

How Did We Do?

Assessing Child Lead Poisoning Case Ascertainment in the US, 1999–2010

Eric M Roberts, MD PhD

Public Health Institute

Eric.Roberts@phi.org

Acknowledgements

Collaborators:

- Paul English, PhD MPH
- Linda Kite, MBA
- Galatea King, MPH
- Daniel Madrigal, MPH
- Jhaqueline Valle, MPH
- Michelle Wong, MPH

This work is a project of the California Environmental Health Tracking Program (CEHTP), funded by the Centers for Disease Control and Prevention

Objectives

1. To understand the role of AAP and CDC guidelines in determining blood lead testing practices
2. To quantify the effectiveness of these guidelines in 39 states with respect to detection of lead-exposed children
3. To understand how our approach to blood lead testing often fails to achieve its intended goals

Background

Child blood lead testing guidelines (1998, 2005, 2016)

- CDC and AAP have advocated targeted (**non-universal**) testing **as long as clinicians could determine exposure risk** for each patient...
 - Via a **questionnaire** administered in the office
 - Based on the age and quality of the patient's local **housing stock**
 - Based on an evaluation of their community provided by **state or local Public Health agencies**
- In the absence of information, universal testing has been indicated

Child blood lead testing guidelines (1998, 2005, 2016)

In the absence of information, universal testing has been indicated

- **Minimum standards for these kinds of data have never been articulated**
- Absent a minimum standard, it is difficult to say that the information provided are insufficient
- Therefore, no one faces a *de facto* requirement to engage in universal testing due to lack of data

Example: Public Health agencies' capacity to evaluate risk

- **States are neither required nor resourced** to conduct studies of exposure prevalence among **representative populations**
- Instead, they aggregate test results from clinics to inform policy, but
 - **No minimum number of tests** required to infer risk in a community (if no one does any testing, there will be no positive tests and we can claim no problem)
 - **No requirement for meaningful geography specified** (county-level reporting is ok)
 - No requirement that **data be shared**
 - *You may need to file a Freedom of Information Act request*
 - *This is still no guarantee of success, even if they data exist*

Implication: Why we evaluate the policy

- Clinicians may choose between universal and targeted testing **based not on what they know** about their communities, **but on what they think they know**
 - “Lead is a Northeast/Midwest problem—we don’t have that here”
 - “The state Public Health agency isn’t contradicting me, so you can’t say I’m wrong”
- For this reason, we cannot take for granted the success of the policy for any given state; therefore, we evaluate:

How effective have clinicians been at detecting lead exposure among their young patients?

Is this important?

- Tension between testing and primary prevention:
 - “The focus of...policy should shift from case identification to primary prevention” (2005 guidelines)
 - “...the goal must be to find all children with excess exposure and interrupt that exposure....” (2005 guidelines)
- The public is focused on the second goal
 - California state legislature has considered mandating testing so that all cases can be identified
 - They were opposed by the AAP with the explicit argument that **the existing guidelines are sufficient to identify all exposed children**
 - Almost universally, **questions about EBLL prevalence are addressed using clinical testing results**

Today's objective

- Evaluate CDC/AAP guidelines as policy:
 - Have they resulted in lead-exposed children being identified?
 - How many EBLL kids did we catch?
 - How many did we miss?
- Our study covers the years 1999-2010

Methods

Three numbers we need to know

1. How many cases of EBLL **are detected** each year?
 - This requires reporting that uses **standardized case definitions**
2. How many cases of EBLL **should be detected** each year?
 - State-specific estimates of prevalence using a statistical model
3. How do these numbers **compare**?
 - We can calculate a **ratio** of observed cases to expected cases

1. How many cases of EBLL were detected each year?

- States can voluntarily report EBLL case counts to CDC
 - Employ standardized definition of “EBLL case”
 - Only consistent for BLL \geq 10.0 mcg/dL during 1999-2010
- This is the only nationally-consistent resource we have for BLL testing results
- During 1999-2010, **39 states (including DC) reported**
 - 18 states only participated intermittently: for these states, we only consider the years for which they had complete reporting
 - 12 states did not participate during 1999-2010

2. How many cases of EBLL should be detected each year?

- This is the hard part!
- Data Source: National Health and Nutrition Examination Survey (NHANES)
 - Nationally representative sample
 - Not amenable to sub-setting by state
- We sought to use NHANES to generate a **model predicting EBLL** based on
 - Race/ethnicity
 - Household poverty
 - Residence in pre-1978 housing
 - Geographic region (Northeast, Midwest, South, West)
 - Year

Why is this difficult?

- Key information missing
 - Age of housing not reported by over 1/3 of NHANES participants
 - Missing-ness is not random: depends on home ownership, age of housing itself, etc.
- How to account for this?
 - Methods exist to deal with Missing-Not-At-Random (MNAR) data
 - Not easy to use with complex datasets like NHANES

Research Article

Received 23 July 2015,

Accepted 8 July 2016

Published online in Wiley Online Library

(wileyonlinelibrary.com) DOI: 10.1002/sim.7067

Analysis of multiple-variable missing-not-at-random survey data for child lead surveillance using NHANES

Eric M. Roberts^{a*†} and Paul B. English^b

Background – Although ongoing, multi-topic surveys form the basis of public health surveillance in many countries, their utility for specific subject matter areas can be limited by high proportions of missing data. For example, the National Health and Examination Survey is the main resource for surveillance of elevated blood lead levels (EBLLs) in US children, but key predictor variables are missing for as many as 35% of respondents. **Methods** – Using a Bayesian framework, we formulate a t -distributed Heckman selection model applicable to the case of multiple missing-not-at-random variables in the context of a complex survey design. We demonstrate the utility of the results by calculating prevalence estimates for lead levels exceeding 2.5, 5.0, and 10.0 $\mu\text{g/dL}$ among children 1 to 5 years of age for a variety of time points and geographies by applying the coefficients to data from the American Community Survey from the US Census.

Results – We present a protocol for estimating posterior distributions of parameters using Gibbs and grid sampling steps. Stark disparities in the prevalence of EBLL by race/ethnicity, age of housing, and poverty are readily quantified, and three- to five-fold differences in predicted prevalence across geographies within the US are presented.

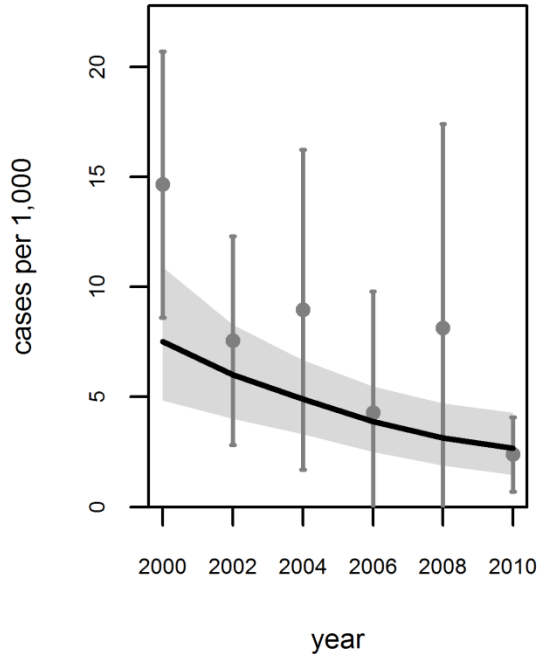
Conclusions – We are able to conduct multivariate analyses of EBLLs that incorporate the crucial variable age of housing, analyses that have not been previously available using these data. This represents an expansion of the

In this way, we modeled EBLL prevalence

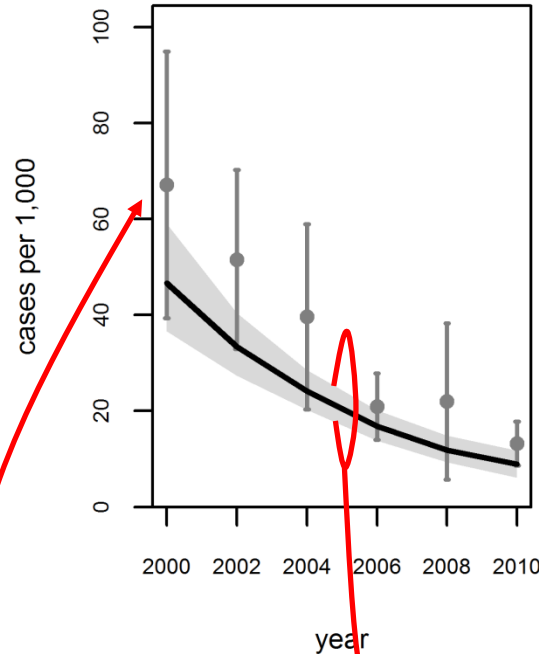
- Among children aged 12 months to 5 years
- Using different definitions of EBLL
 - ≥ 10.0 mcg/dL
 - ≥ 5.0 mcg/dL
 - ≥ 2.5 mcg/dL
- With our models, we can estimate EBLL prevalence
 - Using American Community Survey data as inputs
 - **For any time point and geography covered by NHANES 1999-2010**

How did our method compare to traditional NHANES estimates?

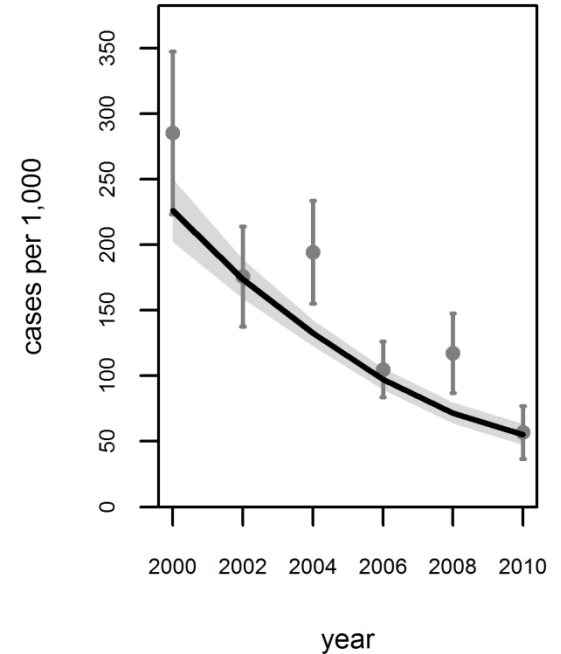
BLL ≥ 10.0 $\mu\text{g/dL}$



BLL ≥ 5.0 $\mu\text{g/dL}$



BLL > 2.5 $\mu\text{g/dL}$



Our method trend estimates

NHANES point estimates

3. How do these numbers compare? ...the big caveats

A. Numbers come from different data collection processes

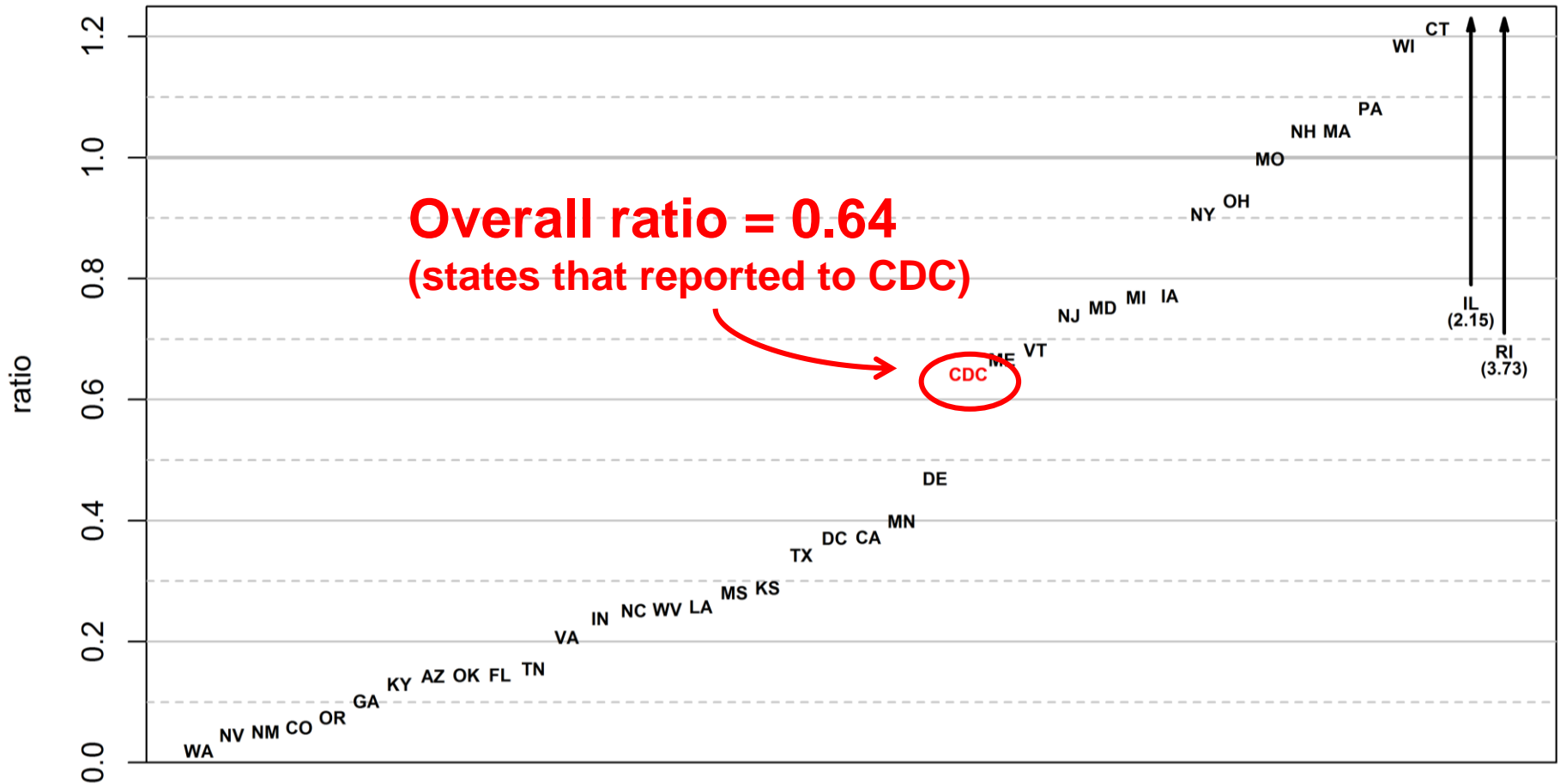
- **Our estimates** are based on a cross-sectional study (NHANES)
 - Participants are tested once during the year
 - Gold standard for determining prevalence and covariates of a disease in a population
- **CDC reports** are like a rolling enrollment study
 - Children can be tested more or less than once per year

B. Our model produces “average expected numbers” of EBLL cases

- Actual number EBLL cases in a state may be more or less than the expected number for any given year (that is, the actual numbers are log-normally distributed around estimates from model)
- Over the long term for the entire nation, the actual and expected numbers should be similar

Results

Comparing reported EBLL cases to our estimates



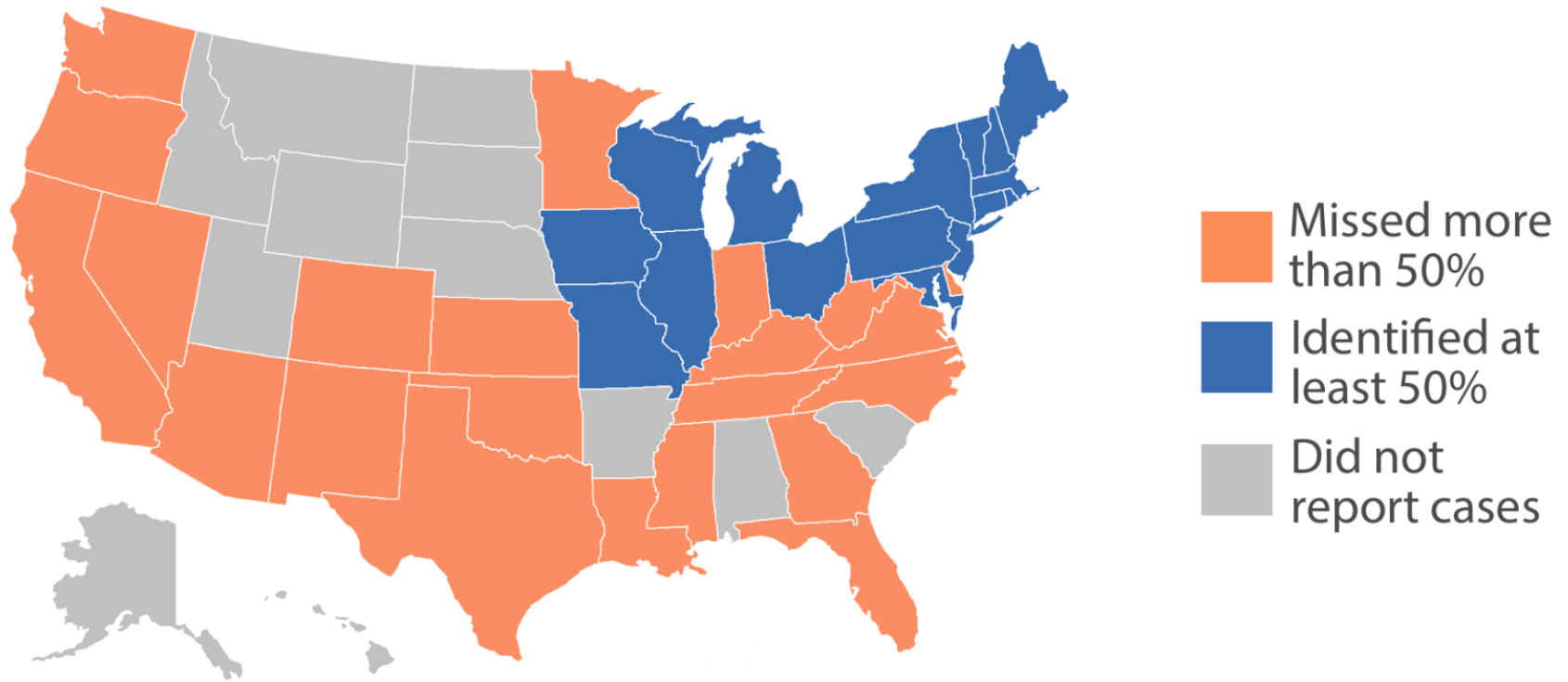
Ratio of cases reported to cases predicted, 1999-2010
(BLL \geq 10.0 mcg/dL, reporting years only)

Results by state

- Overall, about 64% of the expected number of cases were reported to the CDC

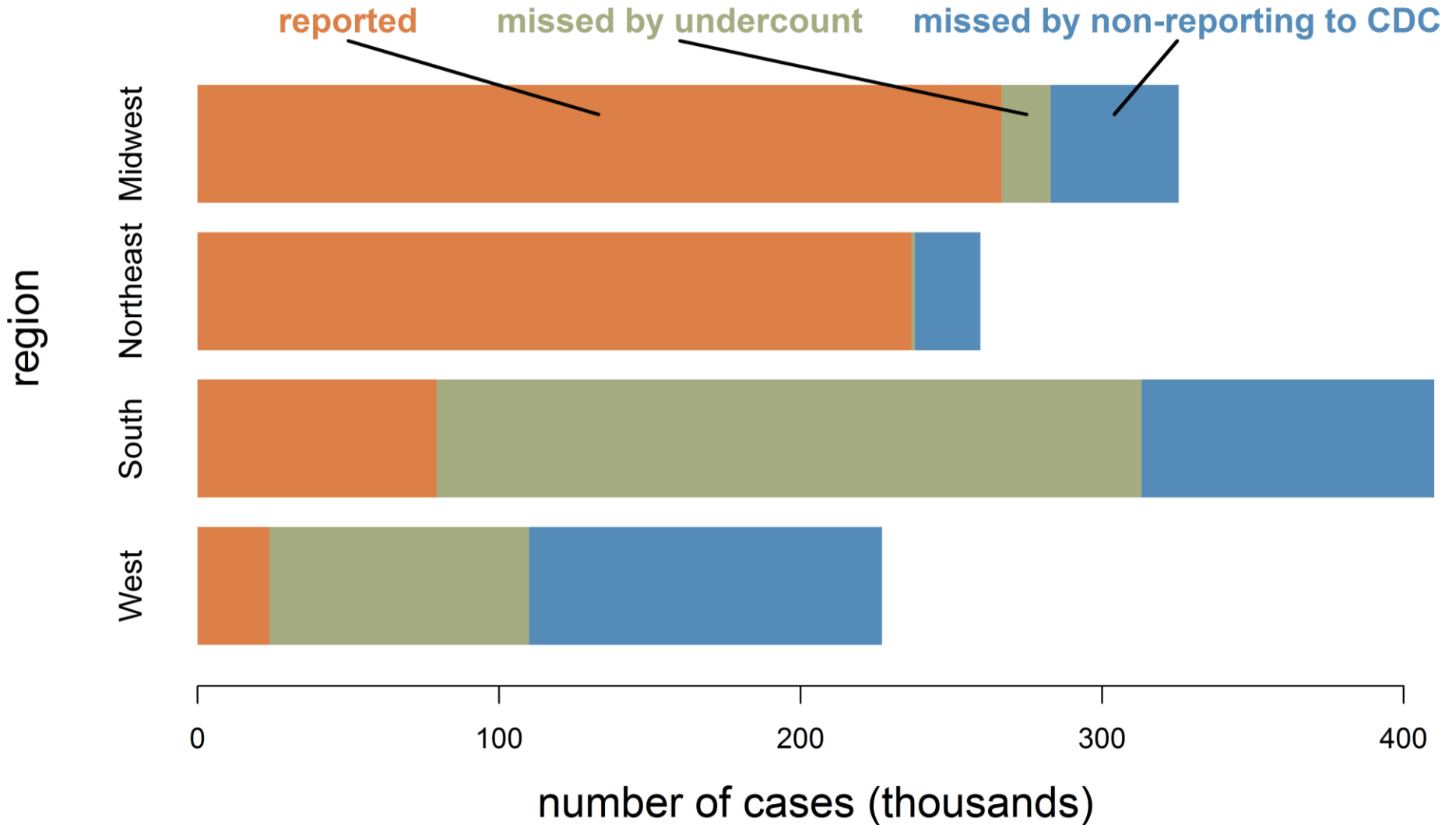
Percentage of expected cases that were reported	Number of states	States
> 60%	16	CT, IA, IL, MA, MD, ME, MI, MO, NH, NJ, NY, OH, PA, RI, VT, WI
20 – 50%	12	CA, DC, DE, IN, KS, LA, MN, MS, NC, TX, VA, WV
< 20%	11	AZ, CO, FL, GA, KY, NM, NV, OK, OR, TN, WA
Did not report to CDC during 1999-2010	12	AK, AR, HI, ID, MT, ND, NE, SC, SD, UT, WY, AL

23 states identified fewer than half of their lead-poisoned children*



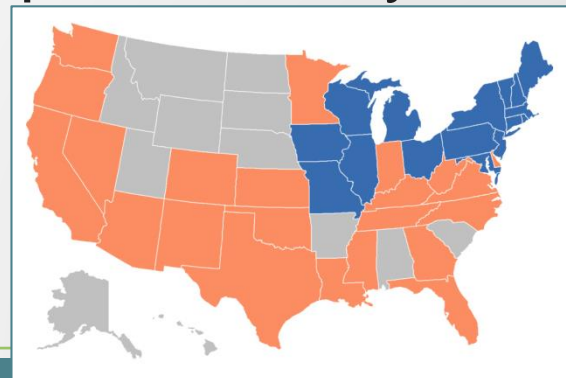
* children age 1-5 years with blood lead levels greater than 10ug/dL

Total estimated cases of EBLL, 1999-2010 by region



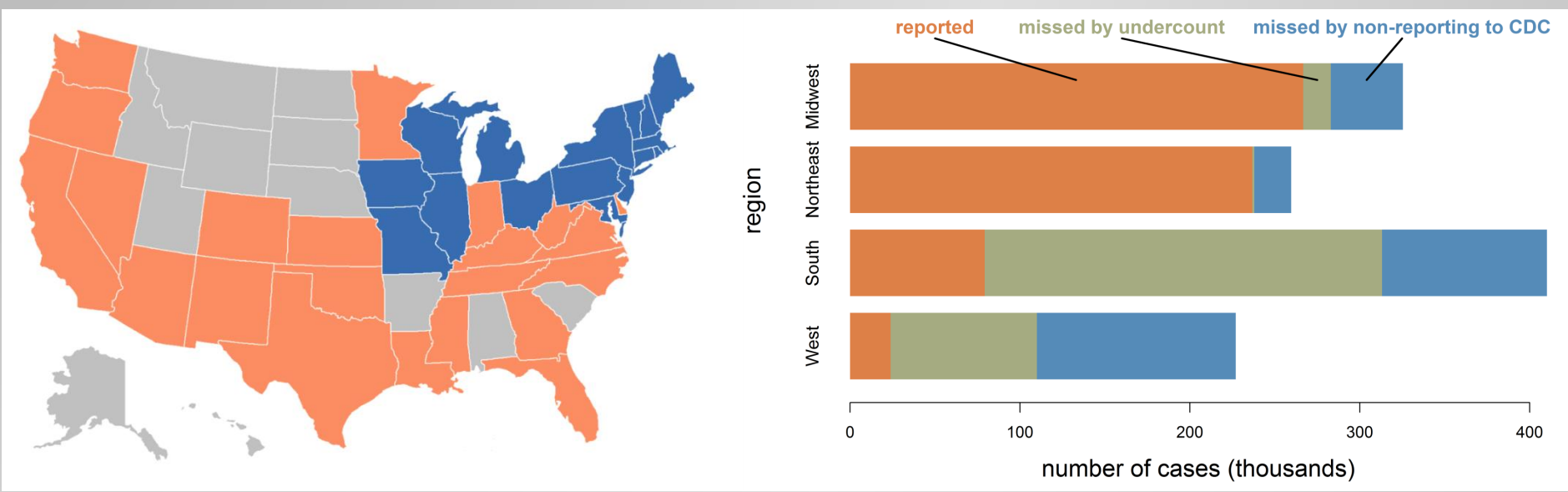
Summary

- EBLL is not just a Midwest/Northeast problem
 - The greatest number of lead-exposed children is actually in the South
 - The lowest ascertainment rate is in the West
- Most of the states that reported to CDC missed more children with EBLL than they caught
 - If the events in Flint, Michigan happened in any of these states, would we know?
 - Could they be happening now?



More caveats

- We compared reported cases to the numbers predicted by a **statistical model**
 - Estimates from rigorous, cross-sectional EBLL prevalence studies would carry more scientific weight than ours
- Some children with EBLL
 - Were not reported to the CDC, but were detected and received services
 - Were reported to the CDC, but did not receive services
- We don't know much about testing patterns in states that don't report data to CDC



Interpretation:
How Did This Happen?

How did this happen?

- **Targeted Testing** largely assumes clinicians will be directed by state and local public health agencies
- Therefore, the logic of the guidelines rests on **the ability for public health agencies to inform clinicians about EBLL risk** in the communities they serve

How do public health agencies determine communities' risks?

- They are almost never resourced sufficiently to conduct independent scientific studies of representative populations
- Therefore, they
 1. Aggregate test results by clinicians,
 2. Hope that the clinicians are doing enough testing on which to build a complete picture

The foundation of lead surveillance?

I hope the Public Health Department tells me if I should do some testing!

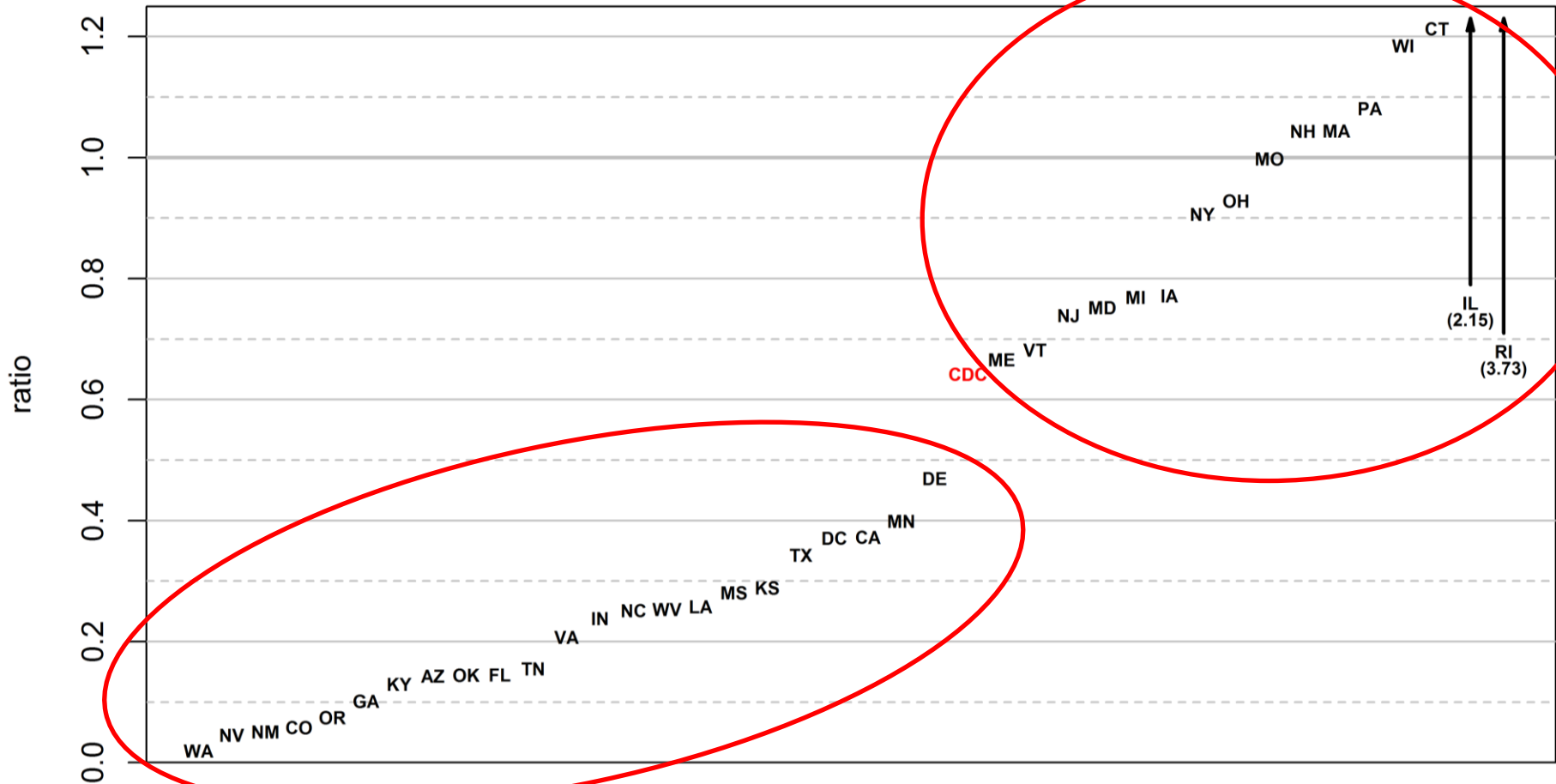


I hope the pediatricians tell us if anyone needs testing!

Two possible outcomes

- 1. Lucky states:** Providers do lots of testing; public health agencies have lots of data that they share with providers
- 2. Unlucky states:** The system breaks down:
 - Providers don't test, so agencies have no data, or...
 - Providers may test but agencies are unwilling or unable to share their data

Do states fall into two distinct groups?



Ratio of cases reported to cases predicted, 1999-2010
(BLL \geq 10.0 mcg/dL, reporting years only)

Conclusions

- If we accept the following **purpose** for AAP practice guidelines:
 - To “identify all children with excess lead exposure, and prevent further exposure to them.” (2005 guidelines)
- **Then—in most of the states evaluated—the practice guidelines failed during 1999-2010**

Recommendations for new guidelines

1. Publically repudiate the practice of basing prevalence estimates for lead exposure on clinical test results unless scientific standards are met
 - For most communities in most states, this means **admitting that we do not know the risk of lead exposure**
2. Allow targeted testing based on data-driven algorithms, but **specify minimum standards for data**
 - Adequately-powered studies based on **representative samples** are the gold standard
 - Reliance on clinical testing results is permissible when standards for **sample size, geographic resolution, and open communication** with clinicians are met
3. Whenever and wherever the above standards are not met, universal testing should be **clearly and emphatically promoted**



PEHSU NATIONAL CLASSROOM

Pediatric Environmental Health Specialty Units



www.pehsu.net/nationalclassroom.html



Webinars

Series of scientific webinars that provide a forum for discourse on scientific issues.

Live and On-Demand

Case Conferences
Journal Clubs
Grand Rounds

CE Available



Online Courses

Evidence-based online courses on a variety of children's environmental health topics.

Interactive and Self-Paced

CE Available



Resource Catalog

Fact sheets, journal publications, reports, and other resources for parents, community members, patients and healthcare professionals

Topics included:
Air Quality, Pesticides,
Natural Disasters, BPA, Mold,
Lead, Mercury



Update on Lead Exposure in Flint, Michigan and East Chicago, Indiana

Susan Buchanan, MD, MPH

Acknowledgements

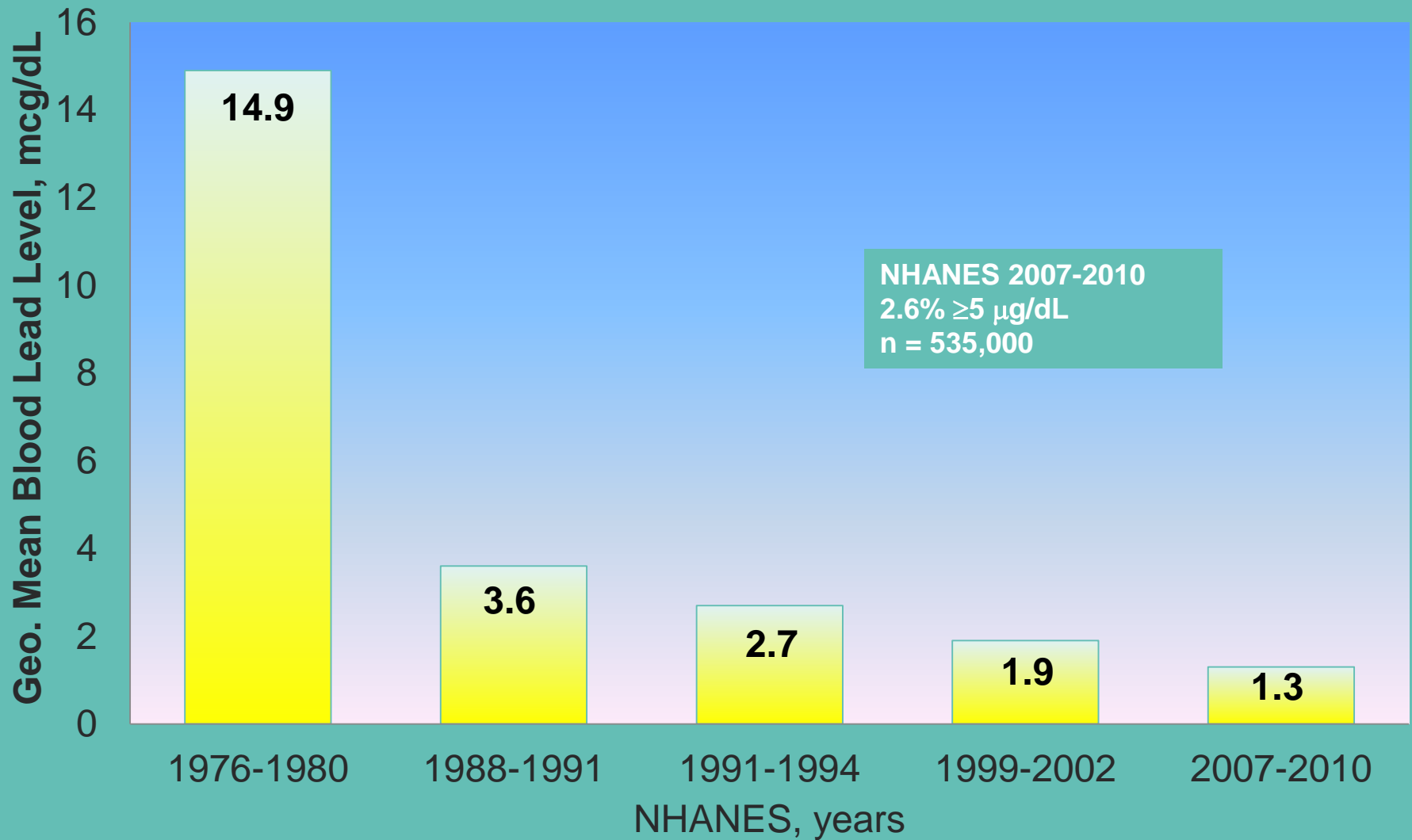
This material was supported by the American College of Medical Toxicology (ACMT) and funded (in part) by the cooperative agreement FAIN: U61TS000238-03 from the Agency for Toxic Substances and Disease Registry (ATSDR).

Acknowledgement: The U.S. Environmental Protection Agency (EPA) supports the PEHSU by providing partial funding to ATSDR under Inter-Agency Agreement number DW-75-95877701. Neither EPA nor ATSDR endorse the purchase of any commercial products or services mentioned in PEHSU publications

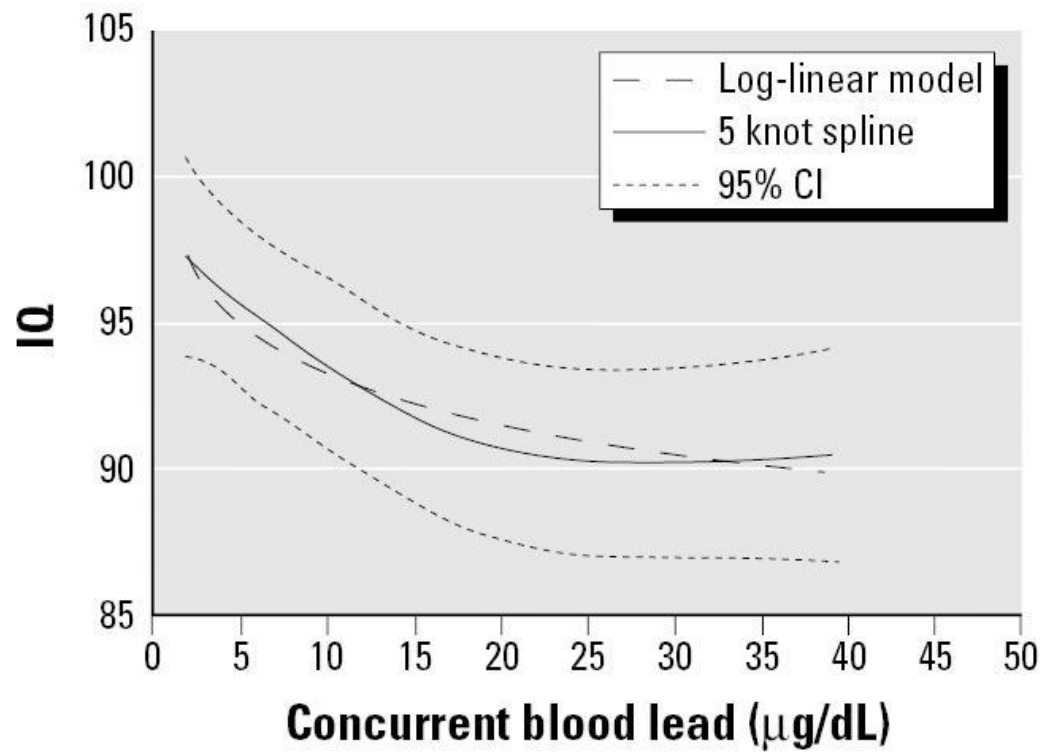
Objectives

- List the causes of elevated blood lead levels in Flint, Michigan and East Chicago, Indiana
- Explain the lead prevention programs that have developed in response to the Flint lead crisis
- Identify the roles of ATSDR and PEHSU in the Flint and East Chicago responses

Geometric Mean Blood Lead Levels in Children Ages 1 to 5 years (National Health & Nutrition Surveys)



Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis



Pooled analysis, 7 studies, N= 1,333

Increase in lead:

- from **2.4 to 10** µg/dL → ↓ **3.9** IQ pts
- from **10 to 20** µg/dL → ↓ **1.9** (95% CI, 1.2-2.6)
- from **20 to 30** µg/dL → ↓ **1.1** (95% CI, 0.7-1.5)

Lanphear et al, *Environ Health Perspect.* 2005 July; 113(7): 894–899.

National Toxicology Program

At mean blood lead levels $< 5\mu\text{g}/\text{dl}$

Sufficient evidence for:

- Attention-related problems
- Greater incidence of problem behaviors
- Decreased cognitive performance

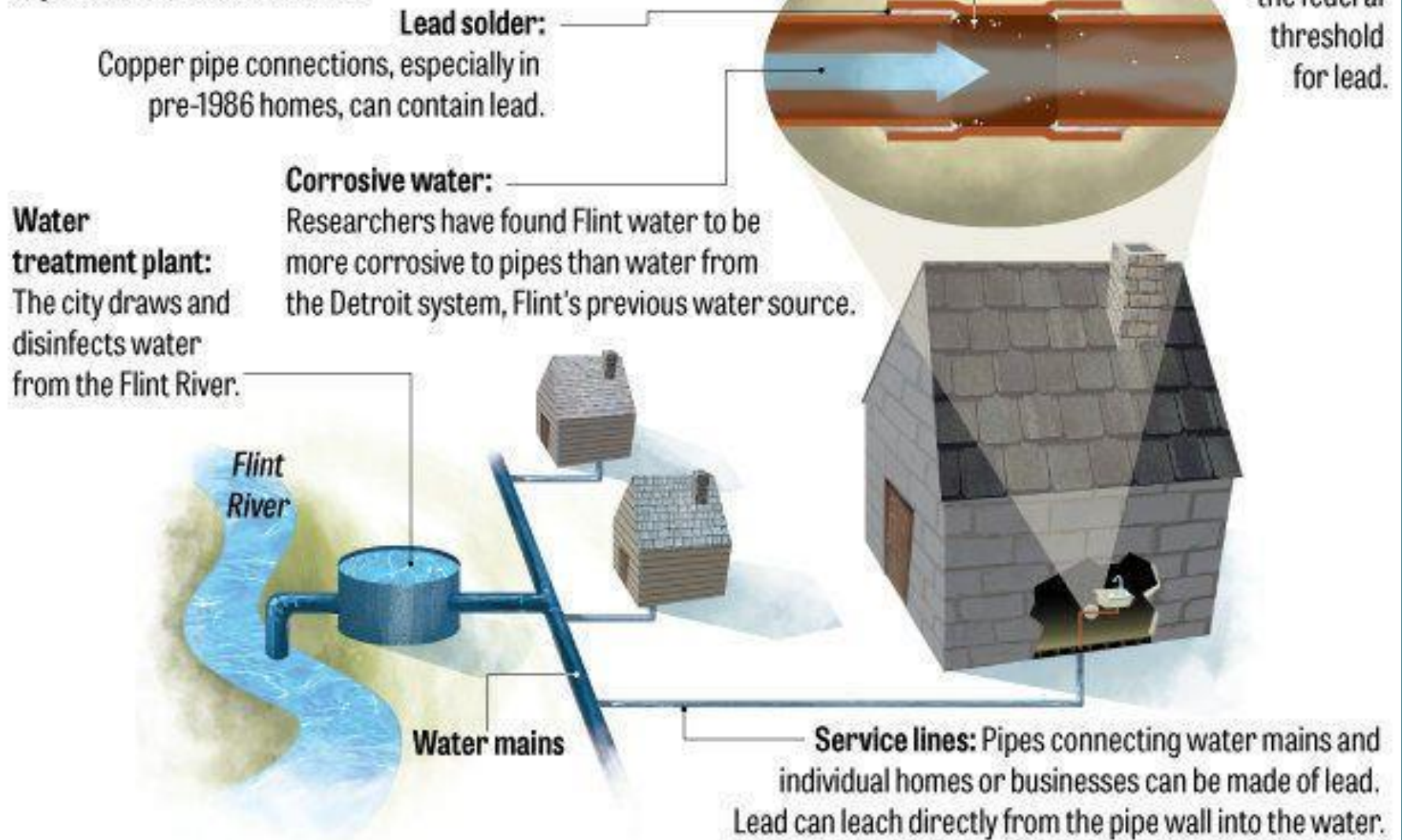


Flint, Michigan



GETTING THE LEAD IN

Tests show toxic lead is leaching into Flint's tap water. Here's how.



Flint Timeline

April 2014

Water switch
from Detroit to
Flint River

Oct 2014

High THMs
noted,
increase in
Legionella
cases noted

Dec 2014

MDEQ notifies
Flint re: high
levels of
TTHMs

Sept 2014

E. Coli levels
high, boil
water alert

Oct 2014

GM
announces
will no longer
use water due
to concerns of
corrosion from
chloride

Flint Timeline, Continued

Jan 2015

State offers bottled water in state offices

Aug 2015

Marc Edwards (Virginia Tech) releases first data re: elevated lead levels in homes – 30% over 15ppb

Oct 2015

Flint water is switched back to Detroit water supply

April – June 2015

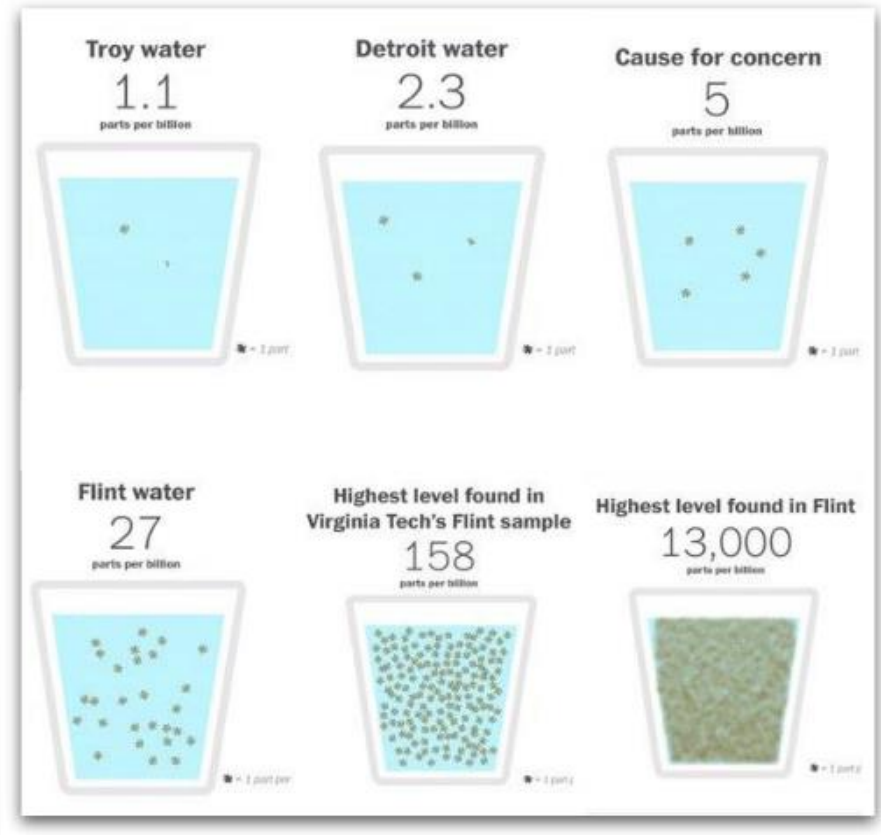
EPA discovers no corrosion control used and homes with elevated lead levels

Sept 2015

Dr. Mona Hanna-Attisha presents data from children's BLLs

Lead levels in tap water

- Lead and Copper Rule 1991: **Action Level 15ppb**
- “Systems are required to **perform public education** when there are lead action level exceedances at more than 10% of the taps sampled, **treat source water** if it contributes significantly to lead levels at the tap, and **replace lead service lines** if the lead levels continue to exceed the action level after optimal corrosion control and/ or source water treatment has been installed”
- **Flint levels**: 40% of the first draw samples > over 5 parts per billion (ppb). Several samples exceeded **100 ppb**, and one sample collected after 45 seconds of flushing exceeded **1,000 ppb**.



flintwaterstudy.org/wp-content/uploads/2016/03/Flint-task-force-report_2438442_ver1.0.pdf&hl=en_US

Drinking Water and BLL

How much does lead in drinking water contribute to blood lead?

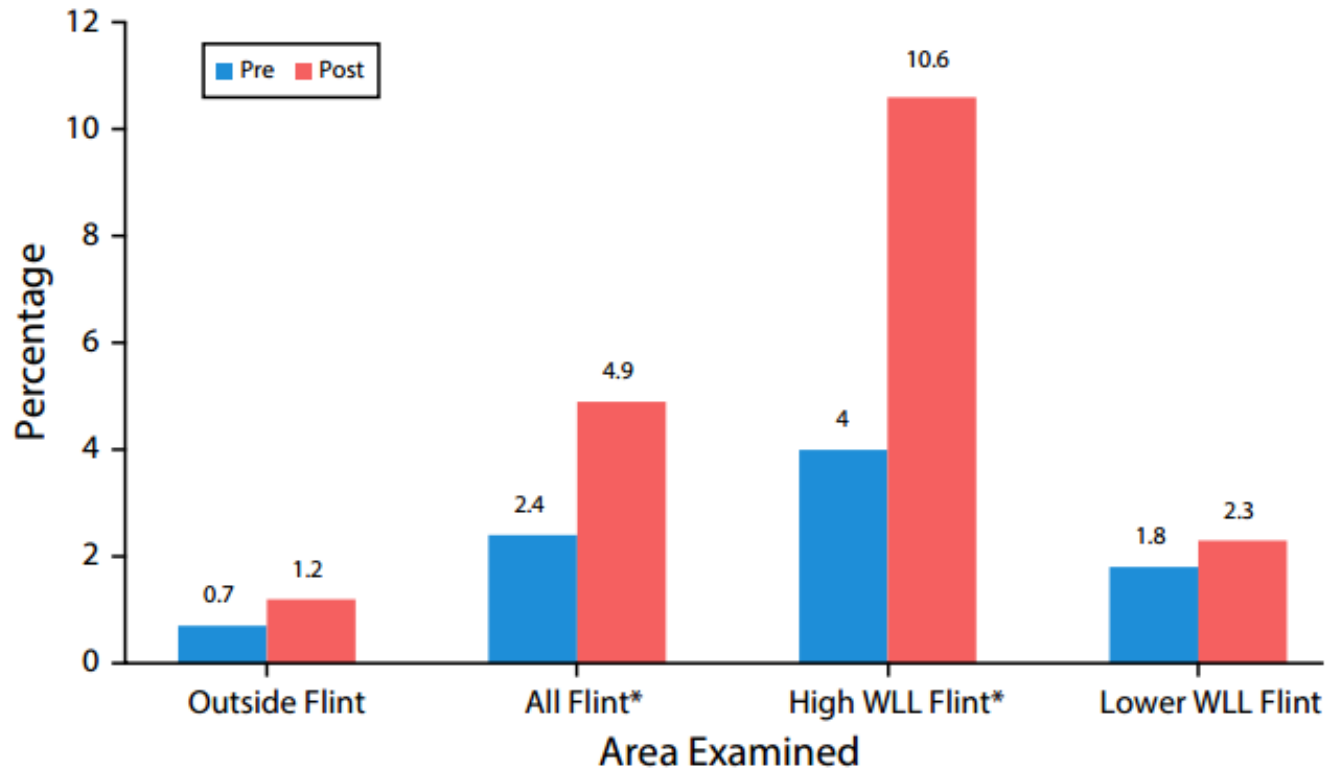


“Tap water once contributed to as much as 10-20% of total Pb exposure in the US.”

No known reports of community mean BLL over “level of concern” due to contaminated drinking water (Pb in plumbing)

National Toxicology Program Monograph on Health Effects of Low-Level Lead 2012

Blood Leads of Flint Children



Note. WLL = water lead level.

* $P < .05$.

Hanna-Attisha M et al. Elevated Blood Lead Levels in Children Associated With the Flint Drinking Water Crisis: A Spatial Analysis of Risk and Public Health Response. *Am J Public Health* 2016, Vol. 106, No. 2, pp. 283-290

OSHA Lead Standard

- Workers are removed when blood lead is **50-60ug/dl**
- Return to work when blood lead decreases to **40ug/dl**



Health Effects to Flint Population*

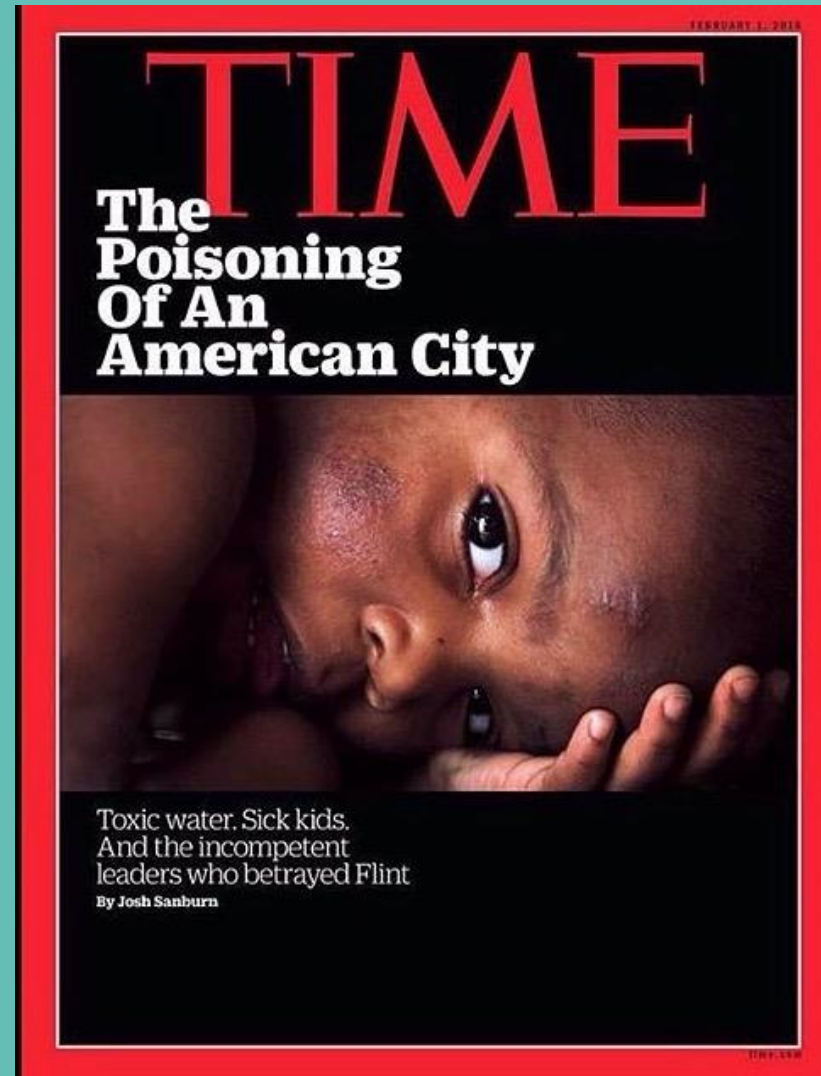
- Rash
- Hair loss
- Tooth loss

*attributed by residents to water contamination



<http://mic.com/articles/133019/22-powerful-photos-show-the-devastating-reality-of-flint-s-water-crisis#.b6yPmkrkJ>

Public Health Messaging



Challenges: public health messaging

Michael Moore

“They are ruined for life and someone needs to tell you the truth about that. They will, forever, suffer from various neurological impediments, their IQs will be lowered by at least 20 points.”



The screenshot shows a news article from The Detroit News. The headline is "Group fears bathing risks in Flint water". The byline is "Jim Lynch and Jacob Carah, The Detroit News" and the date is "11:31 p.m. EDT April 8, 2016". The article includes a photo of a water tower with the text "FLINT WATER PLANT" and a "Buy Photo" button. The article text discusses federal regulators re-assessing Flint's water quality and the safety of bathing and showering in it. It mentions that while no conclusive evidence has emerged indicating widespread dangers, a small sample of water tests conducted by a nonprofit has highlighted gaps in testing and water quality monitoring. The article also notes that the organization contends that current testing focusing on water does not take into account possible harm from lead and other contaminants through inhalation of steam and vapor, as well as absorption through skin. A quote from Scott Smith, chief technology officer and investigator with the New York-based Water Defense, is included: "You can't find what you're not looking for," said Scott Smith, chief technology officer and investigator with the New York-based Water Defense, a nonprofit founded by Academy Award-nominated actor Mark Ruffalo.

Update 2017 -- Flint, Michigan

- Blood lead levels
- Current drinking water supply
- New programs/services
- Residents' perspectives

Current blood lead levels in Flint

TAKING ACTION ON FLINT WATER

FLINT WATER

[Blood Testing](#)

[Sentinel Testing](#)

[Residential Testing](#)

[School Testing](#)

[Establishment Testing](#)

[CLEAR Testing](#)

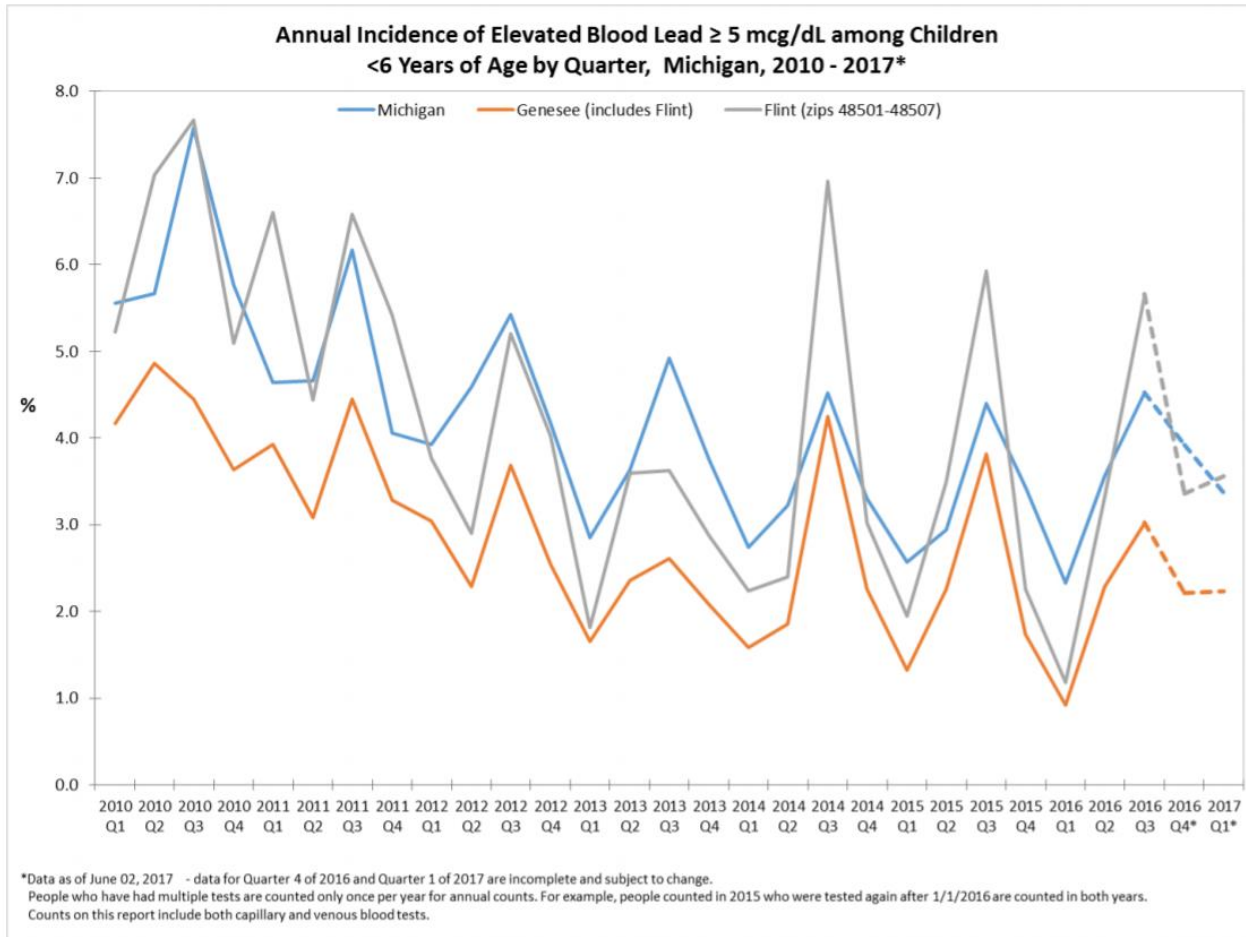
Blood Testing Results

Blood Testing Results

- [June 2 - Flint Blood Lead Level Testing](#) 
- [May 26 - Flint Blood Lead Level Testing](#) 
- [May 19 - Flint Blood Lead Level Testing](#) 
- [May 5 - Flint Blood Lead Level Testing](#) 
- [April 28 - Flint Blood Lead Level Testing](#) 
- [April 21 - Flint Blood Lead Level Testing](#) 
- [April 7 - Flint Blood Lead Level Testing](#) 
- [August 19 - Flint Blood Lead Level Testing Report](#) 
- [August 12 - Flint Blood Lead Level Testing Report](#) 
- [July 29 - Flint Blood Lead Level Testing Report](#) 
- [July 22 - Flint Blood Lead Level Testing Report](#) 
- [July 15 - Flint Blood Lead Level Testing Report](#) 
- [July 8 - Flint Blood Lead Level Testing Report](#) 
- [July 1 - Flint Blood Lead Level Testing Report](#) 

<http://www.michigan.gov/flintwater/>

Blood lead levels in Flint, Michigan



Current drinking water in Flint

- Increased monitoring for coliforms, flushing protocols
- Increased chlorine levels because of stasis
- Lead levels improved.
 - Early 2016: 90th %-ile = **29ppb**
 - Current 90th %-ile = **6-8ppb**
 - Still some homes > **15ppb** (particulate)
- No further discoloration (from iron leaching off water mains)
- Disinfection byproducts (from Flint River water and over-chlorination) now below regulatory limits
- Bottled water still being distributed

Legionnaire's Disease

Flint Area Community Health and Environment Partnership (FACHEP)

- Investigating outbreak of Legionella
- 11% of homes (+) for legionella
 - “Similar outside of Flint and not unexpected”
 - Concern that filters can harbor bacteria

New programs and services

- Lead service line replacement - \$100 million from EPA, goal 6,000/yr; 800 so far
- MSU-Hurley Children's Hospital Pediatric Public Health Initiative (PPHI)
 - Farmer's market gift certificate booklets for schoolchildren
 - Flint lead registry



New programs and services

- EPA grant to Genesee Co. Health Dept
 - “Water 101” for residents

- DOL grant
 - CORE program - Distribution of water filters by trained local residents
 - Filters for homes with lead service lines or unknown status of lines

Residents' perspectives

- No trust in government
- No trust in the drinking water system
- Don't trust the water filters (rated to only 150ppb)
- Bottled water distribution continues. Phase out expected to create extreme anxiety.

Messaging challenges— per Mark Durno, EPA

- Transparency vs. collecting more data before making public
- Announcing to community vs. working with individuals
- Insufficient outreach to med professionals

Cardinal Rules of Risk Communication

1. Accept and involve the public as a partner.
2. Plan carefully and evaluate the outcome of the communication efforts.
3. Listen to the public's concerns.
4. Be honest, frank and open.
5. Work with other credible sources.
6. Meet the needs of the media.
7. Speak clearly and with compassion.

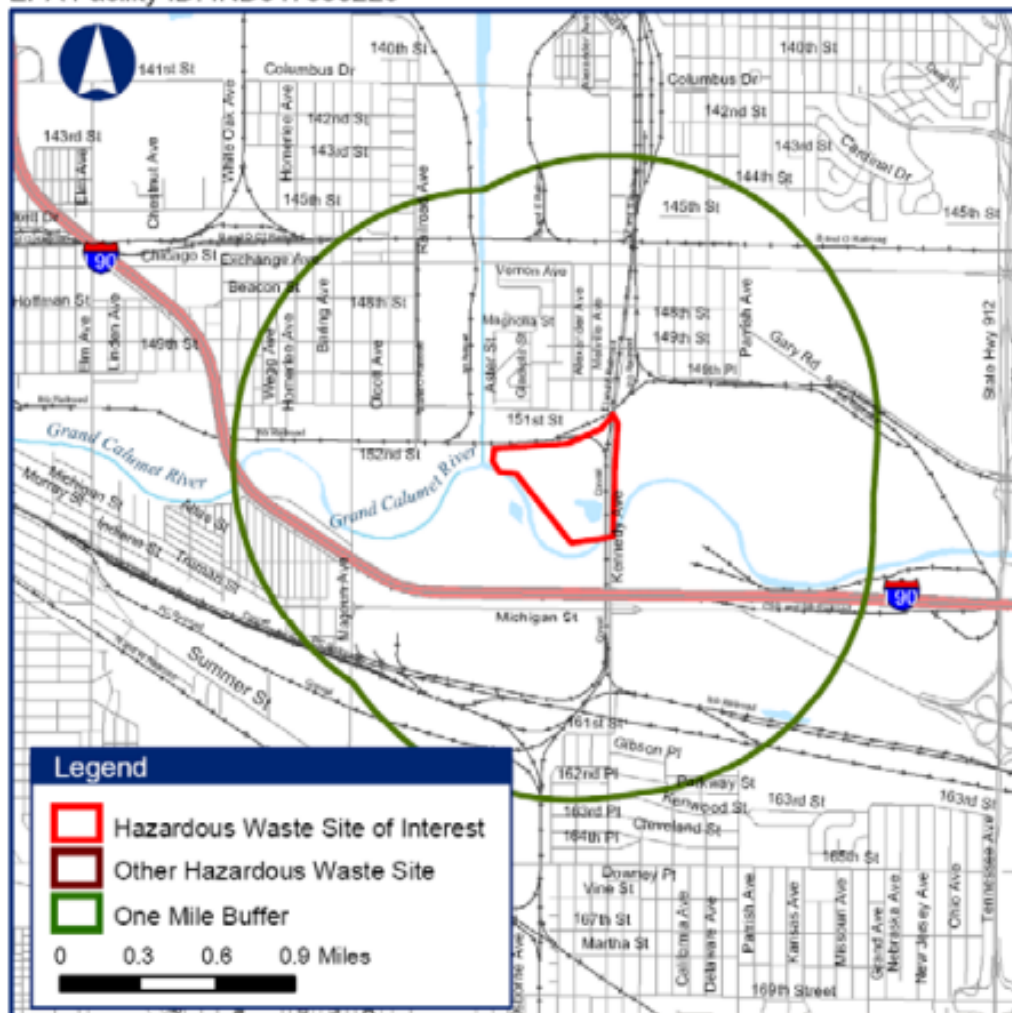
East Chicago, Indiana



U.S. Smelter and Lead Refinery, Inc. East Chicago, IN



EPA Facility ID: IND047030226



Site Location: Lake County, IN



Demographic Statistics Within One Mile of Site*

Total Population	11,818
White Alone	5,102
Black Alone	3,950
Am. Indian & Alaska Native Alone	63
Asian Alone	12
Native Hawaiian & Other Pacific Islander Alone	15
Some Other Race Alone	2,331
Two or More Races	345
Hispanic or Latino**	5,423
Children Aged 6 and Younger	1,513
Adults Aged 65 and Older	1,632
Females Aged 15 to 44	2,610
Total Housing Units	4,862

Base Map Source: Geographic Data Technology, May 2005.

Site Boundary Data Source: ATSDR Geospatial Research, Analysis, and Services Program,
Current as of Generate Date (bottom left-hand corner).

Coordinate System (All Panels): NAD 1983 StatePlane Indiana West FIPS 1302 Feet

Demographics Statistics Source: 2000 U.S. Census

* Calculated using an area-proportion spatial analysis technique

** People who identify their origin as Hispanic or Latino may be of any race.

Soil Lead Levels East Chicago

EPA standard: 400ppm in bare soil in play areas and 1200 ppm for non-play areas

1	Depth	Front - Lead (ppm)	Back - Lead (ppm)
2	0-6 inches	704	805
3	6-12 inches	3,320	1,016
4	12-18 inches	12,900	1,958
5	18-24 inches	16,800	1,166
6	24-30 inches	7,609	1,110
7	0-6 inches	1,240	572
8	6-12 inches	3,230	1,938
9	12-18 inches	2,114	9,230
10	18-24 inches	4,480	7,130
11	24-30 inches	3,017	Native Sand (NS)
12	0-6 inches	2,010	619
13	6-12 inches	8,160	1,486
14	12-18 inches	5,610	2,476
15	18-24 inches	15,100	1,792
16	24-30 inches	14,923	2,778
17	0-6 inches	11,700	1,160
18	6-12 inches	12,100	5,050
19	12-18 inches	20,200	7,930
20	18-24 inches	14,100	7,120
21	24-30 inches	7,777	4,460
22	0-6 inches	1,370	1,773
23	6-12 inches	2,460	1,926
24	12-18 inches	6,420	5,330
25	18-24 inches	8,240	2,850
26	24-30 inches	2,468	2,175
27	0-6 inches	996	333
28	6-12 inches	6,520	1,307
29	12-18 inches	3,810	7,880
30	18-24 inches	2,140	5,930
31	24-30 inches	694	6,694
32	0-6 inches	2,220	2,160

East Chicago - Response

1. Testing – soil, blood screening, indoor dust
2. Outdoors – mulch, excavation
3. Clean up/remediation – indoors
4. Demolition, Re-location
5. Service line replacement



Lead Surveillance in East Chicago

Total tested: >2,000

Percent children <6yo with BLL \geq 5ug/dL = **8-12%**

Besides one child with BLL = 33ug/dL, **none > 10ug/dL. No levels > 5ug/dL since January 2017**



Response – East Chicago



EPA in Indiana

[Contact Us](#) [Share](#)

You are here: [EPA Home](#) » [EPA in Indiana](#) » [West Calumet Housing Complex – East Chicago, Ind.](#)

West Calumet Housing Complex – East Chicago, Ind.

Advice for Residents

EPA has found high levels of lead in soil in parts of the West Calumet Housing Complex. Residents have been notified about results of sampling of soil around their homes. EPA community involvement coordinators have gone door-to-door warning residents not to allow children to play in dirt and providing information on ways to reduce exposure to possible lead in soil. Exposure to high levels of lead in soil can cause various health problems, especially in young children.

To ensure the health and safety of children, the federal Agency for Toxic Substances and Disease Registry, or ATSDR, advises parents to prevent children from playing in dirt or mulch, to wash their children's toys regularly and to wash children's hands after they play outside. All residents should remove shoes before walking into their homes. ATSDR officials also recommend residents in the West Calumet Housing Complex not disturb the mulch or dig or garden in their yards.

West Calumet residents may have their children's blood lead tested by calling the East Chicago Health Department at 219-391-8467.

To learn about preventing children's exposure to lead, visit: [Prevent Children's Exposure to Lead](#)



[Map of West Calumet Housing Complex - East Chicago - Ind.](#)

Contacts

EPA Community Involvement Coordinator

[Janet Pope](#)

(Pope.janet@epa.gov)

312-353-0628

Remedial Project Manager

[Thomas Alcamo](#)

(alcamo.thomas@epa.gov)

312-886-7278

[Timothy Drexler](#)

(drexler.timothy@epa.gov)

312-353-4367

EPA On-Scene Coordinator

[Brad Benning](#)

(benning.bradley@epa.gov)

312-353-7613

[Kristina Behnke](#)

Messaging

Their Soil Toxic, 1,100 Indiana Residents Scramble to Find New Homes

By ABBY GOODNOUGH AUG. 30, 2016



Stephanie King with her daughter Ivianna Prater, 8, at their home in the West Calumet Housing Complex in East Chicago, Ind. Soil at the complex has been found to contain high levels of lead, and Ms. King's 3-year-old son, Jostah, has a worrisome amount of lead in his blood, test results show.

Alyssa Schukar for The New York Times

Thanks for the feedback! [Undo](#)

We'll use your feedback to review ads on this site.

Help us show you better ads by updating your [ads settings](#)

URGENT

West Calumet Housing Complex

East Chicago officials accused EPA of 'breaking trust' in lead cleanup

From the Times coverage of high lead levels at West Calumet series

Sarah Reese sarah.reese@nwi.com, (219) 933-3351 Updated 21 hrs ago



CHOOSE QUALITY... CHOOSE EXPERT CARE

Choose Community Hospital for the orthopedic program and surgeons that Healthgrades has chosen among their 100 Best.

AMERICA'S 100 BEST ORTHOPEDIC SURGEONS 2016 healthgrades

Community Healthcare System® **COMMUNITY Hospital** 901 MooArthur Blvd, Muncie, Indiana 47302 **Learn More**

Latest in section

[Safety at Hanover Schools](#)

[Heritage month celebration planned](#)

Lead is an invisible neurotoxin lurking throughout our environment.

- Test your family
- Test your home
- Test your water

LeadCare® II Blood Lead Testing System.
The only point-of-care test with immediate answers.



Point of care testing: What to do about lead poisoning in the age of error?

Jennifer A. Lowry, MD, FAAP, FAACT, FACMT

Chief, Section of Toxicology and Environmental Health, Children's Mercy, Kansas City
Chair, Council on Environmental Health, American Academy of Pediatrics

- This presentation was supported, in part, by the American College of Medical Toxicology (ACMT) and funded (in part) by the cooperative agreement FAIN: U61TS000238 from the Agency for Toxic Substances and Disease Registry (ATSDR).

- Acknowledgement: The U.S. Environmental Protection Agency (EPA) supports the PEHSU by providing partial funding to ATSDR under Inter-Agency Agreement number DW-75-92301301. Neither EPA nor ATSDR endorse the purchase of any commercial products or services mentioned in PEHSU publications.

Objectives

At the end of this presentation, participants will be able to:

- Recall the events that lead to the FDA/CDC announcement regarding use of Lead Care II for venous testing
- Explain why recommendations by CDC were made
- Discuss the individual needs of patients who received venous testing using point of care testing.

Scope of the Problem

FDA Warns Against Using Magellan Diagnostics LeadCare Testing Systems with Blood Obtained from a Vein: FDA Safety Communication

Date Issued:

May 17, 2017

Audiences:

- Laboratories that use Magellan's LeadCare Testing Systems as part of diagnostic applications.
- Laboratory personnel who interpret the results of Magellan's LeadCare Testing Systems.
- Health care professionals who perform lead tests using Magellan's LeadCare Testing Systems.
- Patients being tested for elevated blood lead levels (BLL) with Magellan's LeadCare Testing Systems, in particular children in high-risk environments with BLL in the 5 to 14 micrograms per deciliter ($\mu\text{g}/\text{dl}$) range.

Medical Specialties:

Pediatrics, Family Medicine, Internal Medicine, Preventive Medicine, Obstetrics/Gynecology, Emergency Medicine, Clinical Pathology, Hematology/Oncology, Laboratory Medicine, Emergency Medicine, Occupational Health, Safety Specialists

Product:

Magellan Diagnostics Inc. manufactures the following lead testing systems affected by this warning: LeadCare, LeadCare II, LeadCare Plus, and LeadCare Ultra.

The LeadCare Testing Systems detect the amount of lead in a blood sample obtained from finger or heel prick (capillary) or from a vein (venous). This warning applies to all four Magellan Diagnostics LeadCare Testing Systems when processing **venous blood samples**, in the United States.

Note: Magellan's LeadCare II is a point-of-care (CLIA-waived) blood lead testing system on which users mostly test capillary blood samples. However, some laboratories also process venous blood samples with the LeadCare II system, which is why this safety communication includes all Magellan LeadCare Testing Systems.

The LeadCare Testing Systems are used in clinical laboratories, doctor's offices, clinics, and hospitals throughout the U.S.

Timeline of Events

August 2014

- Magellan Diagnostics' reports initially recognized possible problems with the performance of their LeadCare Ultra.

November 4, 2016

- Notified customers of similar problems when processing venous blood samples via LeadCare II testing systems and recommended a 4 hour incubation period for blood collection tubes received by laboratories from other facilities.

April 28, 2017,

- Notified customers they should no longer use BD blood collection tubes with lavender or tan-colored tops with their LeadCare Ultra and Plus systems, and should discontinue the 24 hour incubation step.

November 24, 2014

- Sent letter to customers instructing facilities to implement a 24 hour incubation step with the blood sample to mitigate and fully resolve what they noted was a low risk of underestimation of BLL.

November 11, 2016

- Notified customers by bulletin the rubber caps of Becton Dickinson's (BD) K2-EDTA Vacutainer blood collection tubes may introduce a substance into blood sample when used with LeadCare II systems. Instructed facilities to implement a minimum 4 hour incubation step with blood sample to mitigate rubber cap exposure.

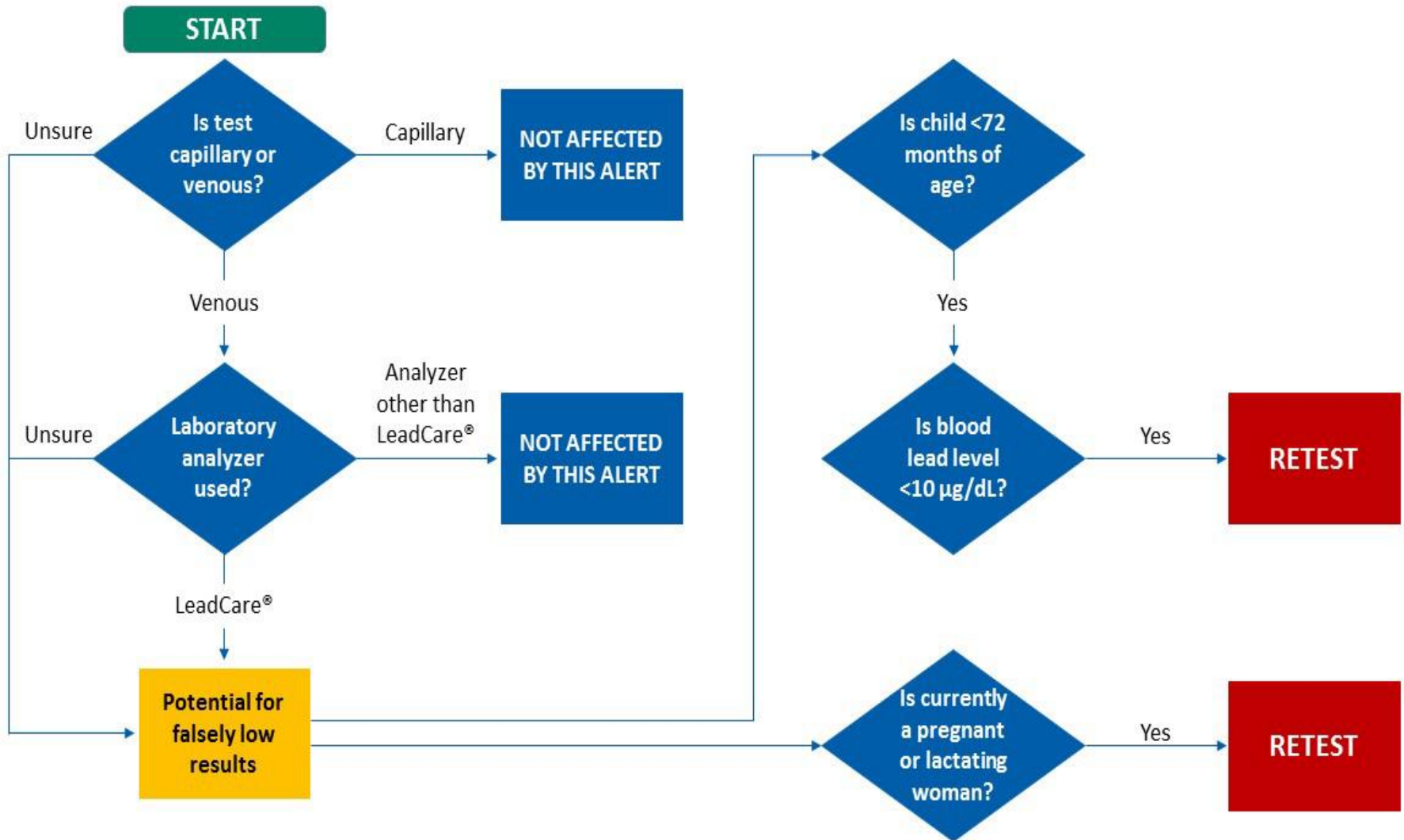
FDA Response

- Review of data supporting the issues contained in customer notifications did not confirm a root cause (including the tubes) for the inaccurate results.
- Found a lack of reliable data:
 - identifying the root cause of the problem,
 - the frequency and extent of inaccurate test results, and
 - adequate effectiveness to support the mitigating steps taken by Magellan.

FDA Response

- No evidence Magellan's LeadCare Testing Systems have the same problem when processing capillary blood samples.
- Unable to identify root cause for inaccurate results, based on data provided by Magellan.
- Conducting studies with the CDC to identify cause and better characterize the extent of problem.
- No reason to believe other lead tests, such as those using mass spectrometry, are affected by this issue.

CDC Response



AAP Response



THE OFFICIAL NEWSMAGAZINE OF THE AMERICAN ACADEMY OF PEDIATRICS

AAP News

News Articles, Environmental Health, Lead

FDA: Blood lead tests may have been inaccurate

by Melissa Jenco, News Content Editor

Some children need to have their blood lead levels rechecked due to inaccurate test results, federal health officials said Wednesday.

Magellan LeadCare Testing Systems used for venous tests have been found to underestimate blood lead levels, providing some patients with a false negative, according to the Food and Drug Administration (FDA).

"Falsely lower test results may lead to improper patient management and treatment for lead exposure or poisoning," the FDA said in a [safety communication](#).

Lead exposure has been associated with health, learning and behavior problems, and no amount is considered safe. Children in at least 4 million households are exposed to high lead levels, according to the Centers for Disease Control and Prevention (CDC).

Most commonly, children's blood is tested for lead via a finger or heel stick known as a capillary test. If the results show elevated lead levels, they need to be confirmed through a venous test in which blood is drawn from the arm. It is the venous tests, if run on Magellan LeadCare Testing Systems, that are of concern.

Magellan Diagnostics has been working to mitigate issues with the test system since August 2014, and the FDA has been unable to determine the cause of the problems.

The CDC is recommending children be retested using another method if they meet all of the following criteria:

- currently under 6 years old,
- had a venous test evaluated on the Magellan LeadCare Testing Systems, and
- had a blood lead level less than 10 µg/dL.

Pregnant or lactating women who had one of these tests also should be retested. Families with concerns should speak with their doctor to determine if retesting is necessary.

"These recommendations are being made to ensure that children who continue to have exposures in environments that contain lead are assessed and receive the resources needed to stop the exposure," said Jennifer A. Lowry, M.D., FAAP, chair of the AAP Council on Environmental Health Executive Committee.

If a child is found to have high blood lead levels, pediatricians should follow the management guidance in the 2016 AAP policy [Prevention of Childhood Lead Toxicity](#). They also can reach out to their local [Pediatric Environmental Health Specialty Unit](#) for additional support.

If a child's new test is negative, a pediatrician can't rule out past exposure but at least can receive some reassurance the exposure is not ongoing.

Dr. Lowry emphasized the importance of prevention and early detection of lead exposure. Pediatricians should ask families regularly about risk factors like low socioeconomic status, recent immigration and living in older buildings and follow up with appropriate testing and resources. They also can educate parents regarding sources of lead like lead-based paints, toys, cosmetics, ethnic spices, certain occupations and hobbies and water from corroding plumbing.

"It's really important to know we can overcome this with good nutrition and good education," Dr. Lowry said.

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™

For Immediate Release: May 17, 2017

Media Contacts: Jamie Poslosky (202-724-3301, jposlosky@aap.org)
Susan Stevens Martin (847-434-7131, ssmartin@aap.org)

American Academy of Pediatrics Urges Parents to Confirm Lead Tests Following FDA Warning *Children age 6 and younger may need to be re-tested if they had a faulty lead test*

Washington, DC— The American Academy of Pediatrics (AAP), following [recommendations](#) from the Centers for Disease Control and Prevention (CDC), is urging parents of children ages 6 and younger who received a venous blood test for lead (in which blood is drawn from the arm), to discuss with their child's pediatrician whether a new test is needed. This recommendation follows a [warning](#) issued today by the U.S. Food and Drug Administration (FDA) about a specific kind of venous blood lead test conducted using Magellan LeadCare Testing Systems that has been found to underestimate the amount of lead in blood samples.

"Pediatricians work every day to ensure children can grow up healthy and thrive, and part of how we do that is to screen and test for lead exposure in children," said Fernando Stein, MD, FAAP, president of the AAP. "Most children are tested for lead poisoning with a finger or heel stick, which is not impacted by today's warning. Parents of children age 6 and younger who have had a venous blood lead test, meaning blood was drawn from their arm, should talk with their pediatrician about whether their child needs to be re-tested. The AAP will work with our pediatrician members to provide those families impacted by today's warning with the resources and guidance they need to protect their children from lead exposure."

Lead poisoning is usually detected by measuring the level of lead in blood. The most common way children's blood is tested for lead is through a finger or heel stick known as a capillary test. If the results show elevated lead levels, they need to be confirmed through a venous test. Children ages 6 and younger whose results were 10 micrograms per deciliter (µg/dL) or lower from this particular faulty venous test may need to be re-tested.

Children in at least 4 million households are exposed to high lead levels, according to the CDC. Low-level lead exposure, even at blood lead concentrations below 5 µg/dL, can increase the risk of intellectual and academic disabilities in children, and is linked to higher rates of neurobehavioral disorders such as hyperactivity and attention deficits, and lower birth weight.

"There is no safe level of lead exposure for children, and the best 'treatment' for lead poisoning is to prevent lead exposure before it happens," said Jennifer Lowry, MD, FAAP, chair of the American Academy of Pediatrics Council on Environmental Health. "Pediatricians have an important role to play by asking questions about a family's risk for lead exposure. Children can be exposed to lead in a variety of ways, such as living in an older home or a home undergoing renovations, or in a home with lead pipes. Certain toys, hobbies and parents' occupations also increase the risk that a child could be exposed to lead, so it's important to talk with your pediatrician about how to lower your child's risk."

Preventing lead exposure is the most reliable and cost-effective measure to protect children from lead poisoning, according to the AAP. Treatment for children with high levels of lead in their blood is to remove them from the environment that poses the hazard, such as older buildings.

AAP Response: Who and why?

The CDC is recommending children be retested using another method if they meet all of the following criteria:

- currently under 6 years old,
- had a **venous** test evaluated on the Magellan LeadCare Testing Systems, and
- had a blood lead level less than 10 µg/dL.

Pregnant or lactating women who had one of these tests also should be retested. Families with concerns should speak with their doctor to determine if retesting is necessary.

"These recommendations are being made to ensure that children who continue to have exposures in environments that contain lead are assessed and receive the resources needed to stop the exposure," said Jennifer A. Lowry, M.D., FAAP, chair of the AAP Council on Environmental Health Executive Committee.

If a child is found to have high blood lead levels, pediatricians should follow the management guidance in the 2016 AAP policy *Prevention of Childhood Lead Toxicity*. They also can reach out to their local **Pediatric Environmental Health Specialty Unit** for additional support.

If a child's new test is negative, a pediatrician can't rule out past exposure but at least can receive some reassurance the exposure is not ongoing.

Dr. Lowry emphasized the importance of prevention and early detection of lead exposure. Pediatricians should ask families regularly about risk factors like low socioeconomic status, recent immigration and living in older buildings and follow up with appropriate testing and resources. They also can educate parents regarding sources of lead like lead-based paints, toys, cosmetics, ethnic spices, certain occupations and hobbies and water from corroding plumbing.

Theories of Cause

- On November 11, 2016, Magellan notified customers by bulletin that the rubber caps of the Becton Dickinson's (BD) **K2-EDTA** Vacutainer blood collection tubes may introduce a substance into the blood sample when used with their LeadCare II systems. The bulletin instructed facilities to implement a minimum 4 hour incubation step with the blood sample to mitigate rubber cap exposure.

Next steps

- FDA and CDC have ongoing investigations to discover the root cause.
- FDA also concerned about reporting of capillary blood lead tests and have ongoing investigation. No details on that at this time.
- AAP reevaluating Lead Policy and considering early revision.
- PEHSU Lead Management Factsheet update soon

Questions?

