A Study Protocol on the Situational Analysis on the Current Practice of Screening and Treatment of Retinopathy of Prematurity (ROP)

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ABSTRACT

Objective: The study protocolaims to provide an overview of the current practice of screening and treatment of ROP in the selected, to estimate the proportion of childhood blindness due to ROP and assess the number of premature babies at risk for ROP.

Methods: The study protocol is a descriptive, cross sectional study design using survey questionnaire to be sent out to pediatric ophthalmologists, vitreo-retina specialists and division heads of the neonatal intensive care units of different hospitals in a selected area. Student records and medical abstracts from local schools for the blind will be obtained and will be reviewed. All qualitative data will be reported by frequency distribution and percentages. Extrapolation on the proportion of ROP in the area will be done.

Conclusion: Results from the study can show an overview of the current situation of ROP in a selected area and provide the framework for recommendations for programs aimed providing criteria for timely screening and treatment of ROP to prevent complications such as childhood visual impairment and blindness in the country.

Keywords: ROP, retinopathy of prematurity, retrolental fibroplasia, ischemic retinopathy, childhood blindness

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INTRODUCTION

According to the World Health Organization (WHO), childhood blindness refers to a group of conditions occurring in childhood, which could result in blindness or severe visual impairment, and are likely to be untreatable later in life. Severe visual loss in childhood can affect productivity, education, and employment opportunities, thereby reducing the quality of life for visually impaired children.

The major causes of blindness in children vary according to socio-economic development. Various diseases such as measles, vitamin A deficiency, ophthalmianeonatorum and malaria, high risk factors such as malnutrition, and lack of health care facilities with appropriate personnel and equipment for treating eye diseases plague the system for treating eye diseases in developing countries. Despite these, even in these countries, ROP is emerging as an important cause of childhood blindness. ²

Retinopathy of Prematurity (ROP), previously known as retrolental fibroplasia, is an ischemic retinopathy affecting premature and low birth weight infants, which may cause some degree of visual loss, ranging from mild to severe. There is altered development of the retinal vascularization leading to abnormal new vessels that may lead to dire consequences like vitreous hemorrhage and retinal detachment. ROP can also lead to complications such as refractive errors, amblyopia, strabismus, glaucoma, blindness and phthisis. Some of the risk factors for the disease are degree of prematurity, low birth weight, poor weight gain, sepsis and exposure to fluctuating supplemental oxygen. ³

Historically, two epidemics of retinopathy of prematurity have been described in industrialized countries. The first epidemic occurred in the 1940's to 1950's which affected babies in the USA and Western Europe. The principal risk factor for this epidemic was the unmonitored indiscriminate use of supplemental oxygen, affecting babies with mean birth weight of 1370g in both the United Kingdom (UK) and the United States (US). The second epidemic was seen in industrialized countries in the 1970's due to the higher survival rates in extremely premature babies. A "third epidemic" has been described in developing countries as survival rates of premature and low birth weight infants are improving. 2 If appropriate screening and treatment guidelines are implemented, however, ROP as a cause of blindness can be a potentially avoided.

³ Prompt and timely intervention is necessary to optimize the long-term outcome of the child's vision.

In this study protocol, the current situation in a selected area as regards ROP management will be evaluated by providing an overview of policies followed by vitreo-retina specialists and pediatric ophthalmologists in Metro Manila. Likewise, an estimate of the proportion of childhood blindness or visual impairment that is caused by ROP will be obtained by information gathered from local schools for the blind. In addition, Neonatal Intensive Care Units (NICUs) in a selected area will be surveyed to provide an estimate of the number of premature babies at risk for ROP.

METHODOLOGY

The study protocol is a descriptive, cross sectional study using survey questionnaire. The primary objectives of the study are to provide an overview of the current practice of screening and treatment of ROP in a selected area, to estimate the proportion of childhood blindness due to ROP in the area and assess the number of premature babies at risk for ROP. All qualitative data will be reported by frequency distribution and percentages and extrapolation will be done.

Pediatric Ophthalmologists and Vitreo-Retina specialists

A list of the practicing pediatric ophthalmologists and vitreo-retina specialists practicing in the selected area will be retrieved from the local ophthalmological society. Questionnaires will be sent out to all pediatric ophthalmologists and vitreo-retina specialists in the area. The prepared forms include questions on the estimated number of ROP cases seen, diagnosed and treated by consultants, screening and treatment criteria used, the kind of treatment modality used for ROP cases in need of treatment and referral to other subspecialist after treatment. Information about the timing of screening and techniques of examination will also be gathered. Respondents will be contacted via phone or email regarding additional information or clarifications. (Appendices 1 and 2)

Estimate the proportion of ROP

A database search of local blind school/s in

the area will be done to estimate the proportion of childhood blindness or visual impairment identified as due to ROP. Student records and clinical abstracts, when available, will be reviewed from the different schools for the blind in the area. Clinical diagnoses were tallied and the percentage of ROP will be taken. For diagnosed ROP cases, data on the age of gestation, birth weight, course in the NICU and previous treatment will be noted.

Neonatal Intensive Care Units

Hospitals with NICU facilities in the area are listed. A survey on the Neonatal Intensive Care Units (NICU) will done using questionnaire forms to be sent to the Division Heads of these hospitals. The forms include questions on the estimated number of premature babies admitted to the NICU by birth weight and gestational age, survival rates of premature infants, presence of necessary equipment and personnel in the NICU, ROP screening policies in their institution and criteria used for referral of infants with high risk for ROP. For additional information and clarifications, respondents will be contacted by the researchers through telephone or email. (Appendix 3)

International studies on ROP screening and treatment in other countries and international societies will be reviewed for comparison with the ROP guidelines set by the local subspecialty societies. Local national programs regarding ROP, if present, will also be reviewed.

All qualitative data will be presented in frequency distribution and percentages and will be presented in tabular form.

DISCUSSION

ROP is considered as an important and emerging cause of childhood blindness. This study aimed to show the current practices of specialists in ROP screening and treatment, the estimated proportion of childhood blindness caused by ROP and the number of premature babies at risk. This proposal aims to establish the proportion of ROP in a selected area and the show the magnitude of the disease in the area though extrapolation. By assessing the NICU prematurity incidence and survival rates, the number of babies at risk for the development of ROP can be determined. The study protocol aims to show the

importance of timely screening and treatment of ROP cases to prevent complications of ROP such as visual impairment and blindness. An advantage of using the survey questionnaire in this study design is the practical way of colleting large information from a large number of specialists in a short period of time and in a cost effective way. However, survey questionnaires are limiteddue tolow response rates, responses based on recollection or estimates and are based on their interpretation of the question. The responses will be limited to the amount of information being asked without further explanation.

CONCLUSION

Results from study designs like this can provide the framework for recommendations for programs aimed providing criteria for timely screening and treatment of ROP to prevent complications such as childhood visual impairment and blindness in the country.

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APPENDIX I

TOOL FOR ASSESSMENT OF RETINOPATHY OF PREMATURITY (ROP) SCREENING AND TREATMENT PROGRAMS

Situation analysis survey for Pediatric Ophthalmologists

FOREWORD

Retinopathy of prematurity (ROP) is an ocular disorder involving abnormal vascular proliferation in the retina of premature infants which can progress to visual impairment or blindness. Severe visual loss in childhood can affect productivity, education and employment opportunities, thereby reducing the quality of life for visually impaired children. According to WHO, childhood blindness refers to a group of conditions occurring in childhood, which could result in blindness or severe visual impairment that are likely to be untreatable later in life. The major causes of blindness in children vary according to socioeconomic development and accessibility of primary health care. In middle-income countries, retinopathy of prematurity is emerging as an important cause of childhood blindness. The aims of this tool are:

- To provide an estimate of the prevalence of childhood blindness or visual impairment that is caused by Retinopathy of Prematurity (ROP)
- To provide an overview of existing national ROP guidelines, policies and recommendations and their utilization
- To assess the current capacity of NICUs with ROP screening programs and treatment facilities

The purpose of the study is to evaluate the current situation of the country in regards to ROP management. Information collected will be intended for planning a national ROP screening and treatment programs.

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Charity patients

Name:		
	s have you been practicing Pediatr	ric
Which hospital olocation.	or clinic do you practice at? Please	e give name and
Private:		
Public:		
	Retinopathy of Prematurity (ROP) cases in your
	atients are referred to you for scr nopathy of Prematurity per week	
	Name of Clinic/Hospital	# of pts
Private patients		

 How many new ROP cases are diagnosed per weeks 	3.	How many	new ROP	cases are	diagnosed	per week?
--	----	----------	---------	-----------	-----------	-----------

	Name of Clinic/Hospital	# of pts
Private patients		
Charity patients		

4. How many among the diagnosed ROP cases are treated per

	Name of Clinic/Hospital	# of pts
Private patients		
Charity patients		

5. How many new and old ROP cases do you see/follow up per

	Name of Clinic/Hospital	# of pts
Private patients		
Charity patients		

5.	Th	ese cases	are usually	referred	to yo	ou by	(specialty): Pleas
	che	ck all tha	t apply.				
		Retina sp	pecialist			Pedia	tric intensivist
		Neonato	logist			Gene	ral pediatrician
		Others_					•

A. Spontaneously Resolved ROP Patients (patients whose retina eventually achieved complete vascularization without the need for any therapy):

1.	What are the usual findings among your patients with
	resolved ROP?
	☐ regression of vessels
	□ vascularization of entire retina
	☐ attached retina
	□ others (please specify)
	u 1 //

2.	What 1s	your	usual	management in	i patients	with	resolved	1
	ROP?							

What is your usual management in patients with resolve
ROP?
□ observation
□ refraction
☐ glasses prescription
□ others

3.	How often do	you s	see/follow	up	these	patients?
	□ weekly					

Ш	1-2 weeks	
	2-4 weeks	

	□ monthly □ 1-2 months □ 3 months □ others Greated ROP patients (s/p cryo/Anti-VEGF/ Laser IO or cost surgical patients)	□ stormy course in the NICU (pneumonia, blood transfusion,etc) □ poor weight gain (failure to gain w days from birth; weight gain less tha ounce each day for every pound bab equal to 15 grams per kilogram per day	reight within a few in a quarter of an by weighs or about			
·	1. What are the usual findings among your patients with resolved ROP? ☐ regression of vessels ☐ vascularization of entire retina ☐ attached retina ☐ others ☐ What is your usual management in patients with resolved ROP? ☐ observation	□ parent's request □ Others(please specify)				
3	☐ refraction ☐ glasses prescription ☐ others					
С. Г	☐ 2-4 weeks ☐ monthly ☐ 1-2 months ☐ 3 months ☐ others Do you do ROP screening?					
	Yes No res, please proceed. If no, then you have completed the	examination Others C. Do you do scleral depression during in				
	tionnaire. Thank you. EENING ROP	ophthalmoscopy? □ Yes □ No				
W	Age: □ ≤28 weeks AOG	d. How do you record the clinical findings? ☐ drawing ☐ photo (pls specify machine used				
	□ ≤30 weeks AOG □ ≤ 32 weeks AOG □ Others (please specify)	4. What is the usual interval of examinations for the following patients:	s/follow up period			
(OR		2-3 months Others			
]	Birth weight	Stage 1 Stage 2				
	$\square \le 1250 \text{ grams}$	Stage 3				
	$\square \le 1500 \text{ grams}$ $\square \le 1800 \text{ grams}$	Threshold dse Stage 4a				
	Others (please specify)	Stage 4b				
(OR	Stage 5/End Stage				
(Other criteria Other babies / larger babies with prolonged oxygen therapy (use of oxygen hood, nasal cannula, nasal prongs, oxygen dependency at 28 days of age or oxygen dependency at 36 weeks corrected gestational age)	TREATMENT 1. Do you treat Retinopathy of Prematurity (I Yes No	ROP) cases?			

2. If yes, how many new and old ROP cases are treated in a week?

Treatment	# Private patients	# Charity patients
Laser Indirect		
Ophthalmoscopy		
Anti-VEGF injection		
Cryotherapy		
Surgery		
Others (pls specify)		

3.	Do you refer to other specialist for treatment of ROP? ☐ Yes ☐ No
4.	When do you refer patients to other specialists for ROP
	treatment?
	☐ Surgical intervention needed
	☐ Laser IO intervention needed
	☐ Anti-VEGF injection needed
	☐ cryotherapy intervention needed
	others (please specify)
_	W. 1
5.	What criteria for treatment do you follow?
	☐ CRYO-ROP Threshold: Zone 1-2, Stage 3, 5 contiguous
	or 8 cumulative clock hours with plus disease
	\square ETROP Type 1 – Zone 1, any stage with plus OR Zone 1,
	stage 3 without plus OR Zone 1-2, Stage 3 with plus

What is your usual treatment for: please check treatment per stage

□ others

	Observe	Cryotx	Laser IO	Anti VEGF	Surgery Please	Others Please
				Please	specify	specify
				specify	procedure	
				drug		
Stage 1						
Stage 2						
Stage 3						
Threshold						
disease						
Stage 4a						
Stage 4b						
Stage 5						

7	What clinical findings do you look for in clinical examination
/ •	
	to say that treatment is completed and satisfactory? (please
	check all that applies)
	☐ regression of vessels
	☐ decreased tortuosity of new vessels
	☐ more quiet ridge
	□ vascularization of entire retina
	□ attached retina
	others (please specify)

8. What is the interval of follow up after treatment?

	weekly	2-3 weeks	monthly	2-3 months	Others
Stage 1					
Stage 2					
Stage 3					
Threshold dse					
Stage 4a					
Stage 4b					
Stage 5					

Thank you for your time.

APPENDIX II

TOOL FOR ASSESSMENT OF RETINOPATHY OF PREMATURITY (ROP) SCREENING AND TREATMENT PROGRAMS

Situation analysis survey for Retina Specialists

FOREWORD

Retinopathy of prematurity (ROP) is an ocular disorder involving abnormal vascular proliferation in the retina of premature infants which can progress to visual impairment or blindness. Severe visual loss in childhood can affect productivity, education and employment opportunities, thereby reducing the quality of life for visually impaired children. According to WHO, childhood blindness refers to a group of conditions occurring in childhood, which could result in blindness or severe visual impairment that are likely to be untreatable later in life. The major causes of blindness in children vary according to socioeconomic development and accessibility of primary health care. In middle-income countries, retinopathy of prematurity is emerging as an important cause of childhood blindness. The aims of this tool are:

- To provide an estimate of the prevalence of childhood blindness or visual impairment that is caused by Retinopathy of Prematurity (ROP)
- To provide an overview of existing national ROP guidelines, policies and recommendations and their utilization
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Name:	5. These cases are usually referred by (specialty): please check all
How many years have you been practicing as Vitreo-Retina Specialist?	that apply: Neonatologist Pediatrician Pediatric Ophthalmologist
Which hospital or clinic do you practice at? Please give name and location.	Others
Private:	 Regarding the criteria for identifying babies at risk of ROP, which do you follow? (please check all that applies) A Age:
Public:	□ ≤ 28 weeks AOG
For numbers 1-4, please give your best estimate. Thank you.	OR
How many patients are referred to you for screening for possible Retinopathy of Prematurity (ROP) per week?	B. Birth weight □ ≤ 1250 grams □ ≤ 1500 grams □ ≤ 1800 grams
Name of Clinic/Hospital # of pts Private patients	☐ Others (please specify)
Private patients	OR
Charity patients	C. Other criteria □ older babies / larger babies with prolonged oxygen therapy (use of oxygen hood, nasal cannula, nasal prongs, oxygen dependency at 28 days of age or oxygen dependency at 36 weeks corrected gestational age)
2. How many new ROP cases are diagnosed per week?	☐ stormy course in the NICU (intubation, sepsis, pneumonia, blood transfusion, etc) ☐ poor weight gain (failure to gain weight within a few
Private patients Mame of Clinic/Hospital # of pts	days from birth; weight gain less than a quarter of an ounce each day for every pound baby weighs or about equal to 15 grams per kilogram per day) □ parent's request
Charity patients	Others (please specify)
3. How many new and old ROP cases do you see/follow up per week? Name of Clinic/Hospital # of pts Private patients # of pts	D. Which among the established guidelines do you usually follow for screening and treatment of ROP? ☐ The Early Treatment for Retinopathy of Prematurity Study (ETROP) ☐ Cryotherapy for Retinopathy of Prematurity Study (CRYO-ROP) ☐ Policy statement of VRSP, PSPOS and PPS ☐ Others (please specify)
	7. Annih sa an in anni anni lla anni anni anni ann
Charity patients	 7. At what age do you usually perform screening for those at risk for ROP? □ 31-33 weeks Post conceptual age □ 4-6 weeks after birth □ whichever is later
4. How many newly diagnosed ROP cases are treated in a week?	□ whichever is earlier □ immediately after referral
Treatment # Private patients # Charity patients	Others
Laser Indirect Ophthalmoscopy Anti-VEGF injection Cryotherapy Surgery	8. Regarding clinical examination of these patients, A. What is your usual topical cycloplegic drugs used? ☐ Tropicamide 0.5% combined with Phenylephrine 0.5% (SanMyd) eyedrops, 1drop q15 mins x 3 doses prior to
Surgery Others (pls specify)	examination ☐ Tropicamide 0.5% eyedrops, then Phenylephrine 0.5% (separate) 1 drop q15mins x 3 doses prior to examination ☐ Others (pls specify drug and dose)

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☐ To	ination	oparacain	e 0.5%	∕₀ imı	mediately		□ vascı □ at	tached reti	of entire re			
	C. Do you do scleral depression during Indirect						12. What is t	he interval	l of follow	ap after tr	eatment?	
	thalmosco	bàs						weekly	2-3 weeks	monthly	2-3 months	Others
□ Ye							Stage 1					
□N	O						Stage 2					
	do you re than 1 ite		clinical	finding	gs? You ma	ıy check	Stage 3 Threshold disease					
	awing with						Stage 4a					
			machin	e used:			Stage 4b					
	OP form	or op)					Stage 5					
E. What	nts:				ns for the fo		☐ Gene	itric Ophtl eral Ophth	ecialist/s af nalmologists almologists specify)	3	ient	
	weekly	2-3 week	ks mon	thly 2-	-3 months	Others	711 1 (. ,.				
Stage 1 Stage 2							Thank you f	or your tin	11C.			
Stage 2 Stage 3				_					APPENI	MY III		
Threshold									7 7 1 1 171 N L)1/X 111		
disease								то от	L DOR 1	2012023		
Stage 4a											ENT OF	
Stage 4b							RETIN	IOPATH	IY OF PI	REMAT	URITY (R	ROP)
Stage 5 Non ROP/							SCREEN	IING AI	ND TRE	ATMEN	IT PROG	RAMS
Immature												
Retina patien	ts						Situa	tion anal	lysis surve	ey for No	eonatal Ca	ıre
stage other	3 without	plus OR	Zone 1	-2, Stag	h plus OR ge 3 with p	lus 		of pren mpairme ood can	nature intent or blin affect pro	fants wh ndness. S oductivit	nich can p Severe vis ty, educati	rogres ual los on and
stage)							quality of					
	Observe	1 1	Laser	Anti	Surgery	Others	to WHO,					
		theraphy	IO	VEGF Please		Please specify	conditions					
				specify		openi,	in blindne					
				drug			to be unt					
Stage 1												
C+ 2							blindness					
Stage 2							developm					
Stage 3							care. In prematuri					
Threshold											is tool are:	
disease					1							
Stage 4a							• To p	rovide a	ın estima	te of th	ne prevale	nce of
Stage 4b							childl	nood blir	ndness or	visual in	mpairmen	t that i
Stage 5							 To pr 	ovide an	overview	of exist	naturity (Reting nation	al ŔOl
		nt is com			linical exar		their • To p	utilizatio rovide a	n n estimat	e on pr	nmendatio rematurity,	acces
☐ regre	ssion of v	essels	new vess	els.			to in	tensive n		are, and	l survival	

• To assess the current capacity of NICUs with ROP screening programs and treatment facilities

The purpose of the study is to evaluate the current situation of the country in regards to ROP management. Information collected will be intended for planning a national ROP screening and treatment programs.

	©2013		
N	ame:		
H	ow many years have you l	been practicing	as a Neonatologist?
Н	ospital Name: Private Public		
1.	Estimate Number of Tomonth?	otal Admissions	in the NICU per
2.	Estimate number of premper month by:	nature babies ad	mitted to the NICU
	Birth weight category: i. ≤ 1500 grams ii. ≤ 2500 grams		⁰ / ₀
	Gestational Age: i. ≤ 30 weeks ii. ≤ 37 weeks	#	0/0
3.	Estimate number of survithe NICU per month by:	iving premature	babies admitted in
	Birth weight category: i. ≤ 1500 grams ii. ≤ 2500 grams		⁰ / ₀
	Gestational Age: i. ≤ 30 weeks ii. ≤ 37 weeks	#	0/0
4.	Estimate number prematu per month by:	are babies admitt	ted in the NICU
	i. those with prolonged of ii. those with stormy cou pneumonia, blood tran iii. those with poor weigh	arse in the NICI	J (intubated, sepsis,
5.	Human Resources:		
	A '1	Number of H	uman Resources
	Availa		
	Neonatologists Neonatology Fellow		
	Pediatician		
	Pediatric Resident		
	CU Nurse		
_	Staff Nurse		
1	Auxillary Nurse		

	available in the NICU: ii. How many preterm babies are supervised by each nurse?
6.	Infrastructure and Equipments:
	i. Are these equiptments available in your NICU? Cots
7.	Does the NICU in your institution have an established referral system for ROP patients to the ophthalmologists? □ Yes □ No
8.	To whom do you refer Retinopathy of Prematurity patients: (please check all that apply) General Ophthalmologists Vitreo-Retina specialists Pediatric Ophthalmologists Fellows of the Ophthalmology Department Others
9.	What criteria do you use for referral of ROP patients?
	Age: □ ≤ 28 weeks AOG □ ≤ 30 weeks AOG □ ≤ 32 weeks AOG □ Others (please specify)
	OR
	Birth weight □ ≤ 1250 grams □ ≤1500 grams □ ≤1800 grams □ Others (please specify)
	OR
	Other criteria Older babies / larger babies with prolonged oxygen therapy stormy course in the NICU (intubation, sepsis, pneumonia, blood transfusion etc) poor weight gain parents request
10	Does your hospital have the facilities for treatment of these ROP patients?
Th	ank you for your time.

i. Please provide an estimate number of human resources

Respiratory Therapist General Doctor