MASTER OF PUBLIC HEALTH

A cooperative program of

Johns Hopkins Bloomberg School of Public Health
&
The IIHMR University

Practicum Training at Public Health Foundation of India, Delhi

by

Dr Geetanjali Kapoor

IIHMR / JHSPH MPH
2013-2015

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'Standardization of a screening instrument for RBSK: a pilot study'

by

Dr Geetanjali Kapoor

Under the guidance of
Professor Barun Kanjilal

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TO WHOMSOEVER MAY CONCERN

This is to certify that Dr Geetanjali Kapoor, student of Master of Public Health Program, has done her practicum training while being associated with Public Health Foundation of India- Delhi on the topic 'Standardization of a screening instrument for RBSK: a pilot study' from3rd Nov 2014 until Januaryend, 2015. The program is offered by Institute of Health Management Research, Jaipur in cooperation with Johns Hopkins Bloomberg School of Public Health, Baltimore. She has successfully carried out the study designated to her during practicum training and her approach to the study has been sincere, scientific and analytical.

The practicum training is in fulfillment of the course requirements. We wish her all success in all her future endeavors.

Dr Ashok Kaushik	Prof Barun Kanjilal	Dr Preeti Negandhi
Dean	Practicum Advisor	Assistant Professor
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CERTIFICATE BY SCHOLAR

This is to certify that the Practicum Project titled **'Standardization of a screening instrument for RBSK: a pilot study'** and submitted by **Dr Geetanjali Kapoor,** Enrollment No: **IIHMR-JHU/MPH/2013-2015/1-2**, under the supervision of **Professor Barun Kanjilal** for award of **Master of Public Health**, carried out during the period from **3rd November 2014 until January-end 2015**, embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.

Geetanjali Kapoor
Signature

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The present report represents my practical work which was conducted during the Master in Public Health course. Although it was conducted as an independent study, it could not have been accomplished without professional help extended by experienced faculty and doctors.

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Contents

PROJECT TITLE - Standardization of a screening instrument for RBSK*: a pilot study

* Rashtriya Swasthya Bal Karyakram or Child Health Screening and Early Intervention Services under the National Rural Health Mission, India

ABSTRACT

Objectives: To develop and validate a screening instrument for birth defects entailed under Child health screening and early intervention services or Rashtriya Swasthya Bal Karyakram (RBSK), for 0-6 years age group.

Methodology: Questionnaire for screening of 9 birth defects was constructed and administered on 40 children in the pre-school age group at the ESI Hospital of Gurgaon city in India. Quota sampling was followed for recruitment of the eligible children and responses to the administered questionnaire were obtained from consenting primary care takers. Validation of the screening tool was assessed by calculating its sensitivity and specificity.

Results: Sensitivity of the screening tool was 100% while the specificity was 91%

Conclusion: The screening tool on birth defects has been constructed with the intention of use by healthcare workers. The tool is brief, easy to comprehend and cost-effective. Being a pilot work, there were several limitations to the study that could compromise on the calculated validity. Recommendations have been put forth for further refinement of the tool prior to its intended use.

Key words: Birth defects, validation, pilot studies, RBSK.

INTRODUCTION

Birth defects are defined as structural or functional abnormalities, including metabolism, that are present since birth.[1] Each year 1 in every 33 babies is born with birth defects in USA[2]. According to the March of Dimes Global Report on Birth Defects (2006) and the Sixty third World Health Assembly Provisional Agenda, serious birth defects constitute 6-7 % of all births across the world.[1,3] Countries such as Sudan, Saudi Arabia, Pakistan, Nigeria, India, Nepal, Egypt have a high prevalence of birth defects (greater than 60 per 1000 live births) while developed nations such as UK, USA, France and Italy have a lower prevalence (less than 50).[4] Incidence of neural tube defects was as high as 6-8 per 1000 live births in certain village clusters of India, which is perhaps one of the highest in the world.[5]

Birth defect or congenital disorder, as they are often known, [3] can arise owing to risk factors which may be genetic, partially genetic or post-conceptional.[1, 6] Maternal malnutrition and poor health, poverty, more consanguineous marriages, increased risk of exposure to teratogens and poor preventive health care are various reasons for a higher magnitude of birth defects in the low and middle income countries.[1, 7]

Serious birth defects can be lethal or cause lifelong disabilities. It can affect any part of the body. Congenital malformations, deformations and chromosomal abnormalities was collectively ranked as the first leading cause of infant death accounting for about 20% of all infant deaths in USA, for the year 2008 and 2009.[8] Global Burden of disease 2004 update states that out of all deaths under-5 years of age, more than one third occur in the period 0-27 (neonatal) period; with congenital anomalies constituting about 7% of neonatal deaths.[4]

Since birth defects can be of varying severity and may not be always apparent at birth, special tests for diagnosis is required.[2] A timely intervention can save lives or reduce the severity in 70% of cases.[1] As public health professionals, it becomes essential to have a multi-disciplinary approach emphasizing on primary, secondary and tertiary level of prevention for birth defects.[9] Primary prevention include steps taken prior to pregnancy that reduce the risk of birth defects;

secondary prevention focuses on an early detection of asymptomatic cases by screening procedures and a timely intervention so as to limit further progress of the disease; tertiary prevention targets on reducing the negative impact of the defect on the child.[9]

Screening for health problems can occur at different age groups such as pre natal, birth, newborns, child, adolescent or geriatric, depending on the intended objectives of the health program. Screening process can bring about apprehensions among the healthy as it intends to identify the high risk population, [10] yet, if followed up well, it also helps to improve the quality of life by reducing co-morbidities[9] and allowing individuals to lead a more productive life.

Simple screening tools which do not pose any risk are welcomed by the parents.[10] Quality of a newly available screening or diagnostic test, and hence its subsequent utility, depends on the test validity, predictive value and repeatability.[11] Validity has two components- sensitivity (ability of a test to correctly identify those with the disease) and specificity (ability of a test to correctly identify those devoid of the disease).[11] Any positive screening result must be followed up in a timely manner so as to facilitate an early diagnosis and better management.

CHILD HEALTH SCREENING AND EARLY INTERVENTION SERVICES- RASHTRIYA BAL SWASTHYA KARYAKRAM

Considering that India did not have a defined approach to screen children for common health ailments until 2012, the Indian government launched the 'Child Health Screening and Early Intervention Services' also known as 'Rashtriya Bal Swasthya Karyakram (RBSK)' with an aim to provide screening and timely management for a set of 30 childhood health conditions or the 4Ds. The 4Ds include - Defects at birth, Diseases in children, Deficiency conditions and Developmental Delays including Disabilities.[12, 13] The 9 birth defects enlisted under RBSK are Neural Tube Defects, Downs Syndrome, Cleft lip-palate, Club foot, Development Dysplasia of the Hip, Congenital Deafness, Congenital Cataract, Congenital Heart Disease and Retinopathy of Prematurity.

RBSK was launched in April 2013 under the National Rural Health Mission (NRHM) by the Ministry of Health and Family Welfare of India.[12] The beneficiaries covered by the program include newborns, attendees of anganwadi centers and students at government schools. As a part of the program, healthcare workers, anganwadi staff and mobile health teams actively screen children and follow them up with timely referrals to specialist centers.[13] Early detection of birth defects, diseases, deficiencies, development delays, including disabilities, as entailed in the program, is a step towards improving the quality of life in the impacted children, reducing the severity of the ailment and towards the achievement of universal health care with priority accorded to the vulnerable and marginalized population .[13]

As early years of a child's life are critical for survival and development, it is hoped that the comprehensive health care provided under the RBSK would help in improvement of overall quality of a child's life and reduce severity of ailments in the impacted children.[12, 13]

OUTLINE OF THE MPH PRACTICUM

The MPH practicum study has been done for gaining a practical experience in the Indian public health setting and for fulfillment of curriculum requirement for the Master in Public Health Program, a collaborative program between Bloomberg School of Public Health, Johns Hopkins and Indian Institute of Health Management Research, Jaipur. The practicum study was conceptualized in conjunction with the research team at Indian Institute of Public Health, Delhi (Public Health Foundation of India-PHFI), which at the same time was planning for a state evaluation of the RBSK. The study got an impetus from the aforementioned program and focuses on the development and validation of a questionnaire (quantitative data collection instrument) to screen birth defects (as entailed under the RBSK) for children in the age group 0-6 years.

Although the RBSK focuses on screening and early intervention, screening questionnaire(s) were not found enlisted anywhere in the operational guidelines of RBSK program.[13] Further, neither could any screening tool be found from online search, which could be readily used by the Indian healthcare workers. Hence, the MPH Practicum is a pilot work on construction of a meaningful and simple questionnaire for screening of the birth defects. It is hoped that the tool which is

being developed by this study, might be of future use to health care workers in the Indian context, owing to reasons such as brevity, cost-effectiveness, ease of comprehension as well as ease of administration and thereby result in long lasting implications for improving child health. The tool was developed both in English and Hindi and consists of easy to understand words.

OBJECTIVES OF THE STUDY

To develop and validate a screening instrument for birth defects entailed under Child health screening and early intervention services or Rashtriya Swasthya Bal Karyakram (RBSK), for 0-6 years age group.

METHODOLOGY

Type of study

The MPH practicum project was conducted as a pilot study at a single center namely Employees' State Insurance Corporation (ESIC) Hospital of Gurgaon city of India. The hospital was chosen as it caters to a pan India population and provides a good representation of the lower socio economic strata of India. (ESIC hospitals provide secondary care to the state industrial workers and their families. Most of the industrial workers hail from various rural areas across India).
The practicum study was of a cross-sectional design and lasted for about 3 months, starting the first week of November, 2014 until end January 2015. Data collection was done over a 5 week period starting 18th Dec 2014 until 24th January 2015.

Approval

Ethical approval for the study was obtained from the parent institute, IIHMR, Jaipur prior to commencement of all practical work. Permission was also obtained from the Medical Commissioner, ESIC Hospitals as well as from the Medical Superintendent, ESIC Hospital Gurgaon for doing the study in the chosen hospital.

Sample size

As per available literature, there are no defined criteria on establishing a sample size for pilot studies and depends on factors such as objectives of the study and other larger studies which are in planning.[14, 15] Since objective of the present study was development and validation of a screening instrument for 9 birth defects and there were time plus fund constraints, a larger study was not feasible. Considering these factors, the sample size was limited to 40 in the current study.

Construction of screening tool (questionnaire) and interpretation

The study began with construction of a question pool by reviewing published literature and online resources on birth defects.[16-37] The initial question pool comprised of about 70 questions and included few images.[19,21,23,26,31] To assess the content validity[38] of the questions, independent discussions with three experts in the field of childhood illnesses was done. This was followed by retention of the most relevant questions thereby shortening the screening questionnaire to a 44 item list. The 44 items consisted of specific questions for each of the 9 birth defects namely neural tube defects[16-19] (6 items), downs syndrome[20-21] (6 items), cleft lip palate[22,23] (5 items), club foot[24-26] (5 items), development dysplasia of the hip[27,28] (4 items), congenital cataract[29,31] (4 items), congenital deafness[32,33] (5 items), congenital heart disease[34,35](6 items) and retinopathy of prematurity[36,37] (3 items).

Each question had 4 possible options namely ‘yes’, ‘no’, ‘not applicable’ and ‘does not know’. As the questionnaire comprised of limited and specific questions per birth defect, any response (excluding ‘not applicable’ and ‘does not know’) which deviated from normalcy, was interpreted as a positive screening result.

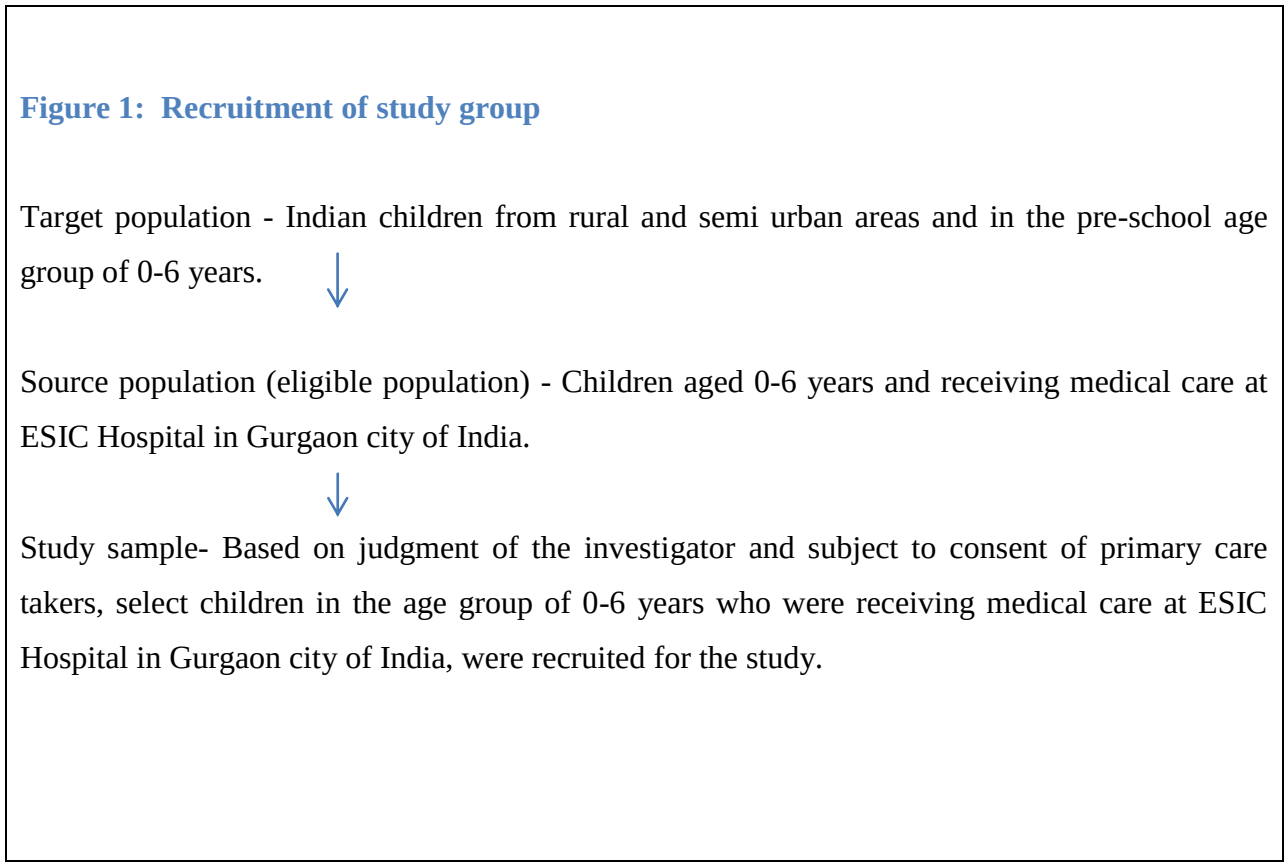
All questions were translated into the regional language (Hindi) and pretested on a select group of professionals and patients for assessing the language comprehensibility (construct validity[38]) of the questions. After incorporation of minor changes to the language, the screening tool was ready for administration to the study group.

Eligibility criteria and sampling method

All those children who were receiving medical care at 3 mutually exclusive departments namely paediatric outpatient unit, paediatric ward and neonatal intensive care unit (NICU) of the chosen hospital, were the source (eligible) population. Identification of the study population from the source population was done by quota sampling[39] and based on the objective discretion of the primary investigator. Children who were 6 years or older were not included in the study. Generally sick children or those born to pregnant mothers with abnormal ultrasonograms were identified. It was presumed that children with birth defects may not have been easily picked up had random selection been done during the limited time frame and that’s why we resorted to quota sampling.[39] Informed consent of the primary caretakers of the identified children was a pre-requisite prior to their final inclusion in the study group.

Fig. 1 illustrates the recruitment of study sample from the bigger source population.

Figure 1: Recruitment of study group



Data collection and method of analysis

The developed questionnaire was administered to the primary caretakers in order to ascertain presence of specific clinical features in their child. Incase more than one primary care giver was present, only one was requested to participate. Child's presence was preferred during the interview as some symptoms could also be verified by the investigator. Responses which deviated from normalcy were interpretation as positive screening result for the specific birth defect. All screening results were written on the questionnaire of each child. Thereafter patient records were checked and the paediatrician's diagnosis (gold standard[40]) was also written on the same questionnaire.

Results were analyzed by calculating the percentage of diseased children who were correctly identified by the screening tool (sensitivity) and percentage of non-diseased children who were correctly identified by the screening tool (specificity).[11] Inter-rater and intra-rater reliability of the screening tool was not assessed.

RESULTS

Primary care takers of all the 40 identified children willingly provided their consent for participation in the study. Written consent was obtained from 38 primary care takers followed by a direct interview in presence of their child. As 2 newborns who were identified for the study, were critical and referred to a tertiary care center, their parents could not be interviewed immediately. Their phone numbers were noted and followed up by seeking their telephonic consent and a telephonic interview.

Out of 40 children, 8 children screened positive for one or more birth defects. However, as per doctor's diagnosis only 5 of these children had birth defects. Thus the screening tool identified 5 true positives and 3 false positives. In addition the tool identified 32 true negatives and 0 false negatives.

Table 1 provides the demographic characteristics of the study group. Mean age was 13.2 months (1.1 years) and sex ratio (M: F) was 1.5: 1. Average time for the interview was 12 minutes.

Table 1: Demographic characteristics of the study group

Sample size- 40
Mean age- 13.2 months (1.1 years)
Male: Female- 1.5:1

Table 2 provides screening results obtained after administration of the developed questionnaire to the primary caretakers of the children recruited for the study.

Table 2: Results obtained on tool (questionnaire) administration for screening birth defects

40 children (study sample)	Children screened positive for birth defects N=8		Children screened negative for birth defects N=32
	Congenital heart disease only	4	
	Cleft palate only	1	
	NTD with DDH	1	
	NTD with club foot	1	
	NTD with CHD	1	

Table 3 provides the validity (sensitivity and specificity) of the screening questionnaire. Validity was not assessed individually for each of the birth defects.

Table 3: Validity of the tool (questionnaire) for screening birth defects

	Birth defect positive (doctor's diagnosis)	Birth defect negative (doctor's diagnosis)
Birth defect positive (screening tool)	5	3
Birth defect negative (screening tool)	0	32
Sensitivity=(5/5) X 100= 100%		
Specificity= (32/35) X 100=91.4%		

DISCUSSION

Birth defects are medical conditions that occur since birth and can be of varying severity.[1] It is considered as an important public health issue [1, 41] and is implicated as a cause of 20% of all infant deaths.[8] Unfortunately the problem is often overlooked in many low and middle income countries owing to poor health care systems and lack of adequate screening programs during pregnancy and early childhood. It is essential that more emphasis gets laid on research, diagnostics and building better health care systems in these countries, thereby facilitating in an early identification and timely referral of suspected cases. Appropriate intervention and good

case management can help in arresting the further progression of the defects, improving the quality of life of impacted children and assessing the true magnitude of the problem.

The present study was done with an objective to standardize a questionnaire for screening birth defects as we could not find any such tool from the available literature and online resources. The intention behind such an objective was to create a readily available tool for use by health care workers while screening for the 9 birth defects that are enlisted under RBSK.[13] Brevity of the tool, simple language, use of pictures and cost-effectiveness are the added advantages of the developed tool. Since the RBSK was launched only in 2013, and has yet to get evaluated, the screening tool which has been developed during the MPH Practicum project can also be beneficial to research teams in their evaluation of RBSK in different Indian geographic regions. The tool can also serve as an aid for screening of birth defects in other related child programs and have long lasting implications in improvement of child health.

Results obtained on administration of the tool over 40 children who were under 6 years and receiving medical care at a secondary care hospital, yielded 5 true positives, 3 false positives, 32 true negatives and 0 false negatives. Doctor's diagnosis was considered as the gold standard against which screening results were assessed.[40] Based on the screening results obtained, the tool was found to have a high sensitivity (high probability of correctly identifying children with birth defects) as well as a high specificity (high probability of correctly identifying the children without birth defects).[11]

We had resorted to quota sampling for this study owing to the following reasons. First, quota sampling is less expensive and ours was a self-budgeted study. Second, we did not have a fixed sampling frame owing to varying daily patient load in the hospital. Third, quota sampling is less labor intensive and could be done in a short period of time, thereby suiting our limited time constraint.[39] Fourth, our study was a pilot work done for construction and validation of an instrument (screening questionnaire), and the study results help us to put forth recommendations for larger similar studies. Unfortunately, more often statistical significance is highlighted to

assess success of a pilot study instead of the feasibility, the latter being the real motive for all pilot work.[15] As stated by Thabane et al about an African proverb from the Ashanti people in Ghana, "*You never test the depth of a river with both feet*"[15].

However, taking cognizance of the fact that a small sample size was screened and non-probability sampling was done, there could have been a selection bias introduced in the study with implications on the validation results.[39] Hence generalizability of the results over a larger population may not be justified in such cases. It has also been noted in earlier studies that because primary caretakers of children are proxy respondents[10], information bias may be introduced in the study. In addition, being a general hospital providing secondary care, children with rare birth defects may not have sought medical care at the chosen study center. Hence not all the 9 birth defects could be screened by the constructed tool and validation could not be calculated for each birth defect separately.

SUGGESTIONS

According to final report of the pooling project, "the ultimate test of the validity and generalizability of scientific observations is the ability, based on them, to predict phenomena and circumstances independent of those used to record the original findings.[42]" Owing to various limitations encountered during the pilot work, suggestions have been put forth for further refinements of the screening tool, in order to better generalize the findings.

1. Tertiary care hospitals or children's hospitals are better equipped in handling complicated and rare health problems. Hence studies conducted at such centers provide a greater chance of selecting impacted cases and also covering the 9 defects.
2. Probabilistic sampling method is more representative of the population, has minimal bias and findings can be better generalized in such a situation.
3. A larger study sample also increases chances of picking up birth defects as compared to a smaller sample.
4. Apart from validation, test-retest and inter-rater reliability may also be assessed for the screening tool.

CONCLUSION

Birth defects are a global public health problem and have a higher prevalence in in low and middle income countries as compared to the developed nations. Early detection and timely management of birth defects is imperative for improving the quality of life of the impacted individual and reducing co-morbidities. The present study was based on construction and validation of a tool for screening of nine birth defects that have been listed in the Rashtriya Bal Swasthya Karyakram, a childhood screening and early intervention program. The tool has been designed for use at the level of health care workers and is available in English as well as Hindi. It is a brief questionnaire format, cost-effective, uses simple language and can be administered with ease. However, as the standardization process was done in form of a pilot project, we experienced limitations in the study. Hence our findings may not be generalizable and we would suggest further standardization of the tool.

REFERENCES

1. Christianson A, Howson CP, Modell B. March of Dimes: Global report on birth defects: The hidden toll of dying and disable children [Internet]. New York: White Plains 2006:29-35; p 4. Available from: http://www.marchofdimes.org/materials/global-report-on-birth-defects-the-hidden-toll-of-dying-and-disabled-children-executive-summary.pdf
2. CDC. Facts about birth defects [Internet]. [updated 2014 Oct 20; cited 2015 Jan 2]. Available from: http://www.cdc.gov/ncbddd/birthdefects/facts.html
3. WHO. Birth defects [Internet]. Provisional agenda item 11.7. Report No.: A63/10. [2010 Apr 1; cited 2015 Jan 2]Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_10-en.pdf?ua=1
4. Mathers C, Fat DM, Boerma J. The global burden of disease: 2004 update [Internet]. World Health Organization; 2008, p 14. Available from: http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf
5. Salvi, Vinita S, Damania KR. "Neural tube defects in India—time for action." The Lancet 366.9489 (2005): 871-872.).
6. CDC. Birth defects: Research and tracking [Internet]. [updated 2014 Oct 28; cited 2015 Jan 2].Available from: http://www.cdc.gov/ncbddd/birthdefects/research.html
7. Centers for Disease Control and Prevention (CDC). "National center on birth defects and developmental disabilities." (2009).
8. Kochanek KD et al. "Annual summary of vital statistics: 2009."Pediatrics (2012): peds-2011.
9. Lemacks, Jodi, et al. "Insights from Parents about Caring for a Child with Birth Defects." International journal of environmental research and public health 10.8 (2013): 3465-3482.
10. Knowles R, Griebsch I, Dezateux C, Brown J, Bull C, Wren C. Newborn screening for congenital heart defects: a systematic review and cost-effectiveness analysis. Health Technol Assess [Internet]. 2005 [cited 2015 Jan 9]: 9(44).
11. Gordis L: Epidemiology. 4th edition. Philadelphia: Saunders, Elsevier; c2009 [cited 2015 Jan 11]. Chapter 5 Assessing the validity and reliability of diagnostic and screening tests.
12. 'Sonia Gandhi launches child health screening programme'. The Hindu [Internet]. 2013 Feb 7. [cited 2015 Jan 1]; Maharashtra (IN). Available from: http://www.thehindu.com/todays-paper/tp-in-school/sonia-gandhi-launches-child-health-screening-programme/article4387457.ece
13. Ministry of Health and Family Welfare, Government of India. Operational Guidelines, Rashtriya Bal Swathya Karyakram (RBSK). Child Health Screening and

Early Intervention Services under NRHM. Available from: http://www.unicef.org/india/7._Rastriya_Bal_Swaasthya_karyakaram.pdf
14. Hertzog MA. Considerations in determining sample size for pilot studies. [Internet]. Research in nursing & health 31.2 (2008): 180-191 [cited Dec 1 2014]. Available from: http://onlinelibrary.wiley.com/doi/10.1002/nur.20247/abstract;jsessionid=B27DFC49C921F274856E6CA67D3DE011.f04t04
15. Thabane L et al. "A tutorial on pilot studies: the what, why and how." BMC medical research methodology 10.1 (2010): 1. Available from: http://www.biomedcentral.com/1471-2288/10/1/
16. Jallo GI. Neural Tube Defects Clinical Presentation [Internet]. Medscape. [Updated 2013 Sep 6; cited 2014 Dec 24]. Available from: http://emedicine.medscape.com/article/1177162-clinical
17. March of Dimes. Birth defects: Neural tube defects [Internet]. [Updated 2012 Nov; cited 2014 Dec 24]. Available from: http://www.marchofdimes.org/baby/neural-tube-defects.aspx#
18. CDC. Spina bifida: Facts [Internet]. [Updated 2014 Aug; cited 2014 Dec 24]. Available from: http://www.cdc.gov/ncbddd/spinabifida/facts.html
19. Neural Tube Defects image. Available from: http://2.bp.blogspot.com/_uiyskjNZYt8/TF_1iRmzqYI/AAAAAAAAB8c/ynllCiKKoiE/s1600/NEURAL+TUBE+DEFECTS.jpg
20. CDC. Birth defects: Facts about Downs Syndrome [Internet]. [Updated 2014 Oct 20; cited 2014 Dec 1]. Available from: http://www.cdc.gov/ncbddd/birthdefects/downsyndrome.html
21. Down syndrome image. Available from: https://www.flickr.com/photos/jaymus/8173708065/in/photolist-dshoD8-dGN3Lv-bD9sbg-71uEti-dGN3Mx-xoZJ2-awP3FZ-arZcM7-bJNoYX-5QfA9a-6ySeWZ-mf99tZ-7MvDMA-2Q1Lkq-4yAum-bEYVQ4-kyhEm-kyhBF-5eGcCi-5qhsuy-4Hfjcb-4UEnk5-ugk65-cDGSKJ-pWtWjw-3c8uJq-pZqY2q-bkZa4V-yEXtK-5QfA9g-62bS24-docr5D-cYmKS-FTgRf-dT2FGp-9PHSVQ-54ALN5-54wXEp-54CqUA-54ynmV-54AUPh-54Beu5-54yqfZ-54B1WC-54BuwL-54x4uH-54Bnmf-54BtaY-54Bgxh-54BovW
22. March of Dimes. Birth defects: Cleft lip and cleft palate [Internet]. [Updated 2011 Nov; cited 2014 Dec 14]. Available from: http://www.marchofdimes.org/baby/cleft-lip-and-cleft-palate.aspx
23. Cleft lip image. Available from: https://www.flickr.com/photos/stlchildrens/14143503579/in/set-72157629528955637
24. March of Dimes. Birth defects: Club foot [Internet]. [Updated 2013 Jan; cited 2014 Dec 14]. Available from: http://www.marchofdimes.org/baby/clubfoot.aspx

25. Mayo Clinic Staff. Clubfoot: Symptoms [Internet]. Mayo Foundation for Medical Education and Research [Updated 2013 Mar 23; cited 2014 Nov 18]. Available from: http://www.mayoclinic.org/diseases-conditions/clubfoot/basics/symptoms/con-20027211
26. Image for clubfoot. Available from: https://www.flickr.com/photos/birthinjuryresources/5474112358
27. Tamai J. Development Dysplasia of the Hip: Presentation [Internet]. Medscape. [Updated 2013 Mar 31; cited]. Available from:http://emedicine.medscape.com/article/1248135-overview#a03
28. Developmental Dysplasia of Hip (DDH) [Internet]. OrthopaedicsOne Review. In: OrthopaedicsOne - The Orthopaedic Knowledge Network. Created 2010 Mar 5. [Updated 2014 Aug 23; cited 2014 Dec 10] Available from: http://www.orthopaedicsone.com/pages/viewpage.action?pageId=30507335
29. Congenital Cataracts [Internet]. NHS [Cited 2014 Nov 12]. Available from: http://www.nhs.uk/conditions/cataracts-childhood/pages/introduction.aspx
30. Bashour M. Congenital Cataract Clinical Presentation [Internet]. Medscape [Updated 2014 Mar 5; cited 2014 Dec 4]. Available from: http://emedicine.medscape.com/article/1210837-clinical#a0217
31. Public Health Image Library. CDC. Image of congenital cataract (Image Id 4284)Available from: http://phil.cdc.gov/phil/advancedsearchresults.asp
32. Tidy C. Deafness in Children [Internet]. Patient.co.uk [Updated 2014 Mar 21; cited 2014 Dec 2]. Available from: http://www.patient.co.uk/doctor/deafness-in-children
33. Hartree N. Hearing testing and Screening in young children [Internet]. Patient.co.uk [Updated 2013 May 13; cited 2014 Dec 2]. Available from: http://www.patient.co.uk/doctor/hearing-testing-and-screening-in-young-children
34. March of Dimes. Birth defects [Internet]. March of Dimes Foundation [Updated 2013 Nov; cited 2014 Dec 2]. Available from: http://www.marchofdimes.org/baby/congenital-heart-defects.aspx
35. CDC. Congenital heart defects: Facts about congenital heart defects [Internet]. CDC [Updated 2014 Jul 18; cited 2014 Dec 5]. Available from: http://www.cdc.gov/ncbddd/heartdefects/facts.html
36. Bashour M. Retinopathy of prematurity ophthalmologic approach: Overview and presentation [Internet]. Medscape [Updated 2014 Aug 25; cited 2014 Dec2]. Available from: http://emedicine.medscape.com/article/1225022-overview
37. Chaudhari S et al. Retinopathy of prematurity in a tertiary care center--incidence, risk factors and outcome. Indian pediatrics [Internet]. 46.3 (2009): 219. [cited 2014 Dec 8]. Available from: http://medind.nic.in/ibv/t09/i3/ibvt09i3p219.pdf
38. Phelan C, Wren J. Exploring reliability in academic assessment [Internet]. UNI Office of Academic Assessment; 2005-06 [cited 2015 Jan 8]. Available from:

scholar.google.co.in/scholar?hl=en&q=https%3A%2F%2Fwww.uni.edu%2Fchfasoa%2Freliabilityandvalidity.htm&btnG=
39. Crawford M. ed. Marketing research and information systems. No. 4. Rome: Food & Agriculture Organization of the United Nations; c1997 [cited 2014 Dec 4]. Chapter 7 Sampling in marketing research. Available from: http://www.fao.org/docrep/W3241E/w3241e08.htm#quota%20sampling
40. Gulati S et al. "INCLEN Diagnostic Tool for Neuromotor Impairments (INDT-NMI) for primary care physician: Development and validation." Indian pediatrics 51.8 (2014): 613-619.
41. Boyle CA, Cordero JF. "Birth defects and disabilities: a public health issue for the 21st century." American journal of public health 95.11 (2005): 1884.
42. Relationship of blood pressure, serum cholesterol, smoking habit, relative weight and ECG abnormalities to incidence of major coronary events: final report of the Pooling Project. J Chronic Dis [Internet]. 1978 [cited 2015 Jan 15]: 31:201-306. Available from: http://www.sciencedirect.com/science/article/pii/0021968178900735

APPENDIX 1: QUESTIONNAIRE FOR SCREENING BIRTH DEFECTS IN CHILDREN AGED 0-6 YEARS

Questions for primary screening of birth defects in 0-6 years	Yes 1 No 2 NA 3 Does not know 4
Section A (Neural tube defects or NTD) **भाग A (न्यूरल ट्यूब दोष)** 1. Does your child have any obvious abnormality along the spine since birth, such as fluid filled cystic mass, dimple, hypo/hyperpigmentation, sinus, skin appendage, hairy patch, asymmetrical gluteal cleft or any discharge? क्या आपके बच्चे को जन्म से रीढ़ की हड्डी पर कोई नुक्स ज़ाहिर है जैसे पानी से भरा हुआ मास, गड्ढा या डिंपल, रंगीन या बेरंग निशान, छेद, खाल पर लटकन, बालदार दाग़ या धब्बा , कूल्हे पर नाबराबर त्वचा या कोई बेहता घाव ? 2. Did your child have a large head at birth? क्या आपके बच्चे का सिर जन्म के समय बड़ा था? 3. Does your child have any weakness of lower limbs with loss of sensation since birth? क्या आपके बच्चे को जन्म से निचले अंगों पर कोई कमजोरी तथा सनसनी है? 4. Does your child have any bladder/bowel dysfunction since birth? क्या आपके बच्चे को जन्म से कोई पेशाब या पाखाना संबंधी बीमारी है? 5. Was your child able to hold neck at 3 months and sit at 6 months? क्या आपके बच्चे ने 3 महीने पर गर्दन पकड़ ली थी और 6 महीने पर बैठ पाया था? 6. Does your child have some resemblance to the following presentation? क्या आपके बच्चे का रुप निम्न दिए गए चित्र जैसा कुछकुछ- है? 	

Section B (Down syndrome)
भाग B (डाउन सिंड्रोम)

7. Is your child's face different from a common child's face ?
   क्या आपके बच्चे का चेहरा एक साधारण बच्चे के चेहरे से अलग है?

8. Does your child have a flat nose and/or slanting eyes since birth?
   क्या आपके बच्चे की जनम से नाक चपटी और/अथवा आंखें झुकी हुई है?

9. Does your child's tongue tend to protrude out of the mouth?
   क्या आपके बच्चे की जीभ मुंह के बाहर रहती है?

10. Have you noted a single deep line on your child's palm?
    क्या आपने अपने बच्चे की हथेली पर इकलौती गहरी रेखा देखी है?

11. Is your child shorter than others of his age and has a heavy built?
    क्या आपका बच्चा अपनी उम्र के दूसरे बच्चों की तुलना में, छोटे कद और भारी शरीर का है?

12. Does your child have some resemblance to the following presentation?
    क्या आपके बच्चे का रुप निम्न दिए गए चित्र जैसा कुछ-कुछ है?

Section C (Cleft lip palate)
भाग C (फांक होंठ तालु)

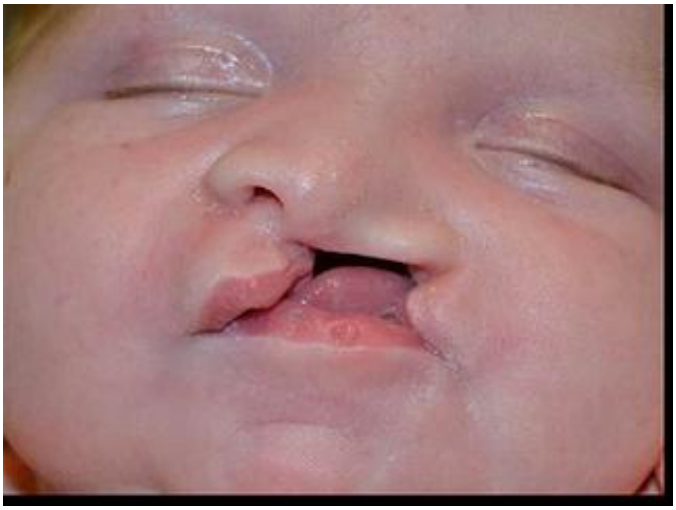
13. Does your child have any cleft on upper lip since birth?
क्या आपके बच्चे का ऊपरी होंठ जन्म से फटा हुआ है?

14. Does your child have any cleft on the palate since birth?
क्या आपके बच्चे के तालु में जन्म से कोई छेद या सुराख़ है?

15. Does your child have any difficulty in feeding since birth?
क्या आपके बच्चे को जन्म से दूध पीने में या खाना खाने में कोई कठिनाई है?

16. Does your child have any speech problem?
क्या आपके बच्चे को बात करने में कोई समस्या है?

17. Does your child have some resemblance to the following presentation?
क्या आपके बच्चे का रुप निम्न दिए गए चित्र जैसा कुछ-कुछ है?



Section D (Talipes- Club foot)
भाग D (क्लब पैर)

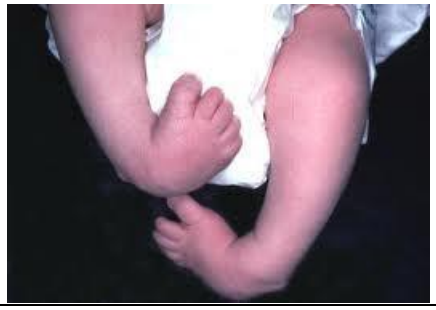
18. Does your child have both the feet of the same size and shape?
    क्या आपके बच्चे के दोनों पैरों का आकार एक जैसा है?

19. Is the top of your child's foot twisted downward and inward?
    क्या आपके बच्चे का पैर बचपन से नीचे तथा अंदर की ओर मुड़ा है?

20. Does your child walk on sides or top of his/her feet instead of sole or bottom of feet?
    क्या आपका बच्चा अपने पैरों के बाहरी हिस्से या पैरों की उँगलियो पर चलता है?

21. Does your child glide when walking?
    क्या आपका बच्चा फिसल कर चलता है?

22. Does your child have some resemblance to the following presentation?
    क्या आपके बच्चे का रुप निम्न दिए गए चित्र जैसा कुछ-कुछ है?



Section E (Developmental dysplasia of the hip- DDH)
भाग E (कूल्हे के विकासात्मक)

23. Have you noted any inequality in your child's leg length?
    क्या आप के बच्चे की दोनों टाँगो की लंबाई एक बराबर है?

24. Does your child have a problem in standing or walking?
    क्या आपके बच्चे को अपने पैरों पर खड़े होने या चलने में कोई समस्या है?

25. Does your child stand or walk with a bend?
    क्या आपका बच्चा टेढ़ा खड़े होता या टेढ़ा चलता है?

26. Does your child have torticollis? क्या आपके बच्चे की गर्दन अकड़ी हुई है?	
Section F (Congenital cataract) **भाग F (जन्मजात मोतियाबिंद)** 27. Is your child's eyesight fine? क्या आपके बच्चे की आंखो की दृष्टि सही है? 28. Is any cloudy patch visible in your child's eye since birth? क्या आपके बच्चे की आंखो में जन्म से कोई सफ़ेद मोतियाँ या बिन्दु है? 29. Does your child have squint? क्या आपके बच्चे की नज़र तिरछी है ? 30. Does your child have some resemblance to the following presentation? क्या आपके बच्चे का रुप निम्न दिए गए चित्र जैसा कुछ-कुछ है? 	
Section G (Congenital deafness) **भाग G (जन्मजात बधिरता)** 31. Does your child have micro pinna or no pinna since birth? क्या आपके बच्चे के दोनो कान जन्म से ठीक आकार के है? 32. Does your child have any hearing deficit since birth? क्या आपका बच्चा जन्म से ठीक सुन पाता है? 33. Did your child have startle response at birth? क्या आपका बच्चा बचपन में उंचे स्वर को सुनकर चौंक जाता था? 34. Could your child speak single words like mama or baba by 1 ½ years of	

age? क्या आपका बच्चा डेढ़ साल की उमर पर मामा या बाबा जैसे एक शब्द बोल सकता था? 35. Does your child mispronounce words? क्या आपका बच्चा शब्दों को गलत बोलता है?	
Section H (Congenital heart disease - CHD) **भाग H (जन्मजात हृदय रोग)** 36. Does your child have fast or troubled breathing? क्या आपका बच्चा बचपन से तेज़ साँस लेता है या साँस लेने में कठिनाई महसूस करता है? 37. Does your child have sweating, tiredness or turns blue when feeding? क्या आपके बच्चे को जनम से, दूध पीने या खाना खाने के समय पसीना आता है, थकान होती है या वह नीला पढ़ जाता है ? 38. Does your child gets dizzy or turns blue while playing? क्या आपके बच्चे को खेलने के समय चक्कर आता है या वह नीला पढ़ जाता है ? 39. Does your child have any blue discoloration on lips, skin or nails? क्या आपके बच्चे के होंठ, त्वचा या नाखून नीले पढ़ जाते है? 40. Does your child have any swelling on legs or around eyes? क्या आपके बच्चे के पैरों पर या आंखों के चारों ओर सूजन रहती है? 41. Does your child squat often? क्या आपका बच्चा अक्सर उकड़ूँ बैठता है?	
Section I (Retinopathy of prematurity) **भाग I (रेटिनोपैथी कुसमयता)** 42. Does your child have visual deficit since birth? क्या आपके बच्चे की दृष्टि जनम से कमज़ोर है? 43. Is the visual deficit progressive since birth?	

क्या आपके बच्चे की दृष्टि में कमज़ोरी लगातार बढ़ रही है? 44. Was your child born very weak and/or prematurely? क्या आपका बच्चा बहुत कमजोर और/या समय से पहले पैदा हुआ था ?	

APPENDIX 2: CONSENT FORM IN ENGLISH

Confidential: for academic and research purpose only

Consent form: for interview of primary caretakers of children aged 0-6 years

Namaste! I am Dr Geetanjali Kapoor, from the IIHMR Jaipur, and am doing a study project.

Purpose of the study:
The study aims at construction of a questionnaire for screening of birth defects in the age group 0-6 years. This can be of help to healthcare workers in detecting birth defects in children and providing timely advice and referral for further check-up and treatment. It will also help in checking the performance of child health programs and provide suggestions for their improvement.

Why selected:
You are being selected because you are the primary caretaker of a child between 0-6 years.

Procedure:
If you agree to take part in this interview, you will be asked some questions regarding your child's health. You will also be asked about any illness during pregnancy and use of medications during that period. This will not take more than 15-20 minutes of your time. The interview will be conducted at a safe and convenient place in the Children's OPD setting of the hospital. After the interview your responses will be compared to hospital records.

Risk, benefits and compensation:
There are no risks during the interview. The responses provided by you will help you to better understand your child's illness. Besides this, your responses will also contribute to the development of a questionnaire for screening of childhood illnesses which will benefit other affected children and their families. Please note that compensation will not be provided for your participation.

Right to Refuse or Withdraw:
The participation is voluntary. You can also exit the same at any point of time. If you choose not to participate, it will not affect your situation in any way.

Privacy, confidentiality and anonymity:
All information provided by you will not be shared with anyone and will be kept private and confidential by anonymizing and removing personal identifiers.

Publication:
The questionnaire developed based upon your responses will be beneficial for academic, medical and research purpose. Besides, it will be published for improvement of child health programs.

Whom to Contact:
If you have any questions, you can ask me now. In case of any queries at a later stage, you can contact me on phone + 91 9717470501 (as provided on the contact slip).
I thank you for your participation and cooperation.

May I ask you questions? Yes ☐ No ☐
Child's name and age
Participant's name and signature
Participant contact number
Participant identification number

Date of interview	*D*	*D*	*M*	*M*	*Y*	*Y*	*Y*	*Y*
Starting time of interview	*HH*				*Min*			
Ending time of interview	*HH*				*Min*			

Investigator's signature

APPENDIX 3: CONSENT FORM IN HINDI

गोपनीय: केवल शिक्षा संबंधित और अनुसंधान के लिए

<u>सहमति फार्म : 0-6 वर्ष की आयु के बच्चों के मुख्य रखवाले (प्राथमिक कार्यवाहक) के इंटरव्यू के लिए</u>

नमस्ते! मैं, डॉ गीतांजलि कपूर, आई आई एच एम आर, जयपुर से हूँ , और एक शिक्षा प्रोजैक्ट (परियोजना) कर रही हूँ।

<u>इस प्रोजैक्ट (परियोजना) का उद्देश्य</u>:

इस प्रोजैक्ट का उद्देश्य 0-6 वर्ष की आयु के बच्चो में जन्म दोष को पता लगाने के लिए, एक प्रश्नावली का निर्माण करना हैं । इस की मदद से स्वास्थ्य सेवा कार्यकर्ता बच्चों में जन्म दोष से प्रभावित स्वास्थ्य समस्याओं का पता लगा सकते हैं और उन्हें समय पर सलाह तथा आगे चेक-अप एवं इलाज के लिए रेफर कर सकते हैं । इससे बाल स्वास्थ्य कार्यक्रमों के कामकाज और उनके सुधार में मदद भी मिलेगी ।

<u>क्यों चुना</u>:

आप को इसलिए चुना जा रहा हैं क्योंकि आप 0-6 वर्ष की आयु के बच्चों के मुख्य रखवाले हो।

<u>विधि (कार्यविधि)</u>:

यदि आप इस इंटरव्यू में भाग लेने के लिए सहमत हैं, तो हम आपसे आपके बच्चे के स्वास्थ्य के बारे में कुछ सवाल पूछेंगे । आप से गर्भावस्था के दौरान किसी भी बीमारी और दवाओं के उपयोग के बारे में भी पूछेंगे । इस दौरान हम आप के 15-20 मिनट से अधिक नहीं लेंगे। यह इंटरव्यू अस्पताल के बाल ओपीडी विभाग में एक सुरक्षित और सुविधाजनक जगह पर आयोजित किया जाएगा। इंटरव्यू के बाद आपके जवाब की तुलना आपके बच्चे के अस्पताल रिकॉर्ड से किया जाएगा ।

<u>खतरा, लाभ और मुआवज़ा</u>:

इंटरव्यू के दौरान कोई खतरा नहीं हैं। आपके जवाब से आपको अपने बच्चे की बीमारी को बेहतर समझने में मदद मिलेगी । इसके अलावा आपके जवाबो की सहायता से एक इस तरह की प्रश्नावली बनाने में मदद मिलेगी जिससे बच्चों में बचपन की बीमारी का जल्दी से जल्दी पता लग सकता और जिससे दूसरे प्रभावित बच्चों और उनके परिवारों को लाभ हो सकता हैं। कृपया ध्यान दें की आपकी भागीदारी के लिए कोई मुआवज़ा नहीं मिलेगा ।

<u>मना करने का या छोड़ने का अधिकार</u>:

इंटरव्यू में भाग लेना या नहीं लेना आपकी मर्जी है। आप इसे किसी भी समय छोड़ सकते हैं । यदि आप भाग नहीं लेना चाहते हैं, तो यह किसी भी तरह से आपके स्थिति को प्रभावित नहीं करेगा।

<u>निजी, गोपनीयता और अज्ञातता</u>:

आप के द्वारा दी गयी <u>सभी</u> जानकारी किसी को नही बताई जाएगी और व्यक्तिगत रूप से निजी तथा गोपनीय रखी जाएगी ।

<u>प्रकाशन</u>:

आपके जवाबो की सहायता से जो प्रश्नावली तैयार होगी, वह शिक्षा, चिकित्सा व भविष्य में खोज के काम आएगी । इस के अलावा यह बाल स्वास्थ्य कार्यक्रम के सुधार के लिए प्रकाशित की जाएगी ।

किससे संपर्क करें:

अगर आपका कोई प्रश्न हैं, तो आप मुझसे अब पूछ सकते हैं। यदि बाद में आपको प्रश्न इस बारे में हो, तो आप मुझे + 91 9717470501 फोन (जोकि पर्ची पर लिखित हैं), पर संपर्क कर सकते हैं।

आपकी भागीदारी और सहयोग के लिए धन्यवाद ।

क्या मैं आप से सवाल पूछ सकती हूँ- हाँ ☐ नहीं ☐

बालक का नाम तथा आयु

भागीदार का नाम तथा हस्ताक्षर

भागीदार का संपर्क नंबर

भागीदार की पहचान संख्या

साक्षात्कार की तिथि	*D*	*D*	*M*	M	*Y*	*Y*	*Y*	*Y*
साक्षात्कार के समय शुरू	*HH*				*Min*			
साक्षात्कार के समय समाप्त	*HH*				*Min*			

जाँच कर्ता के हस्ताक्षर

APPENDIX 4: FIGURES AND TABLES

Figure 1: Recruitment of study group

Target population - Indian children from rural and semi urban areas and in the pre-school age group of 0-6 years.

Source population (eligible population) - Children aged 0-6 years and receiving medical care at ESIC Hospital in Gurgaon city of India.

Study sample- Based on judgment of the investigator and subject to consent of primary care takers, select children in the age group of 0-6 years who were receiving medical care at ESIC Hospital in Gurgaon city of India, were recruited for the study.

Table 1: Demographic characteristics of the study group

Sample size- 40
Mean age- 13.2 months (1.1 years)
Male: Female- 1.5:1

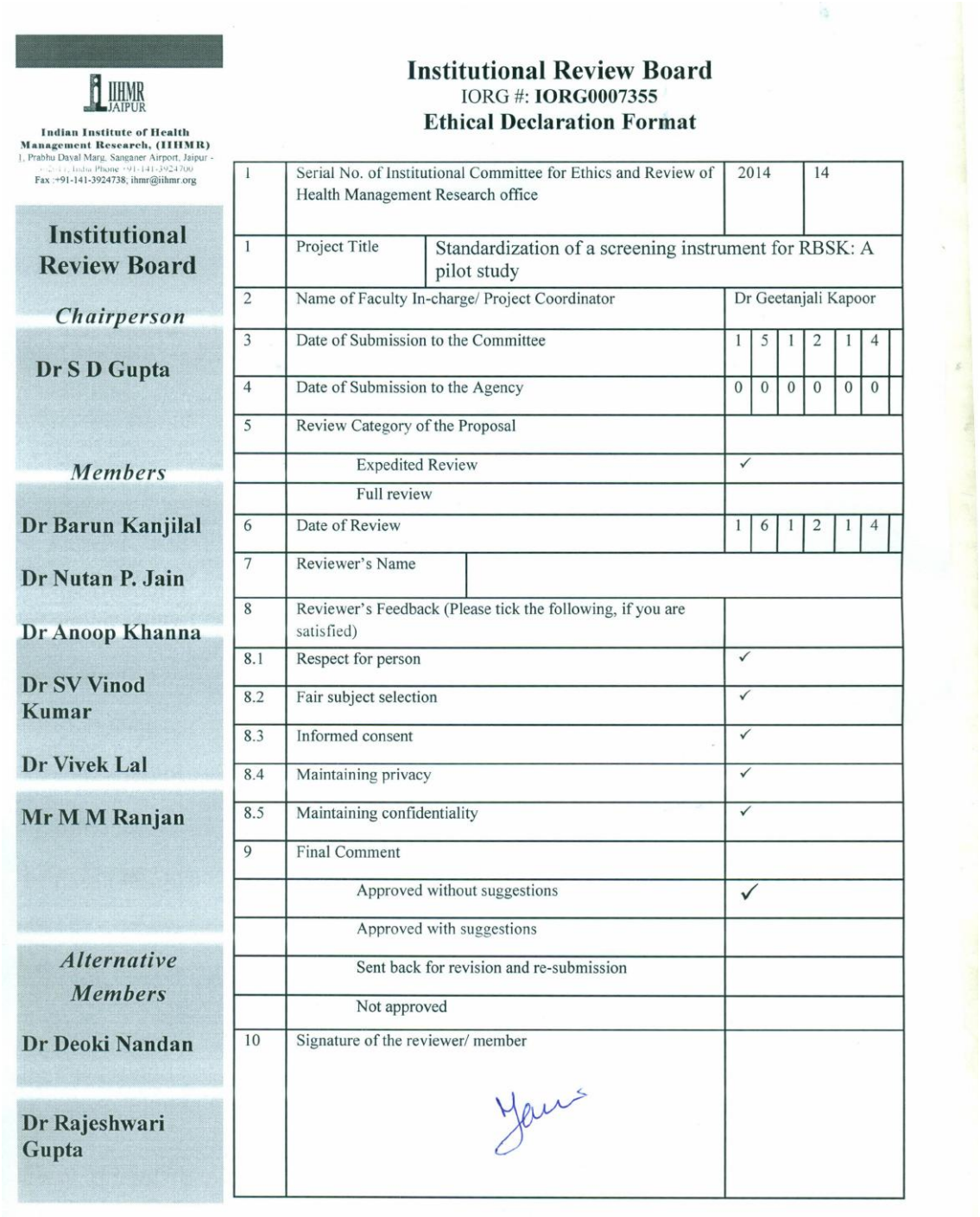
Table 2: Results obtained on tool(questionnaire) administration for screening birth defects

40 children (study sample)	Children screened positive for birth defects N=8		Children screened negative for birth defects N=32
	Congenital heart disease only	4	
	Cleft palate only	1	
	NTD with DDH	1	
	NTD with club foot	1	
	NTD with CHD	1	

Table 3: Validity of the tool(questionnaire) for screening birth defects

	Birth defect positive (doctor's diagnosis)	Birth defect negative (doctor's diagnosis)
Birth defect positive (screening tool)	5	3
Birth defect negative (screening tool)	0	32
Sensitivity=(5/5) X 100= 100%		
Specificity= (32/35) X 100=91.4%		

APPENDIX 5: ETHICAL APPROVAL FROM INSTITUTIONAL REVIEW BOARD, IIHMR, JAIPUR (SCANNED COPY)



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Dr Rajeshwari Gupta

Institutional Review Board
IORG #: **IORG0007355**
Ethical Declaration Format

1	Serial No. of Institutional Committee for Ethics and Review of Health Management Research office						2014		14			
1	Project Title	Standardization of a screening instrument for RBSK: A pilot study										
2	Name of Faculty In-charge/ Project Coordinator						Dr Geetanjali Kapoor					
3	Date of Submission to the Committee						1	5	1	2	1	4
4	Date of Submission to the Agency						0	0	0	0	0	0
5	Review Category of the Proposal											
	Expedited Review						✓					
	Full review											
6	Date of Review						1	6	1	2	1	4
7	Reviewer's Name											
8	Reviewer's Feedback (Please tick the following, if you are satisfied)											
8.1	Respect for person						✓					
8.2	Fair subject selection						✓					
8.3	Informed consent						✓					
8.4	Maintaining privacy						✓					
8.5	Maintaining confidentiality						✓					
9	Final Comment											
	Approved without suggestions						✓					
	Approved with suggestions											
	Sent back for revision and re-submission											
	Not approved											
10	Signature of the reviewer/ member											

APPENDIX 6: ABBREVIATIONS

CHD- Congenital Heart Disease

DDH-Development Dysplasia of the Hip

ESIC-Employees' State Insurance Corporation

MPH- Master in Public Health

NICU-Neonatal Intensive Care Unit

NRHM-National Rural Health Mission

NTD- Neural Tube Defect

PHFI-Public Health Foundation of India

RBSK-Rashtriya Swasthya Bal Karyakram