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Retinopathy of prematurity screening and treatment cost in Brazil

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ABSTRACT

Objective. *To assess the additional cost of incorporating the detection and treatment of retinopathy of prematurity (ROP) into neonatal care services of Brazil's Unified Health System (SUS).*

Methods. *A deterministic decision-tree simulation model was built to estimate the direct costs of screening for and treating ROP in neonatal intensive-care units (NICUs), based on data for 869 preterm infants with birth weight less than 1 500 g examined in six governmental NICUs in the capital city of Rio de Janeiro, where coverage was 52% and 8% of infants were treated. All of the parameters from this study were extrapolated to Brazilian newborn estimates in 2010. Costs of screening and treatment were estimated considering staff, equipment and maintenance, and training based on published data and expert opinion. A budget impact analysis was performed considering the population of preterm newborns, screening coverage, and the incidence of treatable ROP. One- and two-way sensitivity analyses were performed.*

Results. *In Rio de Janeiro, unit costs per newborn were US$ 18 for each examination, US$ 398 per treatment, and US$ 29 for training. The estimated cost of ROP diagnosis and treatment for all at-risk infants NICUs was US$ 80 per infant. The additional cost to the SUS for one year would be US$ 556 640 for a ROP program with 52% coverage, increasing to US$ 856 320 for 80% coverage, and US$ 1.07 million or 100% coverage.*

Conclusions. *The results of this study indicate that providing ROP care is affordable within the framework of the SUS in Brazil, and might be feasible elsewhere in Latin America, considering the evidence of the effectiveness of ROP treatment and the social benefits achieved.*

Key words Costs and cost analysis; retinopathy of prematurity; Brazil.

It is estimated that 15 million preterm babies are born every year, and preterm birth rates are increasing in almost all countries (1). It has also been estimated that preterm birth contributes to 40% of under-5 mortality rates. In response, ministries of health in many emerging-economy countries are increasing the provision and quality of neonatal care. However, the increase in survival is likely to lead to higher morbidity rates, including visual loss from retinopathy of prematurity (ROP), hearing impairment, and learning disabilities (1–4).

ROP, one of the major morbidities associated with preterm birth, has become a significant cause of blindness in children in middle-income countries in Asia, Eastern Europe, and Latin America (5, 6), and is a priority for the VISION 2020 Right to Sight global initiative (7). Blencowe at al. estimated that 32 000 preterm infants become blind or severely visually impaired from ROP each year, with over 10% born in Latin America and the Caribbean, and the highest incidence in the Asia region (2).

Programs to detect infants with severe stages of disease were initiated in developed countries after the International Classification of Retinopathy of Prematurity (ICROP)[3] was developed and evidence of the effectiveness of treatment was clearly demonstrated in the Cryotherapy

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[3] Consensus statement of 23 ophthalmologists from 11 countries providing a uniform nomenclature to describe ROP, first published in 1984 and expanded upon in 1987 and 2005.

for Retinopathy of Prematurity (CRYO-ROP) clinical trial (8–10). Effective care of infants at risk of ROP, usually determined by gestational age and birth weight criteria, requires carefully timed retinal examinations by an ophthalmologist experienced in the examination of preterm infants using an indirect binocular ophthalmoscope. Once treatable disease has been diagnosed, a trained ophthalmologist should perform laser ablation of the peripheral retina under sedation/analgesia within 72 hours to minimize the risk of retinal detachment. All neonatologists, neonatal nurses, and health care providers who care for at-risk infants should be aware of this schedule and play an active role in 1) identifying and preparing the infants to be examined and 2) attending to the infants during examination and/or treatment. Ophthalmologists usually visit the neonatal intensive-care unit (NICU) on a weekly basis, although some monitor patients even more frequently. However, many emerging-economy countries still do not have national policies to regulate the implementation of ROP programs, and coverage of ROP programs is often low (11, 12).

Brazil had more than 191 million inhabitants and more than 2.8 million live births in 2010 (13). According to the World Health Organization (WHO) Global Action Report on Preterm Birth, the number of preterm births has declined over the last few years in Brazil. Nevertheless, it is among the top 10 countries with the highest preterm birth rates in the world (1). Estimates show that 13 500 premature infants weighing less than 1 500 g require eye examinations every year and that approximately 1 000 need laser treatment for severe ROP. In 2008, 20 years since the publication of the CRYO-ROP study, Brazil passed legislation on a national policy to regulate ROP diagnosis and treatment (14). However, as programs are not part of universal health care services in neonatology, not all at-risk preterm babies have access to ROP examination and treatment. In the capital city of Rio de Janeiro, where the data used in this study were obtained, the ROP screening and treatment program is being implemented in governmental NICUs. Ophthalmologists visit more than one NICU and a laser is shared by six NICUs (15). Brazil has invested in neonatal care for the last 20 years. The Unified Health System (*Sistema Único de Saúde*, SUS) provides approximately 76% of neonatal care in the country (16) and patients do not pay user fees. The SUS has stipulated a national standard list for health expenditure, with a daily reimbursement for hospitalization in a NICU of about US$ 240 (17). However, Entringer et al. reported an estimate for the cost of neonatal care in municipal NICUs in the city of Rio de Janeiro of US$ 389 per day (18), which means that local governments must cover the remaining expenses with funds from other sources, such as taxes (19). Within this context, the adoption of ROP screening and treatment might be a financial challenge for the government health system.

The purpose of this study was to address this question and determine whether incorporating the detection and treatment of ROP into neonatal care services provided by the SUS would be affordable. The study used three economic approaches: cost analysis, incremental cost analysis (ICA), and budget impact analysis (20). For the purposes of the study, the cost analysis estimated the unit costs for detecting and treating one infant with severe ROP. The ICA estimated the additional cost for detecting and treating one infant, considering all infants at risk of developing severe ROP. In the budget impact analysis, the research team predicted how incorporating services for ROP will affect the trajectory of spending on neonatal care within the SUS, assuming that ROP programs do not increase the length of stay in the NICU. Estimating the budget impact required data on the incidence of the condition of interest, the proportion diagnosed, and the proportion treated, plus the unit costs for diagnosis and treatment.

MATERIALS AND METHODS

Model structure

A deterministic decision-tree simulation model was built to estimate the direct costs of screening for and treating ROP in NICUs from the SUS perspective. Model input parameters were based on the study by Zin et al. (15), which was carried out between 2004 and 2006 in six government NICUs and one private NICU in the capital city of Rio de Janeiro. Data for 869 preterm infants with birth weight < 1 500 g examined in the six government NICUs between 2005 and 2006 were used. This population represented 52% of infants with birth weight < 1 500 g born in Rio de Janeiro. In that study, 8% of examined babies developed stages of ROP requiring treatment, all of whom were treated. All parameters obtained from the study were extrapolated to Brazilian newborn estimates in 2010 (Table 1). The model considered the probabilities of disease regression or disease progression to the stage requiring treatment in infants in two birth weight groups: < 1 000 g, and ≥1 000–1 500 g. Data from the Rio de Janeiro study (15) also showed that infants in the lower birth weight category and those who were treated regardless of birth weight underwent more examinations by the ophthalmologist (< 1 000 g: four exams for babies not treated and seven exams for babies treated; ≥ 1 000 g: two exams for babies not treated and seven exams for babies treated) (Figure 1). TreeAge Pro 2011 was used to run the model (TreeAge Software Inc., Williamstown, Massachusetts, USA).

Cost analysis

The cost analysis was performed using a real scenario of implementing ROP screening and treatment in NICUs of the SUS in the city of Rio de Janeiro (i.e., the base case). The research team considered all resources required to estimate a unit cost for each examined and treated preterm baby. The use of resources for examination and treatment was based on published data (15) and expert opinion.

The direct costs included staff, equipment and maintenance, and training. Staff costs were estimated based on a team comprising an ophthalmologist, neonatologist, anesthesiologist, nurse, and nurse technician. The time for each diagnostic examination was calculated as follows: 20 minutes for the ophthalmologist, 5 minutes for the nurse, and 30 minutes for the nurse technician. The time required for each treatment was estimated at 3 hours for the ophthalmologist (including the time needed for transport to/from the unit); nurse; neonatologist; and anesthesiologist (including the time required to prepare the baby plus post-procedure care). Staff salaries were estimated according to values paid by the Rio de Janeiro Municipal Health Department.

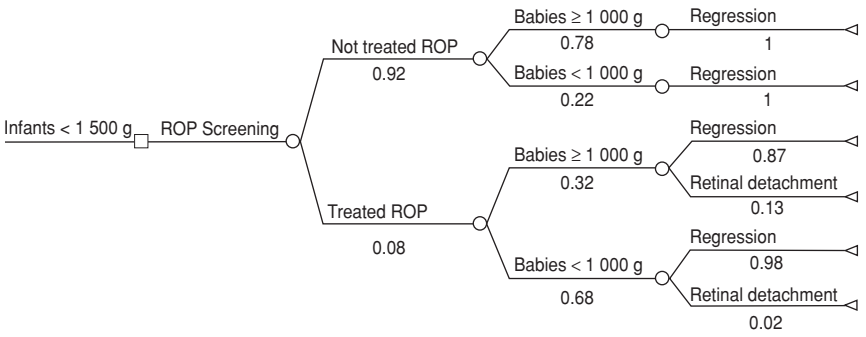
Equipment for ROP diagnosis and treatment included one diagnostic kit (one indirect ophthalmoscope (1.0 Eyetec); a 28-diopter Volk lens; five neonatal lid speculums; and one Roca scleral

TABLE 1. Input, assumptions, and ranges used in sensitivity analyses of model estimating budget impact of providing retinopathy of prematurity (ROP) diagnosis and treatment through the public health system, Rio de Janeiro City, Brazil, 2012

Input variable	Base-case value	Range	Source
ROP treatment			
Probability of babies < 1 500 g not treated	0.92	0.9–0.93	(15)
Probability of babies < 1 500 g treated	0.08	0.07–0.10	(15)
Probability of babies < 1 000 g treated	0.68	0.57–0.78	(15)
Probability of babies ≥ 1 000 g treated	0.32	0.24–0.43	(15)
Probability of babies < 1 000 g not treated	0.22	0.19–0.25	(15)
Probability of babies ≥ 1 000 g not treated	0.78	0.75–0.81	(15)
ROP regression			
Babies ≥ 1 000 g not treated	1	–[a]	(15)
Babies < 1 000 g not treated	1	–	(15)
Babies ≥ 1 000 g treated	0.87	0.68–0.97	(15)
Babies < 1 000 g treated	0.98	0.90–0.99	(15)
Retinal detachment			
Babies ≥ 1 000 g treated	0.13	0.03–0.32	(15)
Babies < 1 000 g treated	0.02	0–0.11	(15)
Budget impact analysis data			
Number of live births (2010)	2 857 554 (100%)	–	(13)
Birth weight < 1 500 g (2010)	36 609 (1.28%)	–	(13)
National health system coverage[b]	27 823 (76%)	–	(16)
Access to neonatal care	22 258 (80%)	–	Author assumption
Number of babies < 1 500 g who survived	13 355 (60%)	–	(23)
Number of babies that would have been examined in Brazil (2010)	6 945 (52%)	–	(15)
Length-of-stay birth weight < 1 500 g (in days)	40	–	(22)
One day hospitalization cost (US$)	240	240–389	(1, 18)

[a] Not applicable.
[b] National Unified Health System (Sistema Único de Saúde, SUS).

FIGURE 1. Decision-analytic model for retinopathy of prematurity (ROP) diagnosis and treatment, Rio de Janeiro City, Brazil, 2012



depressor per unit) and one indirect diode laser (IridexOcuLight™ SLx, 810 nm) for the six units. The Ministry of Health and suppliers provided equipment prices. Maintenance and calibration costs were included. Costs were annualized using a standard discount rate of 5% (21) and an estimated equipment life of 10 years.

A senior ophthalmologist experienced in ROP trained ophthalmologists new to the program using hands-on training with the examination of 100 infants (33 hours) and treatment of 10 infants (30 hours). Time and salaries of the trainers were used to estimate training costs.

Incremental cost analysis

The decision-tree simulation model was used to estimate the cost for one infant, considering all at-risk infants, the total number of exams per at-risk infant, the proportion treated, and the unit costs for diagnosis and treatment. The incremental cost of ROP diagnosis and treatment for all eligible infants in addition to the cost of hospitalization was calculated considering the two estimates of hospitalization daily costs described above (US$ 240 and US$ 389) (17, 18), taking into account the average length of stay in the NICU of 40 days (22) and a 90% occupancy rate.

Budget impact analysis

The ROP program in the city of Rio de Janeiro was used as the base case for the budget income analysis and provided the data on incidence of severe ROP and the proportion treated. The total additional costs that would be incurred over one year by the SUS neonatal care unit were then extrapolated to the whole country. In the base case, screening coverage was 52%, and the incidence of severe ROP was 8% (with all 8% treated) (15). The probability of treatment in the two different birth weight categories is shown in Table 1. Other input parameters included the

population of newborns in Brazil in 2010 with birth weight < 1 500 g or 1.28% (Live Births Information System, SINASC) (13) using a survival rate of 60% among infants with birth weight < 1 500 g (Mortality Information System, SIM) (23). The following assumptions were used: average length of stay in the NICU, 40 days (22); access to neonatal care by preterm infants of approximately 80%; and NICU occupancy rate of 90% (Table 1).

The cost of an NICU stay per day was not included in the ROP budget impact analysis as premature infants with birth weight < 1 500 g were hospitalized because of their clinical condition and ROP diagnosis and treatment did not increase the length of hospital stay.

All costs were expressed in 2012 US$ (2.05 reais/1 US$) (24). No discounting or inflation rate adjustments were applied because of the short time horizon of the study (one year).

Sensitivity analysis. The research team performed a one- and two-way deterministic sensitivity analysis of the budget impact analysis by varying the base-case parameters (staff costs, ROP treatment rates, and coverage) with a significant level of uncertainty that could influence unit cost results. As SUS has different institutional arrangements for NICU services, salaries were also varied. Staff costs were decreased by 30% and increased by 36%; the ROP treatment rate was varied between 7% and 10%; and coverage was increased to 80% and 100% from the base-case value of 52%.

Ethics statement

The ethics boards of the London School of Hygiene and Tropical Medicine and the Fundação Oswaldo Cruz (Fiocruz) Instituto Fernandes Figueira, and Brazil's National Ethics Committee (CONEP), approved the research carried out in the city of Rio de Janeiro (15) that generated the data used in this study. Approval from the ethics committees of each collaborating institution was also granted. The department heads and directors at the hospital NICU also gave their written consent for the study. Mothers or guardians gave their written informed consents for each infant studied.

RESULTS

Cost per infant

The cost for each infant examined was US$ 18 (Table 2). The main cost drivers were for staff, with staff costs making up 78% of the costs, and equipment and maintenance, which accounted for 17%. The cost for each infant treated was US$ 398, with 47% of the cost incurred for equipment and 45% for staff. Training cost per newborn was US$ 29 (Table 2).

Incremental cost

The estimated cost of ROP diagnosis and treatment for all at-risk infants in SUS NICUs in Brazil was US$ 80 per infant. Considering the two estimates of hospitalization daily costs (US$ 240 and US$ 389), the length of stay, and the oc-

TABLE 2. Cost of providing retinopathy of prematurity (ROP) screening and treatment through the public health system,[a] including base-case values and ranges used in sensitivity analyses of budget impact model, Rio de Janeiro City, Brazil, 2012

Cost component per baby with birth weight < 1 500 g	Base-case value (US$[b])	Range (%)
Screening		
Staff		
Ophthalmologist	8	(–30 to +30)
Nurses	6	(–30 to +30)
Equipment and maintenance	3	–[c]
Training	1	–
Subtotal	18	
Treatment		
Staff		
Ophthalmologist	69	(–30 to +30)
Neonatologist or anesthesiologist	69	(–30 to +30)
Nurses	43	(–30 to +30)
Equipment	189	–
Training	28	–
Subtotal	398	
Total	416	

[a] Calculated by authors based on data from expert panel and Ministry of Health databases.
[b] In 2012 US$ (2.05 reais/1 US$) (24).
[c] Not applicable.

TABLE 3. Estimated cost to the public health system of providing retinopathy of prematurity (ROP) screening and treatment for one year, Rio de Janeiro City, Brazil, 2012

Variable	Base case	Scenario 1	Scenario 2
Babies examined for ROP (%)	52	80	100
Budget impact (US$[a])	556 640	856 320	1 070 400

[a] In 2012 US$ (2.05 reais/1 US$) (24).

cupancy rate, the estimated incremental cost to the SUS varied from 0.61% to 0.98%.

Budget impact of ROP care

Using estimates from the base case (the ROP program in the city of Rio de Janeiro), the budget impact analysis indicated that if coverage of the ROP program in Brazil were the same as that in the city of Rio de Janeiro, where 52% of preterm infants were examined, the additional cost to examine and treat infants for one year would be US$ 556 640. Using a coverage rate of 80%, the additional cost would increase to US$ 856 320, and at 100% coverage the extra budget required by the SUS would be US $1.07 million (Table 3).

In one-way sensitivity analysis, if staff costs were increased by 36%, an additional US$ 965 000 would be needed by the SUS to implement a program for ROP each year in Brazil. If staff costs were decreased by 30%, US$ 434 000 would be needed. In two-way sensitivity analysis, an additional budget of US$ 1.061 million would be needed if staff costs were increased by 36% and the ROP treatment rate increased to 10%. A figure of US$ 412 000 was derived when staff costs were reduced by 30% and the ROP treatment rate was reduced to 7%.

DISCUSSION

Perinatal care in Latin American countries has improved significantly, as reflected by the increase in survival rates (25). Hence, the focus has shifted to reducing morbidities and improving the quality of life of surviving infants.

In the 1980s, the first clinical trial on ROP treatment (CRYO-ROP) demonstrated that treatment was highly effective (9, 10). However, ROP remains the leading cause of avoidable blindness in children in Latin America (26) and is among the main causes in Brazil (27).

Cost-effectiveness and indirect cost studies (28, 29) demonstrate the positive effects and longstanding benefits of ROP programs in decreasing the economic burden on families and society. However, the costs of providing this service have been a concern that hinders the implementation of ROP programs in middle-income economies, where access to ophthalmologists with expertise in ROP, and equipment, is limited. The current study describes a model of ROP care that enables a feasible approach for developing countries (ophthalmologists examining infants in more than one NICU with equipment for treatment shared by six units). If a different model is adopted in which each NICU has its own ophthalmologist, the budget will be considerably higher due to extra salary costs as well as training costs.

The study finding that the incremental cost per at-risk baby for examination and treatment was only US$ 80, which is less than 1% of NICU hospitalization costs, indicates that ROP programs are affordable in all neonatal units in Brazil.

The costs for training ophthalmologists to detect and treat ROP accounted for 10% of the total cost of ROP care in this study, which does not represent a significant burden to health care providers, considering the additional future benefits. Training costs were higher than they might be elsewhere, as Brazilian ophthalmologists are not usually exposed to ROP during their residency and there are no standard curricula for ROP for Brazilian residents (30). In the ROP program in the city of Rio de Janeiro, considerable costs in terms of time and financial resources were incurred by a senior ophthalmologist who supervised each of the ophthalmologist trainees while they examined 100 infants and treated 15 infants, as recommended in guidelines developed for Latin America (31). Including ROP as an essential component of ophthalmology residency programs would increase awareness and skills and reduce subsequent training costs.

The sensitivity analyses undertaken in this study reflect the impact of possible variation in the financing structure, organization of service delivery, and population at risk, as well as in access to ROP care/coverage—variables that should be taken into account when deciding whether or not to implement ROP care. Variation between countries in health financing and organization of care mean that the findings of this study cannot be directly applied to other settings.

While knowledge of costs is an important component in decision-making, the feasibility of a program can depend on multiple factors. In the case of ROP, these factors could include whether or not the program is part of the agenda of policy-makers and health professionals, scientific evidence on disease management, regulation of health procedures, and organization of hospital departments for the effective provision of care. Strategies to guarantee the availability of ROP specialists should also be a priority.

Effective implementation of ROP care within the public health policy agenda in Latin America should take into account regional specificities and diverse institutional arrangements in neonatal health care delivery. However, the model for ROP care suggested in this study should be feasible regardless of variability in the local context as it is designed to optimize the use of available resources.

Many counties in Latin America, including Brazil, have the legal framework required for regulating ROP care (32–34). This is a major step forward in making ROP care more widely available, according to Pan American Health Organization (PAHO)/WHO priorities for the region (35).

Limitations

This study had some limitations. First, ROP program coverage in the city of Rio de Janeiro (52% in 2005 and 2006), which was used as the base case, was extrapolated to the whole country, as no official data were available for ROP programs in other locations across Brazil. In addition, the hospitalization cost estimates used in the study (17, 18) were a proxy of the actual cost because no better information was available.

Conclusions

There is no doubt about the importance of preventing blindness and visual impairment from ROP in children. The results of this study indicate that providing ROP care is affordable within the framework of the SUS in Brazil, and might be feasible elsewhere in Latin America, considering the evidence of the effectiveness of ROP treatment and the social benefits achieved.

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Conflicts of interest. None.

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RESUMEN

Costo de la detección y el tratamiento de la retinopatía de la prematuridad en el Brasil

Objetivo. Evaluar el costo adicional de incorporar la detección y el tratamiento de la retinopatía de la prematuridad (RP) en los servicios de atención neonatal del Sistema Único de Salud (SUS) del Brasil.

Métodos. Se estableció un modelo de simulación determinístico en forma de árbol de decisión para calcular los costos directos del tamizaje y el tratamiento de la RP en las unidades de cuidados intensivos neonatales (UCIN), con base en los datos correspondientes a 869 lactantes prematuros con un peso al nacer inferior a 1 500 g examinados en seis UCIN gubernamentales de Rio de Janeiro, capital del estado del mismo nombre, donde la cobertura fue de 52% y se trató a un 7% de los lactantes. Todos los parámetros de este estudio se extrapolaron a los cálculos de recién nacidos brasileños correspondientes al año 2010. Se calcularon los costos de la detección y el tratamiento, teniendo en cuenta el personal, el equipo y la capacitación, con base en los datos publicados y la opinión de los expertos. Se llevó a cabo un análisis de la repercusión presupuestaria considerando la población de recién nacidos prematuros, la cobertura del tamizaje y la incidencia de RP susceptible de tratamiento. Se realizaron análisis de sensibilidad en uno y dos sentidos.

Resultados. En Rio de Janeiro, los costos unitarios por recién nacido fueron de US$ 18 por cada examen, US$ 398 por tratamiento y US$ 29 por capacitación. El costo calculado del diagnóstico y el tratamiento de la RP en todos los lactantes en situación de riesgo de las UCIN fue de US$ 80 por lactante. El costo anual adicional para el SUS de un programa de RP con una cobertura de 52% sería de US$ 556 640, y ascendería a US$ 856 320 para una cobertura de 80%, y a US$ 1,07 millones si la cobertura fuera de 100%.

Conclusiones. Los resultados de este estudio indican que, teniendo en cuenta los datos probatorios de la eficacia del tratamiento de la RP y los beneficios sociales obtenidos, la prestación de asistencia a la RP es asequible en Brasil en el marco del SUS y podría ser factible en otros lugares de América Latina.

Palabras clave Costos y análisis de costo; retinopatía de la prematuridad; Brasil.