

## Original Research Article

# Accuracy of lead risk assessment questionnaire in predicting elevated blood lead levels in children

Kanimozhi Sadasivam<sup>1</sup>, Balaji Chinnasami<sup>2\*</sup>, Apurva Hariharan<sup>3</sup>, Balaji Ramraj<sup>4</sup>,  
Rahul Saravanan<sup>3</sup>, Saravanan Ayyavoo<sup>1</sup>

<sup>1</sup>Department of Physiology, <sup>2</sup>Department of Pediatrics, <sup>3</sup>MBBS Student, <sup>4</sup>Department of Community Medicine, SRM Medical College Hospital and Research Institute, Potheri, Kattankulathur, Chennai, Tamil Nadu, India

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### \*Correspondence:

Dr. Balaji Chinnasami,

E-mail: [balaji.ch@ktr.srmuniv.ac.in](mailto:balaji.ch@ktr.srmuniv.ac.in)

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## ABSTRACT

**Background:** Lead toxicity in children is a serious problem affecting their neurodevelopment. Although CDC mandates screening for lead toxicity regularly in children, India doesn't have any lead related public health program in place. In resource limited India a prescreening lead risk assessment questionnaire will be more economical than universal screening for blood lead levels (BLL). Authors aim to evaluate the accuracy of a validated modified CDC lead risk assessment questionnaire in predicting elevated BLL.

**Methods:** Authors conducted an explorative cross-sectional study from July to August 2017 in 340 children aged 6 months to 6 years. A standardized self-administered questionnaire modified from CDC lead risk assessment questionnaire was administered in the children. Also, BLL were measured in all study subjects using lead care II analyser. Data from questionnaire were compared with BLL to test the accuracy of questionnaire.

**Results:** Blood lead levels was high (>5ug/dl) in 57.9% of study subjects especially in children between 24-35 months. Employment in battery manufacturing companies (P=0.0001), usage of cosmetics (P=0.019), parental smoking history (P=0.001), involvement in painting, arts (P=0.0001) and malnourished children (P=0.018) were the risk factors associated with undesirable BLL. The modified questionnaire had a sensitivity of 87.9% and specificity of 66.7% for detecting elevated BLL.

**Conclusions:** The modified CDC lead risk assessment questionnaire is a sensitive tool in identifying high risk cases of lead toxicity in children.

**Keywords:** Children, Lead toxicity, Questionnaire, Risk factors

## INTRODUCTION

The number one cause of environmental toxicity especially in millions of young Indian children is lead poisoning.<sup>1</sup> The centre for disease control (CDC), the American academy of pediatrics and Indian academy of pediatrics consider a blood lead level (BLL)  $\geq 10\mu\text{g}/\text{dl}$  as lead poisoning.<sup>2</sup> However, in June 2010, the WHO expert committee on environmental toxicity withdrew the

minimal guideline value for lead, as there appears to be no safe BLL in children.<sup>3</sup> In fact it is now proven that neurobehavioral problems are more common at levels below  $5\mu\text{g}/\text{dl}$ .<sup>4</sup> Revised CDC guidelines recommend mandatory screening for lead toxicity by measuring BLL in all children at 6 months and then at regular intervals up to 6 years of age along with a lead risk assessment questionnaire, however the same is not followed in India.<sup>5</sup>

In India, there are no public health programs or guidelines for addressing issues related to lead toxicity in children as a result, health care professionals and authorities have little or no knowledge of the existence of a childhood lead-poisoning problem. With the limited data currently available the prevalence of childhood lead poisoning in India is estimated to be around 54%.<sup>6</sup> With more than half of Indian children affected the calculated economic damage to the country is estimated to be 600,000 crores of INR by 2020.<sup>7</sup> With timely action this condition is totally preventable. In resource limited settings like our country where authors have several other competing health problems, a universal screening of all children for BLL (costs between Rs.450-900/sample) poses great burden to health care.<sup>8</sup> In such scenario a pre-screening lead risk assessment questionnaire will be more cost-effective as it will help identify those at high risk for selective BLL screening rather than universal screening. With this in mind authors set out to evaluate the usefulness of a slightly modified and standardized CDC lead risk assessment questionnaire in India. The objectives of this study were to evaluate the accuracy of lead risk assessment questionnaire as a screening tool for elevated blood lead levels in children, to determine the prevalence of lead poisoning in present study population, to identify the key risk factors associated with increased blood lead levels.

## METHODS

This descriptive, cross-sectional study was done in the department of physiology that is equipped with the Lead care II analyser in conjunction with the department of pediatrics of our medical college. Study was done for a period of two months during July and August 2017 as the potential exposure to external sources of lead is said to be greatest during these warm and humid summer months. The sample size for the present study was calculated to be 340 using the formula  $4pq/d^2$  with prevalence  $p=54\%$  and 10% allowable error. The study was initiated after obtaining the institutional ethical committee clearance (ethics clearance number: 1199/IEC/2017) and written informed consent from children's parents or guardians. The study was conducted strictly in accordance with the ethical guidelines for biomedical research on human subjects by central ethics committee on human research (CECHR), Indian council of medical research (ICMR)-2000 and those as contained in "declaration of Helsinki".

### *Inclusion criteria*

- A convenience sample of all children aged 6 months to 6 years attending the pediatric out-patient department for regular growth monitoring, vaccination, follow-up or illness related visits were enrolled in the study.
- Age group of 6 months to 6 years were selected for the study as they are highly susceptible to the toxic effects of lead especially the growing brain.

### *Exclusion criteria*

- Children previously tested for blood lead levels, those on treatment for lead poisoning and children whose parents denied participation were excluded from the study.

### *Pre-screening lead risk assessment questionnaire*

A self-administered questionnaire (to be filled by the children's parents) has been prepared keeping in mind the five primary risk questions as outlined by the CDC and only slight modifications and additions were done to suit Indian setting.<sup>5</sup> It has been pre-tested in a sample of 30 parents attending paediatric OPD of a different medical college in the same district and validated with the help of community medicine experts. Both English and local regional language version of the questionnaire has been prepared.

In those subjects who are illiterate, the questionnaire was administered by the primary (student) investigator. In brief the questions solicit information related to the child's birth history, birth rank and infant-feeding history, child's age at testing, gender and standard in school, parents' education and occupation, socio-economic background, family size, living conditions (overall health, food habits, passive smoking), nutritional and dietary habits of the child (intake of milk, red meat, fish, eggs, ragi, jaggery, green vegetables and fruits), use of dietary supplements (calcium and iron), medical details (use of ayurvedic, herbal, homeopathic and other alternative medicines) and environmental surroundings of the child (industrial exposure, traffic exposure, hobbies and residential exposure from paints and play toys). Unlike the group of CDC questions, in this questionnaire authors have specifically included "don't know" as a possible response to all five key components instead of only "yes" and "no". Responses like "yes" and "don't know" will be scored as one and "no" will be scored as zero and vice versa depending on the question. Any participant scoring greater than zero will be considered high risk for lead toxicity. A copy of the questionnaire is available as Annexure 1.

### *Estimation of blood lead levels (BLL)*

To study the operating characteristics (sensitivity and specificity) of the questionnaire and prevalence of lead toxicity authors have included measurement of BLL. Blood lead levels were analyzed by finger-prick method using the POCT (Point-of-care analysis)-Lead Care II analyser system (ESA Biosciences Inc, Chelmsford, MA) and lead care blood lead testing kits (ESA, Inc, USA) which is available in the department of Physiology. This system has been shown to be reliable and with similar results to more formal analytic methods like atomic absorption spectrophotometry.<sup>9</sup> It relies on electrochemistry and a unique sensor to detect lead in the whole blood.

### Advantages of POCT-lead care II analyser system

Since it is a Point-of-care analysis like a glucometer, the results are available within 3 minutes. Lead care II is a CLIA (clinical laboratory improvement amendments) waived test and laboratory technologist is not required to perform the test, any person in health care organization with basic knowledge in science can be trained in the use of POCT-lead care II. It does not require indigenous reagents and materials. The data collected from the questionnaire was compared with BLL obtained from lead care II analyser system to test the accuracy of the questionnaire as described below.

### Statistical analysis

Data was entered and analysis was done using SPSS version 21. Descriptive statistics such as percentage, median and interquartile range were used to describe the data. Inferential statistics like chi square test and ROC (receiving operating characteristic) was used to measure the operating characteristics (sensitivity and specificity) establish the validity of the screening tool (questionnaire) with the diagnostic tool (BLL testing). Univariate analysis was employed to identify the key risk factors associated with increased blood lead levels.

## RESULTS

A total of 340 children between the ages of 6 months to 6 years underwent testing for BLL and simultaneously were administered the lead risk assessment questionnaire.

### General description of study population

Among the total population, 59% of them were male children. Based on the revised socio-economic status scale of Kuppaswamy, 69% of the study population belonged to middle class families, 27% belonged to lower class families and 4% belonged to the upper-class families.<sup>10</sup> Almost all children (99%) stayed with their parents. The mean birth weight of the participants was 2.671 kilograms. (SD:491.5). The average age of the subjects' mothers at the time of delivery was 23 years (SD: 3.6). About 43% of the subjects' parents had completed school education. 74% of the subjects' mothers were house wives.

Most of the subjects' mothers (98%) were non-smokers and about 31% of the subjects' fathers were smokers. 62% of the subjects consumed drinking water directly from the public water supply from the street taps without subjecting the water to filtration or boiling. About 10% of the study population were on calcium and iron supplements. And 40% reported administration of traditional ayurvedic/folklore medications to their children.

Table 1 describes the prevalence of lead poisoning among present study population. As it is evident from the table that 22.6% of the survey participants had lead poisoning with the highest value of BLL being 16.1µg/dl and lowest value of BLL was 3.3µg/dl, median value of BLL was 6 µg/dl and the interquartile range was 3.3-9.8 µg/dl. More than half (57.9%) of the study subjects had BLL in the undesirable range (>5µg/dl) and a meagre (19.4%) were under the desirable range of BLL (<5µg/dl).

**Table 1: Prevalence of lead poisoning.**

Blood lead level (µg/dl)	Percentage (n), n=340
Lead poisoning (>10µg/dl)	22.6 (77)
Undesirable range (>5µg/dl)	57.9 (197)
Desirable range (<5µg/dl)	19.4 (66)

Table 2 gives us a clear picture of the prevalence of elevated BLL within different age groups. The prevalence of elevated BLL varied from 32%-86% among the different age groups. Except for infants between 6 to 11 months, other age groups approximately had more than 50% of the children falling under the undesirable range of BLL, especially between the ages of 24-35 months had the highest prevalence of an alarming 86%.

**Table 2: Age wise distribution of elevated blood lead levels.**

Age (months)	Subjects screened N (% of total)	Subjects with BLL in the undesirable range (>5µg/dl)
6-11	31 (9)	10 (32)
12-23	171 (50)	98 (57)
24-35	58 (17)	50 (86)
36-47	48(14)	24 (50)
48-59	15 (4)	7 (46)
60-72	17 (5)	8 (47)
Total	340 (100)	197 (57.9)

Univariate analysis was employed to identify the key risk factors associated with increased blood lead levels revealed the following information. The Pearson's chi-square test or Fisher exact probability was used appropriately for the analysis. From table 3 it is evident that subjects who answered "yes" (score of 1) for the following questions like presence of factory in and around their residence (p=0.026), working in battery manufacturing companies(p=0.0001), use of cosmetics like kajal/ surma (p=0.019), history of cigarette smoking among parents(p=0.001), hobbies involving painting, arts and crafts (p=0.0001), malnourished children(p=0.018) and usage of ayurvedic/folklore medicines (p=0.044) have high probability of having their BLL in the undesirable range. The complete details of the analysis for each questionnaire is available in Table 3.

**Table 3: Univariate analysis of risk factors for lead toxicity with blood lead levels.**

Questions	BLL <5 (desirable range)	BLL >5 (undesirable range)	Chi Square	P-value
<b>Years of stay in locality</b>				
0	7	4	2.592 <sup>\$</sup>	0.173
1	17	29		
<b>Traffic gradation</b>				
0	13	14	0.768	0.381
1	11	19		
<b>Source of water</b>				
0	8	9	0.244	0.621
1	16	24		
<b>Storage of water</b>				
0	23	32	0.053 <sup>\$</sup>	1.00
1	1	1		
<b>Presence of paint chips</b>				
0	17	22	0.112	0.738
1	7	11		
<b>Presence of factory in and around</b>				
0	21	20	4.977	0.026*
1	3	13		
<b>Indulging in factory work</b>				
0	20	9	17.473	0.0001**
1	4	24		
<b>Use of kajal/ surma</b>				
0	19	16	5.519	0.019*
1	5	17		
<b>History of cigarette smoking</b>				
0	16	7	11.927	0.001***
1	8	26		
<b>Usage of chinese toys</b>				
0	6	2	4.131 <sup>\$</sup>	0.059
1	18	31		
<b>Practice of painting or coloring (hobby)</b>				
0	15	3	18.344	0.0001***
1	9	30		
Full-term (0)	22	27	1.117 <sup>\$</sup>	0.446
Pre-term (1)	2	6		
Healthy birth weight (0)	14	21	0.165	0.685
Underweight (1)	10	12		
Exclusively breastfed (1)	20	29	0.238	0.709
Formulated milk (0)	4	4		
Nourished (0)	10	24	5.569	0.018*
Malnourished (1)	14	9		
<b>Supplements provided (iron, vit D etc.)</b>				
0	17	19	1.050	0.306
1	7	14		
<b>Usage of ayurvedic/ folklore medication</b>				
0	20	20	3.429	0.044*
1	4	13		

0- Low risk for lead toxicity, 1- High risk for lead toxicity \$ fisher exact probability. \*P<0.05, \*\* P<0.01 and \*\*\*P<0.001

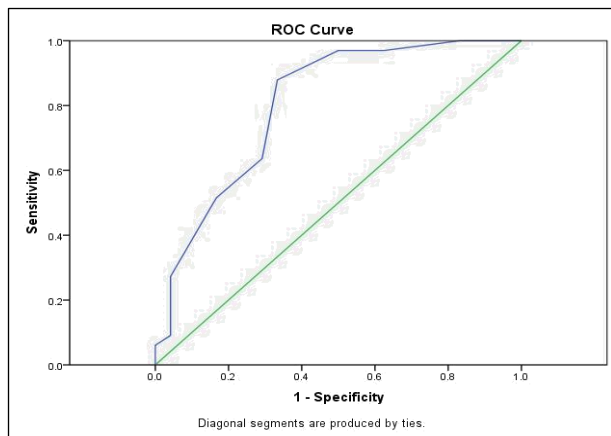
Using the CDC's definition of high risk for lead poisoning (score of 1 at least to any one question), the questionnaire had a sensitivity of 87.9% and specificity

of 66.7% for detecting elevated blood lead levels (BLL) in present study group (Table 4).<sup>5</sup>

**Table 4: Operating characteristic of the questionnaire.**

Cut-off points	Sensitivity	Specificity
6.50	87.9%	66.7%

The area under the ROC curve for lead risk assessment questionnaire is 0.803 (Figure 1), which indicates that this questionnaire is a sensitive tool in detecting cases with high BLL.



(Area under the curve-0.803)

**Figure 1: ROC curve for the lead risk assessment questionnaire.**

## DISCUSSION

Present study found that the prevalence of lead poisoning ( $>10\mu\text{g/dl}$ ) among our primarily middle-class study sample was 22.6% and 57.9% had blood lead levels (BLL) in the undesirable range ( $>5\mu\text{g/dl}$ ). This suggests that lead toxicity is not limited to the lower socio-economic strata as previously described by several authors.<sup>11-13</sup> It is important note that the prevalence of lead toxicity in present study group is less compared to limited studies available in our country.<sup>6,14</sup>

One probable explanation for such an observation could be less sample size of present study, including only those children who visited the hospital rather than doing a random sampling, alternatively it could also be that the actual prevalence in this geographic region is less, as earlier studies were done in a different region of our country. Another noteworthy finding is that our prevalence rate is very high compared to western countries.<sup>15</sup> Because of mandatory screening and general awareness among public and health professional their problem burden seems to very less compared to India.

Also, the questionnaire had a sensitivity of 87.9% and specificity of 66.7% in detecting elevated BLL, with area under the ROC curve being 0.803, thus suggesting that the modified CDC questionnaire developed by us is an effective tool in screening cases with elevated BLL in our population. To the best of our knowledge this is the first

study in our country trying to establish a risk assessment questionnaire as a screening tool for lead poisoning among children. Our data support the CDC recommendation of earlier and more frequent blood testing of children who answer yes or score 1 to at least one question. The revised CDC guidelines recommend mandatory BLL testing of all children at the ages of 6 months and then at regular intervals up to 6 years of age along with a lead risk assessment questionnaire.<sup>5</sup> However, the same is not being followed in India. BLL testing is not mandatory in India as cost for each test ranges between 400-9008 rupees, which poses a great economic burden for health care expenditure to the government as well as for parents who are ready to test in private laboratories. Using this questionnaire as a primary screening tool in all children will help identify high risk cases for mandatory BLL testing will prove as an effective alternative for universal BLL screening. Among the survey questions home environmental survey (chipping paint and remodeling), occupational history and hobbies involving painting, arts and crafts questions appeared to be the most sensitive indicators of elevated BLL than other questions (Table 3).

Questions about cosmetic usage (Kajal/surma), history of smoking and use of alternative folklore medications, when used together, were as effective a screening tool as using all five key questions suggested by CDC. In areas of the country with more lead related industries, questions about job and industrial exposure might be more useful. Similarly, in areas with a higher prevalence of elevated BLL, a question about known contacts with lead toxicity may be a more sensitive screening method. Results similar to present study was reported by David MT et al.<sup>16</sup> Neurobehavioral changes caused by lead are irreversible and places great economic burden on families and societies. Recent cost-benefit analysis shows for every US\$ 1 spent to reduce lead hazards, there is a benefit of US\$ 17-220.<sup>17</sup> This cost-benefit ratio is better than that for vaccines, which is the single most cost-beneficial public health intervention.<sup>18</sup> Based on our evaluation, this questionnaire appears to be a reliable tool in identifying high risk children, thus making it a cost-effective measure for policy makers to replace universal screening and also avoid a painful procedure for some infants.

Limitations of the study were by selection bias as authors enrolled a convenience sample of only those children who visited the hospital rather than a random sampling. Thus, the generalizability of our results to all children has to be viewed with caution as the selection bias may either overestimate or underestimate the true prevalence. Hence, large multi-centric survey using this questionnaire will help establish conclusive results.

## CONCLUSION

The prevalence of lead poisoning (BLL  $>10\mu\text{g/dl}$ ) in present study group is 22.6% and more than half (57.9%)

had blood lead levels (BLL) in the undesirable range (>5µg/dl). This questionnaire appears to be a sensitive tool in identifying high risk cases for BLL testing.

### Recommendations

Lead exposure poses a major environmental health problem in India, where direct studies on a large-scale have not yet been performed to investigate its prevalence especially in pediatric population. This cross-sectional descriptive study was done to resolve the above purpose and to investigate the accuracy of a slightly modified CDC lead risk assessment questionnaire in identifying cases with elevated blood lead levels. The results of present study clearly show that prevalence of lead toxicity is high in our pediatric population and our risk assessment questionnaire is an effective screening method for elevated blood lead levels. Questions about the home environment, occupational history and hobbies were more sensitive indicators of elevated lead levels compared to other questions.

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