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Screening for retinopathy of prematurity (ROP) in South Africa: data from a newly established prospective regional register

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ABSTRACT

Objective Retinopathy of prematurity (ROP) registers enable population-based studies to monitor ROP screening programmes to improve their effectiveness. The aim of this study was to determine the frequency of ROP and the coverage of screening in a South African cohort using a prospective ROP South African (ROPSA) register.

Methods and analysis Infants born from 1 May 2022 to 31 January 2023 and screened prospectively for ROP at five neonatal intensive care units in Cape Town were included. The screening criteria were a gestational age (GA) <32 weeks or birth weight (BW) <1250 g. Data were extracted from the ROPSA register and analysed.

Results 696 of 1154 (60.3%) eligible infants were screened, almost half of whom (45.7%) did not complete screening. ROP was detected in 220 infants (31.6%, 95% CI 28.3% to 35.3%), 7 (1.0%) of whom required treatment. Infants with incomplete screening had a lower mean GA than those who completed screening; 28.7 (SD 1.6, range 25–33) and 29.1 (SD 1.7, range 24–36) weeks, respectively (p=0.004) and a lower mean BW; 1048 (SD 203, range 650–1690) g and 1108.5 (SD 227, range 640–1840) g, respectively (p<0.001).

Conclusions Data from the ROPSA register on the frequency of any ROP and treatment-requiring ROP may be biased due to low screening coverage and high incomplete screening. Reasons need to be explored and corrective interventions initiated. The ROPSA register will enable the impact of these interventions to be monitored. The findings of this study will contribute to the ongoing revision of South African national ROP screening guidelines.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Low-income and middle-income countries (LMICs), such as those in Sub-Saharan Africa (SSA), are currently experiencing the third epidemic of blindness due to retinopathy of prematurity (ROP). As ROP screening programmes are established in SSA, more countries in the region are publishing ROP data. However, data on the coverage of ROP screening programmes are often excluded.

WHAT THIS STUDY ADDS

⇒ Our study demonstrates that ROP registers are a useful and valuable tool to determine the effectiveness of ROP screening programmes in LMIC settings. The register in our study was used to determine the frequency of ROP and to identify limitations (ie, low screening uptake and completion rates) in the current screening programme.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Reasons for the poor uptake and low levels of complete screening need to be explored and corrective measures identified, implemented and evaluated. The register will enable the continuous evaluation of the screening process to ensure improvements in coverage and completeness of ROP screening. This study encourages the adoption of ROP registers in other LMIC and SSA countries.

INTRODUCTION

Retinopathy of prematurity (ROP) was recognised as an avoidable cause of blindness in children by the *Lancet Global Health Commission on Global Eye Health*.[1] In 2010, ROP accounted for an estimated 32 300 cases of visual impairment annually in children worldwide,[2] and in 2019, the WHO recommended ROP screening and treatment as evidence-based best practice for neonatal intensive care in their document *Survive and Thrive*.[3]

There is a paucity of data on the frequency of any ROP and treatment-requiring (type 1) ROP from Sub-Saharan African (SSA) countries, despite evidence suggesting that blindness from ROP is increasing in the region.[4] Single-centre hospital-based studies in South Africa (SA) suggest that the frequency of any ROP ranges from 12.1% to 33.4%.[5–9] However, there are no data on the frequency of ROP in a defined African population.[10]

South Africa was the first country in SSA to establish ROP services in the 1980s,[11] and

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the first to publish national ROP screening guidelines in 2012. The screening criteria in these guidelines are a birth weight (BW) of <1500 g, or a gestational age (GA) of <32 completed weeks, or a BW between 1500 and 2000 g with additional risk factors.[12] In 2006, a study undertaken in a tertiary level neonatal intensive care unit (NICU) in SA suggested that using a BW criteria of <1250 g could safely reduce the screening load in this resource-limited setting.[5] Some ophthalmologists screening in tertiary and secondary level NICUs have adopted this recommendation. The BW criteria of <1250 g is in line with some high-income countries (HICs) such as the Netherlands.[13] However, in low-income and middle-income countries (LMICs), the population of preterm infants at risk of ROP is different due to inadequately controlled risk factors.[14] In these settings, more mature, heavier infants are also developing treatment-requiring ROP. The implications are that applying the criteria established in HICs to LMICs is likely to miss infants with treatable disease.[15]

National databases or registers which document ROP are used in several HIC settings,[16 17] and in some middle-income countries, such as Argentina and Chile.[18 19] A register in SA would allow the systematic collection and monitoring of standardised data on ROP in order to improve services.

The ROP South African (ROPSA) register was established in June 2022 in the Cape Town Metropole region, which is one of the better resourced regions in the country, in collaboration with five NICUs in the region. These public facilities provide healthcare to approximately 75% of the regional population (4.7 million).[20 21]

The aim of this study is to report prospective data on any ROP and treatment-requiring ROP, as well as coverage and completeness of screening, using a newly established ROP register involving five public NICUs in the Cape Town Metropole region of SA.

MATERIALS AND METHODS

ROPSA register

The ROPSA register was designed by the corresponding author (TvdL) in conjunction with coauthor (GH), Tahlia Perumal and administrators from Safe Surgery South Africa. It is currently funded by research funds awarded to the corresponding author. The stakeholders, currently led by the corresponding author (TvdL), are responsible for the research output from the register. They have formed the ROPSA Collaborative Group; members are ophthalmologists, neonatologists, paediatricians, data capturers and statisticians who will review whether any changes in the data collected are required for scale-up. Patients or the public were not involved in the design of the register or the conduct of the study.

The register contains data of all preterm infants identified and screened for ROP at least once within the Cape Town Metropole. Three tertiary level and two secondary level hospitals are the only NICUs in the region with ophthalmologists who provide ROP screening for all infants born in the Cape Town Metropole region. The register uses the Health Insurance Portability and Accountability Act and Protection of Personal Information Act compliant REDCap software. This secure web-based platform, developed by Vanderbilt University, is used to store and manage online databases.[22]

Study population

A prospective study was conducted on a cohort of preterm infants born in the Cape Town Metropole region between 1 May 2022 and 31 January 2023. The following criteria for ROP screening were used in each NICU: GA of <32 completed weeks or a BW of <1250 g. Infants with GA ≥32 weeks or BW ≥1250 g were also eligible if they had additional risk factors or an unstable clinical course, as stipulated in the SA guidelines. The additional risk factors include hyperoxia and fluctuating oxygen saturations, blood transfusions, thrombocytopaenia and exchange transfusions.[12] Preterm infants eligible for screening were identified by neonatal staff during the first 1–2 weeks of admission. The majority of infants receive their first screening examination during admission. Infants with a GA below 24 weeks and a BW below 500 g have extremely high mortality rates and are not actively managed and were excluded from the study.[23]

Regional neonatal mortality rates are quantified by BW categories. In 2023, these figures ranged from 46.8% to 76.1% (BW <1000 g) and 3.0% to 7.1% (BW 1000–1499 g) in the three tertiary level hospitals and were 42.1% and 48.3% (BW <1000 g) and 2.1% and 6.1% (BW 1000–1499 g) in the two secondary level hospitals (personal communication ROPSA Collaborative Group members).

Screening procedure

First screening examinations were scheduled at 4–6 weeks postnatal age (PNA) or at 31–33 weeks postmenstrual age (PMA), whichever came later. Pupils were dilated using 2.5% cyclopentolate and 0.5% phenylephrine eye drops applied every 15–20 minutes, 1 hour before examination. Binocular indirect ophthalmoscopy with a 28-dioptre lens was performed in the NICU or adjacent areas. A speculum and indenter were used following topical anaesthesia according to the examiner's preference. All examinations were performed by qualified ophthalmologists or supervised ophthalmology residents on a weekly or biweekly basis. Screening findings for each infant were documented on the ROP screening template. Infants who completed the full screening process (i.e., met the indications for the termination of screening according to the SA guidelines) were described as having completed screening; those who did not complete the whole process were described as having incomplete screening. The indications for termination of screening used were (a) full retinal vascularisation, or (b) zone 3 retinal vascularisation without previous zone 1 or 2 ROP, or (c) attaining a PMA of 45 weeks with no stage 3 ROP in zone 2 or any ROP in zone 1, and (d) complete regression of ROP.[12]

The severity of ROP was classified according to the revised International Classification of ROP.[24] The most

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severe level of ROP in either eye was determined as the ROP status for each infant. Treatment was indicated for type 1 ROP as outlined in the Early treatment of ROP study, that is, ROP in zone 1, any stage with plus disease, or stage 3 without plus disease; or stage 2 or 3 ROP with plus disease in zone 2.[25]

Data management

Anonymised data of infants screened were extracted from medical records by the primary author (TvdL), with the assistance of a trained student with experience in research and data capture, at regular intervals after completion of screening and treatment. After checking the data, they were entered into the online ROPSA register. Validation of the data was supported by the intuitive REDCAP interface and the audit trails of captured data. Reports and statistical analysis assisted in detecting outliers, whose records could be rechecked and confirmed.

To determine the coverage of the ROP screening in the region, data were obtained from the provincial health data centre of the Western Cape Province. This resource, initiated in 2015, collects and stores person-level clinical data for all individuals accessing public health facilities in the study region.[26]

Statistical analysis

All the analyses were performed using SAS V.9.4 statistical software (SAS Institute). The paper presents the analyses of neonatal characteristics, that is, BW (g), GA (w), gender, single/multiple births and the signs of ROP.

Normally distributed data are described using means, SD and ranges, with medians and IQRs for skewed data. Categorical data are described using numbers and percentages. χ^2 tests (type 3 analysis) were used for overall comparisons among NICUs with respect to the various factors of interest, and z tests were used for comparisons of differences between NICUs. T-tests, using the Satterthwaite method when required, were used to compare the GA and BW of infants who did and who did not complete screening. Due to the small number of treated infants, the Kruskal-Wallis non-parametric test was used to compare treated and untreated infants. All tests used a significance level of 5%.

RESULTS

Study population

Between 1 May 2022 and 31 January 2023, 1879 infants were born in the region who fulfilled the GA or BW criteria for screening, that is, GA<32 completed weeks, or BW<1250 g. After the exclusion of outliers, 1154 infants who survived to at least 6 weeks PNA or 33 weeks PMA (i.e., the time for the first screening examination) were eligible for screening. Altogether 696 of these infants were screened for ROP; 85.2% (593/696) were screened in the three tertiary hospitals and 14.8% (103/696) in the secondary hospitals. Five additional infants were screened who fell outside the BW and GA criteria as they had additional risk factors (figure 1). None developed ROP, and they were excluded from the analysis to better understand the cohort meeting the BW and GA criteria.

Screening coverage and completeness of screening

The screening coverage of eligible infants who fulfilled the BW or GA criteria was 60.3% (696/1154 infants), 318 (45.7%) of whom did not complete screening

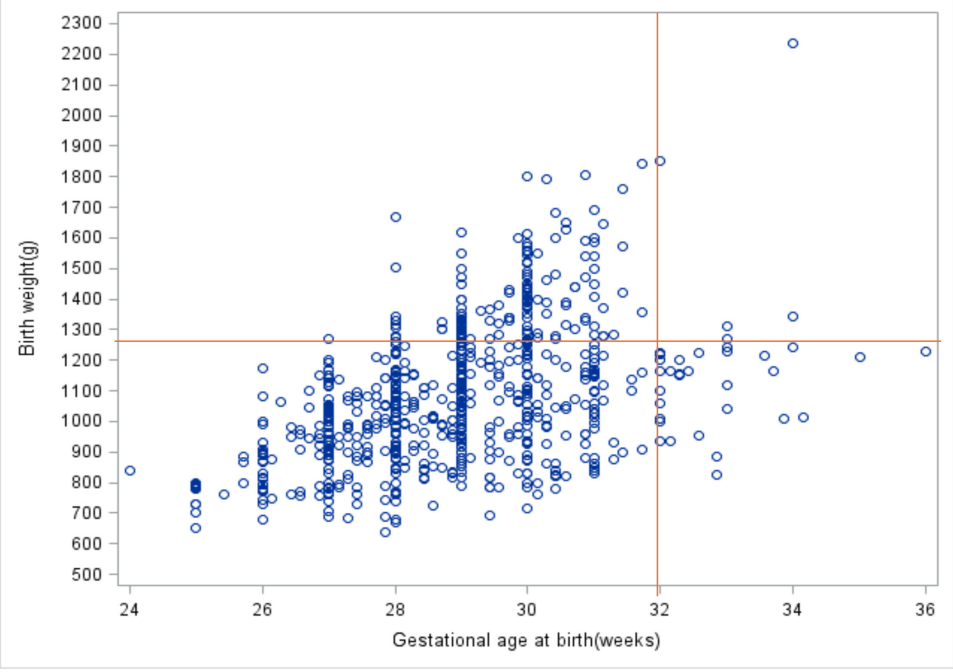

Figure 1 Infants screened in five neonatal units in the region, by birth weight (BW) (grams) and gestational age (GA) (weeks) (n=701). Horizontal and vertical lines show the BW and GA screening criteria, respectively.

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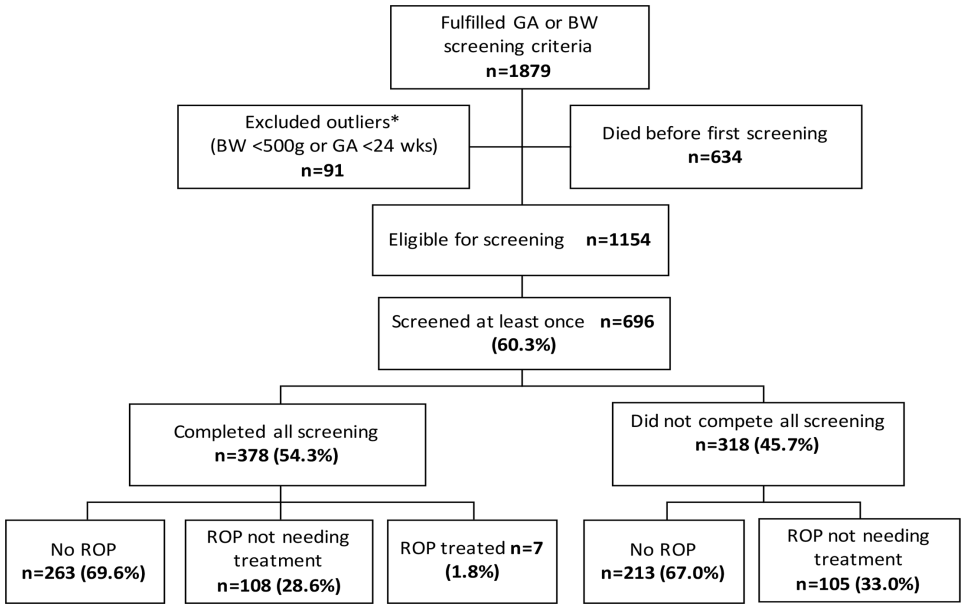

Figure 2 Flow chart of infants eligible for screening in the region and the outcome of screening. *Outliers excluded based on high mortality rates of these infants in the Cape Town Metropole region.[23] BW, birth weight; GA, gestational age; ROP, retinopathy of prematurity.

(figure 2). The proportion of infants who completed screening varied between the three tertiary level hospitals (ie, 85.6%, 72.8% and 35.6%) but were similar in the secondary hospitals (57.9% and 50.0%).

Characteristics of infants screened

There was no sex difference in the 696 infants screened (341/696, 49% male) and 80% were singleton births. Their mean GA was 28.9 (SD 1.7, range 24–36) weeks, and the mean BW was 1080.9 (SD 218.4, range 640–1840) grams. Infants screened were significantly more preterm in the tertiary hospitals than in the secondary units, having lower GAs (p=0.019) and BWs (p<0.001).

The infants underwent a total of 1821 screening examinations (mean 3.0, SD 1.6, range 1–13 per child). Infants with incomplete screening had fewer examinations than those who completed screening: mean 2.1 (SD 1.5, range

Table 1 Gestational age (GA) and birth weight (BW) of infants who completed screening and those with incomplete screening

	Completed screening		Incomplete screening		
	N	%	N	%	
	378	54.3	318	45.7	P value
GA (weeks)					
Mean (SD, range)	29.1 (1.7, 24–36)		28.7 (1.6, 25–33)		0.004
GA subgroups					
24–25	9	53	8	47	
26–27	74	45	90	55	
28–29	161	55.5	129	44.6	
30–31	114	58.8	80	41.2	
≥32 weeks	20	65	11	35	0.071
BW (grams)					
Mean (SD, range)	1108.5 (227, 640–1840)		1048 (203, 650–1690)		<0.001
BW subgroups					
<1000 g	130	47.4	144	52.6	
1000–1249 g	157	57.3	117	42.7	
≥1250–1500 g	91	62	57	38	0.010

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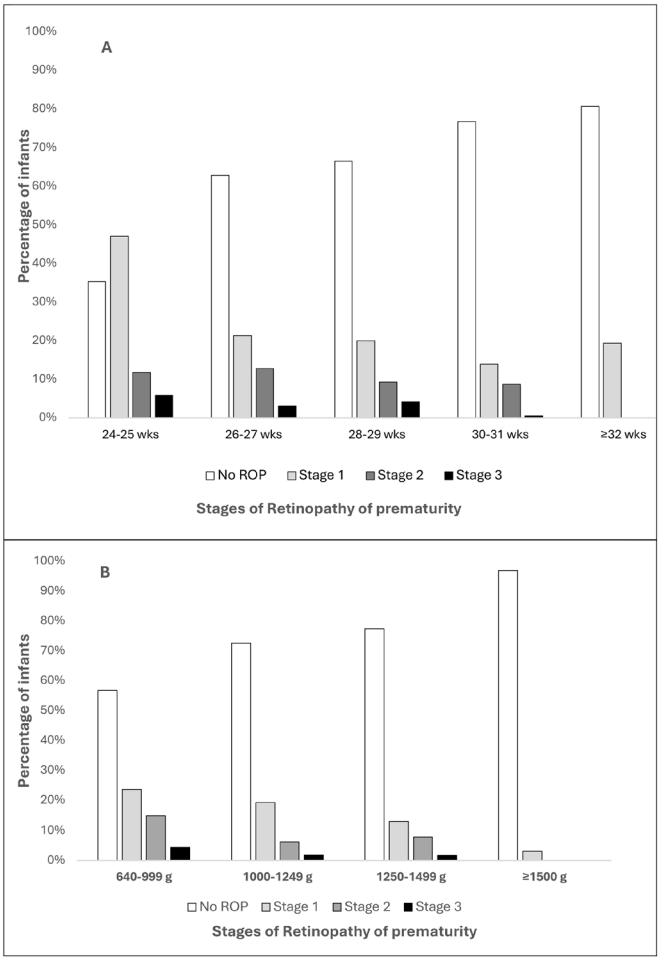

Figure 3 Maximum stage of ROP in infants screened for ROP (n=696), by gestational age (A) and birth weight (B). ROP, retinopathy of prematurity.

1–13) vs mean 3.0 (SD 1.6, range 1–13), respectively, p<0.001. The last examination occurred at a higher mean PMA in infants who completed screening than in those with incomplete screening: 41.7 (SD 6.0, range 33.1–92.4) and 37.0 (SD 4.6, range 30.0–59.8) weeks, respectively (p<0.001), and at a higher mean PNA: 12.6 (SD 6.2, range 4.4–64.6) and 8.3 (SD 4.7, range 2.4–29.6) weeks, respectively (p<0.001). Among those with incomplete screening, 45.9% had only one examination, 26.1% had two examinations and 28.0% had three or more examinations compared with 10.3%, 35.7% and 54.0%, respectively, for those who completed screening (online supplemental sFigure 1).

Infants who completed screening had significantly higher BWs and GAs than infants who did not (table 1). Most infants with incomplete screening failed to attend follow-up appointments (290, 91.2%), they had died (8, 2.5%) or were referred outside the region (8, 2.5%). In 12 (3.8%) infants, the reason for incomplete screening was not specified.

ROP data

Among the 696 infants, 220 (31.6%, 95% CI 28.3% to 35.3%) developed any ROP. Mild ROP (stages 1–2) was noted in 201 (28.8%) infants and stage 3 in 19 (2.8%) infants (figure 3A,B). No infants developed stage 4, 5 ROP or aggressive ROP. The prevalence of ROP varied greatly among hospitals from 18% to 48.7% (p<0.001). However, the prevalence of ROP was similar in the complete and incomplete screening group: 30.4% vs 33.0%, respectively, p=0.46.

Infants with any ROP had a mean GA of 28.5 (SD 1.7, range 24–33) weeks compared with 29.1 (SD 1.7, range 25–36) weeks in those without ROP (p<0.001). Those with any ROP had a mean BW of 1003 (SD 171.5, range 670–1570) g compared with 1117 (SD 228.4, range 640–1840) g in those without (p<0.001). There were no sex differences in infants with and without ROP (51.4% males with any ROP compared with 47.9% without ROP, p=0.395) (table 2).

Seven infants (1%) developed type 1 ROP, all of whom were treated. All treated infants fell within the screening criteria used in the region. Six were treated with anti-VEGF injections (Avastin) in both eyes while one infant received anti-VEGF in one eye and laser treatment in the other eye. The mean GA of treated infants was significantly lower than all other screened infants: 27.4 (SD 1.4, range 25.7–29) weeks and 29 (SD 1.7, range 24–36) weeks, respectively (p=0.024). The mean BW was also significantly lower: 910 (SD 116.9, range 725–1065) g and 1082.7 (SD 218.6, range 640–1840) g, respectively (p=0.024).

DISCUSSION

To our knowledge, no other SSA studies have reported regional or national population data on the proportion of preterm infants who need to be screened for ROP, and only a few international studies report the proportion of eligible surviving infants who are screened.[13 17 27] In this study, almost one-third of eligible preterm infants died before screening was initiated, and 60% of survivors were screened at least once, but almost half did not complete screening. Reasons why infants were not screened at all or did not complete screening will need to be explored, and interventions to address the barriers developed, pilot-tested and evaluated. In three studies in India, where only 79%, 39% and 36% of eligible infants were screened, a range of interventions, often in combination, such as initiating screening prior to discharge, counselling and educating caregivers, travel reimbursements, a helpline and project manager, increased the proportions of screened infants to 96%, 88% and 95%, respectively.[28–30]

In our study, nearly one-third of the infants screened developed any ROP, and only 1% required treatment. All the infants requiring treatment fell within the regional screening criteria (GA of <32 completed weeks or a BW of <1250 g). Comparing our findings with other studies is challenging,[31] as most have been retrospective reviews

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Table 2 Characteristics of infants with and without retinopathy of prematurity (ROP) (n=696)

	All infants	No ROP		Any ROP		
	N	N	%	N	%	
Total	696	476	68.4%	220	31.6%	P value*
Sex						
Male	341	228	47.9	113	51.4	0.395
Female	355	248	52.1	107	48.6	
Singleton/multiple birth (nine missing infants)						
Singleton	548	376	80	172	80	0.918
Multiple	139	96	20	43	20	
Gestational age (GA) (weeks)						
Mean (SD, range)	28.9 (1.7, 24–36)	29.1 (1.7, 25–36)		28.5 (1.66, 24–33)		<0.001
GA subgroups						
24–25	17	6	35	11	65	
26–27	164	103	62.8	61	37.2	
28–29	290	193	66.6	97	33.4	
30–31	194	149	76.8	45	23.2	
≥32 weeks	31	25	81	6	19	0.335
Birth weight (BW) (grams)						
Mean (SD, range)	1081 (218, 640–1840)	1117 (228.4, 640–1840)		1003 (171.5, 670–1570)		<0.001
BW subgroups						
<1000 g	274	156	57	118	43	
1000–1249 g	274	199	73	75	27	
1250–1500 g	148	121	82	27	18	0.174

*Comparison between no ROP and any ROP group.

with differences that impact on the frequency of ROP, such as variable study designs, sample sizes, screening criteria, survival rates, and the characteristics of the infants screened. The available data from the Cape Town Metropole[6 7] show similar proportions of infants with any ROP and treatment requiring ROP (online supplemental sTable 1). This most likely reflects the similar level of neonatal care in public sector NICUs in the region over the past few decades.

The prevalence of any ROP is lower in hospitals in other regions of SA, which may, in part, be explained by the consistent use of wider screening criteria (BW<1500 g) which would include a larger number of infants at lower risk of ROP.

Variation in the quality of neonatal care, and hence the survival of preterm infants most at risk of ROP, also influences the prevalence of ROP. For example, in a study of seven NICUs in Rio de Janeiro, Brazil, NICUs with higher survival rates (i.e., ≥80%) had a lower prevalence of type 1 ROP and smaller preterm infants were affected compared with NICUs with survival rates <80%.[32] In the Cape Town Metropole, the survival of infants with a BW <1500 g is estimated to be 70.4%, compared with 66.5% in other regions in the country.[33 34]

The proportion of infants developing type 1 ROP is influenced by a complex interaction of several factors including the quality of neonatal care to control modifiable risk factors, the case mix of infants admitted who survive and the screening criteria used.[11 32] Type 1 ROP in our study was lower than in HICs using similar criteria: Netherlands (2.6% in infants GA <32 weeks or BW <1250 g) and the UK (4% in infants GA <32 weeks and BW ≤1500 g).[13 35] In our study, a key contributor to the low proportion of type 1 ROP is that infants with GA <24 weeks or BW <500 g are not actively managed and have high mortality rates. This was reflected in our cohort as no infant with a GA <24 weeks or BW <500 g was screened for ROP. In contrast, nano-premature infants (BW <600 g or GA <24 weeks) who are now surviving in HICs are at very high risk of type 1 ROP.[36] In addition, loss to follow-up may have underestimated the proportion of infants with any ROP and with type 1 ROP, particularly as those who did not complete screening were more immature than those who completed screening.

As in other studies,[13 35 37] the risk and severity of ROP were inversely related to GA and BW, and all infants treated had BWs of <1250 g and GAs of <30 weeks. Reassuringly, none of the five infants screened who fell outside the BW and GA screening criteria had any ROP. A limitation of this study was that it was not possible to assess the risk of type 1 ROP in the cohort of infants with BWs in the range ≥1250 g but <1500 g. Widening the screening criteria for

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this purpose would have added a considerable burden to the healthcare service. In recent regional studies, all infants requiring treatment had a BW <1250 g.[6 7] Further studies are required to determine whether a screening cut-off of <1250 g is safe in all NICUs in SA.

Although laser treatment is still considered the gold standard treatment for type 1 ROP, all infants in our study were treated with intravitreal anti-VEGF agents, apart from one eye which was treated with laser. This is most likely due to the easier and more cost-effective administration of anti-VEGF agents compared with laser.[38]

The prospective, population-based nature of this study is a strength, made possible by the use of a register prospectively collecting data on ROP screening and treatment in the region. Sustained regional or national ROP registers are uncommon in middle-income countries. Notably, Argentina and Chile have established registers which have benefitted from the support and engagement of their Ministries of Health.[18 19] The ROPSA register was established to assess its feasibility and usefulness in an African resource-constrained setting. A current limitation is that data are being entered by one of the authors, which is not sustainable or scalable. Data from this register will be used to advocate for more resources, including trained personnel, and more rigorous quality control and validation methods. We envision that this is the beginning of a sustainable national ROP register in SA and a model for the African context. Considering the resources required for ROP screening and the implications of blindness due to ROP, it is important to track changes in the frequency of treatment requiring ROP and the characteristics of affected infants over time, which is possible with a register. Indeed, the Swedish ROP register (SWEDROP) has demonstrated the clinical impact of a national register, as SWEDROP data have enabled lowering the GA screening criteria from <32 weeks to <30 weeks. This has safely reduced the number of unnecessary screening examinations and the cost of ophthalmic care.[17 37]

In conclusion, this study of ROP and the screening process has demonstrated that a register for ROP is feasible in this setting, and the findings will be used to advocate that the register is scaled up nationally with ongoing monitoring to identify trends. Further studies are required to identify barriers to screening and to evaluate interventions, to update screening criteria and increase the completeness of screening so that no child with treatable disease is missed.

Data from this newly established ROPSA register have provided useful regional data on the frequency of ROP, as well as screening coverage and the completeness of screening. The findings will be used to advocate with the Ministry of Health and donors for resources to maintain the register in Cape Town and to scale it up to other regions in the country. It has also provided the only population-based ROP screening data in SA and will contribute to the ongoing revision of the South African national ROP screening guidelines.

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