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Portable wide-field digital imaging for screening of neonatal visual impairment causes in Rio de Janeiro, Brazil: a budget impact analysis

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ABSTRACT

Objective To estimate the budget impact of portable wide-field digital imaging incorporation on screening neonatal causes of childhood blindness and visual impairment in Rio de Janeiro, Brazil.

Design Budget impact analysis.

Setting Rio de Janeiro, Brazil.

Primary and secondary outcome measures The primary outcome was the direct cost of indirect binocular ophthalmoscopy, red reflex test and portable wide-field digital image screening comprising all babies born in Rio de Janeiro's government maternity wards. The secondary outcome was the budget impact of implementing portable wide-field digital image screening in Rio de Janeiro, Brazil.

Results Considering 100% coverage of maternity wards, the total budget impact between 2020 and 2024 would be US$3 820 706.04, ranging from US$3 139 844.34 to US$6 099 510.35. The additional cost would be US$3 124 457.28, ranging from US$2 714 492.26 to US$4 880 608.63.

Conclusion The cost of universal digital imaging screening corresponds to less than 1% of the government health budget of the city of Rio de Janeiro. The information provided in this study may help government decision-makers evaluate the feasibility of implementing this new strategy in the municipal setting. Further health economic evaluations should be performed to verify the affordability of the implementation of this screening strategy in the Brazilian scenario, taking into account scarce human resources.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study addresses the budgetary impact of portable wide-field digital imaging as a model of universal neonatal eye screening.
⇒ Non-medical health professionals were trained to perform imaging capture.
⇒ Face validity was performed with skilled government health policy makers to confirm feasibility.
⇒ The study is a theoretical model with assumptions and literature-based premises.

INTRODUCTION

Worldwide, around one million children are blind from eye diseases (excluding refractive errors), and at least 25% of the cases could have been avoided if preventive measures, diagnosis and treatment had been implemented in a timely manner.[1] In Brazil, despite the socioeconomic diversity and scarcity of population data in several regions, it is estimated that 0.5 per 1000 children are blind.[2] Childhood visual impairment has a direct impact on child development and has socioeconomic implications. In the USA, Wittenborn *et al*[3] estimated an economic burden of eye disorders in children of US$6 billion per year. In Peru, Dave *et al*[4] calculated a national lifetime burden of raising all visually impaired children secondary to retinopathy of prematurity (ROP) of around US$500 million. Early diagnosis and treatment of ocular diseases can reduce cost, prevent visual impairment and improve the quality of life of affected individuals and their families.[1 2 4]

The constitution of Brazil defines health as a universal right and a state responsibility, and in 1988 the Brazilian Unified National Health System (SUS) was officially created. SUS is the Brazilian health system that reaches universal health coverage to every person legally living in the country.[5] The government health system is financed by tax revenues and social contributions from all three levels of government (federal, state and municipal).[6] Approximately 76% of the Brazilian population are covered by SUS; in other words, the majority of the population depend on this healthcare system.[7]

In Rio de Janeiro, as well as in other Brazilian urban centres, the main causes of childhood visual impairment are ROP, infectious diseases, optic nerve abnormalities, cataract and glaucoma.[8 9] Currently, there are two different screening strategies to identify

these diseases in Brazil: the red reflex test (RRT) and the indirect binocular ophthalmoscopy (IBO). In 2002, RRT was included among other neonatal screening strategies in the state of Rio de Janeiro for all newborns.[10] It can identify any opacification of the transparent media of the eye, but with low sensitivity (17.5%) in detecting posterior diseases of the eye when compared with IBO and wide-field digital imaging (WFDI).[11] It is performed by a paediatrician in the maternity ward using a direct ophthalmoscope before hospital discharge.[2] In Brazil, 98% of live births are hospital-based and babies are discharged 48 hours after birth.[12 13]

ROP is a potentially blinding disease that occurs in preterm infants, with the highest risk in those born at less than 32 weeks of gestational age (GA) and/or birth weight (BW) below 1500 g. The diagnosis is by IBO performed by a skilled ophthalmologist while the infant is still in neonatal intensive care or after discharge from care.[12]

Currently these screening methods are not able to cover all live births, mainly due to lack of trained professionals.[13 14] In addition to insufficient coverage, the referral networks are usually inefficient, which leads to a delay in diagnosis and treatment.[15] Portable WFDI as an ROP screening method was proven, despite the high initial cost of the equipment, to be a cost-effective strategy.[7 16] It also has good accuracy (sensitivity over 70%) in identifying clinically significant (type 2 or worse) ROP when compared with indirect ophthalmoscopy.[17 18]

Several large studies have demonstrated the results of universal neonatal eye screening. Although the majority of findings were retinal haemorrhages, some babies who would not be screened routinely required further referral and treatment.[19–22] Wide-field neonatal anterior and posterior eye imaging performed by a non-ophthalmologist and immediate image referral and analysis by an ophthalmologist in a tertiary centre might contribute to early diagnosis and increase coverage.[23]

It is important to provide an economic evaluation framework to make the best use of clinical evidence and health resources in order to support healthcare decision-making.[24] The purpose of this study was to estimate the budget impact of portable WFDI for universal newborn screening from the perspective of the SUS from 2020 to 2024 in the city of Rio de Janeiro.

MATERIALS AND METHODS

Population

The number of newborns eligible for both RRT and IBO in government maternity wards in the city of Rio de Janeiro was estimated for 2020–2024 using autoregressive integrated moving average (the ARIMA model) based on an 11-year time live birth series (2008–2018).[25]

Study design

This is a budget impact analysis (BIA) based on a static model that used a cost calculator developed in an Excel 365 spreadsheet (Microsoft, USA). A theoretical assumptive study model was created based on population parameters, epidemiological parameters (rate of examinations and re-examinations of preterm newborns), assumptions and costs associated with the screening models. The BIA of adoption of portable WFDI was compared with a reference scenario based on RRT and IBO.

Maternity ward survey

The study identified 24 government maternity wards, 23 with neonatal intensive care units, in the city of Rio de Janeiro. An ROP screening programme was implemented in 92% of the maternity wards (22 of 24). Together, these maternities admitted almost 60% (54 000) of all live births in the city in year 2018.[26]

Neonatal screening model

The study population was stratified into three hypothetical screening strategies: (1) RRT of all newborns except those requiring ROP screening (reference scenario); (2) IBO for ROP screening (reference scenario); and (3) WFDI (alternative scenario) for both populations of newborns.

Reference scenarios

RRT would be performed on full-term and premature newborns with no indication for ROP screening,[2] executed by a paediatrician using a direct ophthalmoscope, before hospital discharge. Consumables are not needed to perform the test.

Infants born with BW ≤1500 g and/or GA <32 weeks would be submitted to IBO by a skilled ophthalmologist. The first examination would be performed between the fourth and sixth week of life and subsequent re-examinations performed according to the classification of the disease until its resolution.[12] For estimate purposes, the rate of ROP re-examination was based on Zin *et al*.[27] It was assumed that preterm infants screened for ROP would not be submitted to RRT.

Alternative scenario

In the alternative screening strategy, WFDI would be performed on all newborns by two nurse technicians before hospital discharge. Imaging of preterm infants with BW ≤1500 g and/or GA <32 weeks would follow the Brazilian ROP screening guidelines.[12] Images would be sent to ophthalmologist readers so ocular abnormalities could be identified and patients who needed proper diagnosis and treatment would be referred to a specialised eye care centre.[14] Preterm infants with non-readable images or with suspected images of ROP type 2 or worse would be submitted to IBO while still under neonatal care.

For this study, the RetCam Portable (Natus Medical Incorporated, Pleasanton, California, USA) ('RetCamP') was used to calculate costs. The device consists of a high-resolution camera that captures images of anterior and posterior segments of the eye. As it is a portable device, it could be shared among maternities close to each other, with transportation of the RetCamP provided by a driver.

In order to estimate the number of devices and professionals needed to cover all units, the following was considered: number of live births per maternity, baby's length of stay after birth, distance among units and the efficiency (examinations/day) of the nurse technician responsible for performing the examination. The Google Maps platform was used to calculate the distance among units as well as fuel cost (gasoline).

Cost analysis

Costs were estimated from the SUS perspective and a micro-costing analysis was used to estimate strategy costs. Estimate costs were based on the Brazilian National Procedure Table published elsewhere,[28] plus other official sources, when necessary. The following items were considered to perform IBO and WFDI: proxymetacaine hydrochloride 0.5% eye-drops, tropicamide 1% eye-drops, phenylephrine 2.5% eye-drops, gauze, glucose solution and ophthalmic jelly (for digital imaging), as well as a nurse and a nurse technician to assist the ophthalmologist during IBO.[29] It was assumed that 20.8% of preterm babies with ROP type 2 or worse and 5% of infants with non-readable images would be submitted to IBO.[30]

Prices of the incorporated equipment (direct and indirect ophthalmoscope, 28-dioptre Volk lens and neonatal lid speculum) were based on Brazilian official sources.[28] Costs of portable wide-field digital camera, spare parts (pedal and lens) and maintenance were based on market value provided by the manufacturer. In addition, an insurance quote was provided for the device. A 5% value of the unit price was assumed for equipment maintenance. When necessary, costs were annualised using a standard discount rate of 5%,[31] with an estimated 10-year equipment lifespan.

Wage values for human resources were estimated on the amount of time each professional dedicated to his/her activities in the screening processes. It was assumed that RRT would be carried out by the paediatrician in 5 min. In order to reflect the ROP screening reference scenario, the ophthalmologist's workload was simulated. The estimated time spent with each patient was 20 min for the ophthalmologist, 5 min for the nurse and 30 min for the nurse technician.[29] The ophthalmologist's training values were based on Zin *et al*[29] and were taken into account for the professional price calculation.

The cost of human resources to perform digital imaging included training two neonatal nurse technicians for equipment set-up, imaging and equipment dismantle. This training was performed in two phases separated by 1 month in order to verify the learning curve to perform the procedure. In addition, the interpretation of images by two ophthalmologists was timed and the average time spent was used to calculate the predicted ophthalmologist cost.

Budget impact model

A statistical model was used for the BIA. In this model, the new intervention unit cost was multiplied by the number of individuals in every year from 2020 to 2024.

Three hypothetical scenarios, taking into account 100%, 75% and 50% coverage of portable WFDI, were considered, calculating each budget impact. Targeting a better deal (reduced price), the purchase of all the equipment would take place in the first year, but delivery would be gradual, based on a market share of 60% on the first year and 10% on each consecutive year, until complete coverage could be reached by 2024.

The incremental budget impact was calculated through the cost difference between the reference (IBO and RRT) and the alternative (WFDI) scenarios. In 2019 all costs were expressed in US dollars (3.94 reais/US$1, mean rate from March to July 2019),[32] and the unit cost of the examination was calculated based on the number of live births in 2018. Inflationary adjustments were not introduced, in accordance with Brazilian[31] and international[33] recommendations.

Sensitivity analysis

A sensitivity analysis was achieved by scenarios.[31] Two scenarios were created: the best scenario with lower limit of the parameter variation and the worst scenario with upper limit of the parameter variation.[24] To create the best scenario, the following reductions were considered: 5% for the exchange rate, 74% in human resource cost and 200% in consumables cost. In regard to the worst reference scenario, the exchange rate would increase by 5%, human resource cost by 32% and consumables cost by 85%.

Validation

Face validity was executed through an interview with two experts from the Rio de Janeiro Health Department with over 20 years of experience in management, planning and coordination of neonatal care and who also had extensive operational and logistics knowledge of the municipal maternity wards. An interview guide was developed to obtain information regarding the programme's feasibility (practical aspects related to the implementation of the programme), resource availability (personal information related to the cost of the programme) and care units' infrastructure (information related to the current healthcare network). Internal validity was executed by members of this study through a review of all formulas, calculations and parameters used to create the model structure.

Patient and public involvement

No patients were involved.

RESULTS

Number of estimated procedures

The number of procedures based on the population assessment estimate through the time horizon of 2020–2024 for each screening model is shown in table 1. Between 2020 and 2024 a variance was observed in the number of procedures for IBO, RRT and WFDI of 2.29%, 0.34% and 0.41%, respectively.

Table 1 Estimated number of procedures for each screening model from 2020 to 2024

Year	Red reflex test (95% CI)	Indirect binocular ophthalmoscopy*	Wide-field digital imaging (95% CI)
2020	60 846 (54 684 to 67 701)	2095	62 941 (56 866 to 69 666)
2021	61 190 (54 363 to 68 873)	2175	63 365 (56 635 to 70 896)
2022	61 010 (52 887 to 70 380)	2132	63 142 (55 129 to 72 319)
2023	61 104 (52 230 to 71 485)	2155	63 259 (54 506 to 73 419)
2024	61 054 (51 355 to 72 585)	2143	63 197 (53 627 to 74 476)

*Number of examinations and re-examinations in preterm infants, born at less than 32 weeks of gestational age and/or birth weight below 1500 g. Calculated by the difference between the wide-field digital imaging and the red reflex test.

Cost analysis

Direct costs of the screening strategies

Table 2 discloses the direct costs of human resources, capital, transportation and consumables related to IBO, RRT and WFDI in the city of Rio de Janeiro, Brazil. The total cost per examination is US$34.36, US$0.75 and US$14.19, respectively.

Detailed costs for human resources, equipment, maintenance, insurance, consumables and fuel are shown in table 3.

Cost and efficiency of WFDI

Imaging capture and training

Between the first and second phase of the neonatal nurse technician training, there was a 31.7% reduction in the necessary time to perform all steps of wide-field imaging (including device set-up and dismantle) and a 45% decrease in time to perform the examination (patient registration, capture and selection of images), reflecting a training learning curve. At the end of the training period, each team was able to perform an examination every 13 min, which translated to 10–13 examinations during a 6-hour period. To provide screening for all live births, it would be necessary to have 25 fixed teams and 3 additional teams due to cover vacation and maternity leave, with a total of 56 professionals.

Image interpretation

On average, 12 images were read per hour, that is, a total of 1200 examinations per month. Six ophthalmologists would be necessary to read all images taken from all live births every year.

Portable digital camera distribution in the city of Rio de Janeiro

To cover scenario 1 (100% coverage), scenario 2 (75% coverage) and scenario 3 (50% coverage), 12, 9 and 7 portable digital cameras would be required, respectively. Hospitals would have their own equipment and staff if there were more than 100 babies to be examined per week or the hospitals were far apart. Thus, in scenario 1, five units would have their own device and two teams of nurse technicians (totalling 10 professionals) dedicated to screening. In 19 units that share seven devices, the number of imagers would vary from two to four (total of 40 professionals), depending on the number of births at each health centre.

Budget impact of WFDI screening

The total budget impact of WFDI for 100% coverage of maternity wards was US$3 820 706.04 in the 5-year horizon. Compared with the reference scenario, the incremental budget impact was US$3 124 457.28. The budget impact considering different levels of coverage in maternity wards and the sensitivity analysis are shown in table 4.

Face validity

During face validity, the interviewed experts pointed out some obstacles and possibilities with WFDI adoption. They both agreed that there is a deficit in the screening

Table 2 Direct costs (in US dollars): indirect binocular ophthalmoscopy, red reflex test and wide-field digital imaging, Rio de Janeiro City, Brazil, 2019

	Red reflex test	Indirect binocular ophthalmoscopy	Wide-field digital imaging
Cost items	Cost per examination (US$)	Cost per examination (US$)	Cost per examination (US$)
Human resources	0.74	30.32	5.85
Capital	0.01	3.16	7.19
Consumables	–	0.87	1.13
Transportation	–	–	0.02
Total	0.75	34.36	14.19*

Values in 2019 US dollars (3.94 reais/US$1).
*Combined strategy (wide-field digital imaging+indirect binocular ophthalmoscopy)=$14.27.

Table 3 Unitary costs (in US dollars): indirect binocular ophthalmoscopy, red reflex test and wide-field digital imaging, Rio de Janeiro City, Brazil, 2019

	Indirect binocular ophthalmoscopy		Red reflex test		Wide-field digital imaging	
Items	Quantity	Unitary cost (US$)	Quantity	Unitary cost (US$)	Quantity	Unitary cost (US$)
Human resources*						
Physician	7	930.71	24§	930.71	6	930.71
Nurse technician	22‡	330.20	–	–	56	330.20
Nurse	22‡	458.38	–	–	–	–
Driver	–	–	–	–	8	468.46
Equipment	22	2348.45	24	151.57	12	110550.00
Insurance†	–	–	–	–	12	2838.36
Equipment maintenance†	22	117.42	24	7.58	12	10164.56
Consumables	Per examination	1.00	–	–	Per examination	1.13
Fuel (gasoline)		–	–	–	Per week	5.60

*Unitary cost corresponds to monthly salary.
†Per year.
‡10% of the workday would be allocated to assist in the examination.
§5% of the workday would be allocated to perform the examination.

coverage in government maternity wards in the city of Rio de Janeiro. It has been estimated that screening coverage for term newborns ranges from 70% to 80% and from 70% to 100% for premature infants (ROP screening). Furthermore, there is a lack of trained professionals, such as ophthalmologists and paediatricians, to perform screening tests in the reference scenario. Considering the reported obstacles, there is ample room to offer a new universal screening that would provide an opportunity to increase coverage.

DISCUSSION

To the best of our knowledge, this is the first budget impact study carried out in Brazil for implementation of the WFDI system in the government health system that also addresses a public policy proposal to reduce childhood visual impairment.

Currently, in the city of Rio de Janeiro, the main cause of visual impairment and blindness in children is related to neonatal factors, mainly ROP, followed by cataract, glaucoma and intrauterine infections.[9] RRT must be performed in the maternity ward by a trained paediatrician before hospital discharge.[34] No official data or published studies were found regarding screening outcomes of the RRT in the city of Rio de Janeiro. However, a study carried out in the northeastern region of Brazil found that just over 30% of newborns with a suspected red reflex were properly referred and evaluated by an ophthalmologist.[35]

Table 4 Total budget impact and incremental budget impact of the wide-field digital imaging for coverage of 100%, 75% and 50% of maternity wards, Rio de Janeiro City, Brazil, 2019

Budget impact			
	100% coverage	75% coverage	50% coverage
Total budget impact of wide-field digital imaging			
Best scenario*	$3 139 844.34	$2 465 530.82	$1 804 016.19
Base case†	$3 820 706.04	$2 988 559.67	$2 175 596.75
Worst scenario‡	$6 099 510.35	$4 796 774.02	$3 662 056.48
Incremental budget impact of wide-field digital imaging§			
Best scenario*	$2 714 492.26	$2 040 178.73	$1 378 664.10
Base case†	$3 124 457.28	$2 292 310.92	$1 479 347.99
Worst scenario‡	$4 880 608.63	$3 577 872.30	$2 443 154.76

Values in 2019 US dollars (3.94 reais/US$1).
*Reductions considered: 5% of exchange rate, 74% of human resource costs and 200% of consumables costs.
†Base case: average of the parameter (exchange rate, human resource costs and consumables costs) variation.
‡Increases considered: 5% of exchange rate, 32% of human resource costs and 85% of consumables costs.
§Cost difference between the reference and the alternative scenarios.

Unfortunately, although RRT has been mandatory since 2002[10] and IBO is recommended for ROP screening,[29] not all ophthalmology residency programmes offer ROP training and there is lack of trained ophthalmologists to cover all units in the country. Abreu Caligaris *et al*[36] found that neonatal screening is insufficient, resulting in delayed diagnosis and treatment of neonatal ocular diseases.

Worldwide, new strategies have emerged as an alternative for universal screening, including the use of the WFDI system.[23] Studies in China and India suggest that WFDI can increase access to newborn eye screening and improve accuracy in identifying eye injuries.[19 23] A Brazilian study found that WFDI is highly superior in detecting ocular abnormalities in newborns compared with RRT. While WFDI detected abnormalities that would require immediate referral in 6.5% of eyes, RRT identified irregularities only in 1.7%, representing an overall sensitivity of less than 1%.[21]

Implementation of universal WFDI, between 2020 and 2024, for all term and preterm infants born in government maternity hospitals in the city of Rio de Janeiro would imply total expenses of approximately US$3.8 million, considering 100% coverage of maternities (scenario 1). For the same period, US$696.248 would be spent in the reference scenario, which represents an incremental budget impact of US$3.1 million. The total budget impact of incorporation of wide-field imaging corresponds to nearly 0.25% of the municipal and federal resources allocated in the city's government health system in 2018. In considering 50% coverage (scenario 3), the proportion would be 0.15%, and for 75% coverage (scenario 2) it would be 0.20%.[37]

In Brazil there is no budget impact or cost-effectiveness threshold for new technology incorporation process, making it difficult to interpret economic assessments for decision-making.[38] Caetano *et al*[39] demonstrated that between 2012 and 2016 the main factors that determined the incorporation of new technologies in Brazil were the additional clinical benefits over technologies already available and the low financial budgetary impact of the technology. In this context, for the purpose of comparing strategies, WFDI could be a technology to bring additional clinical benefits to RRT.

There are study limitations that should be addressed. Because this study is a BIA, the results might contain inherent uncertainty.[34] In the study we create assumptions about the structural model elements and variates input values over the time horizon to predict the future. Therefore, it was important to create different scenarios in the sensitivity analyses to minimise sources of uncertainty on the outcome of the study. Also, the accuracy of digital camera in most studies was based on ROP screening[19 20] and reports of complete economic evaluation were also based on the same population.[16] Even so, despite the absence of accuracy studies of universal screening, it is assumed that the accuracy for other diseases must be higher than ROP. Regarding economic evaluation studies, expanding coverage through universal screening can reduce the cost of the procedure, making the screening proposal more efficient. Besides, the costs of remote grading system reading centre were not calculated, as we considered a tertiary centre where all resources were already available.

RetCamP has particular limitations, such as resolution of the images, especially when there is no clear ocular media, and difficulty in capturing images of dark fundus or of extreme periphery (zone III).[40 41] Another limitation is the scarcity of data related to the structure and coverage of the current model (RRT) of neonatal screening. Moreover, there is limited data disclosure from the ROP screening network. In this study, we tried to simulate the coverage network of the reference scenario through assumptions that were discussed during the face validity process.

Face validity, despite being considered an important stage in BIA studies,[31] is not yet routinely performed in economic evaluation reports. In the present study, the specialist's knowledge of the Rio de Janeiro neonatal government healthcare added value to this research.

Moreover, the portable wide-field digital camera handling was important to estimate the cost of human resources and the efficiency of the examination. Our results show an efficiency gain after the learning period, with a reduction of examination execution time of almost 50%. In addition, the technology would reduce the opportunity cost of the paediatrician and the ophthalmologist since it could be handled by non-medical healthcare professional force.

It is still not well known if the implementation of universal WFDI would be appropriate worldwide. The majority of ocular abnormalities found in universal screening studies are transitory and will not necessarily compromise visual development.[19] However, the Brazilian health system has some peculiarities that may justify the implementation of universal WFDI in the country. First, the majority of deliveries are in hospital units[42] and as a routine the child remains at least 48 hours in the maternity ward before hospital discharge.[43] Second, similar to India, there is an important lack of trained professionals to perform the current screening methods, making it impossible to cover all live births.[19] Third, referral networks are usually inefficient, leading to a delay in diagnosis and treatment.[15] Considering the Brazilian scenario, universal WFDI could be a solution to improve the quality and efficiency of neonatal screening, especially because a reading centre based in a tertiary hospital may facilitate referral and consequently treatment of blinding eye diseases.

CONCLUSION

The results provided by our study can help healthcare managers assess the feasibility of incorporating WFDI in government maternity hospitals in Rio de Janeiro. Less than 1% of the resources allocated to the city's government healthcare system could be invested over a 5-year

period to improve identification of the causes of childhood visual impairment, thus considering it one of the highest government healthcare priorities. Furthermore, future studies should be carried out to calculate the budget impact of the implementation of WFDI in the Brazilian health system.

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Patient consent for publication Not required.

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