Report to the Legislature

Revision of the MDH Childhood Blood Lead Clinical Treatment and Case Management Guidelines

January 2011

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MINNESOTA MDH DEPARTMENT OF HEALTH

Protecting, maintaining and improving the health of all Minnesotans

January 27, 2010

Dear Partners in Lead Poisoning Prevention,

I am pleased to provide you with a copy of the Minnesota Department of Health (MDH) 2010 Blood Lead Level Guidelines Revision: Clinical Treatment and Case Management Guidelines Report to the Legislature (Report). The Report was required by the Laws of Minnesota 2010, Chapter 144, Section 9504, Subdivision 12 in response to concerns over the effects of low-level lead exposure in children.

The Report presents revisions to the clinical and case management guidelines, including recommendations for protective health actions and follow-up services when a child's blood lead level (BLL) exceeds 5 µg/dL. To assist in the revision process, MDH recruited an expert panel of highly knowledgeable individuals in the areas of lead testing in children, management of lead poisoning cases, and lead abatement.

The final format of the guidelines is the result of a compromise between concerns over low-level lead exposure and concerns over the best use of limited resources. On balance, the new guidelines reflect, to the best extent possible, the diverse recommendations of the expert panel.

The State of Minnesota has consistently played a leading role in identifying and addressing public health issues related to lead exposure. More information about childhood lead poisoning is available on the MDH Lead Program website at: http://www.health.state.mn.us/divs/eh/lead . If you would like additional information regarding the MDH Lead Program, please feel free to contact Linda Bruemmer, Environmental Health Division Director at (651) 201-4739 or linda.bruemmer@health.state.mn.us.

Sincerely,

Edward Ehlinger, M.D., M.S.P.H.
Commissioner
P.O. Box 64975
St. Paul, MN 55164-0975

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Executive Summary

Lead exposure at high levels (>10 µg/dL) has been shown to have an adverse effect on cognitive function in children. Mosby's Medical Dictionary defines cognitive function as "an intellectual process by which one becomes aware of, perceives, or comprehends ideas. It involves all aspects of perception, thinking, reasoning, and remembering." There is growing evidence that exposure to lead at low levels (<10 µg/dL) may also have a negative effect on cognitive functioning in children. In response to concerns over the effects of low-level lead exposure in children, the 2009-2010 Legislature directed MDH to revise clinical and case management guidelines to include recommendations for protective health actions and follow-up services when a child's blood lead level (BLL) exceeds 5 µg/dL.

Before making any revisions to the current clinical treatment and case management guidelines, MDH recruited an expert panel consisting of highly knowledgeable and experienced individuals in the areas of lead testing in children, management of lead poisoning cases, and lead hazard reduction. The expert panel included representatives from public health agencies, health plans, and a nonprofit organization specializing in lead abatement, a physician representing the Minnesota Medical Association, and key MDH staff.

The lead clinical and case management guideline revision meeting was held on 11/10/10. All meeting attendees agreed that as the level of lead exposure increases there is an increasingly negative effect on cognitive functioning in children and that there is no "safe" level of lead exposure. In addition, all meeting attendees agreed that primary prevention (e.g. reducing lead hazards based on housing characteristics rather than blood lead testing) must be a priority to help reduce lead exposure in children.

Changes for both sets of guidelines included adding new guidelines for BLLs between 5 and 9.9 µg/dL, and shifting some of the guidelines previously listed for all BLLs < 10 µg/dL to a new category of all BLLs < 5 µg/dL. In addition, for the 5-9.9 µg/dL range, a recommendation was added for a confirmatory venous test within 3 months to ensure that medical management is targeted only to those cases with confirmed lead exposure above 5µg/dL.

The final format of the guidelines is the result of a compromise between concerns over low-level lead exposure and concerns over the best use of limited resources. On balance, the new guidelines reflect, to the best extent possible, the diverse recommendations of the expert panel. While recommendations for test results < 10 ug/dL are appropriate, it is critical to remember that results > 10 ug/dL are, and should remain, the highest priority for medical and public health resources

Introduction

MDH has developed and published four different guidelines for lead addressing blood lead screening, clinical treatment, and case management for children, and blood lead screening for pregnant women. These guidelines were developed by collaborative workgroups to aid health care professionals and physicians in identifying lead poisoning in children and treating elevated blood lead levels (EBBLs). This report will focus on published guidelines for blood lead clinical treatment and case management. The clinical treatment and case management guidelines were first published in the summer of 2001, and were revised in 2006 to reflect current state statutes and knowledge gained from multiple years of implementation. Further information and copies of all blood lead guidelines published by MDH may be found at the MDH Lead Program website: http://www.health.state.mn.us/divs/eh/lead/guidelines/index.html

The negative effect of lead exposure at high levels (>10 micrograms of lead per deciliter of blood, µg/dL) on cognitive function in children is well established. Mosby's Medical Dictionary defines cognitive function as "an intellectual process by which one becomes aware of, perceives, or comprehends ideas. It involves all aspects of perception, thinking, reasoning, and remembering." There is growing evidence that exposure at lower levels (<10 µg/dL) may also have a negative effect on cognitive functioning in children. In response to concerns over possible effects at low levels of lead exposure, House File No. 419 was passed during the 2009-2010 Legislative session, mandating a revision of the clinical and case management guidelines to include recommendations for protective health actions and follow-up services when a child's blood lead level exceeds 5 µg/dL.

The text of House File No. 419, which was passed and incorporated into Minnesota Statute, is listed below:

Section 1. Minnesota Statutes 2008, section 144.9504, is amended by adding a subdivision to read:

Subd. 12. Blood lead level guidelines. (a) By January 1, 2011, the commissioner must revise clinical and case management guidelines to include recommendations for protective health actions and follow-up services when a child's blood lead level exceeds five micrograms of lead per deciliter of blood. The revised guidelines must be implemented to the extent possible using available resources.

(b) In revising the clinical and case management guidelines for blood lead levels greater than five micrograms of lead per deciliter of blood under this subdivision, the commissioner of health must consult with a statewide organization representing physicians, the public health department of Minneapolis and other public health departments, and a nonprofit organization with expertise in lead abatement.

In response to the above statute, MDH convened a meeting with experts in the area of lead poisoning in children, including physicians, public health departments, and a nonprofit organization with expertise in lead abatement. Meeting attendees reviewed current guidelines, a relevant literature review, and data on the number of children in Minnesota with blood lead level (BLL) results above 5 µg/dL. This report constitutes submission of the revisions made by MDH to the current clinical and case management guidelines. This report also provides an overview of the measures taken by MDH to make informed guideline revisions.

Review

Before making any revisions to the current clinical treatment and case management guidelines, MDH recruited a group of knowledgeable and experienced individuals in the areas of lead testing in children, management of lead poisoning cases, and lead hazard reduction. Meeting attendees included representatives from public health agencies, health plans, and a nonprofit specializing in lead hazard reduction, a physician representing the Minnesota Medical Association, and key MDH staff. A list of the individuals who attended the meeting can be found in **Appendix A**.

The lead clinical and case management guideline revision meeting was held on November 10, 2010 and was facilitated by MDH. The agenda for the meeting can be found in **Appendix B**. Prior to the meeting, attendees were sent materials for review including current guidelines, a review of relevant published literature, and background data from the MDH blood lead surveillance database.

A copy of the literature review sent to meeting attendees can be found in **Appendix C**. The literature review included summaries of publications focused on BLLs < 10 µg/dL. These summaries were divided into three sections: 1) government recommendation, review and opinion papers, 2) prevalence studies, and 3) research studies. The literature review was provided to help pull together what is known about the effects of BLLs < 10 µg/dL, and what experts and government agencies are recommending be done to address these low levels of lead exposure. The research studies summarized in the literature review provided evidence for an association between BLLs < 10 µg/dL and cognitive functioning in children, and many ended with a call for primary prevention.

A copy of the background data table provided at the November 10th meeting can be found in **Appendix D**. MDH maintains a blood lead surveillance system containing results from blood lead tests on all Minnesota residents. Data for the background table was obtained from the Blood Lead Information System (BLIS), which includes blood test records dating back to 1992. The data table listed the total number of children below six years of age tested for lead poisoning in Minnesota in 2007, 2008 and 2009. The number of tests performed was listed for each of the following result ranges: < 5, 5-5.9, 6-6.9, 7-7.9, 8-8.9, 9-9.9, 10-14.9, and > 15 µg/dL. Data for results between 5 and 9.9 µg/dL were listed separately due to the specific focus on changing guidelines for BLLs in this range.

The meeting started with an overview of the current clinical treatment, case management and screening guidelines for Minnesota, and a review of related publications on health effects and recommended management of BLLs between 5 and 9.9 µg/dL. This was followed by a

discussion on what should be done for children with BLLs between 5 and 9.9 µg/dL, and what can realistically be done taking current resources into account.

Topics of discussion during the meeting included the following:

- The high false positive rate seen with capillary testing, and the need for follow-up venous testing
- Methods that can be used to improve the false positive rate seen with capillary testing, specifically success seen with thorough washing of children's hands before testing
- A request to look into the number of labs reporting "normal" on their reports for results < 10 µg/dL
- The variance seen in lab reporting of results, which can be as high as ±4 µg/dL, although most labs are able to achieve a margin of error of ±2 µg/dL
- Public resources vs. family resources for removing lead from a child's environment
- The need to balance the limited time available to health care providers to address all health concerns during clinic visits with the desire to inform patients of potential lead risks
- Establishing a reasonable expectation for health care provider response to current and future lead exposure as documented by a blood lead test

All meeting attendees agreed that as the level of lead exposure increases there is an increasingly negative effect on cognitive functioning in children and that there is no "safe" level of lead exposure. In addition, all meeting attendees agreed that primary prevention (e.g. reducing lead hazards based on housing characteristics rather than blood lead testing) must be a priority to help reduce lead exposure in children.

Considerable time was also spent discussing the table providing background data on the overall number of children tested in 2007-2009, and the number of children in each result category. Specifically, much of this discussion focused on the number of children with BLLs between 5-5.9 µg/dL. The data in the table reported a very high number of children in the 5-5.9 µg/dL range (n = 8,417 in 2009). Since additional actions were being discussed for children in the 5-9.9 µg/dL range, this number caused concern for some meeting attendees as it was directly related to the resources required to meet updated recommendations. The reason for the high number of children in this BLL category was thought to be the result of labs reporting results as "< 5 µg/dL" instead of providing a specific number. These "< 5 µg/dL" results were then rounded up to a value of 5 µg/dL when the data was analyzed for the background data table. This ultimately resulted in a large number of children being categorized in the 5-5.9 µg/dL category when they should have been categorized in the < 5 µg/dL category.

Shortly after the meeting was concluded, MDH staff compiled a list of meeting notes and identified items that needed follow-up actions. The data table was revised so that BLLs reported as "< 5 µg/dL" were not rounded up, but were instead correctly included in the "< 5 µg/dL category". This resulted in a large reduction in the number of children in the 5-5.9 µg/dL category (n = 1,737 in 2009 versus the previously reported n = 8,417). A data table with these updated numbers can be found in **Appendix D**. The number of labs using the term "normal" for results < 10 µg/dL was also assessed. It was concluded that the majority of labs only list the

blood lead level results, and do not indicate that any results are considered "normal", although this language may be used in the clinic setting when results are discussed with parents.

The draft revised clinical treatment and case management guidelines were sent to all meeting attendees for review on 11/19/10. Written comments were received from a number of reviewers regarding the revised clinical treatment guidelines. These comments are included in **Appendix E** along with a copy of the 11/19/10 draft version of the clinical treatment guidelines. No comments were received regarding the 11/19/10 draft version of the case management guidelines, thus, they are not included in the appendix. In response to comments, an updated version of the clinical treatment guidelines were prepared by MDH and distributed to the expert panel via email on 12/10/10. Additional comments were received relating to the 12/10/10 draft version of the clinical guidelines. These comments are included in **Appendix F** along with a copy of the 12/10/10 draft version of the clinical treatment guidelines. The final guidelines presented in this report represent an attempt to respond to and balance all comments received.

Revisions

After the meeting, MDH staff revised the current clinical treatment and case management guidelines to attempt to incorporate the issues discussed. The reader should note that although MDH was required to examine both sets of guidelines, the purpose of each is different. The clinical treatment guidelines were developed to assist physicians in providing appropriate care in clinical settings, while the case management guidelines were developed to assist local public health in providing consistent and comprehensive management of elevated blood lead cases. Therefore, only those recommendations applicable to the specific target audience were included in the respective guidelines.

Children participating in the Supplemental Food Program for Women, Infants, and Children (WIC) have traditionally been considered to be at risk for exposure to lead. The Minnesota WIC population was not included in the current definition of high risk based on data from a series of pilot studies. In 2005-2006, MDH funded studies of blood lead levels in WIC recipients in Hennepin and Ramsey Counties, counties with the highest proportion of EBLLs among children less than 6 years in the state. Results showed the proportion of EBLLs and the average BLL among WIC children were below corresponding figures in the general population, based on BLIS data. Additional data was collected from four counties (Blue Earth, St. Louis, Stearns, and Winona) and showed similar results. Therefore, participation in WIC in Minnesota does not appear to indicate an additional risk to lead exposure. Detailed reports of these studies are available on the MDH website (www.health.state.mn.us/lead). All MDH lead guidelines will be revised to remove WIC as an exposure risk factor.

Revisions to the guidelines were crafted by MDH to address issues raised in comments to both the 11/19/10 draft version and the 12/10/10 draft version. In general, comments on the revised guidelines revolved around a two major issues. A summary of each major issue is listed below, followed by a summary of the actions taken by MDH to address the reviewer comments:

Comment Area 1: There was concern raised over extending available lead response resources to children with BLLs < 10 µg/dL.

Some reviewers commented that actively responding to these very low levels would be taking resources away from children with BLLs at higher levels that may need them more. There also was concern that the revised clinical treatment guidelines would put added strain on the office based clinicians. Due to the short time frame of office visits, clinicians often feel pressured for time to fully address all medical issues confronting a patient. This is especially true for education and counseling, which can take a lot of time. One reviewer stated that expecting low level lead poisoning issues to take a central place during these visits is not realistic taking into account the many other concerns which may be pressing in terms of children's health. These commentators advocated for no changes to the guidelines based on scarce resources.

Other reviewers pointed out that there is no apparent threshold for the negative health effects of exposure to lead and that neurological damage to the child is both permanent and has far-reaching consequences for society. Therefore, recommendations are needed for exposures < 10 µg/dL to identify current exposure pathways and help prevent future exposure. These commentators advocated for the addition of several recommended actions for BLLs < 10 µg/dL.

There were very divergent views within the group on the appropriate level of response for low level lead exposure.

MDH Response: First, it is important to note that the clinical treatment and case management guidelines were developed to aid health care professionals and physicians in identifying lead poisoning in children and treating EBBLs. These guidelines are not required actions, and the ultimate responsibility for deciding what is right for a specific child remains with that child's clinician or case manager. It should be noted, however, that BLLs of 5 µg/dL or above are nearly three times the mean levels seen in the general population. The most recent data from the National Health and Nutrition Examination Survey (NHANES) (1999-2004) showed a geometric mean BLL of 1.9 µg/dL in children aged 1 to 5 years (Jones et al. 2009, see literature review, **Appendix C**). In addition to being well above the population mean, the level of 5 µg/dL is above the analytical limit of detection (LOD) of many Clinical Laboratory Improvement Amendment (CLIA) certified laboratories performing lead testing, meaning that the child in question has most likely been exposed to some abnormal source of lead. Therefore, some measured response is appropriate to help identify and address the lead exposure route.

Second, the guidelines attempt to target limited health care resources by targeting medical management recommendations to venous results > 5 µg/dL. Capillary results between 5 and 9.9 µg/dL, which have been shown by previous MDH studies to be false positives 66% of the time, require a venous confirmation test. The specific level of 5 µg/dL was chosen because it is the historic analytical reporting threshold for CLIA-certified labs and therefore is familiar to health professional dealing with lead. In addition, no threshold has been found for the toxicity of lead exposure, and thus, any number chosen could be considered arbitrary. A specific BLL threshold is used partly because a specific number was needed to assist clinicians and health professionals in deciding what actions to take for each child. Results < 5 µg/dL do not receive medical management, but rather receive anticipatory guidance to help identify potential sources of lead and a review of lead risks in one year to help ensure that new exposures are identified.

Finally, in response to these comments, some specific recommendations for children with BLLs < 5 µg/dL were removed from the clinical treatment guidelines compared to the previous < 10 µg/dL action recommendations. Therefore, the amount of resources spent on children with capillary results near the LOD is reduced.

Comment 2: Two reviewers commented on the high false positive rates seen with capillary tests. Specifically, there was concern about the resources that would be required to get children with capillary BLLs of 5-9.9 µg/dL back to the clinic for a repeat venous test when the capillary test may have been a false positive in the first place. There was also concern that levels of 5 µg/dL are nearing the LOD of many CLIA-certified laboratories performing lead testing.

MDH Response: As described in the response to the previous comment, the confirmatory venous test is only applicable for BLLs of > 5 µg/dL. Limiting the re-test is an attempt to reduce the health care resources needed to address low level lead exposure. In addition, uncertainty will be reduced as laboratory performance continues to gradually improve with advances in analytical equipment and methods. MDH acknowledges that the confirmatory venous tests will likely show that some of the capillary tests were false positives and that there may be some difficulty in getting children back in for a venous test. However, after weighing multiple factors, we believe the addition of this recommendation is justified to ensure that lead exposure is identified accurately via a venous test and in a timely manner.

Changes for both sets of guidelines included adding new guidelines for BLLs between 5 and 9.9 µg/dL, and indicating that all families receive an overview of high risk categories. Children are considered at high risk for lead poisoning if they are living in Minneapolis or St. Paul, receive services from Minnesota Care (MnCare) or Medical Assistance (MA), or fit one of the following criteria: a) live in or regularly visit a home built before 1960; b) live in or regularly visit a home built between 1960 and 1978 that is being, or has been, renovated; or c) sibling/playmate has EBL. Residing in an older home, poverty and age have persisted over the years as the major risk factors for higher lead levels in children (Jones et al. 2009). The Anticipatory Guidance and review of lead risk factors in one year were retained for BLLs < 5 µg/dL to ensure that all families are aware of the wide range of potential lead exposure routes and that changing exposure factors for families are identified. Finally, for the 5-9.9 µg/dL range, a recommendation was added to both sets of guidelines for a confirmatory venous test within 3 months and to provide culturally appropriate lead poisoning prevention literature. An overview of specific changes to the guidelines is presented in **Table 1** and **Table 2** later in this document.

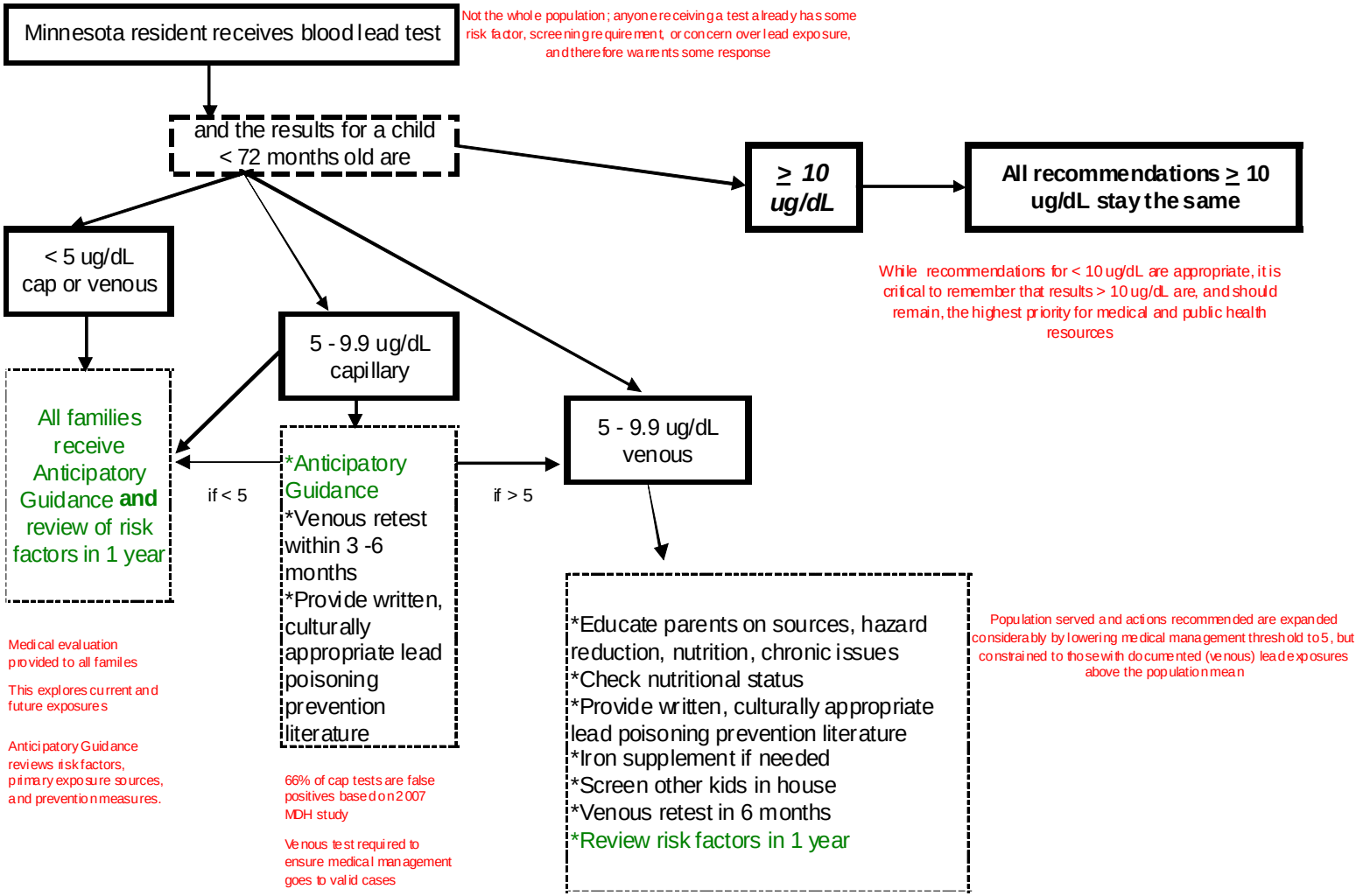
The final format of the guidelines is the result of a compromise between concerns over low-level lead exposure (e.g., addition of actions for 5-9.9 µg/dL) and concerns over the best use of limited resources (e.g., basing medical management on venous results; removing some actions from the < 5 µg/dL range). On balance, the new guidelines reflect, to the best extent possible, the diverse recommendations of the expert panel. An overview of the final decision process for a blood lead test result < 10 µg/dL is found in **Figure 1** on the following page.

The final and complete versions of the revised Blood Lead Clinical Treatment Guidelines for Minnesota and Blood Lead Case Management Guidelines for Minnesota can be found in

Figure 1: Childhood Blood Lead Clinical Treatment Guidelines for Minnesota

Decision flow chart

Draft December 2010



Appendices G & **H**, respectively. The guidelines presented in **Appendices G** & **H** contain yellow highlighted areas to identify areas that were changed compared to the 2006 versions.

Specific revisions made to the clinical treatment guidelines are listed in **Table 1** below**.** Specific revisions made to the case management guidelines are listed in **Table 2** below**.** All aspects of the guidelines not listed in the table stayed the same. To aid the reader in understanding the changes to the guidelines, the tables presented below are best viewed side by side with the full guidelines as presented in **Appendices G and H**.

Table 1: Childhood Blood Lead Clinical Treatment Guidelines for Minnesota Revisions (all alphanumeric numbers except footnotes are assumed to be µg/dL)

Revision	Reasons for Revision
Front Side (table with checkmarks) of Guidelines	
General Format Changes	
The previous < 10 result column was changed to a < 5 result column, and a new 5-9.9 result column was added.	A 5-9.9 column was needed for recommendations for protective health actions and follow-up services for children with BLLs of 5 or above, and a column was needed for guidelines for BLLs < 5.
The two following recommendations included in the previous < 10 column were not included in the new < 5 column: 1) Ask questions to identify sources of lead in the child's environment, and 2) Assess for lead poisoning at every well-child visit.	There was concern over the use of already limited resources to focus on BLLs below 5 and it was decided that recommending anticipatory guidance and a review of risk factors in one year was satisfactory to help identify any new exposure for these low level BLLs.
The 5-9.9 recommendations were prioritized based on venous test results.	To make sure that resources are focused on the children that need them most, some recommendations are based on the more reliable venous results.
The definition of a high risk child was amended; WIC was removed as a risk factor.	WIC participants in Minnesota have been shown to not have an elevated risk for lead exposure.
Medical Evaluation Section	
A footnote ([1]) was added to the first guideline in the first row.	This footnote functions as a reminder that capillary tests are only screening tests due to the high number of false positives identified using this method. Capillary tests > 5 should always be followed by a confirmatory venous test.
For capillary results of 5-9.9, a guideline was added (in first row) to do a confirmatory venous draw within three months.	Since capillary results are only a screening test, children with BLLs in the 5-9.9 range should have a follow-up venous test within three months to prevent responding to false positive results which are common with capillary tests.
The recommendation to check nutritional status was moved from the children exhibiting clinical symptoms area (e.g. row five) and was instead combined with the recommendation for ruling out iron deficiency and treating if present.	It was decided that the nutritional status check shouldn't be limited to only children with clinical symptoms and that it would be a good fit with the iron deficiency recommendation.

The recommendation to check nutritional status and rule out iron deficiency was added to the 5-9.9 column for venous results > 5 (previously, checking for iron deficiency was only included for BLLs of 10 or above, and checking nutritional status was only included for BLLs of 15 or above).	It was decided that an additional cohort of children should have their nutritional status and iron deficiency status checked.
Medical Management Section	
Under Anticipatory Guidance, a specific list of lead risk factors was added to assist in discussions with the family. All children <5, and capillary results between 5 and 9.9, should receive verbal Anticipatory Guidance.	Anticipatory Guidance informs the family of potential lead exposure pathways and risk factors. While results in this range do not have confirmed lead exposure, they do have risk factors (which caused the test to be requested in the first place).
The recommendation to provide culturally appropriate lead poisoning prevention educational materials was added for all results > 5.	While all results > 5 can benefit from information in written form, families with lower level exposures especially need to have some method beyond a verbal discussion to engage/reconnect with lead educational material
The recommendation to educate family was added to the 5-9.9 column for venous results (this was previously only included for BLLs of 10 or above).	It was decided that families with venous BLLs of 5 or above, or any family with a BLL > 10, should be provided with education.
The recommendation to provide iron supplementation if deficient was added to the 5-9.9 column (this was previously only included for BLLs of 10 or above).	It was decided that children with venous BLLs of 5 or above, or any child with a BLL > 10, should be provided with iron supplementation if they are deficient.
The "educate family" recommendation was revised to include discussing the removal of lead exposure instead of only discussing reducing this exposure.	Parents frequently have the ability to remove sources of lead exposure and should be educated about ways they can reduce *and* remove exposure.
Follow-up/Comment Section	
A recommendation to review risk factors in one year was included for all test results.	Lead risk factors may change for a family within a year and should be routinely checked.
A footnote ([3]) was added to this section highlighting the fact that additional guidelines for public health case management, screening children, and screening pregnant women are also available from MDH.	For those who only have a copy of the Clinical Treatment Guidelines, this footnote provides information about additional guidelines available through MDH that may be useful.
The recommendation to screen other children in the home if the result is a venous test was added to the 5-9.9 column (this was previously only included for BLLs of 10 or above).	Due to the high false positive rate found with capillary tests, it was decided that other children in the home should only be screened if the result is from a venous test.
The recommendations for a repeat venous test were combined from two rows to one row, and a specific timeline for the repeat venous was added to each result column for BLLs of 5 or above.	Combining the rows made the guidelines easier to understand, and adding the specific timelines within each result column clarified the recommended timeline for repeat venous tests.
Back Side (text columns) of Guidelines	
Similar to the front side of the Clinical Treatment Guidelines, the < 10 section on the back side was changed to the < 5 section, and a new 5-9.9 section was added.	See above.
All revisions made to the front side of the Clinical Treatment Guidelines are also reflected in revisions made to the back side.	See above.

All aspects of the guidelines not listed in the table above stayed the same. Although revisions to the case management guidelines are not identical to those made to the clinical treatment guidelines, great care was taken to ensure that families receive consistent messages from both physicians and case managers.

Table 2: Childhood Blood Lead Case Management Guidelines for Minnesota Revisions (all alphanumeric numbers except footnotes are assumed to be µg/dL)

Revision	Reasons for Revision
Front Side of Guidelines	
A footnote ([1]) added to the Capillary column.	This footnote highlights results from a MDH study that showed the high rates of false positives in capillary tests and provides information on the best way to avoid false positives (thorough hand washing with soap and water).
The previous < 10 row was changed to a < 5 µg/dL row, and a new 5-9.9 row was added (All recommendations included in the previous < 10 row are now included in both the < 5 and 5-9.9 rows).	A 5-9.9 row was needed to add recommendations for protective health actions and follow-up services for children with BLLs of 5 or above, and another row was needed for recommendations for BLLs < 5.
In every result row in both the Capillary and Venous columns after the recommendation to "provide education materials to the family" the statement "including an overview of high risk categories" was added.	A discussion of high risk categories was added to the Clinical Treatment guidelines, and in order to maintain consistency between both sets of guidelines, this recommendation was also added to the Case Management guidelines.
A footnote ([3]) was added to the recommendation described above in every row.	This footnote was added to help clarify what factors should be taken into consideration when identifying a child as high risk.
In the 5-9.9 row, the following guideline was added to the Capillary column: "Contact family with the recommendation to have a follow-up venous test within three months".	Since capillary results are only a screening test, children with BLLs in the 5-9.9 range should have a follow-up venous test within three months.
In the 5-9.9 row in the Venous column the following recommendation was added: "Ask questions to identify possible sources of lead in child's environment".	This recommendation was added for BLLs of 5-9.9 and 10-14.9 to help get parents involved in identifying and reducing/removing existing sources of lead.

Implementation

Multiple strategies will be used to implement the updated clinical treatment and case management guidelines.

While recommendations for < 10 ug/dL are appropriate, it is critical to remember that results > 10 ug/dL are, and should remain, the highest priority for medical and public health resources. As the lead program transitions to a more comprehensive "healthy homes" approach it will be especially important to ensure that available resources are targeted to areas of greatest need.

Therefore, all MDH guidelines will be routinely reviewed to ensure that housing-based health hazards are being addressed in the most effective manner.

The updated clinical guidelines will be submitted to the Minnesota Medical Association (MMA) for their review and endorsement. MDH will also request guidance from the Environmental Health Committee of MMA regarding the best methods to make physicians and other health care providers aware of the revised guidelines. Given that the clinical guidelines are primarily targeted to health care providers and that MMA represents that group for Minnesota, any changes required by MMA to secure endorsement will be made by MDH.

The updated case management guidelines will be submitted to the Minnesota Nurses Associations (MNA) for their review and endorsement. The case management guidelines will also be distributed to public health nurses in all counties in Minnesota by the MDH Lead State Case Monitor. Public health nurses for each county will then distribute the updated guidelines to clinics in their county. Given that the case management guidelines are primarily targeted to public health nurses, and that MNA represents that group for Minnesota, any changes required by MNA to secure endorsement will be made by MDH.

A press release will be issued by MDH to help publicize the updated clinical treatment and case management guidelines and to describe reasons for the changes. The new guidelines will be also be posted on the MDH website:http://www.health.state.mn.us/divs/eh/lead/guidelines/index.html Finally, information on the new guidelines will be included in all future presentations and education documents provided by MDH staff.

The revisions to the MDH Childhood Blood Lead guidelines will help ensure that health care professionals are provided with the most current information and recommendations for addressing lead poisoning prevention. Ultimately, reducing exposure to lead will support the goal of protecting, maintaining, and improving the health of all Minnesotans.

Appendix A - Meeting Attendees

Childhood Blood Lead Clinical Treatment Guidelines for Minnesota
2010 Revision Workgroup

In response to HF419 from 2010 legislative session, the following workgroup was assembled:

Organization	Meeting Attendee(s)
Minneapolis Health and Family Support	Megan Ellingson
Minneapolis Lead and Healthy Homes	Lisa Smestad
St. Paul/Ramsey County Public Health	Stephanie Hartman
Sustainable Resources Center	Dan Newman Dan Wiersgalla
Minnesota Visiting Nurses Association	Nancy Hickerson
Minnesota Medical Association	Beth Baker
CLEARCorps	Megan Curran
Minnesota Center for Environmental Advocacy	Paul Aasen
Hennepin County Environmental Health	Susan Palchick Jack Brondum
Health Plans: **Medica** **UCare** **HealthPartners** **HealthPartners**	 Patty Trier Laura Green Tanya Hagre Rachel Nygard
MDH Child and Teen Check Up Program	Cynthia Ahler
MDH Lead Program Staff	Daniel Symonik Larry Gust Erik Zabel Randi Callahan Gretchen Cutler

Appendix B - Meeting Agenda

Childhood Blood Lead Clinical Treatment Guidelines for Minnesota 2010 Revision Workgroup

November 10, 2010, 9:00 a.m. – 12:00 p.m.
Red River Room, MDH Snelling Office Park
1645 Energy Park Drive, St. Paul, MN 55108

Agenda:

9:00 – 9:15	**Welcome and Introductions**
9:15 – 9:25	**Overview of Statute and Meeting Goals**
9:25 – 9:35	**Review of Current Guidelines, including 2006 update** • **Clinical Treatment** • **Case Management** • **Screening**
9:35 – 10:15	**Review of Related Publications/Research on Effects and Recommended Management of BLLs < 10 µg/dL**
10:15 – 10:30	**BREAK**
10:30 – 11:30	**Discussion – What should be done for BLLs > 5 µg/dL? What can be done?**
11:30 – 11:45	**Summarize Consensus Items**
11:45 – 12:00	**Next Steps** • **Draft Report** • **Submission to Legislature** • **Implementation**

Appendix C - Literature Review

Childhood Blood Lead Clinical Treatment Guidelines

Literature Review
November 10, 2010

This document provides summaries of publications focused on BLLs < 10 µg/dL. Summaries are divided into the following three sections: 1) government recommendation, review and opinion papers, 2) prevalence studies, and 3) research studies. These summaries are provided to help pull together what is known about the effects of BLLs < 10 µg/dL, and what experts and government agencies are recommending we do to address these low levels of lead exposure. The research studies provide a good amount of evidence for an association between BLLs < 10 µg/dL and cognitive functioning in children. A common theme is the realization that there is no effective treatment for BLLs < 10 µg/dL. Therefore, many papers end with a call for primary prevention.

1) Recommendation Papers/Reviews

This section includes two papers from CDC: the first one reviews the current research on BLLs < 10 µg/dL and provides recommendations on managing lead exposure at low levels, and the second revisits testing in Medicaid-eligible children. A brief summary of recent data on Minnesota Medicaid children follows. The rest of the papers in this section are reviews/opinion papers focused on recent research and the question of whether to lower the lead intervention level at this time. The summary of SM Bernard's paper is also followed by summaries of two published responses to the paper.

CDC's Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). Interpreting and managing blood lead levels < 10 µg/dL in children and reducing childhood exposures to lead. Recommendations of the ACCLPP. (2007)

The report summarizes the findings of a review by the ACCLPP of clinical interpretation and management of blood lead levels (BLLs) < 10 µg/dL. Research conducted since 1991 has strengthened evidence that a child's physical and mental development can be affected at BLLs < 10 µg/dL, and CDC recognizes that a BLL of 10 µg/dL does not represent a threshold for harmful effects. Included in the review were 23 published reports that analyzed the relationship between BLLs < 10 µg/dL and cognitive measures in 16 separate populations. The workgroup concluded that a causal association between lead exposure and cognitive function is likely, but the potential for residual confounding makes the strength and shape (i.e., are the effects of lead greater at lower levels?) of this association uncertain. The workgroup noted that no safe BLL has been identified in children. Future research assessing the effects of BLLs < 10 µg/dL is needed in diverse populations with careful attention to potential confounders and social factors. Additional research is also needed to evaluate the effectiveness of strategies to lower exposure to lead including strategies applied in the medical office and home, and interventions through medical, public health and environmental means. Screening strategies should be evaluated to determine the most appropriate ages and the utility of strategies applied at the community level. Lead surveillance strategies should test ways to identify changing patterns of environmental risks

and subpopulations exposed to established and emerging sources of lead. Studies also needed to improve laboratory methods and performance monitoring. **Recommendations for clinicians:** When a child has a BLL approaching 10 µg/dL more frequent blood screening might be appropriate, especially if child is < 2 years old, at high risk for exposure, or is tested at the start of warm weather. Recommended management guidelines should be instituted if a child's BLL increases to ≥ 10 µg/dL . Advocate for services that foster primary prevention and promote participation in early enrichment programs for all children low-resource families who live in high risk areas. **Recommendations for government agencies:** Increase efforts to resolve lead-based paint hazards before children are exposed. Expand programs that promote primary prevention, and develop systems to inform clinicians and parents about these programs. Develop and implement strategies to encourage safe elimination of lead hazards using trained workers and lead-safe work practices. Establish jurisdictional policies that mandate ensuring lead safety in housing and enforce. Develop and apply systematic approaches to prevent exposure to any amount of lead in food or consumer products. Promote implementation of primary prevention programs that target areas, populations and activities of highest risk. Expand resources for housing remediation and establish a regulatory infrastructure. Expand availability and promote use of early enrichment programs for low SES, at-risk children.

AM Wengrovitz, MJ Brown. Recommendations for blood lead screening of Medicaid-eligible children aged 1-5 years: an updated approach to targeting a group at high risk. (2009)

Data from the National Health and Nutrition Examination Survey (NHANES) indicate substantial decreases in both the percentage of children in the US with elevated blood lead levels (EBLLs) and in mean BLLs among all age and ethnic groups. This data suggests that the disparity in EBLLs between Medicaid-eligible children and non-Medicaid eligible children is diminishing. As disparities among subpopulations have decreased, it has become more difficult to accurately assess the risk for lead exposure among children. This is especially true on a national level since NHANES cannot measure prevalence in small populations. State and local data are now more important than national data for developing lead exposure prevention policies at the state and local level. A new screening strategy is needed that accounts for local variations in risk and disparities at a local level. Updated CDC recommendations for screening of children who are eligible for Medicaid include 1) update lead screening policies for Medicaid-eligible children, 2) improve rates of blood lead screening among Medicaid-eligible children determined to be at increased risk, 3) design and implement updated surveillance and evaluation strategies. **Conclusion:** To ensure that Medicaid-eligible children at-risk are identified and treated 1) decisions regarding the level of risk for EBLLs among Medicaid-eligible children should be made by state and local health departments, 2) lead screening tests should be provided at WIC sites and new blood lead technologies should be considered (e.g., filter paper), and 3) current surveillance systems should be refined to include other measures of risk exposure such as environmental measures so that they are not solely dependent on BLL testing for identifying risk for lead poisoning.

Data from Minnesota: **EW Zabel, S Castellano. Lead Poisoning in Minnesota Medicaid Children, 1999-2003.**

This report presented data on blood lead testing in Minnesota Medicaid children from 1999-2003. In 2003, the rate of EBLLs in Medicaid children was approximately twice

the rate of EBLLs in non-Medicaid children. The rates in children less than 72 months were 3.5% (Medicaid) and 1.9% (non-Medicaid). The rates in children 9-30 months were 3.3% (Medicaid) and 1.7% (non-Medicaid). While this report showed that the rate of EBLLs continued to decline in both Medicaid and non-Medicaid children, Medicaid children still had nearly twice the rate of EBLLs in 2003. Data from 2004 to 2009 continued to show declining rates of EBLLs in both Medicaid and non-Medicaid children, with rates continuing to be higher in Medicaid children.

SM Bernard. Should the Centers for Disease Control and Prevention's childhood lead poisoning intervention level be lowered? American Journal of Public Health (2003)
There is still substantial uncertainty regarding the health outcomes of blood lead levels (BLL) < 10 µg/dL. Little research has been done (**several more studies have been done since this report was published*), and some question whether it is even feasible to discern impacts at such low levels, although this might become easier with advances in measurement of lead exposure and cognitive development. All study results must be interpreted with caution. Screening to detect BLLs < 10 µg/dL offers no clear benefit to most children. The one exception is children aged 12 months or younger, who should have short-term follow-up screening if their BLL is 5 µg/dL or higher. It is very unlikely that there would be intervention beyond education for children with BLLs between 5 and 10 µg/dL as many health departments have limited resources. Lowering the intervention level would likely result in a return to universal screening requirements due to the high proportion of children with BLLs > 5 µg/dL. This would be disadvantageous to children with BLLs > 10 µg/dL since available funds would be spent on screening and would be diverted from children most at-risk. **Conclusions:** Current data do not support lowering the screening lead level below 10 µg/dL. Lead poisoning prevention efforts can be improved by revising the follow-up testing schedule for infants aged 12 months or less with BLLs ≥ 5 µg/dL; making parent/guardian education universal and improving the risk-screening questionnaire; enhanced compliance with targeted screening recommendations and federal health program requirements; and stopping the use of the CDC intervention level in establishing primary prevention goals.

Published response to SM Bernard's paper:

HL Needleman and PJ Landrigan - Am J Public Health (2004):
Only health-based criteria should be used when setting a health standard, not economic considerations or limited options for intervention. We must again lower the officially defined standard to protect America's children.

MJ Brown, PJ Meehan - Am J Public Health (2004):
Bernard's suggestions deserve further consideration. Also relevant to this discussion is the lack of effective interventions to lower elevated BLLs. This fact, along with the recent reports of health effects of BLLs < 10 µg/dL suggest creative strategies for primary prevention are needed. Shifting the focus to primary prevention does not require changing the intervention level or preclude using this level as one tool to identify high-risk children. It is extremely important to continue to focus on these populations. Primary prevention should be the highest priority, including effective partnerships with

housing and other agencies to direct abatement and prevention resources to high-risk neighborhoods.

K Koller, T Brown, A Surgeon, and L Levy. Recent developments in low-level lead exposure and intellectual impairment in children. Environmental Health Prospectives (2004)

There is little dispute about the effects of high levels of lead on child development, but positions on the effects of low-level exposure tend to be in two directions. Some argue that low level lead-induced neurotoxicity has a casual role in cognitive loss and in the subsequent development of juvenile delinquency and socially disruptive behavior, while others argue that parental variables are far more important to a child's cognitive development than low-level lead exposure. It is hard to determine the true relationship between low-level lead exposure and cognitive development in epidemiologic studies because of the large numbers of confounders that must be considered (SES, parental IQ, home environment, genetics, sex of the child, nutrition). No single study should be treated as a source of convincing evidence. Instead, multiple studies showing the same results in different populations (and preferably using different methodology) are needed to reach any type of conclusion. In addition, some confounders may actually modify the effect of lead exposure on cognitive development. For example, the magnitude of the effect of lead exposure has been shown to depend on SES up to certain levels.

Conclusion: Findings from studies of around 1300 children support an association between childhood lead exposure and cognitive impairment and extend the range of concern to children with lifetime average blood lead levels < 10 µg/dL. Lead exposure accounts for a small amount of variance in cognitive abilities (4%) while social and parenting factors account for much more (40%). Instead of chasing after lower and lower lead thresholds, available funds should focus on the complex social issues associated with lead exposure in a small segment of the population.

SG Gilber, B Weiss. A rationale for lowering the blood lead action level from 10 to 2 µg/dL. Neurotoxicology (2006)

Elevated BLLs have a high cost for the individual and are an economic drain on society. There is now sufficient and compelling scientific evidence to support action by the CDC to lower the blood lead action level in children to 2 µg/dL. The current level of 10 µg/dL is too high because historically policy makers and public health officials have only acted to remove sources of lead exposure after this level is exceeded. Local initiatives to reduce lead exposure are unlikely to occur until CDC itself moves in that direction. The current 10 µg/dL "level of concern" acts as a surrogate for inaction. Rationale for reducing the CDC action level to 2 µg/dL: 1) there is sufficient evidence that children suffer from cognitive and behavioral deficits at BLLs < 10 µg/dL, 2) successful programs are established and can be refined and extended, 3) the current CDC level gives public agencies and commercial interests the ability to argue against taking measures to reduce childhood lead exposure, 4) a level of 2 µg/dL provides a tangible goal.

DC Bellinger. Lead. Pediatrics (2004)

Lead poisoning is an entirely preventable childhood disease. Studies continue to show effects of lead exposure at lower and lower levels. The CDC screening guideline of 10 µg/dL should not be interpreted as a threshold for toxicity. This level has been given biological significance incorrectly by many. Apart from complete residential lead abatement, we know little about other environmental, nutritional, or social interventions that are effective or cost-effective.

2) Prevalence Studies

This section includes two prevalence studies examining BLLs < 10 µg/dL. This first uses NHANES data from 1988-1994, and the second updates this information with NHANES data from 1999-2004 and also examines blood lead testing.

SM Bernard, MA McGeehin. Prevalence of blood lead levels ≥5 µg/dL among US children 1 to 5 years of age and socioeconomic and demographic factors associated with blood lead levels ≥ 5 but < 10 µg/dL, Third National Health and Nutrition Examination Survey, 1988-1994). Pediatrics (2003)

In response to the question of whether to lower the screening and intervention level to 5 µg/dL, this study examined the prevalence of BLLs ≥ 5 µg/dL and the socioeconomic and demographic characteristics of children with BLLs ≥ 5 but < 10 µg/dL. Data came from NHANES III, and venous blood samples were collected from 4,624 children aged 1-5 years. Over a quarter of the children had a BLL ≥ 5 µg/dL (26%) and most of these children had levels below 10 µg/dL (76%). Prevalence of BLLs ≥ 5 µg/dL was very high in specific populations: 47% of non-Hispanic black children, 42% of Medicaid participants, 43% of children living in pre-1946 housing. Children with well-established risk factors were most likely to have a BLL ≥ 5 µg/dL, with the number of risk factors increasing with higher BLLs. **Conclusion:** Changing the CDC's recommended threshold from 10 µg/dL to 5 µg/dL would result in a large increase in the number of at-risk children identified. Sources of lead exposure are not as well defined for BLLs ≥ 5 µg/dL but < 10 µg/dL. Lead exposure from multiple sources is suggested by the prevalence of BLLs in this range, and by the fact that many children in this range have uncertain risk factors.

RL Jones et al. Trends in blood lead levels and blood lead testing among US children aged 1 to 5 years, 1988-2004. Pediatrics (2009)

The objective of this study was to evaluate trends in children's BLLs and the extent of blood lead testing in at-risk children. This study augments previous work summarized above by Bernard et al. by using NHANES data from 1999-2004. Overall, BLLs shifted lower from 1988-1991 to 1999-2004. Distribution of BLLs in the 1999-2004 data were as follows: < 1 µg/dL (14%), 1 - < 2.5 µg/dL (55%), 2.5 - < 5 µg/dL (23.6%), 5 - < 7.5 µg/dL (4.5%), 7.5 - < 10 µg/dL (1.5%), ≥ 10 µg/dL (1.4%). These estimates can be generalized only to the US population and it cannot be assumed that they represent local higher risk areas. The percentage of children previously tested increased almost fourfold from levels seen in 1998-1991, and importantly, a large increase was seen in the highest-risk children. The data suggest targeted testing has not resulted in a decrease in testing among the highest-risk children, although fewer than half of children in Medicaid had been tested previously. Mean BLLs and the distribution of BLLs continued to be higher for low-income children, non-Hispanic black children, and children living in houses built before 1950. **Conclusion:** Children's BLLs continue to decline, even in high-risk groups. Efforts must continue to test children at high risk for lead poisoning, and to identify and control sources of lead to maintain progress and eliminate disparities. The vast majority of children still have some low-level exposure to lead and primary prevention will play an important role in efforts to further control lead exposure.

3) Research Studies

This section includes summaries of research studies that have examined the association between BLLs < 10 µg/dL and cognitive function in children, including many of the studies reviewed by the CDC's Advisory Committee on Lead Poisoning Prevention.

BP Lanphear, K Dietrich, P Auinger, C Cox. Cognitive deficits associated with blood lead concentrations < 10 µg/dL in US children and adolescents. Public Health Reports (2000)
The purpose of this study was to examine the relationship between relatively low BLLs (< 10 µg/dL) and cognitive function in children and adolescents aged 6-16 years. Data came from NHANES III (1988-1994). Venous blood samples were collected from 4,853 children and adolescents aged 6-16 years. All participants completed tests of arithmetic and reading skills, nonverbal reasoning, and short-term memory. All analyses were adjusted for child's gender, racial ethnic background, iron status, cotinine level (to measure exposure to tobacco smoke), region of country, marital status and education level of "family reference person" (usually head of household), and the Poverty Index Ratio. A significant inverse relationship was found between BLL < 10 µg/dL and scores on all tests, and between BLL < 5 µg/dL and scores on the arithmetic and reading tests. **Conclusion:** Cognitive deficits are associated with BLLs below 5 µg/dL. Results support conclusion that there is no detectable threshold for adverse effects, and argue for a reduction in what is thought of as an acceptable range for a BLL from 10 µg/dL to 5 µg/dL or lower. Findings also underscore the importance of prevention, and argue for a shift from management of children with high levels of lead to primary prevention of lead exposure.

RL Canfield et al. Intellectual impairment in children with blood lead concentrations below < 10 µg per deciliter. The New England Journal of Medicine (2003)
The objective of this study was to examine the association between low-level lead exposure (< 10 µg/dL) and children's performance on intelligence tests at three and five years of age. Venous blood samples were collected at 6, 12, 18, 24, 36, and 60 months of age on 172 children born in the United States between 1994 and 1995. All analyses were adjusted for child's sex, birth weight and iron status, mother's IQ, race, tobacco use during pregnancy, and years of education, yearly household income, and total score for the Home Observation for Measurement of the Environment (HOME) Inventory. BLL was examined four ways: lifetime average, peak, concurrent, and average blood lead concentration in infancy. **Conclusion:** Intellectual functioning at ages three and five years was significantly inversely associated with lifetime average, concurrent and peak BLL. The estimated loss in IQ was greater in children whose BLL remained below < 10 µg/dL compared to children with higher BLLs. The results suggest that there may be no threshold for the consequences of lead exposure, and considerably more children are affected by lead exposure than previously thought. Because there is no effective treatment for children with moderately elevated BLLs, the results of this study and others argue for a shift towards primary prevention of lead exposure.

BP Lanphear et al. Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. Environmental Health Perspectives (2005)
There is emerging evidence that lead is associated with deficits in IQ at levels below 10 µg/dL. Questions persist because some studies have involved only small numbers of children, have included children who may have had a BLL > 10 µg/dL at some point, or did not include adjustment for important confounders. It is critical to estimate the relationship between lead exposure and intellectual function with greater precision because of the policy implications. This

study pooled data from seven prospective cohort studies (participating sites included Boston, Cleveland, Mexico City, Port Pirie Australia, Rochester, New York, and Yugoslavia). The final model included data from 1,333 children and adjusted for maternal IQ, HOME Inventory score, birth weight, and maternal education. This study found evidence of lead-related intellectual deficits among children with BLLs < 7.5 µg/dL, and no evidence of a threshold was found. The IQ deficits found were significantly greater at levels < 7.5 µg/dL. **Conclusions:** The results of this study add to the evidence of the consequences of BLLs < 7.5 µg/dL and underscore the importance of primary prevention.

TA Jusko, CR Henderson, BP Lanphear, DA Cory-Slechta, PJ Parsons, RL Canfield. Blood lead concentrations <10 µg/dL and child intelligence at 6 years of age. Environmental Health Perspectives (2008)

This study was done in response to a statement from CDC that the "overall weight of evidence supports an inverse association between blood lead levels < 10 µg/dL and the cognitive function of children" but that available data were limited by a small number of "directly relevant cohort studies" that include multiple measures of lead exposure in early life and information on important confounders. The same cohort was used as in Canfield et al. but this study used data on IQ collected at 6 years of age instead of 3 and 5 years of age. An inverse association was found between peak BLL and IQ down to levels of 2.1 10 µg/dL. Results showed that BLLs were inversely related to IQ scores whether lead exposure was measured by lifetime or infancy average, max (peak) exposure, or measured the same day as the IQ tests. Children with BLLs between 5 and 10 µg/dL had significantly lower IQ scores than children with BLLs < 5 µg/dL. **Conclusion:** Results reinforces the conclusion that children are adversely affected by BLLs < 10 µg/dL. Findings add to the evidence that the effect of lead exposure on child intellectual development is larger for equal increments of lead < 10 µg/dL than at higher levels.

MM Tellez-Rojo et al. Longitudinal associations between blood lead concentrations lower than 10 µg/dL and neurobehavioral development in environmentally exposed children in Mexico City. Pediatrics (2006)

Data from a prospective study in Mexico City, Mexico, was used to evaluate the dose-response relationship between BLLs < 10 µg/dL and neurodevelopment in children (n=384) at 12 and 24 months of age. Analyses were adjusted for maternal age and IQ, and children's birth weight and gender. Children's BLLs at 24 months were significantly inversely associated with both mental and development scores. **Conclusion:** Results indicate that children's neurodevelopment is inversely related to BLLs beloW 10 µg/dL. As seen in other studies, associations were larger among children with BLLs < 10 µg/dL than among children with BLLs > 10 µg/dL.

EW Zabel, MC Falken, M Sonnabend, M Alms, D Symonik. Prevalence of elevated blood lead levels evaluation of a lead-risk-screening questionnaire in rural Minnesota. Journal of Environmental Health (2005)

The objective of this study was to determine the prevalence of EBLLs in three rural counties in west-central Minnesota and to evaluate a lead-risk-screening questionnaire. Many rural areas in the US have very low rates of blood lead testing in children, even though two of the major risk factors for lead poisoning are common (old homes and poverty). Taken together, three risk factor questions predicted 90 percent of BLLs ≥ 10 µg/dL, and all BLLs ≥ 20 µg/dL. Risk for lead poisoning can be more difficult to identify geographically in rural areas compared to urban

areas. Thus, a large majority of children will continue to require testing in rural areas that have a high percentage of old homes and children living in poverty. In this study, targeted screening was an effective way to identify lead-poisoned children in rural areas of Minnesota.

Appendix D – Background Data Tables

Background Data Table: Number of children (less than 6 years of age) tested in 2007-2009 with BLLs < 5 µg/dL, 5-9.99 µg/dL and ≥ 10 µg/dL

BLL	Capillary	Venous	Unknown	Total	% Total
			2009		
< 5	69,232	12,535	1,661	**83,428**	**87.8**
5-5.9	7,645	741	31	**8,417**	**8.9**
6-6.9	828	196	13	**1,037**	**1.1**
7-7.9	513	122	9	**644**	**0.7**
8-8.9	306	88	5	**399**	**0.4**
9-9.9	226	40	3	**269**	**0.3**
10-14.9	306	193	2	**501**	**0.5**
> **15**	130	147	0	**277**	**0.3**
Total				***94,972***	
			2008		
< 5	71,963	13,156	1,743	**86,862**	**89.8**
5-5.9	5,502	634	37	**6,173**	**6.4**
6-6.9	954	207	13	**1,174**	**1.2**
7-7.9	638	137	6	**781**	**0.8**
8-8.9	362	71	6	**439**	**0.5**
9-9.9	261	62	4	**327**	**0.3**
10-14.9	373	204	0	**577**	**0.6**
> **15**	193	175	0	**368**	**0.4**
Total				***96,701***	
			2007		
< 5	70,043	13,442	2,303	**85,788**	**91.8**
5-5.9	2,483	530	61	**3,074**	**3.3**
6-6.9	1,288	245	25	**1,558**	**1.7**
7-7.9	726	183	20	**929**	**1.0**
8-8.9	504	98	11	**613**	**0.7**
9-9.9	325	70	9	**404**	**0.4**
10-14.9	424	296	0	**720**	**0.8**
> **15**	179	197	0	**376**	**0.4**
Total				***93,426***	

Background Data Table (with updated numbers for BLL = 5-5.9): Number of children (less than 6 years of age) tested in 2007-2009 with BLLs < 5 µg/dL, 5-9.99 µg/dL and ≥ 10 µg/dL

BLL	Capillary	Venous	Unknown	Total	% Total
			2009		
< 5	75,684	13,016	1,668	**90,368**	**95.2**
5-5.9	1,420	288	29	**1,737**	**1.8**
6-6.9	747	185	11	**943**	**1.0**
7-7.9	444	119	8	**571**	**0.6**
8-8.9	289	76	5	**370**	**0.4**
9-9.9	208	46	3	**257**	**0.3**
10-14.9	273	186	0	**459**	**0.5**
> 15	121	146	0	**267**	**0.3**
Total				***94,972***	
			2008		
< 5	76,056	13,510	1,744	**91,310**	**94.4**
5-5.9	1,614	300	38	**1,952**	**2.0**
6-6.9	878	204	11	**1,093**	**1.1**
7-7.9	579	127	6	**712**	**0.7**
8-8.9	346	69	6	**421**	**0.4**
9-9.9	246	60	4	**310**	**0.3**
10-14.9	341	205	0	**546**	**0.6**
> 15	186	171	0	**357**	**0.4**
Total				***96,701***	
			2007		
< 5	70,043	13,442	2,303	**85,788**	**91.8**
5-5.9	2,483	530	61	**3,074**	**3.3**
6-6.9	1,288	245	25	**1,558**	**1.7**
7-7.9	726	183	20	**929**	**1.0**
8-8.9	504	98	11	**613**	**0.7**
9-9.9	325	70	9	**404**	**0.4**
10-14.9	424	296	0	**720**	**0.8**
> 15	179	197	0	**376**	**0.4**
Total				***93,426***	

Appendix E – Comments on Draft Revised Guidelines:

November 19, 2010 Version

The draft version of the Clinical Guidelines distributed to the expert workgroup on 11/19/10 is included with changes compared to the 2006 version highlighted in yellow.

Comments submitted addressing the 11/19/10 version are then compiled and presented

NOTE: No comments were received on the draft Case Management Guidelines; therefore, only the draft Clinical Guidelines are presented here.

Childhood Blood Lead Clinical Treatment Guidelines for Minnesota

These guidelines were created for children from 6 to 72 months of age.	Blood Lead Levels in Micrograms Per Deciliter (ug/dL)					
	<5	**5-9.9**	**10-14.9**	**15-44.9**	**45-59.9**	**60+**
Medical Evaluation						
If capillary[1] result, **confirm with venous draw** within:		3 Months If high risk[2]	3 Months	1 Week	48 Hours	**IMMEDIATELY**
Inquire to identify possible sources of lead in the child's environment: • age of home, • condition of painted surfaces, • pica, • remodeling, • occupations/hobbies, • folk remedies *Contact the MDH for a list of additional lead sources.*	X	X	X	X	X	X
Check nutritional status (especially iron and calcium) • Rule out iron deficiency and treat if present		X	X	X	X	X
Complete diagnostic evaluation (history, labs, iron studies, physical exam)			X	X	X	X
If exhibiting clinical symptoms check neurologic & developmental status (especially language skills and concentration ability)				X	X	X
Check abdominal x-ray Other diagnostic tests: BUN, CBC, Creatinine, UA and liver enzymes					X	X
TREAT AS AN EMERGENCY - potential encephalopathy						X
Medical Management						
Anticipatory Guidance–discuss primary sources of lead poisoning and measures to keep children safe from lead; provide lead poisoning prevention literature	X	X				
Assess for lead poisoning risk at every well-child visit	X	X				
Educate family–discuss: • Potential sources of lead and ways to reduce or remove exposure; review and provide literature • Dangers of improper lead abatement/remodeling • Nutrition–encourage high iron/high calcium diet • Chronic nature of problem (need to monitor frequently)		X	X	X	X	X
Iron supplement if deficient		X	X	X	X	X
IDENTIFY AND REMOVE LEAD SOURCE			X	X	X	X
Persistently high levels in this range may require more aggressive treatment *Consult MDH for information regarding chelation treatment*				X	X	X
Be sure to stop iron therapy prior to chelation				X	X	X
This level requires chelation–recommend the use of succimer per routine dosage *Consult the MDH for further information/referral if needed*					X	X
In-home treatment indicated only in situations of: • Lead-safe environment • Highly compliant family • Home health care monitoring					X	X
Discharge inpatient cases ONLY to LEAD-SAFE ENVIRONMENT					X	X
Follow-up/Comment[3]						
Review risk factors in 1 year	X	X				
Screen other children in the home if result is a venous test		X	X	X	**IMMEDIATELY**	**IMMEDIATELY**
Repeat venous test		6 months	3 months	1-3 months	1 week	48 hours
Repeat venous and diagnostic tests 14 days **after** chelation therapy is complete.					X	X
MDH or the local public health department will conduct an environmental inspection and public health nursing home visit for children up to 72 months of age.				X	X	X

[1] Venous specimens are considered diagnostic tests; Capillary (e.g. finger-stick) specimens are considered screening tests
[2] A high risk child is < 2 years old and either at high risk for exposure (e.g. lives in home built before 1978) or receives services from Minnesota Care (MnCare), the Supplemental Food Program for Women, Infants, and Children (WIC), or Medical Assistance (MA)
[3] Additional guidelines for public health case management, screening children, and screening pregnant women are also available from MDH

Childhood Blood Lead Clinical Treatment Guidelines for Minnesota

< 5 ug/dL

Medical Evaluation
- Ask questions to identify potential sources[1] of lead in the child's environment:
  - *Age of home (built before 1978)*
  - *Condition of painted surfaces*
  - *Pica*
  - *Remodeling*
  - *Occupations/hobbies*
  - *Folk remedies*

Medical Management
- Anticipatory Guidance–discuss primary sources of lead poisoning and measures to keep children safe from lead; provide lead poisoning prevention literature
- Assess for lead poisoning risk at every well-child visit

Follow-up/Comment[2]
- Review risk factors in 1 year

5-9.9 ug/dL

Medical Evaluation
- If capillary result, confirm with venous draw within 3 months if child is high risk[3]
- Ask questions to identify potential sources of lead in the child's environment (see <5 ug/dL for partial list)
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency; treat if present*

Medical Management
- Anticipatory Guidance–discuss primary sources of lead poisoning and measures to keep children safe from lead; provide lead poisoning prevention literature
- Assess for lead poisoning risk at every well-child visit
- Educate family by discussing:
  - *Potential sources of lead and ways to reduce or remove exposure; review and provide literature*
  - *Dangers of improper abatement/remodeling*
  - *Nutrition-encourage high iron/high calcium diet*
  - *Chronic nature of problem (need to monitor frequently)*
- Iron supplement if deficient

Follow-up/Comment[2]
- Review risk factors in 1 year
- Screen other children in the home if result is venous test
- Repeat venous test in 6 months

10-14.9 ug/dL

Medical Evaluation
- If capillary result, confirm with venous draw within 3 months
- Ask questions to identify potential sources of lead in the child's environment (see <5 ug/dL for partial list)
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency; treat if present*
- Complete diagnostic evaluation (history, labs, iron studies, physical exam)

Medical Management
- **Identify and remove lead source**
- Educate family by discussing items listed in "Medical Management" for 5 – 9.9 ug/dL
- Iron supplement if deficient

Follow-up/Comment[2]
- Screen other children in the home
- Repeat venous test in 3 months

15-44.9 ug/dL

Medical Evaluation
- If capillary result, confirm with venous draw within 1 week
- Ask questions to identify potential sources of lead in the child's environment (see <5 ug/dL for partial list)
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency; treat if present*
- Complete diagnostic evaluation (history, labs, iron studies, physical exam)
- If exhibiting clinical symptoms check neurologic and developmental status, especially language skills and concentration ability

Medical Management
- **Identify and remove lead source**
- Educate family by discussing items listed in "Medical Management" for 5 – 9.9 ug/dL
- Iron supplement if deficient
- Persistently high levels in this range may require more aggressive treatment
- Be sure to stop iron therapy before chelation *(consult MDH for information regarding chelation treatment)*

Follow-up/Comment[2]
- Screen other children in the home
- Repeat venous lead in 1 to 3 months (higher levels require more frequent monitoring)
- MDH or local public health department conducts an environmental inspection and public health nursing home visit for children up to 72 months of age.

45-59.9 ug/dL

Medical Evaluation
- If capillary result, confirm with venous draw within 48 hours
- Ask questions to identify potential sources of lead in the child's environment (see <5 ug/dL for partial list)
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency; treat if present*
- Complete diagnostic evaluation (history, labs, iron studies, physical exam)
- If exhibiting clinical symptoms check neurologic and developmental status, especially language skills and concentration ability
- Check abdominal x-ray
  - *Other diagnostic tests: BUN, CBC, Creatinine, UA and liver enzymes*

Medical Management
- **Identify and remove lead source**
- **This level required chelation** - recommend the use of succimer per routine dosage *(consult MDH for information/referral if needed)*
- Educate family by discussing items listed in "Medical Management" for 5 – 9.9 ug/dL
- Iron supplement if deficient
- Persistently high levels in this range may require more aggressive treatment
- Be sure to stop iron therapy before chelation *(consult MDH for information regarding chelation treatment)*
- In-home treatment indicated only in situations of:
  - *Lead-safe environment*
  - *Highly compliant family*
  - *Home health care monitoring*
- Discharge inpatient cases ONLY to LEAD-SAFE ENVIRONMENT

Follow-up/Comment[2]
- Screen other children in the home immediately
- Repeat venous test in 1 week (higher levels require more frequent monitoring)
- Repeat venous and diagnostic tests 14 days after chelation therapy is complete
- MDH or local public health department conducts an environmental inspection and public health nursing home visit for children up to 72 months of age.

>60 ug/dL

Medical Evaluation
- If capillary result, confirm with venous draw immediately
- Ask questions to identify potential sources of lead in the child's environment (see <5 ug/dL for partial list)
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency and treat if present*
- Complete diagnostic evaluation (history, labs, iron studies, physical exam)
- If exhibiting clinical symptoms check neurologic and developmental status, especially language skills and concentration ability
- Check abdominal x-ray
  - *Other diagnostic tests: BUN, CBC, Creatinine, UA and liver enzymes*
- TREAT AS AN EMERGENCY – potential encephalopathy

Medical Management
- **Identify and remove lead source**
- **This level required chelation** - recommend the use of succimer per routine dosage *(consult MDH for information/referral if needed)*
- Educate family by discussing items listed in "Medical Management" for 5 – 9.9 ug/dL
- Iron supplement if deficient
- Persistently high levels in this range may require more aggressive treatment
- Be sure to stop iron therapy before chelation *(consult MDH for information regarding chelation treatment)*
- In-home treatment indicated only in situations of:
  - *Lead-safe environment*
  - *Highly compliant family*
  - *Home health care monitoring*
- Discharge inpatient cases ONLY to LEAD-SAFE ENVIRONMENT

Follow-up/Comment[2]
- Screen other children in the home immediately
- Repeat venous test in 48 hours (higher levels require more frequent monitoring)
- Repeat venous and diagnostic tests 14 days after chelation therapy is complete
- MDH or local public health department conducts an environmental inspection and public health nursing home visit for children up to 72 months of age.

[1] Contact MDH for a potential list of lead sources or see www.health.state.mn.us/lead

[2] Additional guidelines for public health case management, screening children, and screening pregnant women are also available from MDH

[3] Venous specimens are considered diagnostic tests; capillary are screening tests. A high risk child is < 2 years old and either at high risk for exposure (e.g. lives in home built before 1978) or receives services from Minnesota Care (MnCare), the Supplemental Food Program for Women, Infants, and Children (WIC), or Medical Assistance (MA)

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MINNESOTA DEPARTMENT OF HEALTH

For more information about lead, contact the Minnesota Department of Health at (651) 201-4610
If you require this document in another format, such as large print, Braille, or cassette tape, call:
(651) 201-5000 or (800) 657-3908 or MDH TTY (651) 201-5797

Received from Paul Aasen, Minnesota Center for Environmental Advocacy, via email on December 3, 2010:

> *These updates look very good. Thanks for you and your team's work on this project.*

Received from Dr. Beth Baker, representing the Minnesota Medical Association, via email on December 2, 2010:

> *I think the new changes to the lead guidelines look good on the whole. I do have some concern about whether this will put added strain on office based clinicians who are seeing these children. I think many providers run out of time to do everything they want to do at each office visit so we often have to prioritize what is most important and sometimes education and counseling which takes alot of time is not a high priority*
>
> *So I have some suggested recommendations:*
>
> *Do the clinicians really need to provide educational material to family or ask questions to identify sources of lead if lead levels are less than 5 ug/dl? Do they need to do anticipatory guidance if blood lead is < 5 and assess risk for lead poisoning risk at every well child visit?*
>
> *Do they need to review risk factors in 1 year if blood lead < 5?*
>
> *Do they need to check nutritional status on every child with capillary blood lead 5-9.9 or only if they don't get a repeat venous blood lead?*

Received from Dr. James Nordin attached to an email, dated November 29, 2010:

> *I am James D. Nordin, MD, MPH, a practicing pediatrician at HealthPartners Medical Group, and a clinical investigator at HealthPartners Research Foundation. I practiced on the near south side in Minneapolis for some years, and since then I have practiced just south of downtown St Paul, both areas with increased prevalence of excess blood lead in children. I have been involved in studying and dealing with excess lead in children in the Twin Cities for over 30 years, with numerous publications on the issue.**
>
> *I was involved in crafting the current state plan for excess lead intake in children, and have studied the issue intensively. I have been the ICSI Immunization Work Group Leader since its inception. I have been on the ICSI Preventive Services Work Group for many years, which has jurisdiction over recommendations for lead screening programs. This teaches a focus on careful consideration of the evidence in deciding what clinical and public health practice should be.*
>
> *From my perspective, the bill to essentially lower the action level on the blood lead to 5 mcg/dl is poor public health practice. It will result in a decrement of the public health of*

our children rather than an improvement. This is true for two reasons.

First, The "within available resources" phrase (which is appropriate) means that resources will be diverted from higher risk children to serve this new much larger group for whom intervention will have very modest impact at best. This bill goes against one of the first rules of public health: given limited resources, target them where they will do the most good.

Second, and just as important, a good screening test needs to be available. One of the requirements for a good screening program is that there is a reliable test with reasonable positive predictive value which is easy to do. That is really not the case at levels below 10, when done by fingerstick (which almost all BLLs are). Timely confirmation by venipuncture currently occurs in only about 20% of those with elevated fingerstick levels.

A fingerstick BLL of 5.0-9.9 µg/dl is unlikely to predict an accurate venous level. In Hennepin County in 1995-2009, the percent of false-positive fingerstick values among children with positive lead tests was 66% in those testing at 20+ µg/dl; 75% in those at 15.0-19.9 µg/dl; and 80% in those at 10.0-14.9 µg/dl. The positive predictive value of a capillary lead test drops with dropping prevalence has gone from 14.5% in 1995 to 0.8% in 2009, according to statewide Blood Lead Information System (BLIS) data, so currently, the positive predictive value will be at least an order of magnitude less than the figures above. At levels below 10.0 mcg/dl the performance of fingerstick blood lead tests will be extremely poor.

In this situation, the performance of the whole system falls apart. Most programmatic resources are spent chasing down those who may or may not even have elevated levels in order to get a venous draw done. Most of the effort gets wasted and the focus on children in whom intervention will make a big difference is lost.

I have one specific comment. The suggestion that this take a central place in the limited time clinicians have to do anticipatory guidance is not realistic. There are many other concerns which are equally pressing in terms of children's health.

I believe the previous state plan by MDH is the best possible strategy for using limited resources to have the maximum impact on lead toxicity in children. I strongly urge that the language in this bill not be adopted, and that the current plan remain in place. While at first blush it appears that lowering the action level for BLL to 5 mcg/dl will improve the public health, in this situation the opposite would occur and public health would be harmed.

Nordin JD, Rolnick SJ, Ehlinger E, Nelson AF, Arneson TJ, Cherney LM, Griffin JM. Lead levels in high risk and low risk young children in the Minneapolis-St. Paul metropolitan area. Pediatrics 1998;101(1):72-6.
Nordin JD, Rolnick SJ, Griffin JM. Prevalence of excess lead absorption and associated risk factors in children enrolled in a midwestern HMO. Pediatrics 1994 February.
Nordin JD. Lead poisoning, a Minnesota perspective. Minnesota Med 1992 November.

Stang HG, Nordin JD. ZEP screening for iron deficiency and lead poisoning: a survey of a low risk HMO population. HMO Pract 1990;4:109-13.

Received from Dr. Jack Brondum, Hennepin County Human Services & Public Health Department attached to an email, dated December 3, 2010:

1. MDH

a. Meeting 11/10/10. The meeting involved some very direct discussion and conversation but seemed cursory considering the complexity of the issue at hand.

The legislation was clearly directive in defining the minimum of who would be involved in the evaluation of lowering the blood lead level (BLL) action level. It was good to see that MDH expanded the list of invitees to include some people with clinical and health care expertise. I hope that the Commissioner will further reach out to toxicologists, pediatricians, family practitioners, and nurse practitioners before completing her assessment of the question of lowering the BLL action level.

b. Scientific literature: The lead literature is very large; however, the written scientific reference material provided before the meeting was reasonably representative of the most important papers. The CDC's 2005 report, 'Preventing Lead Poisoning in Young Children,' was not included, however, and it does contain some interpretations of the IQ-BLL relationship that are not offered elsewhere. The guest editorial by Brown and Rhoads (2008) in Environmental Health Perspectives, 'Responding to blood lead levels <10 µg/dl,' and their subsequent commentary provide additional important interpretations of this relationship and also merit review.

I raised the issue of the statistical methods used to develop the so-called 'supra-linear' model of the IQ-BLL relationship, in which lower BLLs produce greater decrements of IQ than do higher BLLs. This model is reported by Canfield et al. (2003), Téllez-Rojo et al. (2006), Jusko et al. (2008), and in a post-2003 re-analysis of Bellinger et al. (1991) by its authors. Jusko et al. (2008) studied the same population as Canfield et al. (2003), with the addition of a single data point at age 6 for these children, so the concordance is not surprising. I mention these papers particularly, because their results are primarily responsible for the drive to lower the action BLL from 10 to 5 µg/dl. The supra-linear model is scientifically questionable and should bring into serious question the quality of such reports. The biological mechanisms for this model offered by authors are very limited in number and themselves implausible. Canfield et al. (2003) cite a single paper in which tissue cultures were washed in highly-concentrated aqueous solutions of four heavy metals, and the observed toxic effects on the cells were interpreted as possibly mediated by the immune system. Téllez-Rojo et al. (2006) attribute supra-linearity to an 'exquisitely sensitive pathway that is saturated rapidly' for which they cite no references. No other explanations are offered by study authors. However, another explanation more firmly anchored empirically is offered by Dr. George Rhoads, Chair of the CDC's Advisory Committee on Childhood Lead Poisoning in the CDC's 2005 report 'Preventing

Lead Poisoning in young Children'. He attributes the finding to social confounding, providing a detailed explanation and illustrations of how this might occur.

A summary of the meta-analysis by Lanphear et al. (2005) was also included in the MDH mail-out. This analysis incorporates seven studies in which the relationship of IQ to BLL was considered in children and adolescents from around the world. Meta-analysis is a secondary investigative tool. The meta-analyst imposes on the work of others assumptions and restrictions for which the original work wasn't necessarily intended, and meta-analytical results should therefore be treated with particular caution. In this study, the authors interpreted the results as showing that, on balance, a negative relationship exists between IQ and BLL. Less emphasized, however, is the fact that in two of the cohorts of children – Boston and Kosovo - a positive relationship was found between IQ and BLL. Also, among the remaining five cohorts, the slope of the negative relationship ranged from nearly flat to quite steep. Despite the paper's summary conclusion, the response of IQ to BLL was actually far from monolithic, a fact made all the more relevant by the apparent absence of any IQ-BLL relationship in the general population of the U.S

Koller et al. (2004): In addition to the papers cited above, I single out this paper for its importance in emphasizing the need for perspective, a position also taken by the CDC's 2005 report 'Preventing Lead Poisoning in Young Children' and in the editorial by Brown and Rhoads (2008). The basic message is that the cognitive and other health effects of lead are dwarfed in importance by social factors. Prevention or correction of socially deleterious influences through early childhood education, improved maternal education, proper parenting, and other measures will overwhelmingly improve the lot of affected children relative to any putative gain obtained by eliminating lead from the environment. This message is usually overlooked in discussions of BLL action levels.

c. The MDH Blood Lead Information System (BLIS): An as yet unanswered question is how will progress in lead exposure reduction be monitored in children with BLLs of 5.0 to 9.9 µg/dl? No environmental cleaning methods are currently available to reduce BLLs to this level or lower, and BLIS is already approaching the limits of accuracy in the information it can provide. For example:

Capillary testing is generally inaccurate, yet it is the most frequently used form of BLL testing. According to BLIS data, in Hennepin County in 1995-2009, among children with a positive capillary test of 20+ µg/dl and a subsequent confirmatory venous test, the capillary test was falsely positive 66% of the time; among those with 15.0-19.9 µg/dl, 75% were false-positive; and among those with 10.0-14.9 µg/dl, 80% were false-positive. How likely is it, then, that a capillary test of 5.0-9.9 µg/dl will be confirmed by venous test? Would a clinician consider it medically necessary or ethical to perform a venous test to confirm such a level?

In Hennepin County, the proportion of capillary to venous tests rose 2.4-fold from 1995 to 2009, while the number of lead tests rose from about 17,000 to about 23,000, i.e., BLIS

is gathering ever more information of ever diminishing quality. Perhaps a reevaluation of the objectives of BLIS is in order?

The proportion of children with EBLLs in Hennepin County has dropped from 14.5% in 1995 to 0.8% in 2009. A similar drop has been observed statewide. The positive predictive value of a test is related to its sensitivity and specificity (properties inherent in the test) and the prevalence of the disorder in the population. We don't know the prevalence of EBLLs in the population, but BLIS provides the best surrogate estimate available. Using Bayesian analysis, the 18-fold drop in EBLL prevalence in Hennepin County from 1995 to 2009 suggests that a capillary BLL of 10+ µg/dl would have about 0.6% chance of detecting a genuine EBLL in the population in 2009. The chance of detecting a true BLL of <10 µg/dl in 2010 and subsequently would be further reduced.

Since 2001, BLIS has contained a variable (LESSTHAN) indicating whether the BLL was below the limit of detection (LOD) of the CLIA-certified laboratory or other facility/device performing the lead testing. In Hennepin, the proportion of BLLs below the LOD varied from about 13 to 18% in 2001-2006, then rose to 21% in 2007, 31% in 2008, and 51% in 2009, i.e., more than half of all tests reported for Hennepin children less than 6 years old are now below the LOD. Additionally, the proportion of BLLs reported below an LOD of 5.0 µg/dl has risen from essentially 0% in 2001-2006 to 16% in 2009. In short, we are not that far away from having to say that all BLLs are non-detectable, a laudable and achievable objective, but not one that suggests a need for more legislation to lower the BLL action level further.

d. As a laboratory test approaches the LOD, the uncertainty of the reported value grows relatively larger, i.e., one is less certain that a BLL of 5 µg/dl actually represents 5 µg/dl than that a BLL of 10 µg/dl represents a BLL of 10 µg/dl (Murphy et al. 2009, Palmer et al. 2006, CSLI 2001). Lowering the BLL action level from 10 µg/dl to 5 µg/dl will therefore increase the amount of uncertainty inherent in providing BLL clinical guidance,

e. MDH lead treatment guidelines document: I don't believe that any changes are needed. This is an already complicated and difficult to read document. During the West Hennepin Lead Surveillance Project of 2002-3, pediatricians and family practitioners we worked with commented on the document's complexity. The most recently dated version of the guidelines is, in my opinion, adequate to protect Minnesota children from sources of lead exposure, given their shrinking numbers.

2. Practical consideration - urban vs. suburban and Out-State practice. If adopted, should the changes recommended by this bill apply everywhere in Minnesota? The bill's implementation would impose a disproportionate burden of lead testing on suburban and Out-State practitioners where BLLs have consistently been lower than in Minneapolis and St. Paul. In Hennepin County, for example, the proportion of BLLs below the LOD was greater in the suburbs than in Minneapolis in every year from 2001 to 2009, as summarized in Table 1.

Table 1: Hennepin urban vs suburban * lessthan Crosstabulation

			lessthan		Total
				No	Yes	
Hennepin urban vs suburban	Mpls	Count	19	82965	18528	101512
		% within Hennepin urban vs suburban	.0%	81.7%	18.3%	100.0%
	suburbs	Count	10	57292	23065	80367
		% within Hennepin urban vs suburban	.0%	71.3%	28.7%	100.0%
Total		Count	29	140257	41593	181879
		% within Hennepin urban vs suburban	.0%	77.1%	22.9%	100.0%

BLLs in Hennepin suburban children, particularly those found in the County's most rural Far West suburbs, more closely reflect statewide BLLs than BLLs in Minneapolis children. Table 2 shows the proportion of BLLs below the LOD in Minneapolis and Hennepin Suburban Rings 1 and 2, and the Far West suburbs in 2001-9. In 2009, the last year for which complete information is available, the proportion of BLLs below the LOD had risen to 39.2% in Minneapolis children and 62.5% in suburban children; in Far West suburban children, the proportion was 66.0%.

Table 2: Ring_JB * lessthan Crosstabulation

			lessthan			Total
				No	Yes	
Ring_JB	Mpls	Count	19	82965	18528	101512
		% within Ring_JB	.0%	81.7%	18.3%	100.0%
	Ring 1	Count	5	26422	9452	35879
		% within Ring_JB	.0%	73.6%	26.3%	100.0%
	Ring 2	Count	5	27848	12127	39980
		% within Ring_JB	.0%	69.7%	30.3%	100.0%
	Far West	Count	0	3022	1486	4508
		% within Ring_JB	.0%	67.0%	33.0%	100.0%
Total		Count	29	140257	41593	181879
		% within Ring_JB	.0%	77.1%	22.9%	100.0%

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Appendix F – Comments on Draft Revised Guidelines:

December 10, 2010 Version

The draft version of the Clinical Guidelines distributed to the expert workgroup on 12/10/10 is included with changes compared to the 2006 version highlighted in yellow

Comments submitted addressing the 12/10/10 version are then compiled and presented

NOTE: No comments were received on the draft Case Management Guidelines; therefore only the draft Clinical Guideline tables are presented here.

Childhood Blood Lead Clinical Treatment Guidelines for Minnesota

These guidelines were created for children from 6 to 72 months of age.	Blood Lead Levels in Micrograms Per Deciliter (ug/dL)					
	<5	**5-9.9**	**10-14.9**	**15-44.9**	**45-59.9**	**60+**
Medical Evaluation						
If capillary[1] result, **confirm with venous draw** within:		3 Months If high risk[2]	3 Months	1 Week	48 Hours	**IMMEDIATELY**
Inquire to identify possible sources of lead in the child's environment: • age of home, • condition of painted surfaces, • pica, • remodeling, • occupations/hobbies, • folk remedies *Contact the MDH for a list of additional lead sources.*		X If high risk[2]	X	X	X	X
Check nutritional status (especially iron and calcium) • Rule out iron deficiency and treat if present		X If high risk[2]	X	X	X	X
Complete diagnostic evaluation (history, labs, iron studies, physical exam)			X	X	X	X
If exhibiting clinical symptoms check neurologic & developmental status (especially language skills and concentration ability)				X	X	X
Check abdominal x-ray Other diagnostic tests: BUN, CBC, Creatinine, UA and liver enzymes					X	X
TREAT AS AN EMERGENCY - potential encephalopathy						X
Medical Management						
Anticipatory Guidance–discuss primary sources of lead poisoning and measures to keep children safe from lead; provide lead poisoning prevention literature (provide literature only if high risk[2])	X	X				
Assess for lead poisoning risk at every well-child visit		X If high risk[2]				
Educate family–discuss: • Potential sources of lead and ways to reduce or remove exposure; review and provide literature • Dangers of improper lead abatement/remodeling • Nutrition–encourage high iron/high calcium diet • Chronic nature of problem (need to monitor frequently)		X If high risk[2]	X	X	X	X
Iron supplement if deficient		X If high risk[2]	X	X	X	X
IDENTIFY AND REMOVE LEAD SOURCE			X	X	X	X
Persistently high levels in this range may require more aggressive treatment *Consult MDH for information regarding chelation treatment*				X	X	X
Be sure to stop iron therapy prior to chelation				X	X	X
This level requires chelation–recommend the use of succimer per routine dosage *Consult the MDH for further information/referral if needed*					X	X
In-home treatment indicated only in situations of: • Lead-safe environment • Highly compliant family • Home health care monitoring					X	X
Discharge inpatient cases ONLY to LEAD-SAFE ENVIRONMENT					X	X
Follow-up/Comment[3]						
Review risk factors in 1 year		X If high risk[2]				
Screen other children in the home if result is a venous test		X	X	X	**IMMEDIATELY**	**IMMEDIATELY**
Repeat venous test		6 months	3 months	1-3 months	1 week	48 hours
Repeat venous and diagnostic tests 14 days **after** chelation therapy is complete.					X	X
MDH or the local public health department will conduct an environmental inspection and public health nursing home visit for children up to 72 months of age.				X	X	X

[1] Venous specimens are considered diagnostic tests; Capillary (e.g. finger-stick) specimens are considered screening tests
[2] A high risk child is < 2 years old and either at high risk for exposure (e.g. lives in home built before 1978) or receives services from Minnesota Care (MnCare) or Medical Assistance (MA)
[3] Additional guidelines for public health case management, screening children, and screening pregnant women are also available from MDH

< 5 ug/dL

Medical Evaluation
- NA

Medical Management
- Anticipatory Guidance–discuss primary sources of lead poisoning and measures to keep children safe from lead; provide lead poisoning prevention literature if high risk[1]

Follow-up/Comment[2]
- NA

5-9.9 ug/dL

Medical Evaluation
- If capillary result, confirm **with venous draw** within 3 months if child is high risk[1]
- If high risk[1] ask questions to identify potential sources of lead[3] in the child's environment
- If high risk[1] check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency; treat if present*

Medical Management
- Anticipatory Guidance–discuss primary sources of lead poisoning and measures to keep children safe from lead; provide lead poisoning prevention literature if high risk[1]
- Assess for lead poisoning risk at every well-child visit if high risk[1]
- Educate family if high risk[1] by discussing:
  - *Potential sources of lead and ways to reduce or remove exposure; review and provide literature*
  - *Dangers of improper abatement/remodeling*
  - *Nutrition–encourage high iron/high calcium diet*
  - *Chronic nature of problem (need to monitor frequently)*
- Iron supplement if deficient if high risk[1]

Follow-up/Comment[2]
- Review risk factors in 1 year if child is high risk
- Screen other children in the home if result is venous test
- Repeat venous test in 6 months

10-14.9 ug/dL

Medical Evaluation
- If capillary result, confirm **with venous draw** within 3 months
- Ask questions to identify potential sources of lead[3] in the child's environment
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency; treat if present*
- Complete diagnostic evaluation (history, labs, iron studies, physical exam)

Medical Management
- **Identify and remove lead source**
- Educate family by discussing items listed in "Medical Management" for 5 – 9.9 ug/dL
- Iron supplement if deficient

Follow-up/Comment[2]
- Screen other children in the home
- Repeat venous test in 3 months

15-44.9 ug/dL

Medical Evaluation
- If capillary result, confirm **with venous draw** within 1 week
- Ask questions to identify potential sources of lead[3] in the child's environment
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency; treat if present*
- Complete diagnostic evaluation (history, labs, iron studies, physical exam)
- If exhibiting clinical symptoms check neurologic and developmental status, especially language skills and concentration ability

Medical Management
- **Identify and remove lead source**
- Educate family by discussing items listed in "Medical Management" for 5 – 9.9 ug/dL
- Iron supplement if deficient
- Persistently high levels in this range may require more aggressive treatment
- Be sure to stop iron therapy before chelation *(consult MDH for information regarding chelation treatment)*

Follow-up/Comment[2]
- Screen other children in the home
- Repeat venous lead in 1 to 3 months (higher levels require more frequent monitoring)
- MDH or local public health department conducts an environmental inspection and public health nursing home visit for children up to 72 months of age.

45-59.9 ug/dL

Medical Evaluation
- If capillary result, confirm **with venous draw** within 48 hours
- Ask questions to identify potential sources of lead[3] in the child's environment
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency; treat if present*
- Complete diagnostic evaluation (history, labs, iron studies, physical exam)
- If exhibiting clinical symptoms check neurologic and developmental status, especially language skills and concentration ability
- Check abdominal x-ray
  - *Other diagnostic tests: BUN, CBC, Creatinine, UA and liver enzymes*

Medical Management
- **Identify and remove lead source**
- **This level required chelation** - recommend the use of succimer per routine dosage *(consult MDH for information/referral if needed)*
- Educate family by discussing items listed in "Medical Management" for 5 – 9.9 ug/dL
- Iron supplement if deficient
- Persistently high levels in this range may require more aggressive treatment
- Be sure to stop iron therapy before chelation *(consult MDH for information regarding chelation treatment)*
- In-home treatment indicated only in situations of:
  - *Lead-safe environment*
  - *Highly compliant family*
  - *Home health care monitoring*
- Discharge inpatient cases ONLY to LEAD-SAFE ENVIRONMENT

Follow-up/Comment[2]
- Screen other children in the home immediately
- Repeat venous test in 1 week (higher levels require more frequent monitoring)
- Repeat venous and diagnostic tests 14 days **after** chelation therapy is complete
- MDH or local public health department conducts an environmental inspection and public health nursing home visit for children up to 72 months of age.

>60 ug/dL

Medical Evaluation
- If capillary result, confirm **with venous draw** immediately
- Ask questions to identify potential sources of lead[3] in the child's environment
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency and treat if present*
- Complete diagnostic evaluation (history, labs, iron studies, physical exam)
- If exhibiting clinical symptoms check neurologic and developmental status, especially language skills and concentration ability
- Check abdominal x-ray
  - *Other diagnostic tests: BUN, CBC, Creatinine, UA and liver enzymes*
- TREAT AS AN EMERGENCY – potential encephalopathy

Medical Management
- **Identify and remove lead source**
- **This level required chelation**- recommend the use of succimer per routine dosage *(consult MDH for information/referral if needed)*
- Educate family by discussing items listed in "Medical Management" for 5 – 9.9 ug/dL
- Iron supplement if deficient
- Persistently high levels in this range may require more aggressive treatment
- Be sure to stop iron therapy before chelation *(consult MDH for information regarding chelation treatment)*
- In-home treatment indicated only in situations of:
  - *Lead-safe environment*
  - *Highly compliant family*
  - *Home health care monitoring*
- Discharge inpatient cases ONLY to LEAD-SAFE ENVIRONMENT

Follow-up/Comment[2]
- Screen other children in the home immediately
- Repeat venous test in 48 hours (higher levels require more frequent monitoring)
- Repeat venous and diagnostic tests 14 days **after** chelation therapy is complete
- MDH or local public health department conducts an environmental inspection and public health nursing home visit for children up to 72 months of age.

[1] Venous specimens are considered diagnostic tests; capillary are screening tests.
[2] A high risk child is < 2 years old and either at high risk for exposure (e.g. lives in home built before 1978) or receives services from Minnesota Care (MnCare) or Medical Assistance (MA)
[3] Additional guidelines for public health case management, screening children, and screening pregnant women are also available from MDH
[4] Contact MDH for a potential list of lead sources or see www.health.state.mn.us/lead

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IC #141-0074

NOTE: No comments were received on the Case Management Guidelines; therefore only the draft Clinical Guideline tables are presented above

Received from Dan Newman, Sustainable Resources Center, via email on December 17, 2010:

> *SRC does not support these latest changes in the draft of the clinical guidelines. By limiting the recommended actions for children testing with blood lead levels between 5 and 9.9 mg/dL to high risk children, as defined, the guidelines are an inadequate and insufficient response to the real dangers of lead to children.*
>
> *Every young child with a blood lead level over 5 will have some level of permanent impairment. Failure to fully inform parents of the risks, the possible sources of lead, and what they can do to protect their child is not a responsible response. According to the latest BLL results provided by MDH there were fewer than 3900 children in Minnesota in 2009 who tested between 5 and 9.9. Implementation of the November 19th guidelines for fewer than 3900 children is not an onerous expectation of clinicians. If every child's family received 30 minutes of education that would amount to less than 1 FTE statewide.*
>
> *The proposed definition of high risk is < 2 years old, and either at high risk for exposure (e.g. lives in a home built before 1978) or receives services from MnCare, WIC or MA. Under these proposed guidelines a child age 25 months could test at 9.9 and live in a 1920's house and all that would be recommended is anticipatory guidance delivered verbally. No venous confirmation, no education on possible effects, no printed materials. A child age 12 months could test at 9.9 and, if they did not live in a pre-1978 home or be on a public program, they would again get only verbal guidance. They may be being poisoned at their day care setting, but they would not meet the definition of high risk. I could go on with examples of how these revised proposals fail to respond to real risks.*
>
> *The uncertainty over blood lead test results should not be a reason to pass the risk of that uncertainty onto the children being tested.*
>
> *It is our view that the November 19th version of the clinical guidelines represented the consensus of the review group, and that this version does not. We urge the Department of Health to adopt that earlier draft.*

Received from Paul Aasen, Minnesota Center for Environmental Advocacy, via email on December 17, 2010:

> *Thanks to SRC and Dan for detailing concerns about the latest draft of the clinical guidelines. MCEA shares these same concerns. To reiterate some of the concerns:*
>
> - *The goal is to update the guidelines to reflect current information. The Nov 19 draft of the guidelines achieved that goal; the current version does not.*
> - *The conditions set in the current draft leave too many children at risk and effectively unattended.*

- *The anticipated number of affected children, and therefore clinicians, is lower than originally estimated and should not be considered a barrier to implementing more protective measures.*
- *Uncertainty in analytic tests is not a reason to restrict the scope of implementation. Doing so transfers the "risk" of clinician inconvenience/time/cost to the patient - as a real health risk.*

MCEA supports adoption of the November 19 version of the clinical guidelines.

Received from Dr. Jack Brondum, Hennepin County Human Services & Puiblic Health Department, attached to an email dated December 16, 2010:

1. These latest guideline revisions alleviate in no meaningful way physician concerns about "how much must be covered in each office visit." It is apparent that they were prepared by a person or persons unfamiliar with work in a clinical setting.

2. If "it is important to note that these guidelines are not required actions", why was so much effort expended on their revision and thus taken away from other public health activities?

3. Why are WIC children included among "high risk" children (Footnote 3, Case Mgmt_Front 1_2010.pdf; Footnote 2, Clinical Draft 2010 p1_V2.pdf; Footnote 1, Clinical Draft 2010 p2_V2.pdf)? Based on recent CDC recommendations, blood lead screening strategies for WIC and other Medicaid recipients should "reflect local risk for EBLL" (CDC 2009). In 2005-6, MDH funded studies of blood lead levels in WIC recipients in Hennepin and Ramsey Counties, counties with the highest proportion of EBLLs among children less than 6 years in the State. In both, the proportion of EBLLs and the average BLL among WIC children were below corresponding figures in the general population, based on BLIS data. Detailed reports of these studies are available on the MDH website (MDH 2006a, 2006b).

References

CDC. Recommendations for Blood Lead Screening of Medicaid-Eligible Children Aged 1--5 Years: an Updated Approach to Targeting a Group at High Risk. MMWR. August 7, 2009/ 58(RR09);1-11. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5809a1.htm, (Accessed 12/16/10).

MDH. 2006a.
http://www.health.state.mn.us/divs/eh/lead/reports/legislative/appendixf.pdf, (Accessed 12/16/10).

MDH. 2006b.
http://www.health.state.mn.us/divs/eh/lead/reports/legislative/appendixe.pdf. (Accessed 12/16/10).

Received from Nancy Hickerson, Minnesota Visiting Nurses Association, via email dated December 20, 2010:

> *As a Public Health Nurse who works closely with clinics and families, I am concerned that due to time constraints and lack of understanding that still exists with healthcare providers, families will not get the appropriate information, children will remain in the same environment with no changes implemented, and lead levels potentially increase until their next well child check the following year. I believe it would be appropriate to retest with venous testing those children with capillary ebl's of <5 in a more timely manner (within 3 mos).*

Received from Patty Bowler and Angela Hackel, Minneapolis Department of Health and Family Services, attached to an email dated December 17, 2010 (see next two pages):

Minneapolis
City of Lakes

Department of Health & Family Support

250 South 4th Street – Room 510
Minneapolis, MN 55415-1372

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Fax 612 673-3866
TTY 612 673-2157

www.ci.minneapolis.mn.us/dhfs

December 17, 2010

Commissioner Sanne Magnan
Minnesota Department of Health
Health Department
625 Robert Street N
PO Box 64975
St Paul, MN 551640975

Dear Dr. Magnan,

I am writing this letter in response to the second version of the revised *Childhood Blood Lead Clinical Treatment Guidelines for Minnesota* that include clinical actions to be taken around blood lead levels between 5-9.9 ug/dL. Minneapolis Department of Health and Family Support staff participated in a meeting on November 10, 2010, and were pleased to see our feedback reflected in the first version of the Guidelines. However, there were concerns with the changes made in the second edition of the guidelines issued on December 10th.

In particular we are concerned about adding the language "if at high risk" in the anticipatory guidance and in the educate family sub-sections of the medical management category of the guidelines. I believe that discussions about including the caveat of "if at high risk" pertained to follow-up testing. At the November 10th meeting there was concern over re-testing; in light of the 2009 data provided showing that there were 10,766 5-9.9 ug/dL cases state-wide. Later, when the data set was revised to represent only actual cases, the number decreased to 3,878. With a lower actual number of cases, the concern about retesting seems less urgent and the need to incorporate "at risk" verbiage in the guidelines less necessary. The first version of the guidelines developed through consensus at the November 10th meeting did not include the "at risk" verbiage in the medical management portion of the guidelines--anticipatory guidance and educate family subsections.

We appreciate the concern expressed by providers to MDH of comprehensively providing anticipatory guidance and education to families. However, Minneapolis clinics have requested that all policies related to lead be streamlined. If polices are not streamlined clinic staff cannot guarantee that the policies will be followed, as it becomes difficult for staff to track which patients fall under which "at risk" category.

The Minneapolis Department of Health and Family Support's proposes a compromise for the guidelines: utilize the same definition of *high risk* categories as outlined in the *Childhood Blood Lead Screening Guidelines*. *High risk* categories as identified in these guidelines are:

- **The child lives within the city limits of Minneapolis or St. Paul;**
- **The child receives services from MinnesotaCare (MnCare), the Supplemental Food Program for Women, Infants, and Children (WIC), or Medical Assistance (MA) which includes the Prepaid Medical Assistance Program (PMAP);**
- **The child does not fit the criteria above, and the answer to any of the following questions is "Yes" or "Don't Know":**

- During the past six months has the child lived in or regularly visited a home, childcare, or other building built before 1950?
- During the past six months has the child lived in or regularly visited a home, childcare, or other building built before 1978 with recent or ongoing repair, remodeling or damage (such as water damage or chipped paint)?
- Has the child or his/her sibling, playmate, or housemate had an elevated blood lead level?

We hope that our recommendations will be taken into consideration. In addition, we are willing to participate in any follow up conversations around this issue.

Thank you in advance for your consideration.

Sincerely,

Gretchen Musicant
Commissioner
Minneapolis Department of Health and Family Support

Copy Dan Symonik

Appendix G - Revised Childhood Blood Lead Clinical Treatment Guidelines for Minnesota:

Final Version

Childhood Blood Lead Clinical Treatment Guidelines for Minnesota

These guidelines were created for children from 6 to 72 months of age.	Blood Lead Levels in Micrograms Per Deciliter (ug/dL)					
	<5	5-9.9	10-14.9	15-44.9	45-59.9	60+
Medical Evaluation						
If capillary[1] result, **confirm with venous draw** within:		3 Months	3 Months	1 Week	48 Hours	IMMEDIATELY
Check nutritional status (especially iron and calcium) • Rule out iron deficiency and treat if present		X If venous result	X	X	X	X
Complete diagnostic evaluation (history, labs, iron studies, physical exam)			X	X	X	X
If exhibiting clinical symptoms check neurologic & developmental status (especially language skills and concentration ability)				X	X	X
Check abdominal x-ray Other diagnostic tests: BUN, CBC, Creatinine, UA and liver enzymes					X	X
TREAT AS AN EMERGENCY - potential encephalopathy						X
Medical Management						
Anticipatory Guidance–discuss high risk categories[2], primary sources of lead poisoning and measures to keep children safe from lead, including • age of home (built before 1978), • condition of painted surfaces (chipped/peeling), • pica, • remodeling, • occupations/hobbies, • folk remedies *Contact the MDH for a list of additional lead sources.*	X	X If capillary result				
Provide written, culturally appropriate lead poisoning prevention educational materials		X	X	X	X	X
Educate family–discuss: • Potential sources of lead and ways to reduce or remove exposure • Review and provide lead poisoning prevention literature • Dangers of improper lead abatement/remodeling • Nutrition–encourage high iron/high calcium diet • Chronic nature of problem (need to monitor frequently)		X If venous result	X	X	X	X
Iron supplement if deficient		X If venous result	X	X	X	X
IDENTIFY AND REMOVE LEAD SOURCE			X	X	X	X
Persistently high levels in this range may require more aggressive treatment *Consult MDH for information regarding chelation treatment*				X	X	X
Be sure to stop iron therapy prior to chelation				X	X	X
This level requires chelation–recommend the use of succimer per routine dosage *Consult the MDH for further information/referral if needed*					X	X
In-home treatment indicated only in situations of: • Lead-safe environment • Highly compliant family • Home health care monitoring					X	X
Discharge inpatient cases ONLY to LEAD-SAFE ENVIRONMENT					X	X
Follow-up/Comment[3]						
Review risk factors in 1 year	X	X				
Screen other children in the home if result is a venous test		X	X	X	IMMEDIATELY	IMMEDIATELY
Repeat venous test		6 months	3 months	1-3 months	1 week	48 hours
Repeat venous and diagnostic tests 14 days **after** chelation therapy is complete.					X	X
MDH or the local public health department will conduct an environmental inspection and public health nursing home visit for children up to 72 months of age.				X	X	X

[1] Venous specimens are considered diagnostic tests; Capillary (e.g. finger-stick) specimens are considered screening tests and are prone to false-positive results
[2] A high risk child lives in Minneapolis or St. Paul, receives services from Minnesota Care (MnCare) or Medical Assistance (MA), or fits one of the following criteria: a) lived in or regularly visits home built before 1960; b) lived in or regularly visits home built between 1960 and 1978 that is being, or has been, renovated; or c) sibling/playmate has EBL.
[3] Additional guidelines for public health case management, screening children, and screening pregnant women are also available from MDH

MINNESOTA MDH DEPARTMENT OF HEALTH

Division of Environmental Health
Environmental Surveillance and Assessment Section
Environmental Impacts Analysis Unit
P.O. Box 64975
St. Paul, Minnesota 55164-0975

Childhood Blood Lead Clinical Treatment Guidelines for Minnesota

< 5 ug/dL

Medical Evaluation
- Anticipatory Guidance–discuss high risk categories[2], primary sources of lead poisoning and measures to keep children safe from lead, including
  - *age of home (built before 1978),*
  - *condition of painted surfaces (chipped/peeling),*
  - *pica,*
  - *remodeling,*
  - *occupations/hobbies,*
  - *folk remedies*

Contact the MDH for a list of additional lead sources[4]

Medical Management
- NA

Follow-up/Comment[3]
- Review risk factors in 1 year

5-9.9 ug/dL

Medical Evaluation
- If capillary result[1], confirm **with venous draw** within 3 months
- Anticipatory Guidance–discuss high risk categories[2], primary sources of lead poisoning and measures to keep children safe from lead; see < 5 ug/dL for details
- If venous result, check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency; treat if present*

Medical Management
- Provide lead poisoning prevention literature if venous test
- Educate family if venous test by discussing:
  - *Potential sources of lead and ways to reduce or remove exposure; review and provide literature*
  - *Dangers of improper abatement/remodeling*
  - *Nutrition–encourage high iron/high calcium diet*
  - *Chronic nature of problem (need to monitor frequently)*
- Iron supplement if deficient if venous test

Follow-up/Comment[3]
- Review risk factors in 1 year
- Screen other children in the home if result is venous test
- Repeat venous test in 6 months

10-14.9 ug/dL

Medical Evaluation
- If capillary result, confirm **with venous draw** within 1 month
- Anticipatory Guidance–discuss high risk categories[2], primary sources of lead poisoning and measures to keep children safe from lead; see < 5 ug/dL for details
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency; treat if present*
- Complete diagnostic evaluation (history, labs, iron studies, physical exam)

Medical Management
- **Identify and remove lead source**
- Educate family by discussing items listed in "Medical Management" for 5 – 9.9 ug/dL
- Provide lead poisoning prevention literature
- Iron supplement if deficient

Follow-up/Comment[3]
- Screen other children in the home
- Repeat venous test in 3 months

15-44.9 ug/dL

Medical Evaluation
- If capillary result, confirm **with venous draw** within 1 week
- Anticipatory Guidance–discuss high risk categories[2], primary sources of lead poisoning and measures to keep children safe from lead; see < 5 ug/dL for details
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency; treat if present*
- Complete diagnostic evaluation (history, labs, iron studies, physical exam)
- If exhibiting clinical symptoms check neurologic and developmental status, especially language skills and concentration ability

Medical Management
- **Identify and remove lead source**
- Educate family by discussing items listed in "Medical Management" for 5 – 9.9 ug/dL
- Provide lead poisoning prevention literature
- Iron supplement if deficient
- Persistently high levels in this range may require more aggressive treatment
- Be sure to stop iron therapy before chelation *(consult MDH for information regarding chelation treatment)*

Follow-up/Comment[3]
- Screen other children in the home
- Repeat venous lead in 1 to 3 months (higher levels require more frequent monitoring)
- MDH or local public health department conducts an environmental inspection and public health nursing home visit for children up to 72 months of age.

45-59.9 ug/dL

Medical Evaluation
- If capillary result, confirm **with venous draw** within 48 hours
- Anticipatory Guidance–discuss high risk categories[2], primary sources of lead poisoning and measures to keep children safe from lead; see < 5 ug/dL for details
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency; treat if present*
- Complete diagnostic evaluation (history, labs, iron studies, physical exam)
- If exhibiting clinical symptoms check neurologic and developmental status, especially language skills and concentration ability
- Check abdominal x-ray
  - *Other diagnostic tests: BUN, CBC, Creatinine, UA and liver enzymes*

Medical Management
- **Identify and remove lead source**
- **This level required chelation**- recommend the use of succimer per routine dosage
- *(consult MDH for information/referral if needed)*
- Persistently high levels in this range may require more aggressive treatment
- Educate family by discussing items listed in "Medical Management" for 5 – 9.9 ug/dL
- Provide lead poisoning prevention literature
- Iron supplement if deficient
- Be sure to stop iron therapy before chelation *(consult MDH for information regarding chelation treatment)*
- In-home treatment indicated only in situations of:
  - *Lead-safe environment*
  - *Highly compliant family*
  - *Home health care monitoring*
- Discharge inpatient cases ONLY to LEAD-SAFE ENVIRONMENT

Follow-up/Comment[3]
- Screen other children in the home immediately
- Repeat venous test in 1 week (higher levels require more frequent monitoring)
- Repeat venous and diagnostic tests 14 days **after** chelation therapy is complete
- MDH or local public health department conducts an environmental inspection and public health nursing home visit for children up to 72 months of age.

60 ug/dL

Medical Evaluation
- If capillary result, confirm **with venous draw** immediately
- Anticipatory Guidance–discuss high risk categories[2], primary sources of lead poisoning and measures to keep children safe from lead; see < 5 ug/dL for details
- Check nutritional status (especially iron and calcium)
  - *Rule out iron deficiency and treat if present*
- Complete diagnostic evaluation (history, labs, iron studies, physical exam)
- If exhibiting clinical symptoms check neurologic and developmental status, especially language skills and concentration ability
- Check abdominal x-ray
  - *Other diagnostic tests: BUN, CBC, Creatinine, UA and liver enzymes*
- TREAT AS AN EMERGENCY – potential encephalopathy

Medical Management
- **Identify and remove lead source**
- **This level required chelation**- recommend the use of succimer per routine dosage *(consult MDH for information/referral if needed)*
- Persistently high levels in this range may require more aggressive treatment
- Educate family by discussing items listed in "Medical Management" for 5 – 9.9 ug/dL
- Iron supplement if deficient
- Be sure to stop iron therapy before chelation *(consult MDH for information regarding chelation treatment)*
- In-home treatment indicated only in situations of:
  - *Lead-safe environment*
  - *Highly compliant family*
  - *Home health care monitoring*
- Discharge inpatient cases ONLY to LEAD-SAFE ENVIRONMENT

Follow-up/Comment[3]
- Screen other children in the home immediately
- Repeat venous test in 48 hours (higher levels require more frequent monitoring)
- Repeat venous and diagnostic tests 14 days **after** chelation therapy is complete
- MDH or local public health department conducts an environmental inspection and public health nursing home visit for children up to 72 months of age.

[1] Venous specimens are considered diagnostic tests; Capillary (e.g. finger-stick) specimens are considered screening tests and are prone to false-positive results

[2] A high risk child lives in Minneapolis or St. Paul, receives services from Minnesota Care (MnCare) or Medical Assistance (MA), or fits one of the following criteria: a) lived in or regularly visits home built before 1950; b) lived in or regularly visits home built before 1978 that is being renovated; or c) sibling/playmate has EBL

[3] Additional guidelines for public health case management, screening children, and screening pregnant women are also available from MDH

[4] Contact MDH for a potential list of lead sources or see www.health.state.mn.us/lead

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MINNESOTA DEPARTMENT OF HEALTH

For more information about lead, contact the Minnesota Department of Health at (651) 201-4610
If you require this document in another format, such as large print, Braille, or cassette tape, call: (651) 201-5000 or (800) 657-3908 or MDH TTY (651) 201-5797

Appendix H - Revised Childhood Blood Lead Case Management Guidelines for Minnesota:

Final Version

Childhood Blood Lead Case Management Guidelines for Minnesota

(This document is intended for use by local public health agencies and their partners. It should be used in conjunction with the *Childhood Blood Lead Case Management Guidelines for Minnesota – Reference Manual*)

REMINDER: *BLOOD LEAD SCREENING IS REQUIRED AT 12 AND 24 MONTHS FOR ALL CHILDREN RECEIVING MEDICAL ASSISTANCE (MA) (OR UP TO SIX YEARS OF AGE IF NOT PREVIOUSLY TESTED)*

	Capillary CAPILLARY TESTS ARE CONSIDERED A SCREENING TEST ONLY[1], VENOUS TESTS ARE CONFIRMATORY	**Venous**
< 5 µg/dL	▪ Provide educational materials[2] to the family, including an overview of high risk categories[3].	▪ Provide educational materials[2] to the family, including an overview of high risk categories[3].
5 – 9.9 ug/dL	▪ Provide educational materials[2] to the family, including an overview of high risk categories[3]. ▪ Contact the family with the recommendation to have a follow-up venous test within three months.	▪ Provide educational materials[2] to the family, including an overview of high risk categories[3]. ▪ Ask questions to identify possible sources of lead in child's environment *(see back for list of sources)*
10 - 14.9 µg/dL	**Within one month:** ▪ Provide educational materials[2] to the family, including an overview of high risk categories[3]. ▪ Contact the family with the recommendation to have a follow-up venous test. **VENOUS RETEST WITHIN THREE MONTHS**	**Within one month:** ▪ Provide educational materials[2] to the family, including an overview of high risk categories[3]. ▪ Contact family with the recommendation to have a follow-up venous test within three months from the last blood lead test. ▪ Ask questions to identify possible sources of lead in child's environment *(see back for list of sources)*
According to Minnesota Statute, all venous results above 15 ug/dL require an environmental assessment		
15 – 44.9 µg/dL	**Within one week:** ▪ Provide educational materials[2] to the family, including an overview of high risk categories[3]. ▪ Contact the family to have a follow-up venous test. ▪ If feasible, contact the medical care provider regarding a follow-up venous test. ▪ Offer the medical care provider MDH's screening, treatment, and pregnancy guidelines. **VENOUS RETEST WITHIN ONE WEEK**	▪ **Within one week:** Arrange for initial home visit.[4] *(in primary language when possible).* ▪ Complete an in-depth assessment of: medical, environmental, nutritional, and developmental needs. ▪ Provide educational materials[2] to the family, including an overview of high risk categories[3]. ▪ Make necessary referrals. ▪ Communicate with the risk assessor assigned to the case. ▪ Encourage the family to obtain a follow-up venous test ***within three months*** from the last test. Higher levels require more frequent monitoring. ▪ Contact the family and/or medical care provider regarding the need for follow-up venous testing if venous follow-up not completed within three months from the last test.
45 – 59.9 µg/dL	**Within two business days:** ▪ Provide educational materials[2] to the family, including an overview of high risk categories[3]. ▪ Contact the family to have a follow-up venous test. ▪ Contact the medical care provider regarding a follow-up venous test. ▪ Ensure that the medical care provider is aware of the screening, treatment, and pregnancy guidelines available from the MDH. **VENOUS RETEST WITHIN TWO BUSINESS DAYS**	▪ **Within two business days:** Arrange for initial home visit.[4] *(in primary language when possible).* ▪ Complete an in-depth assessment of: medical, environmental, nutritional, and developmental needs. ▪ Provide educational materials[2] to the family, including an overview of high risk categories[3]. ▪ Make necessary referrals. ▪ Attempt to facilitate alternative, lead-safe housing. ▪ Communicate with the risk assessor assigned to the case. ▪ Contact the medical care provider to determine blood lead level, medical status, treatment and follow-up plans. At this level the medical care provider will most likely provide chelation therapy *(see MDH treatment guidelines)* and the child will need more frequent monitoring of their blood lead level.
≥ 60 µg/dL	**Immediately:** ▪ Provide educational materials[2] to the family, including an overview of high risk categories[3]. ▪ Contact the family to have a follow-up venous test. ▪ Contact the medical care provider regarding a follow-up venous test. ▪ Ensure that the medical care provider is aware of the screening, treatment, and pregnancy guidelines available from the MDH. **VENOUS RETEST IMMEDIATELY**	▪ **Immediately:** Arrange for initial home visit.[4] *(in primary language when possible).* ▪ Complete an in-depth assessment of: medical, environmental, nutritional, and developmental needs. ▪ Provide educational materials[2] to the family, including an overview of high risk categories[3]. ▪ Make necessary referrals. ▪ Attempt to facilitate alternative, lead-safe housing. ▪ Communicate with the risk assessor assigned to the case. ▪ Contact the medical care provider to determine blood lead level, medical status, treatment and follow-up plans. At this level the medical care provider will most likely provide chelation therapy *(see MDH treatment guidelines)* and the child will need more frequent monitoring of their blood lead level. **The child may be hospitalized at this level.**

[1] MDH data shows that approximately 68 % of elevated capillary test results are false positives (e.g. a high result was not confirmed by subsequent venous test). The best way to reduce contamination in capillary specimens is by thorough hand washing with soap and water.
[2] Use suggested educational materials in the appropriate language (see *Childhood Blood Lead Case Management Guidelines for Minnesota – Reference Manual*).
[3] A high risk child lives in Minneapolis or St. Paul, receives services from Minnesota Care (MnCare) or Medical Assistance (MA), or fits one of the following criteria: a) lived in or regularly visits home built before 1960; b) lived in or regularly visits home built between 1960 and 1978 that is being, or has been, renovated; or c) sibling/playmate has EBL.
[4] When possible, it is recommended to complete at least one follow-up home visit.