



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

Wendy E. Saunders
Executive Deputy Commissioner

June 2009

Dear Doctor/Health Care Provider:

The purpose of this letter is to share new materials on childhood lead poisoning with you, developed by the New York State Department of Health (NYSDOH). A growing number of epidemiological studies show that blood lead levels (BLLs) between 5 and 10 $\mu\text{g}/\text{dL}$ in young children are associated with learning disabilities, behavior problems, and lowered intelligence. Such low-level exposure to lead harms thousands of children each year, whose BLLs do not fit the current definition of lead poisoning. Some of your young patients are undoubtedly affected: New York has more pre-1950 housing containing lead paint than any other state in the nation, found in approximately 43 percent of all of New York's dwellings.

In response to our greater understanding of lead's effects on pediatric health, the NYSDOH has developed new educational materials for use in your office that will help parents understand their children's blood lead test results. A copy of these educational materials is enclosed. In addition, all laboratory blood lead test reports in New York State (NYS) will now include the following comment language: "Blood lead levels in the range of 5-9 $\mu\text{g}/\text{dL}$ have been associated with adverse health effects in children aged 6 years and younger." The term "normal" should no longer be used to describe detectable BLLs less than 10 $\mu\text{g}/\text{dL}$.

Both the federal Centers for Disease Control and Prevention (CDC) and the NYSDOH urge medical providers to do more to identify and proactively address children's BLLs. In 2007, the CDC issued new recommendations for the interpretation and management of BLLs less than 10 $\mu\text{g}/\text{dL}$ in children.¹ Consistent with NYS regulations, the CDC stresses that *all* parents of young children should receive anticipatory guidance on lead poisoning prevention. The CDC also recommends that providers consider more frequent testing (i.e. more than annually) for children whose BLLs are approaching 10 $\mu\text{g}/\text{dL}$, particularly children under two years old, or at high risk for lead exposure.

NYS Public Health Law and regulations require medical providers to test all children for lead with blood lead tests at age one year *and again* at age two years. A recent analysis of NYS blood lead test data showed that 8.5 percent of children who had BLLs of 5 to 9 $\mu\text{g}/\text{dL}$ at age one had BLLs of 10 $\mu\text{g}/\text{dL}$ or higher when tested again at age two, underscoring the importance of the second screening test at age two. Providers are also required to assess lead risk at each well-child visit for all children ages six months to six years, and if risk is found, perform blood lead tests, or refer for testing, and to provide anticipatory guidance for all families about lead poisoning prevention as part of routine care.

¹ Centers for Disease Control and Prevention. Interpreting and Managing Blood Lead Levels < 10 mcg/dL in Children and Reducing Childhood Exposures to Lead: Recommendation of CDC's Advisory Committee on Childhood Lead Poisoning Prevention. MMWR 2007;56(No. RR-#8): [1-16]. Posted on: www.health.state.ny.us/environmental/lead/

Thank you for your efforts to eliminate childhood lead poisoning in NYS. The new educational materials can be photocopied, printed from the NYSDOH Web site, or ordered with the enclosed order form. Also enclosed is contact information for county health departments and regional lead resource centers. If you have any questions or would like additional information, please contact your local health department, or the NYSDOH Lead Poisoning Prevention Program at 518-402-5706, or visit: www.health.state.ny.us/environmental/lead/.

Sincerely,

Richard F. Daines, M.D.
Commissioner of Health

cc: Lead Poisoning Prevention Program



STATE OF NEW YORK DEPARTMENT OF HEALTH

Wadsworth Center

The Governor Nelson A. Rockefeller Empire State Plaza

P.O. Box 509

Albany, New York 12201-0509

Richard F. Daines, M.D.
Commissioner

Wendy Saunders
Executive Deputy Commissioner

June 2, 2009

Dear Colleague,

Some time ago we contacted clinical laboratories holding a New York State permit for blood lead testing, and requested input on proposed comment language for interpreting blood lead concentrations $<10 \mu\text{g/dL}$. We are grateful to the numerous professionals who provided insightful and constructive comments. Several expressed concern that laboratories could be overwhelmed with enquiries from pediatric health care providers regarding the commentary language on laboratory test reports for blood lead.

To address this concern, we have been coordinating efforts with the Department of Health's Bureau of Child and Adolescent Health to inform pediatric health care providers about the new evidence for associations between adverse health effect and blood lead levels in the range $5-9 \mu\text{g/dL}$. We feel it would be preferable to implement the requirement on commentary language for blood lead levels simultaneously with plans to provide updated materials to pediatric health care providers on the new evidence for associations between adverse health effects and blood lead levels in the range $5-9 \mu\text{g/dL}$. This resulted in a delay on our part while the materials for health care providers were finalized, but we are now ready to move forward on both fronts.

With respect to the specific comments that were received regarding commentary language, our responses are provided in the attachment. On the whole, there was a general consensus on the need to alert pediatricians to the potentially harmful effects of exposure to lower levels of lead. Some commenters, however, appeared to misunderstand our proposed standard as a policy change in the threshold currently defined by the US Centers for Disease Control and Prevention (CDC) as a level of concern in children. It was never our intention to change the action threshold of $10 \mu\text{g/dL}$, above which specific public health interventions are recommended. Rather, it was our intention to highlight the emerging consensus among environmental epidemiologists, medical practitioners and public health professionals as recognizing that chronic exposure to lead at levels below $10 \mu\text{g/dL}$ are associated with adverse health effects.

Several commenters pointed out that our original proposed language, "*Blood lead levels $<10 \mu\text{g/dL}$ have been associated with adverse health effects in young children*", implied that such adverse health effects were evident at blood lead levels below $5 \mu\text{g/dL}$. We accept that, as it is written, the standard might infer that lead is harmful below $5 \mu\text{g/dL}$, when in fact the cited scientific literature has specifically identified blood lead exposures in the interval $5-9 \mu\text{g/dL}$ as associated with adverse health effects. To address this specific issue, the proposed comment language was modified to:

"Blood lead levels in the range $5-9 \mu\text{g/dL}$ have been associated with adverse health effects in children aged 6 years and younger"

This commentary language has been designated as Blood Lead Standard 11 (BL 11), and it will be required of all laboratories holding a New York State permit in the category Toxicology - Blood Lead. The effective date for implementation will be September 1, 2009.

We appreciate your input and cooperation in developing robust standards for blood lead testing. Questions regarding laboratory standards can be directed to Ms. Beth Johansen at 518-402-4186. Technical questions concerning lead testing can be directed to Dr. Mary Fran Verostek, Assistant Section Head, Blood Lead Reference System Lab 518-474-4924.

Sincerely,

Richard Jenny, Ph.D. Director
Clinical Laboratory Evaluation Program

Patrick J. Parsons, Ph.D.
Chief, Lab of Inorganic and Nuclear Chemistry
Section Head, Blood Lead Reference System Lab

**NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY REFERENCE SYSTEM
LEAD TESTING STANDARD 11
COMMENTS and RESPONSES**

In February 2008, we provided to blood lead testing laboratories the proposed reporting standard for blood lead as stated below. We received several comments and revised the standard to address those comments.

	Proposed Standard	Guidance
BL11	Blood Lead Standard 11 Reference ranges on patient reports must indicate that blood lead levels less than 10 µg/dL have been associated with adverse health effects in young children.	Reports should not indicate that lead levels less than 10 µg/dL are "normal".

The following is the blood lead reporting standard that will become effective on September 1, 2009.

	Revised Standard – Implementation Sept 1, 2009	Guidance
BL11	Blood Lead Standard 11 Reference ranges on patient reports must indicate that blood lead levels in the range 5-9 µg/dL have been associated with adverse health effects in children aged 6 years and younger.	Reports should not indicate that lead levels less than 10 µg/dL are "normal".

Responses to Comments made by blood lead testing laboratories after review of the proposed blood lead reporting standard.

Comment 1
Is it a regulatory requirement that a comment interpreting BLL results be included with the test value? If not, then maybe it would be simpler to preclude labs from offering any comment on the BLL, i.e., say nothing about <10 ug/dL as normal or otherwise. The idea would be to move away from seeing that number anywhere on the result page. If it is required then the standard could read: "BLLs > 0 ug/dL are associated with adverse health effects". If necessary, there could be a comment about the detection limit of that lab's methodology. The Guidance would then read: "Exposure to lead resulting in BLLs >0 ug/dL is associated with adverse health effects, including effects on children's intellectual functioning."

Response:

Laboratory test comments can be required under NYS regulatory oversight of clinical laboratories. This is desirable to ensure uniform reporting and interpretation of specific test results that have a public health impact.

We have modified the language of the comment to address concerns about laboratory specific detection limits.

We have not defined specific adverse health effects in the comment language, but have left that issue to a more detail guidance letter that will be distributed to pediatric health care providers.

Comment 2

We received your request for comment on the proposed blood lead standard 11 (BL11). At our laboratory, our detection limit is 1.0 ug/dL and we report levels of 2 and 3 ug/dL. To the best of our knowledge, levels this low have not been shown to have adverse health effects even in children. (The evidence is stronger for adverse health effects between 5 and 10 ug/dL). Reporting that levels this low have been associated with adverse health effects, may cause inappropriate parental concern and perhaps, inappropriate medical inquiry/intervention. We favor the approach the CDC is considering and that is to lower the reference range to 5 ug/dL.

Response:

We have modified the language of the comment to address concerns about laboratory specific detection limits. The text now is specific to blood lead levels in the range 5-9 µg/dL.

Comment 3

While I am in agreement that lead levels below 10 ug/dl are a concern among “young children” (how young?), I think there needs to be some defined lower limit. Our lab reports results greater than 2 ug/dl using anodic stripping.

I think the obvious question clients will have is whether lead results of <2 is associated with adverse health effects in this population since this result is also technically <10. In that case, what is “normal”? It will also be confusing on the report since we need to define the upper limit of normal in the LIS which may not match the comment.

The CDC website suggests that the reason there is a 10 ug/dl cutoff is that most labs can not distinguish levels below this value. They mention: Finally, there is no evidence of a threshold below which adverse effects are not experienced. Thus, any decision to establish a new level of concern would be arbitrary and provide uncertain benefits.

Perhaps a comment which suggests that that lead levels below 10 ug/dl should be interpreted with caution and have been associated with adverse health effects in young children...This may not be an improvement.

Response:

We have modified the language of the comment to address concerns about laboratory specific detection limits. The text now is specific to blood lead levels in the range 5-9 µg/dL.

We have specified young children as aged 6 years or younger. This is consistent with the cited research studies and with public health recommendations for screening children for lead exposure.

Comment 4

The language of the comment could be confusing. I imagine with the comment as it is written, I will receive calls from physicians wanting to know more about lead deficiencies causing adverse health defects in children. This is opposite of what you are wanting to relay to the physician. What about changing the comment to "Any detectable level of lead in the blood can be associated with adverse health effects in young children". This comment should be attached to all pediatric blood lead testing reports irregardless of the level detected.

Response:

We are coordinating our efforts with our colleagues in the Department of Health's Bureau of Child and Adolescent Health to inform pediatric health care providers about the new evidence for associations between adverse health effect and blood lead levels in the range 5-9 µg/dL. Specifically, pediatric health care providers will be receiving guidance on interpretation on, and changes in recommended interventions for, children with BLLs between 5-9 µg/dL.

Comment 5

... agreed that some alert is needed. would like to see this incorporated into the pediatrician's handbook for lead and the application to class 1 thru class 5. Would like to see a recommendation for risk reduction in class 2 a, such as a note for environmental history & nutrition education. The reports may cause family anxiety with no recourse. Hand book should include recommendations for risk reduction.

Will check if reporting system routinely uses the word "normal" on the report. Concerned that the note will be missed since all notes are printed on the bottom of the page.

Response:

See response to comment above.

Comment 6

In reference to the letter of 2/18/08, the proposed wording will cause us great hardship. We copied the form used by the NYSDOH lead lab 20 years ago and currently order 10-20,000 forms at a time. To reformat the ranges with the language proposed, it would require a complete form change. I am in complete agreement with the intent of the language but do not have the space on the form for such a long sentence. I would like to propose removing "normal" from the < 10ug/dl and replacing it with "possible adverse effects". We believe this phrase would more easily fit into the spacing available on our form.

Response:

There will be some flexibility in phasing in this reporting requirement, and consideration will be given to laboratories using manual reporting methods, where space for reporting comments is limited.

Comment 7

The NYDOH proposed on February 15, 2008 that an interpretive comment be appended to any result for which a blood lead concentration above the method limit of detection of the assay but less than 10 µg/dL is reported. The specific language proposed is:
"Blood lead levels <10 µg/dL have been associated with adverse health effects in young children."

Please consider our comments and concerns about this proposal:

1. We prefer the use of “concentration” rather than “level.”
2. The comment does not identify the limit of detection for the analytical method employed, and therefore implies that a blood lead concentration of “0.1 µg/dL” could be associated with adverse health effects. This implication may be confusing and too vague to be clinically useful.
3. We recognize, however, that concentrations of lead in blood less than 10 µg/dL could be clinically significant. Dictating the specific language used on a laboratory report is, in our opinion, inappropriate, without consensus of national or international scientific, epidemiologic, and clinical experts. Until the Centers for Disease Control or other similar organization provides a specific threshold for safety, we advise that the NYDOH standard should require that a comment be made which alerts the clinician/client who ordered the test that a concentration of lead less than 10 µg/dL may contribute to adverse health effects in young children, but that the NYDOH should not require or dictate the specific language to be used.

Thank-you for your consideration. We look forward to reviewing the final standard revisions.

Response:

1. *There will be some flexibility in implementing the exact text. Equivalent words may be used.*
2. *We have modified the language of the comment to address concerns about laboratory specific detection limits. The text now is specific to blood lead levels in the range 5-9 µg/dL.*
3. *It was not our intention to change the CDC/NYS action threshold of 10 µg/dL, above which specific public health interventions are recommended. Rather, it was our intention to highlight the emerging consensus that chronic exposure to lead at levels 5-9 µg/dL are associated with adverse health effects. While some flexibility will be given to implementing the exact text, the essence of the comment must be to convey the current consensus that adverse health effects are associated with blood lead levels of 5-9 µg/dL.*

Comment 8

I think that the proposed verbiage will cause some confusion for individuals interpreting the reports....>10 ug/dL is bad, but so is < 10 ug/dL? Any level of lead detected is possibly detrimental, even <2.0 ug/dL which is as low as we can report?

Response:

The threshold at 10 µg/dL is an action level above which specific public health interventions are recommended. While we recognize that blood lead levels in the interval 5-9 µg/dL have been associated with adverse health effects, no specific intervention is recommended at this time. We feel that the revised language for the comment coupled with more detailed information on interpretation that will be sent to pediatric health care providers, addresses the concerns expressed by the commenter.