




## Misclassification and the Public Health Impact of Using Defective Sensors with LeadCare® Blood Lead Testing Instrument – United States

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## Background

- Previous comparisons of results obtained with LeadCare® and GFAAS have supported the use of portable testing units for onsite screening
- In May, 2005 proficiency testing revealed negative bias (mean -25%; 95% CI: -15 to 35%) in blood lead levels (BLL s) using the LeadCare® portable blood lead testing device
- On May 19, 2005 LeadCare's manufacturer began a recall of defective BLL testing sensors

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## Background - Continued

- The 8 lots of recalled testing sensors were distributed between September, 2004 and May, 2005 and had expiration dates ranging from February, 2005 to July, 2006
- The distribution and use of recalled sensors may have resulted in misclassification of BLL's among approximately 500,000 individuals
- The public health impact of this recall has not been quantified

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## Objectives

- The research questions for the current study were:
  - Has the average BLL for individuals decreased when compared to the average BLL before the defective sensors were on the market?
  - Has the bias adversely affected any of the individuals in that medical, environmental, or worker protection did not happen in a timely way?

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## Study Design

- Laboratory data were requested from 15 high volume LeadCare® US clients
- Requested all results from January 1, 2003 to June 30, 2005
- Data collected included test date, sample type, result, sensor lot number, age, and re-test results (when available)

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## Results

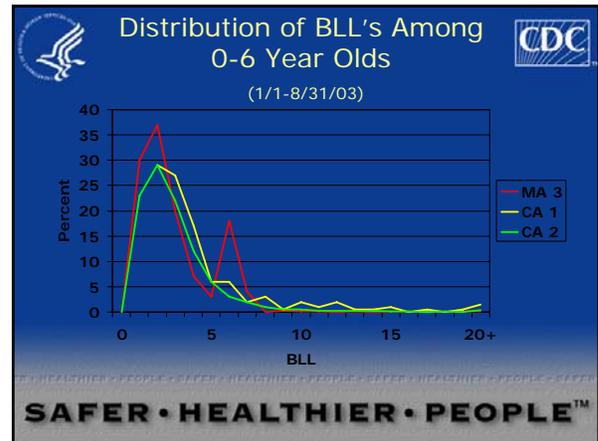
- 8 of 15 (53%) clinical sites contributed 26,883 patient records
- Among these, 12,573 contained lot number identification
- All results were obtained using capillary samples

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### Contributing Facilities

	Time Period 1 Mean (n)	Time Period 2 Mean (n)
<b>Northeast</b>		
NY 1*	2.33 (3)	2.24 (1,741) <sup>b</sup>
MA 1*	1.63 (7)	1.61 (5,831)
MA 2†	-	11.65 (106)
MA 3	2.45 (793) <sup>a</sup>	2.04 (2,484) <sup>b</sup>
<b>Midwest</b>		
MI		2.88 (3,764)
MO†		4.42 (357)
<b>West</b>		
CA 1	4.36 (232)	2.87 (4,258)
CA 2	3.20 (2,101) <sup>a</sup>	2.55 (5,056)

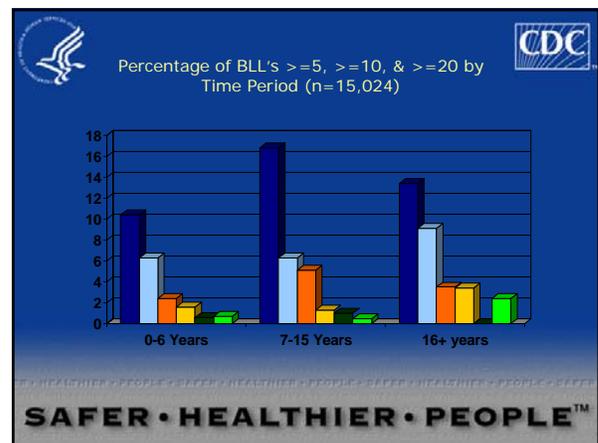
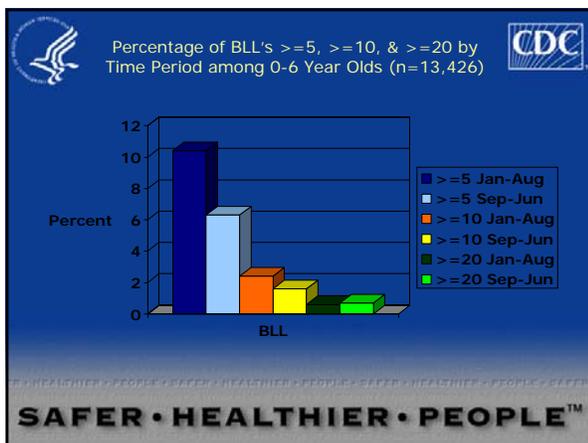


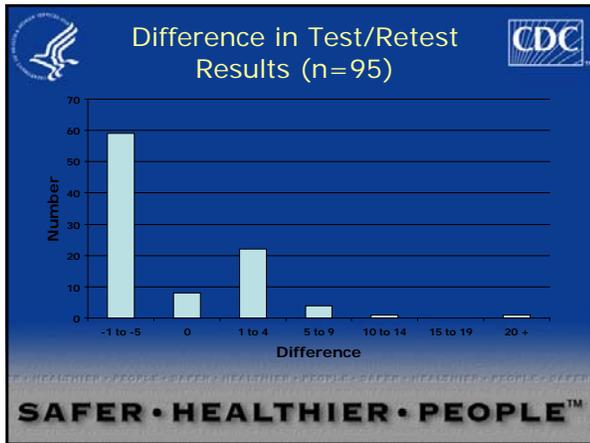
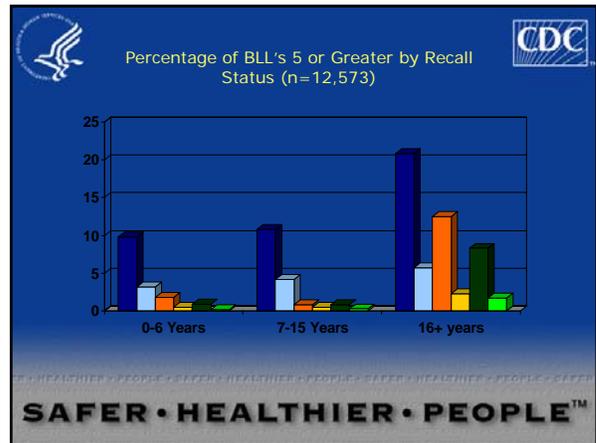
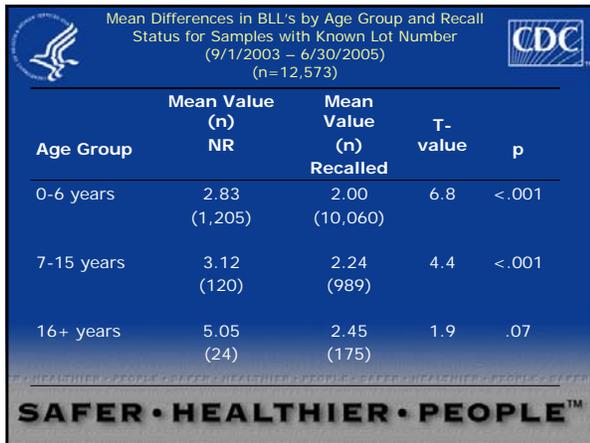
### Comparison of 0-6 Year Olds with BLL's ≥ 10

	Percent ≥ 10
National Estimate, 1991-1994 <small>Source: MMWR 52(SS10):2003</small>	2.2%
MA 3	.5%
CA 1	2.1%
CA 2	2.1%

### Table 1. Mean Differences in BLL's by Age Group and Availability of Defective Sensors (n=15,024)

Age Group	Not Available (1/1-8/31/03)	Available (9/1/03-6/30/05)	T-value	p
	Mean (n)	Mean (n)		
0-6 years	3.09 (3,001)	2.55 (10,425)	7.6	<.001
7-15 years	3.78 (196)	2.56 (1,164)	4.5	<.001
16+ years	3.33 (29)	2.84 (209)	.98	.33

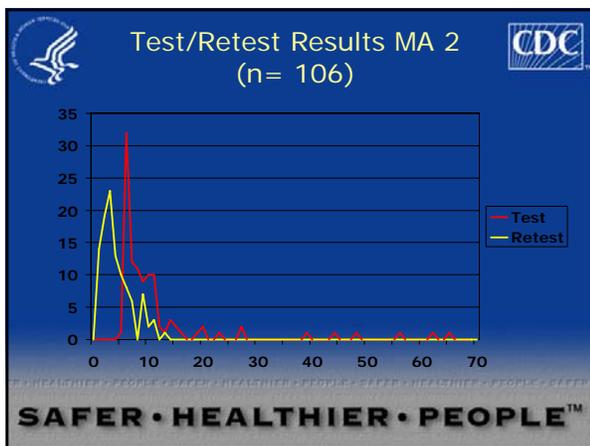




Test/Retest Difference by Treatment Category (N=95)

BLL	0 - 9	10 - 14	15 - 19	20-44	≥45
0 - 9 (84)	41	7	36	0	0
10 - 14 (9)		6	3	0	0
15 - 19 (1)			0	1	0
45 - 69 (1)	1			0	0

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- Summary and Conclusions
- Significant negative bias among BLL's when defective sensors were available
  - Significant negative bias among BLL's when defective sensors were used
  - Older children and adults may have been more severely impacted
  - Misclassification may have affected the treatment of more than 50% of those tested with defective sensors
  - Poor technique may result in misclassification
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## Recommendations



- ✦ Continued proficiency testing to identify defective testing systems
- ✦ Individuals tested between September, 2003 and May, 2005 with BLL's greater or equal to 5 should be retested
- ✦ The LeadCare® field testing unit should not be used for confirmatory testing

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## Limitations



- ✦ Small sample of laboratories
- ✦ Limited geographical area
- ✦ Small number of retested patients
- ✦ Limited demographic information
- ✦ Capillary samples

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## Thank You



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