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Swedish National Register for Retinopathy of Prematurity (SWEDROP) and the Evaluation of Screening in Sweden

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Objectives: To evaluate screening for retinopathy of prematurity (ROP) in Sweden and to investigate possible modifications of the present screening guidelines.

Methods: Infants in Sweden with a gestational age (GA) of 31 weeks + 6 days or less are screened for ROP. Data from the Swedish national register for ROP (SWEDROP) during 2008 and 2009 were extracted and compared with a national perinatal quality register.

Results: In SWEDROP, there were 1791 infants born before a GA of 32 weeks from January 1, 2008, through December 31, 2009. Another 70 infants were registered in the perinatal quality register but not in SWEDROP (dropout rate, 3.8% [70 of 1861 infants]). Seven infants died before termination of screening. In the final study cohort (1784 infants), 15.6% had mild ROP and 8.5% had severe ROP. Treatment was performed in 4.4% of the infants, none of whom had a GA at birth of more than 28 weeks. Nine infants with a GA of more than 28 weeks at birth developed stage 3 ROP, which regressed spontaneously. The total number of examinations was 9286 (964 in infants with a GA of 31 weeks), and the mean (range) number of examinations of each infant was 5.2 (1-30).

Conclusions: The SWEDROP, a quality register for ROP, has a national coverage (ie, participation) of 96%. Data from 2008 to 2009 show that it seems possible to reduce the upper limit for screening in Sweden by 1 week, including only infants with a GA of 30 weeks + 6 days or less. However, such a change should be combined with a strong recommendation to neonatologists to refer also severely ill and more "mature" infants.

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SCREENING FOR RETINOPATHY of prematurity (ROP) has been in use since the 1980s and fulfills criteria for screening described by the World Health Organization.[1] However, screening examinations are resource intensive, require specially trained ophthalmologists, and are stressful for the infants. Avoidance of unnecessary examinations is therefore important.

Screening guidelines should be adapted to the country in which the infant was born and continuously be revised and improved.[2] Furthermore, national guidelines should be based on prospective epidemiologic studies. In Sweden, the first recommendations for screening were based on a population-based study in the Stockholm area and included infants with a gestational age (GA) at birth of less than 33 weeks (≤32 weeks + 6 days).[3] One decade later, a new population-based study in the same geographical area suggested a reduction of the upper screening limit to less than 32 weeks (≤31 weeks + 6 days).[4] Recently, a national study including all infants with a GA of less than 27 weeks, born in Sweden from April 1, 2004, through March 31, 2007, resulted in recommendations to postpone the start of eye screening of these infants to a postmenstrual age (PMA) of 31 weeks, as opposed to a postnatal age (PNA) of 5 weeks in more "mature" infants.[5]

The web-based Swedish national register for ROP (SWEDROP) was initiated in 2006 (http://www.medscinet.com/rop/default.aspx). The aims of the present study were to evaluate various aspects of screening for ROP in Sweden with the help of SWEDROP and to investigate possible modifications of the present screening guidelines.

METHODS

Infants with a GA of less than 32 weeks in Sweden are screened for ROP. Examinations start at 5 weeks PNA and continue at intervals of 1 to 2 weeks until the retina is fully vascular-

Table 1. Stage of ROP and Treatment in Relation to GA at Birth in the Total Study Cohort of 1784 Infants

Variable	Weeks, No. (%) of Infants										
	22 (n = 11)	23 (n = 45)	24 (n = 72)	25 (n = 111)	26 (n = 144)	27 (n = 194)	28 (n = 210)	29 (n = 263)	30 (n = 335)	31 (n = 399)	Total (N = 1784)
No ROP	0	5 (11.1)	21 (29.2)	26 (23.4)	73 (50.7)	122 (62.9)	164 (78.1)	238 (90.5)	314 (93.7)	391 (98.0)	1354 (75.9)
Stage 1	0	1 (2.2)	6 (8.3)	19 (17.1)	21 (14.6)	31 (16.0)	16 (7.6)	9 (3.4)	11 (3.3)	5 (1.3)	119 (6.7)
Stage 2	2 (18.2)	9 (20.0)	22 (30.6)	32 (28.8)	28 (19.4)	28 (14.4)	18 (8.6)	13 (4.9)	5 (1.5)	2 (0.5)	159 (8.9)
Stage 3	8 (72.7)	29 (64.4)	21 (29.2)	33 (29.7)	22 (15.3)	12 (6.2)	12 (5.7)	3 (1.1)	5 (1.5)	1 (0.3)	146 (8.2)
Stage 4	1 (9.1)	1 (2.2)	1 (1.4)	0	0	1 (0.5)	0	0	0	0	4 (0.2)
Stage 5	0	0	1 (1.4)	1 (0.9)	0	0	0	0	0	0	2 (0.1)
Treatment	8 (72.7)	23 (51.1)	11 (15.3)	19 (17.1)	9 (6.3)	4 (2.1)	4 (1.9)	0	0	0	78 (4.4)

Abbreviations: GA, gestational age; ROP, retinopathy of prematurity.

ized or until ROP has regressed. According to Early Treatment for Retinopathy of Prematurity recommendations, eye examinations are performed twice weekly in case of type 2 ROP and treatment is performed in case of type 1 ROP.[6] A protocol is filled in at every examination and follows the infant, even when transferred to other departments. The results of the screening are registered in SWEDROP when the last examination is performed. Neither infants who are born abroad and transferred to a Swedish neonatal intensive care unit nor infants who are born in Sweden and transferred abroad during the neonatal period are registered in SWEDROP.

The SWEDROP is associated with a perinatal quality register. In the present study, data on infants registered in SWEDROP and born from January 1, 2008, through December 31, 2009, were compared with data on infants registered in the perinatal quality register during the same period. Criterion for inclusion in the study was survival until termination of ROP screening. Information on ethnicity is not available in SWEDROP, but epidemiologic statistics (Swedish Medical Birth Registry 2004-2010; K. Källen, PhD, written communication, May 2012) reveal that 18.7% of infants in Sweden are born to non-Nordic mothers (Europe/United States, 5.6%; Africa/Asia, 11.8%; and South America, 1.3%).

During the study period, neonatologists referred some infants for ROP screening with a GA of greater than 31 weeks (>31 weeks and 6 days). These infants were also registered in SWEDROP and will be described separately in this article.

To analyze the relationship between GA and severity of ROP, analysis of variance was performed. The independence test of contingency tables (χ^2 test) was used to analyze differences in the incidence of ROP and the frequency of treatment between boys and girls. The Pearson test for bivariate correlations was used to analyze the relationship between PMA and PNA at the earliest detection of any ROP, stage 3 ROP, and first treatment in relation to GA at birth, and to analyze the relationship between GA and number of examinations.

The study was approved by the ethics committee of the Faculty of Medicine, Uppsala University.

RESULTS

STUDY COHORT

During 2008 and 2009, there were 218 003 children born in Sweden (Statistics Sweden). In SWEDROP, 1791 infants with a GA of less than 32 weeks were born during that study period. Seven of these infants died before termination of ROP screening, giving a final study cohort of 1784 infants.

Another 70 infants with a GA of less than 32 weeks were registered in the perinatal quality register but neither screened for ROP nor registered in SWEDROP, giving a dropout rate of 3.8% (70 of 1861 infants). Fifty-seven of these infants had a GA of 31 weeks, 8 of 30 weeks, 3 of 29 weeks, and 2 of 28 weeks.

The mean (range) GA at birth of the study cohort was 28.4 (22-31) weeks, and the mean (range) birth weight was 1242 (307-2380) g. Of the 1784 infants, 997 (55.9%) were boys and 787 (44.1%) were girls, giving a male-to-female ratio of 1.27.

RETINOPATHY OF PREMATURITY

Some stage of ROP was found in 430 (24.1%) of the 1784 infants (**Table 1**); 15.6% had mild ROP (stages 1-2) and 8.5% had severe ROP (stages 3-5). Type 1 ROP was found in 64 infants (3.6%), and aggressive posterior ROP was seen in 5 infants.

Treatment for ROP was performed in 78 infants (4.4%) (Table 1); of these, 28 (35.9%) received more than 1 treatment. Information on plus disease was available in 76 of the 78 treated infants. Of these 76 infants, type 1 ROP was found in at least 1 eye in 64 infants (84.2%). Stage 3 ROP with plus disease was noted in all but 1 who had stage 2 ROP and plus disease. Type 2 ROP was found in 12 of the 76 treated infants (15.8%), all of whom had stage 3 ROP but no plus disease.

The mean GA at birth was significantly related to the severity of ROP (analysis of variance; $P < .001$). The mean (range) GA at birth of infants with no ROP was 29.2 (23-31) weeks, with mild ROP was 26.5 (22-31) weeks, with severe ROP was 25.1 (22-31) weeks, and with treated ROP was 24.3 (22-28) weeks. The number of infants with no ROP, mild ROP, severe ROP, and treated ROP in relation to GA at birth is illustrated in **Figure 1** and **Figure 2**. Details of the 9 infants (patients 1-9) with stage 3 ROP and GA greater than 29 weeks + 0 days are described in **Table 2**. None of them had plus disease. Details of the 6 infants with stages 4 and 5 ROP are given in **Table 3**.

No significant differences were found between boys and girls regarding incidence or severity of ROP. Nearly 24% (23.6%) of the boys had some stage of ROP compared with 24.8% of the girls. Severe ROP was seen in 8.2% of the boys and in 8.8% of the girls, and treatment was performed in 4.8% and 3.8%, respectively.

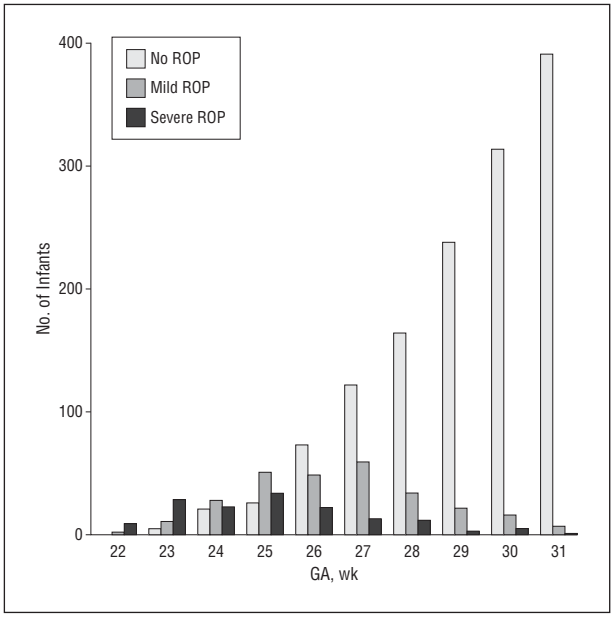

Figure 1. Number of infants with no, mild, and severe retinopathy of prematurity (ROP) in the total study cohort (1784 infants) in relation to gestational age (GA) at birth.

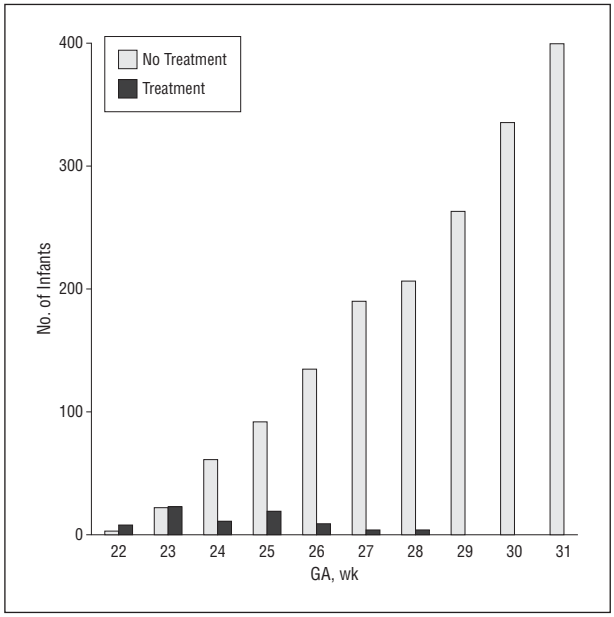

Figure 2. Number of infants with and without treatment for retinopathy of prematurity in the total study cohort (1784 infants) in relation to gestational age (GA) at birth.

AGE AT DETECTION OF ANY ROP, STAGE 3 ROP, AND FIRST TREATMENT

In 75 (17.4%) of the 430 infants with any ROP, there was already some stage of ROP at the first eye examination. The mean, median, and range of PNA and PMA at detection of any ROP in the remaining 355 infants are presented in **Table 4**.

Data on detection of stage 3 ROP were available in 132 of the 151 infants with stage 3 ROP or more. Three of these infants had stage 3 ROP at the first examination. Postnatal age and PMA at detection of stage 3 ROP in the remaining 129 infants are reported in Table 4. For information on age at first treatment in the 78 treated infants, see also Table 4.

Age at detection of ROP and stage 3 ROP and at first treatment (PNA and PMA) in relation to GA at birth is presented in **Table 5**. There were significant ($P = .01$) positive correlations between GA and PMA regarding detection of any ROP ($r = 0.573$), stage 3 ROP ($r = 0.438$), and age at first treatment ($r = 0.479$) (Pearson product moment correlation). Concerning GA and PNA, there were negative correlations regarding detection of any ROP ($r = –0.333$) ($P = .01$) and stage 3 ROP ($r = –0.318$) ($P = .01$), but there was no significant correlation with age at first treatment ($r = –0.130$).

EXAMINATIONS FOR ROP

The mean (range) age at the first eye examination of the 1784 infants in the study population was 5.3 (0-16.7) weeks. A total of 1413 infants (79.2%) had the first examination before the sixth postnatal week, 1653 (92.7%) before the seventh postnatal week, and 1715 (96.1%) before the eighth postnatal week.

The total number of performed examinations of all infants in the study cohort was 9286, and the mean (range) number of examinations per infant was 5.2 (1-30). The mean (range) number of examinations per infant in the 1354 infants without ROP was 3.5 (1-13), in the 279 with mild ROP was 8.4 (2-21), and in the 151 with severe ROP was 15 (4-30). There was a significant correlation between low GA at birth and higher number of examinations ($r = –0.696$; Pearson product moment correlation). The mean number of examinations in infants with various GAs at birth is illustrated in **Figure 3**, and the total number of performed examinations for all infants in each week of gestation is shown in **Figure 4**.

INFANTS WITH A GA AT BIRTH OF MORE THAN 31 WEEKS

There were 59 infants registered in SWEDROP with a GA at birth of more than 31 weeks. Four of 44 infants with a GA of 32 weeks at birth had ROP, of whom 2 had stage 3 ROP without need of treatment. Details of the 2 infants (patients 10 and 11) with stage 3 ROP are illustrated in Table 2. None of the remaining 15 infants (8 with a GA of 33 weeks, 4 with a GA of 34 weeks, 1 with a GA of 35 weeks, and 2 with a GA of 36 weeks) developed ROP.

COMMENT

The present evaluation of the SWEDROP register shows a high national coverage (96%), and there seems to be a high quality of ROP screening in Sweden, expressed as initiation and frequency of eye examinations. During the study period (2008-2009), 8.5% of the infants born with a GA of less than 32 weeks developed severe ROP, that is, stage 3 ROP or higher, and 4.4% were treated. None of the treated infants had a GA at birth of more than 28 weeks. Only 9 infants older than that age developed stage 3 ROP, which regressed spontaneously.

Table 2. Description of Infants With Stage 3 ROP and GAs of More Than 29 Weeks + 0 Days at Birth

Patient Identifier	GA, wk	BW, g	Sex	Right Eye		Left Eye	
				ROP Stage	ROP Zone	ROP Stage	ROP Zone
1	29 + 1	NA	F	3	III	2	III
2	29 + 2	950	F	3	II	3	II
3	29 + 3	1315	M	3	III	2	III
4	30 + 5	1610	M	3	II	2	II
5	30 + 1	888	F	3	III	2	III
6	30 + 2	1035	M	No ROP	. . .	3	II
7	30 + 5	1325	F	3	II	2	III
8	30 + 6	1285	M	3	III	No ROP	. . .
9	31 + 1	954	F	3	III	2	III
10	32 + 1	1224	M	1	II	3	II
11	32 + 1	2695	M	3	II	3	II

Abbreviations: BW, birth weight; GA, gestational age; NA, not available; ROP, retinopathy of prematurity.

Table 3. Description of the 6 Infants With Stages 4 and 5 ROP in Either Eye[a]

Patient Identifier	GA, wk	BW, g	Sex	Max ROP, R/L	Zone, R/L	No. of Exams	PNA, wk, at First Exam	ROP at First Exam	PNA/PMA, wk, at First TX	TX (and No. of Laser Spots) (First TX Marked)	
										R	L
1	24 + 2	756	M	3/5	III /I	26	6.5	No	14/38 + 2	**1007** + 959 + 984 = 2950	**874** + 1589 + NA = NA
2	23 + 3	565	F	4A/3	II/II	26	5	No	12/34 + 3	**3480**	**2118**
3	27 + 1	1039	F	4A/4A	II/II	21	5.5	No	15/52 + 1	**930** + 759 = 1689	**773** + 778 = 1551
4	25 + 4	830	M	3/5	II/I	15	6	No	11 + 5 /37 + 2	**186** + 573 = 759	**841**
5	24 + 0	670	M	4A/4B	I/I	19	6.5	No	12/36	**1339** + 200 + vitrectomy	**1429** + 172 + vitrectomy
6	22 + 5	533	F	4A/4A	II/II	14	8	Yes	10.5/33	**1604** + vitrectomy + lensectomy	**1498** + vitrectomy

Abbreviations: BW, birth weight; exam, examination; GA, gestational age; L, left; max, maximum; NA, not available; R, right; ROP, retinopathy of prematurity; TX, treatment.
[a] All these infants had plus disease. Boldface type indicates number of laser spots performed at the first treatment.

Continuous improvements in neonatal care have led to increased survival rates of prematurely born infants and a new population of extremely preterm infants (Extremely Preterm Infants in Sweden Study).[7] Therefore, screening guidelines for ROP must continually be revised and improved, preferably with the help of population-based studies.[2] This was the main reason that a Swedish register for ROP—SWEDROP—was initiated in 2006. The importance of a high national coverage of a register cannot be overestimated before the conclusions and modifications of a screening program are considered. It was therefore reassuring but not altogether satisfactory that the dropout frequency in the register during the study period was 3.8%. Furthermore, a high quality of screening must be ascertained before changes in the program are initiated. The quality of the screening during the study period, evaluated as the timing of the first examination and the frequency of examinations, showed good adherence to national guidelines. Seventy-nine percent of the infants had the first eye examination before their sixth postnatal week and 93% before their eighth postnatal week.

National screening guidelines are usually based on GA at birth and/or birth weight.[8,9] Repeated population-based Swedish studies have revealed GA at birth, as opposed to birth weight, to be the most important risk factor for ROP in our population,[3-5,10] and it has therefore been the main criterion for ROP screening in our country. This is also confirmed in the present national cohort of 2008 and 2009. The GA criterion, however, requires adequate pregnancy dating, and 97% of pregnancies in Sweden are in fact dated by ultrasound.[7] In the present study, the most immature infants had the highest incidence of ROP, stage 3 ROP, and treatment-requiring ROP. No infant with a GA greater than 28 weeks (28 weeks + 6 days) was treated, and only 9 of 1784 infants with a GA at birth of 29 to 31 weeks developed stage 3 ROP. All but 1 of the latter infants had stage 3 ROP in only 1 eye. None of them developed plus disease or were treated. For the time being, risk factors for ROP other than GA and birth weight are not registered in SWEDROP, and therefore

Table 4. PNA and PMA at Detection of ROP, Stage 3 ROP, and First Treatment in the Study Population

Variable	Weeks			
	PNA		PMA	
	Mean	Median (Range)	Mean	Median (Range)
Any ROP (n = 355)	8.6	8.3 (5.4-17.1)	34.5	34.1 (29.1-45.3)
Stage 3 ROP (n = 129)	11.4	11.1 (5.7-19.9)	36.6	36.1 (31.4-45.9)
First treatment (n = 78)	12.6	12.4 (7.3-20.6)	37.0	36.4 (32.3-46.6)

Abbreviations: PMA, postmenstrual age; PNA, postnatal age; ROP, retinopathy of prematurity.

Table 5. PNA and PMA at Earliest Detection of ROP and Stage 3 ROP and at First Treatment, in Relation to GA at Birth

	Weeks					
	Earliest ROP (n = 355)		Earliest Stage 3 ROP (n = 129)		First TX (n = 78)	
GA, wk	PNA	PMA	PNA	PMA	PNA	PMA
22	7.7	29.7	9.4	31.4	10.4	32.4
23	6.1	29.1	9.6	32.6	10.9	33.9
24	6.7	30.7	8.0	32.0	11.4	35.4
25	6.3	31.3	7.0	32.0	7.3	32.3
26	5.9	31.9	8.1	34.1	8.7	34.7
27	5.6	32.6	5.7	32.7	10.9	37.9
28	5.6	33.6	7.1	35.1	8.7	36.7
29	5.6	34.6	6.9	35.9		
30	5.4	35.4	6.4	36.4		
31	5.6	36.6	8.6	39.6		

Abbreviations: GA, gestational age; PMA, postmenstrual age; PNA, postnatal age; ROP, retinopathy of prematurity; TX, treatment.

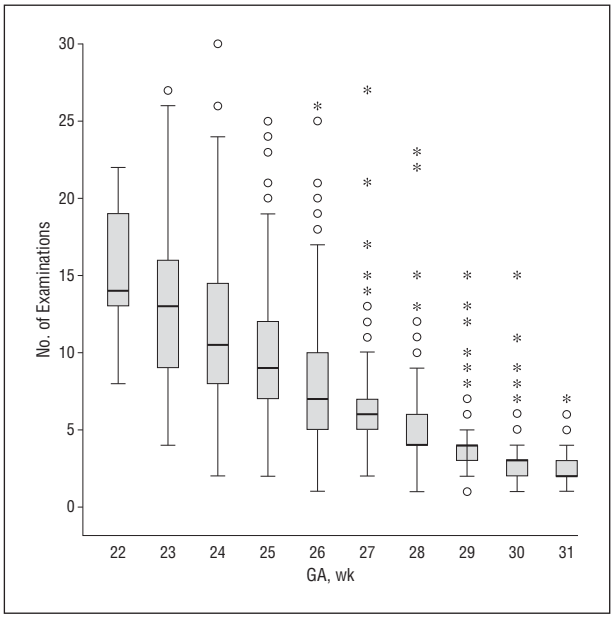

Figure 3. Number of examinations in relation to gestational age (GA) at birth (weeks) in the total study population of 1784 infants. The horizontal line in each box indicates the median, while the top and bottom borders of the box mark the 25th and 75th percentiles, respectively. Circles indicate outliers (1½ box lengths) and stars indicate extreme outliers (3 box lengths).

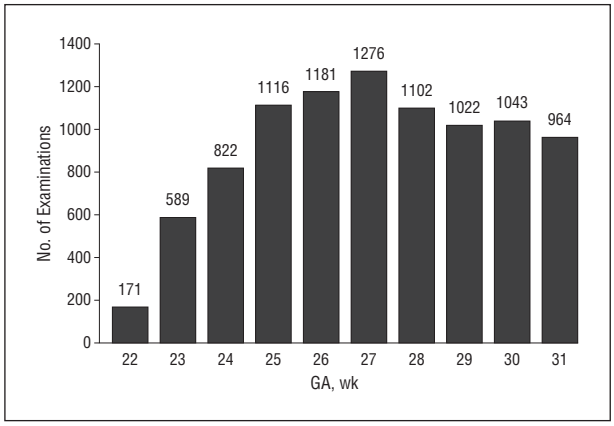

Figure 4. Total number of examinations of the 1784 infants in the total study cohort in relation to gestational age (GA) at birth.

their importance for prediction of ROP and inclusion in national guidelines cannot be evaluated.

On the basis of analysis of SWEDROP data from 2008 and 2009, it seems reasonable to reduce the limit of screening by 1 week, including only infants with a GA at birth of less than 31 weeks (31 weeks + 0 days), as a first step. British, American, and Canadian screening guidelines also seem to regard it less likely that infants with a GA at birth of 31 weeks (31 weeks + 0 days to 31 weeks + 6 days) need to be included in screening programs.[8,9,11] British guidelines state that all infants with a GA of less than 31 weeks (up to 30 weeks + 6 days) "must" be screened, while all infants with a GA of less than 32 weeks (up to 31 weeks + 6 days) "should" be screened for ROP.[9] American guidelines recommend examinations of infants with a GA of 30 weeks or less, but they add "if necessary" regarding those with a GA of 31 and 32 weeks at birth.[8]

In SWEDROP, there were also 59 infants registered with a GA above the present Swedish screening criterion, probably referred by neonatologists because of general illness. Retinopathy of prematurity was noted in 4 of these infants, of whom 2 had stage 3 ROP (Tables 2 and 5). Both infants had a GA of 32 weeks at birth and were extremely ill with failing kidney and heart function, respectively. Such infants will fall outside existing guidelines in many countries and are the reason that some screening guidelines encourage neonatologists to refer also older infants if they are very ill with several comorbidities. Hence, American guidelines include a second criterion, that is, "unstable clinical course" in infants with a GA greater than 30 weeks or a birth weight greater than 1500 g,[8] and Canadian guidelines encourage referral of infants with a "severe and complex neonatal clinical course."[11] This corroborates with the finding by Fortes Filho et al[12] that infants with a GA of 31 weeks or less at birth developed ROP owing to general immaturity, whereas more mature infants with a GA of 32 weeks or more developed ROP because they were "sicker" with more comorbidities.[12] We concur and believe that a reduction of the upper screening limit by 1 week, to less than 31 weeks + 0 days, should be combined with a strong

request to neonatologists to refer also older infants if they are generally ill or have several comorbidities.

Most national ROP guidelines recommend ROP screening be initiated at approximately 4 to 6 postnatal weeks, whereas some postpone the first examination in the most immature infants.[8,9] American guidelines propose that infants with a GA of 27 weeks or less have their first examination at a PMA of 31 weeks, while more "mature" infants should be examined at a PNA of 4 weeks.[8] National guidelines from Great Britain state that infants born before 27 weeks GA (26 weeks + 6 days) should have the first examination at 30 to 31 weeks PMA, and initiation of the screening should be undertaken between 4 and 5 weeks in "older" infants.[9] Up to 2010, Swedish screening guidelines recommended the first eye examination take place in the fifth postnatal week, regardless of GA at birth. A recent national study (Extremely Preterm Infants in Sweden Study) of 506 infants born with a GA of less than 27 weeks found that the first examination could be postponed to a PMA of 31 weeks.[5] The present evaluation of SWEDROP data for 2008 and 2009 supports these recommendations. None of the infants were treated for ROP before a GA of 32 weeks and none developed stage 3 ROP before 31 weeks. Regarding infants with a GA at birth of 27 weeks or more, however, the onset of stage 3 ROP never occurred before a PNA of 5 weeks (Table 5). Hence, it appears that the old recommendation to start screening at a PNA of 5 weeks should remain in these "less immature" infants.

Treatment aspects were also analyzed in the present study. Type 1 ROP was noted in 84.2% of the treated infants, and type 2 ROP with stage 3 ROP without plus disease was seen in the remaining 15.8%. Hence, type 1 ROP criteria were fulfilled in most of the infants and personal judgment was taken into account in the individual infant, as recommended by the ETROP group.[6] Too many children (36%), however, are still given more than 1 laser session in our country. It was recently reported that the extremely immature infants in the Extremely Preterm Infants in Sweden Study had a high number (30%) of laser sessions[13] compared with other studies[6,14] and, in accordance with an Australian study,[15] recommended that retinal surgeons should aim at covering the entire avascular area with laser effects at the first treatment. The present results concur with this recommendation.

To our knowledge, SWEDROP is the first established national register for ROP. It has previously been shown that national quality registers are good tools for evaluation and improvement of health care and treatment of various diseases.[16] In Sweden, we have the advantage of personal identification numbers, facilitating identification of patients with a certain disease. A particular strength with SWEDROP is the high national coverage (ie, participation) shown in this study, providing a good basis for evaluation of screening and treatment routines for ROP in our country. A limitation with the register, however, is of course the large number of examiners throughout our elongated country.

To conclude, analysis of SWEDROP data during 2008 to 2009 confirms that the start of screening for ROP can be postponed to a PMA of 31 weeks, but not later, in infants with a GA at birth of 26 (26 + 6) weeks or less. In older infants with a GA of 27 weeks or more, the start of screening should remain at 5 weeks postnatal age. It seems possible to reduce the upper criterion for ROP screening in Sweden by 1 week, that is, including all infants with a GA at birth of 30 (30 + 6) weeks or less. This would save many infants from unnecessary examinations and reduce the yearly number of screening examinations by 10% (964 of 9286). However, there would still be only a small portion of all screened infants who need treatment for ROP (78 [5.6%] of 1385), indicating that factors other than GA should be sought to improve the cost-benefit ratio of screening. More important, neonatologists should be encouraged to also refer infants with higher GAs if they are severely ill with other comorbidities.

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