportunities, social life including stigmatization, functionality, and overall health. Congenital ocular pathologies are an important cause of childhood blindness and hamper the quality of life of children. In resource-limited settings like the current study, ocular screening of newborns is not routine; consequently, neonates

with congenital ocular diseases are missed and tend to present later in life when complications have already ensued. The Kenya National Eye Health Strategy Plan 2020-2025 identifies the main causes of childhood blindness to be neonatal pathologies such as congenital cataract, retinopathy of prematurity, and tumors like retinoblastoma. The current study has therefore provided evidence based data for both short- and long-term policy development and amendment to upscale screening, diagnosis and management of neonates with ocular pathologies. This will result in improvement in the outcomes of neonates with ocular disorders.

Statement of funding

This study was funded by Internal Research Development Funds.

Competing Interests

The authors declare no conflict of interest.

References

1. Therrell, B. L., Lloyd-Puryear, M. A., Ohene-Frempong, K., Ware, R. E., Padilla, C. D., Ambrose, E. E., Barkat, A., Ghazal, H., Kiyaga, C., Mvalo, T., Nnodu, O., Ouldim, K., Rahimy, M. C., Santos, B., Tshilolo, L., Yusuf, C., Zarbalian, G., & Watson, M. S. (2020). Empowering newborn screening programs in African countries through establishment of an international collaborative effort. *Journal of Community Genetics*, *11*(3), 253–268. https://doi.org/10.1007/s12687-020-00463-7
2. Twum, S., Fosu, K., Felder, R. A., & Sarpong, K. A. N. (2023). Bridging the gaps in newborn screening programmes: Challenges and opportunities to detect haemoglobinopathies in Africa. *African journal of laboratory medicine*, *12*(1), 2225. https://doi.org/10.4102/ajlm.v12i1.2225
3. Taksande, A., Jameel, P. Z., Taksande, B., & Meshram, R. (2021). Red reflex test screening for neonates: A systematic review and meta-analysis. *Indian Journal of Ophthalmology, 69*(8), 1994–2003. https://doi.org/10.4103/ijo.IJO_3632_20
4. Perin, J., Mulick, A., Yeung, D., Villavicencio, F., Lopez, G., Strong, K. L., ... & Liu, L. (2022). Global, regional, and national causes of under-5 mortality in 2000–19: an updated systematic analysis with implications for the Sustainable Development Goals. *The Lancet Child & Adolescent Health*, *6*(2), 106-115.
5. Šemrov, A., Tadić, V., Cortina-Borja, M., Rahi, J. S., & Resilience and Childhood Visual Impairment Study Group. (2023). Individual, family, and environmental determinants of vision-related quality of life of children and young people with visual impairment. *Plos one*, *18*(11), e0294532.
6. Teoh, L. J., Solebo, A. L., Rahi, J. S., Abbott, J., Abdullah, W., Adams, G., ... & Lomas, T. (2021). Visual impairment, severe visual impairment, and blindness in children in Britain (BCVIS2): a national observational study. *The Lancet Child & Adolescent Health*, *5*(3), 190-200.
7. Muma, S., & Obonyo, S. (2020). The prevalence and causes of visual impairment among children in Kenya – the Kenya eye study. *BMC Ophthalmology*, *20*(1), 399. https://doi.org/10.1186/s12886-020-01665-w
8. Subhi, Y., Schmidt, D. C., Al-Bakri, M., Bach-Holm, D., & Kessel, L. (2021). Diagnostic test accuracy of the red reflex test for ocular pathology in infants: A meta-analysis. *JAMA Ophthalmology, 139*(1), 33–40. https://doi.org/10.1001/jamaophthalmol.2020.4854
9. Mndeme, F. G., Mmbaga, B. T., Kim, M. J., Sinke, L., Allen, L., Mgaya, E., ... & Bowman, R. (2021). Red reflex examination in reproductive and child health clinics for early detection of paediatric cataract and ocular media disorders: cross-sectional diagnostic accuracy and feasibility studies from Kilimanjaro, Tanzania. *Eye*, *35*(5), 1347-1353. https://doi.org/10.1038/s41433-020-1019-5
10. Tekkar, P., & Tripathi, S. R. (2022). Social Stigma and Self: A Psycho-social Study of People with Visual Impairment. *Indian Journal of Health & Wellbeing*, *13*(3).
11. Sakaria, R. P., Davidson, J. M., Coleman, N., Wilcox, A., & Talati, A. J. (2022). Improving red reflex screening in a Level III NICU through a quality improvement-based approach. *Hospital Pediatrics, 12*(12), 1093–1100. https://doi.org/10.1542/hpeds.2022-006520
12. Shafer, G., Bhakta, K., Gandhi, B., Patel, D., Casini, G., & Talati, A. J. (2025). Improving completion of the red reflex examination at neonatal intensive care unit discharge: A practice im-

provement initiative. *BMJ Open Quality, 14*(4), e003440. https://doi.org/10.1136/bmjoq-2025-003440

13. Yang, J., Li, Y., Chen, H., & Zhou, Y. (2022). Neonatal retinal hemorrhage: Prevalence, risk factors, and clinical outcomes in a Chinese cohort. *BMC Ophthalmology, 22*(1), 356.
14. Blazon, M. N., Rezar-Dreindl, S., Wassermann, L., Neumayer, T., Berger, A., & Stifter, E. (2024). Retinopathy of prematurity: Incidence, risk factors, and treatment outcomes in a tertiary care center. *Journal of Clinical Medicine, 13*(22), 6926. https://doi.org/10.3390/jcm13226926
15. Ling, X., Chen, Y., Zhang, J., & Wang, H. (2024). Risk factors for retinopathy of prematurity in very low birth weight infants: A multicenter study in China. *Frontiers in Pediatrics, 12*, 1423456.
16. AlShahri, A. H. M., Alkhathami, A. M., AlAnzi, A. J. F., Al Dawsar, F. M., Duheem, A., Alanzi, A. A. M., ... & Alotaibi, R. M. M. (2024). Retinal Hemorrhages: Etiologies, Diagnostic Approaches, and Management Strategies for Ocular and Systemic Disorders. *Integrative Biomedical Research*, *8*(8), 1-8.
17. Oliveira, J. S., Catarino, S., Magalhaes, A., Rocha, G., & Silva, R. S. (2024). The Red Reflex Test and Leukocoria in Childhood. *Acta Médica Portuguesa*, *37*(9), 638-646.
18. Ismail, M. F., Khalafalla, I., Omar Sheck, Z., Farah, F. A., Mohamed, I. A., Qarbote, A. I., … Mumin, B. A. (2025). Prevalence and associated factors of retinopathy of prematurity in sub-Saharan Africa: A systematic review and meta-analysis. *BMC Ophthalmology, 25*(1), 4572. https://doi.org/10.1186/s12886-025-04572-0
19. Ndyabawe, I., Namiiro, F., Muhumuza, A. T., Nakibuka, J., Otiti, J., Ampaire, A., … Nsibirwa, G. S. (2023). Prevalence and pattern of retinopathy of prematurity at two national referral hospitals in Uganda: A cross-sectional study. *BMC Ophthalmology, 23*(1), 3195. https://doi.org/10.1186/s12886-023-03195-7
20. Singh, V. M., Badakere, A., Patil-Chhablani, P., & Kekunnaya, R. (2021). Profile of congenital cataract in the first year of life from a tertiary care center in South India—A modern series. *Indian Journal of Ophthalmology*, *69*(4), 932–936. https://doi.org/10.4103/ijo.IJO_1558_20
21. Martins, T. G. D. S., Andreghetto, L. D. A. F., Brito, R. M., Provenzano, L. B., & Fowler, S. (2022). Evaluation of the prematurity retinopathy and other eye changes in the newborn. *Einstein (Sao Paulo)*, *20*, eAO6692.
22. Baldino, V. M. C. L., Eckert, G. U., Rossatto, J., & Wagner, M. B. (2020). Red reflex test at the maternity hospital: results from a tertiary hospital and variables associated with inconclusive test results. *Jornal de Pediatria*, *96*, 748-754.
23. Chen, L., Feng, Y., & Xu, Z. (2025). Neonatal retinal hemorrhage and retinopathy of prematurity: A critical review of current practices and future directions. *Therapeutic Advances in Ophthalmology, 17*, 25158414251386295. https://doi.org/10.1177/25158414251386295
24. Toli, A., Perente, A., & Labiris, G. (2021). Evaluation of the red reflex: an overview for the pediatrician. *World journal of methodology*, *11*(5), 263.
25. Moges, T., Alemu, H., & Abebe, T. (2023). Retinopathy of prematurity in Ethiopia: Prevalence, risk factors, and outcomes. *BMC Pediatrics, 23*(1), 512.
26. Eldeen, S. M., Ali, S., & Salama, H. (2022). Clinical characteristics, diagnosis, and management outcome of surfactant deficiency respiratory distress syndrome in term and near-term neonates. A retrospective observational study. *Acta Bio Medica: Atenei Parmensis*, *93*(6), e2022337
27. PolicyVault Africa. (2020). *National Eye Health Strategic Plan 2020–2025*. Nairobi: Ministry of Health. https://www.policyvault.africa/wp-content/uploads/policy/KEN823.pdf
28. PATH Early Childhood Development. (2024). *Kenya Newborn and Child Health Strategic Plan 2023–2026*. PATH. https://pathecd.org/wp-content/uploads/2024/06/2-Kenya-Newborn-and-Child-Health-Strategic-Plan-2023-26.pdf
29. Malik, A. N. J., Mnedeme, G. F., Iriya, N., Bahati, P., Marealle, H., Blaikie, A., & Mafwiri, M. (2025). Evaluation of primary healthcare worker training to screen children under 5 years of age with the Arclight ophthalmoscope in Tanzania. *BMJ Paediatrics Open, 9*(1), e003520. https://doi.org/10.1136/bmjpo-2025-003520
30. Nassir, M. (2024). Seeing the signs: Saving children's sight through red reflex screening at Kwale Eye Centre, Kenya. *Arclight Project Blog*. https://arclightprojectshop.co.uk/blogs/news/seeing-the-signs-saving-children-s-sight-through-red-reflex-screening
31. Blaikie, A. (2024). The Arclight and fundal reflex test: Shining the light on retinoblastoma in Africa. *WE C Hope Blog*. https://wechope.org/tag/eye-health-in-africa/

32. Manthorp, C. (2024). Understanding the ROP epidemic in Africa. *Retina Today, October 2024*, 45–48. https://retinatoday.com/articles/2024-oct/understanding-the-rop-epidemic-in-africa

33. Wassermann, L., Rezar-Dreindl, S., Blazon, M. N., Berger, A., & Stifter, E. (2024). Oxygen therapy and risk of retinopathy of prematurity: Evidence from a European NICU cohort. *European Journal of Pediatrics, 183*(7), 2567–2575.

Publisher's Note

All claims, opinions, data, and conclusions expressed in this article are solely those of the author(s) and contributor(s), and do not necessarily represent those of Open Access Pub, the journal, its editors, or reviewers. Open Access Pub does not guarantee or endorse any product, method, instruction, or claim discussed in the article, and disclaims responsibility for any injury to people or property resulting from ideas, methods, instructions, or products referred to in the content.