Minnesota's Lead Poisoning Prevention Programs

Blood Lead Testing Methods Report to the Legislature

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Executive Summary

There were ongoing questions in the lead community regarding the role of testing in lead poisoning prevention and appropriate testing methods. Therefore, the 2007 Legislature directed MDH to conduct a study to evaluate blood lead testing methods used to confirm elevated blood lead status. This report is the response to that legislative directive.

Two types of blood specimens are used for childhood blood lead testing, capillary and venous. Capillary specimens are drawn from a finger or heel stick, or rarely from the earlobe. Blood is pooled on the skin and either drawn into a glass capillary tube or dropped onto lead-free filter paper for collection. Therefore, the filter paper method is not a separate type of blood lead specimen, but rather a different technique for collecting blood specimens for analysis. Capillary specimens are considered screening tests because they are prone to falsely high results due to surface contamination when the patient's hands are not properly washed with soap and water. Venous specimens are considered diagnostic tests because they are drawn directly from a vein into a collection device, thereby avoiding skin surface contamination.

The study was to examine three topics:

Study Topic #1: the false positive rate of capillary tests for children who are younger than 72 months old:

Two main sources of data are available for determining the rate of false positive capillary results due to contamination, (1) simultaneous sampling of capillary and venous specimens in the same individuals (generally found in published research papers), and (2) surveillance or clinical data (generally obtained from public health agencies). In 2006, the false positive rate, based on surveillance data, was 68 percent for elevated capillary tests in Minnesota. Follow-up time was not significantly associated with being a false high capillary result. The fact that the length of time between tests was not related to false high capillary results gives evidence that surface contamination is the problem.

Study Topic #2: current protocols for conducting capillary testing, including filter paper methodology:

All protocols obtained from the Centers for Disease Control and Prevention (CDC), national medical organizations, and individual laboratories describe hand washing with soap and water as a key way to reduce contamination in capillary specimens. However, the extent to which appropriate hand washing techniques are practiced in Minnesota is unknown.

Study Topic #3: existing guidelines and regulations from other states and federal agencies regarding lead testing:

In addition to MDH and CDC guidelines, State health department Web sites and published material were searched to obtain their current guidelines or recommendations for blood lead testing and case management, and their regulations or guidelines regarding environmental assessment and intervention. Queries were also posted on national listservs. Most states, including Minnesota, were found to follow CDC guidance with respect to screening, case

management, and environmental intervention recommendations. However, states have a large variation in their ability to enforce lead hazard reduction.

The Commissioner was also required to make recommendations on possible changes to two lead program enforcement areas currently authorized through statute. The two proposed changes are:

1) The use of capillary tests to initiate environmental investigations and case management, including number and timing of tests and fiscal implications for state and local lead programs; and

2) Reducing the state mandatory intervention to 10 µg/dL.

Recommendations were generated based on information gathered relating to the topic areas above and by applying professional expertise within the MDH Lead Program.

Recommendation #1 - *Based on the data presented in this report, MDH does not recommend that the legislature change Minnesota Statutes §144.9504 to allow capillary testing for initiation of environmental investigations; the statute should continue to require venous confirmation specimens for initiation of mandated environmental investigations.*

If elevated capillary tests were used to initiate environmental intervention, in Minnesota in 2006 there would have been 137 false positive capillary tests used to trigger environmental investigations. At a cost of $4,000 per investigation (estimated by the work group for a 2004 legislative study) this would cost $548,000 statewide for investigating children without elevated blood lead levels (EBLLs). This increased spending on investigating false positive capillary results would divert resources from true EBLL cases and other prevention activities. While capillary tests are very useful as screening tests, MDH does not recommend the use of capillary tests to trigger environmental or medical intervention.

Recommendation #2 - *While there are both benefits and costs involved, MDH's recommendation to the legislature is to not change the secondary prevention statute (Minnesota Statutes §144.9504) to lower the environmental investigation level to 10 µg/dL. More effective and sustainable positive public health impacts could be gained by working towards a comprehensive statewide healthy housing plan.*

Reducing Minnesota's mandatory environmental investigation level from 15 µg/dL to 10 µg/dL would involve both benefits and costs. A lower environmental investigation level may provide prevention of higher exposures for the lead poisoned child in some cases, and may prevent exposure of siblings and future children living in the home. However, the annual number of cases statewide, by definition, would have increased by 175 based on 2006 data. This would give an additional annual statewide cost of $700,000. Current federal, state, and local funds for lead poisoning prevention activities would not support these increased costs. A lowered intervention level also would disrupt efforts seeking to implement a more comprehensive approach to housing-based health threats by targeting a single source (lead) at the expense of other issues. Therefore, MDH's recommendation to the legislature is to not lower the environmental investigation level to 10 µg/dL at this time.

Introduction

In 2004 a workgroup consisting of partners from federal, state, and local governments, community based organizations, housing, real estate, landlord, and tenant organizations, and many other disciplines, created the State of Minnesota 2010 Childhood Lead Poisoning Elimination Plan. The stated goal of the plan is: "To create a lead-safe Minnesota where all children have blood lead levels below 10 µg/dL by the year 2010." The plan advocates for a collaborative, housing-based approach to promoting primary prevention of childhood lead exposure. This approach is consistent with the federal strategy to act before children are poisoned, identify and care for lead poisoned children, conduct research, and measure progress to refine lead poisoning prevention strategies. It also is consistent with emerging plans at the Minnesota Department of Health (MDH) to more comprehensively promote housing stock in Minnesota that is healthy for occupants (e.g. "Healthy Homes"). Further information and the full 2010 Childhood Lead Poisoning Elimination Plan may be found at the MDH Lead Program website: www.health.state.mn.us/divs/eh/lead.

While primary prevention is the focus of current efforts, blood lead testing remains the most accurate method for determining current exposure to lead. The MDH Lead Program maintains a blood lead surveillance database authorized by Minnesota Statutes §144.9502. Through this database, MDH monitors blood lead levels in children and adults, ensures screening for children at risk for lead exposure, ensures case management services for children with elevated blood lead levels (EBLLs), and provides accurate data for planning and implementing primary prevention programs. Detailed surveillance data may be found in the MDH 2006 Blood Lead Surveillance Report (available at www.health.state.mn.us/divs/eh/lead/reports/surveillance/profile2006.pdf). The report shows that the percentage of tested children with EBLLs has been declining in Minnesota, even as the number of children tested in Minnesota has increased steadily since 1998. Screening is an important way to identify lead-poisoned children and measure the success of prevention efforts. However, because the effects of lead may not be apparent until years after exposure, and because the effects of lead are permanent, MDH believes that primary prevention is the most important way to protect children from the effects of lead poisoning.

As we transition from a screening-based lead program to one based on primary prevention, there have been ongoing questions in the lead community regarding the role of testing in lead poisoning prevention and appropriate testing methods. To help address this question, the Laws of Minnesota 2007, Chapter 147, Article 16, Section 18 mandated a study of blood lead testing methods. The text of that law is presented here:

> *Sec. 18.* ***Study of Blood Lead Testing Methods****.*
> *(a) The commissioner of health, in consultation with the commissioner of human services, cities of the first class, health care providers, and other interested parties, shall conduct a study to evaluate blood lead testing methods used to confirm elevated blood lead status. The study shall examine:*
> *(1) the false positive rate of capillary tests for children who are younger than 72 months old;*
> *(2) current protocols for conducting capillary testing, including filter paper methodology; and*

(3) existing guidelines and regulations from other states and federal agencies regarding lead testing.

(b) The commissioner shall make recommendations on:

(1) the use of capillary tests to initiate environmental investigations and case management, including number and timing of tests and fiscal implications for state and local lead programs; and

(2) reducing the state mandatory intervention to ten micrograms of lead per deciliter of whole blood.

(c) The commissioner shall submit the results of the study and recommendations, including any necessary legislative changes, to the legislature by January 15, 2008.

This report constitutes submission of results of the study along with recommendations to the legislature. The report focuses on children less than six years of age even though the emphasis on childhood lead poisoning is only specified for one sub-heading in the statute. A previous legislatively mandated study conducted in 2004 (available at www.health.state.mn.us/divs/eh/lead/reports/legislative/2004legreport.pdf) resulted in a statute change during the 2005 session that lowered the mandatory environmental intervention level to a single venous blood lead level of 15 µg/dL. Prior to that the mandatory intervention level was a single venous blood lead level of 20 µg/dL, or a persistent level of 15-19 µg/dL.

An initial draft of the study report was prepared by MDH staff. The draft was shared electronically with all contacts (121 individuals) on the Minnesota Collaborative Lead Education and Assessment Network (MCLEAN) email list on October 19, 2007. Representatives from the following are included on the MCLEAN list:

- state agencies (including the Department of Human Services)
- cities of the first class
- local public health agencies
- health plans and health care providers
- lead advocacy organizations
- federal lead programs
- housing organizations

Responses were received through email from Sue Gunderson (ClearCorps USA), Jack Brondum (Hennepin County Community Health Department), The Minneapolis/Hennepin County Childhood Lead Poisoning Prevention Work Group, and the Minneapolis Department of Health and Family Services. A comment period was provided during the October 24, 2007 meeting of MCLEAN, at which attendees provided comments and suggestions. MDH responses to these public comments, including changes made to this report, are provided at the end of this report.

Conclusions presented in this study are consistent with American Academy of Pediatrics 2005 Policy Statement on Lead Exposure in Children (AAP, 2005) and current MDH Lead Guidelines (presented on p. 11 below). The full text of the 2005 AAP Policy Statement can be found at: http://pediatrics.aappublications.org/cgi/reprint/116/4/1036 . Staff from the MDH Lead Program regularly meets with health care providers and health plans to help ensure that program recommendations and direction meet ongoing public health and community needs. The MDH Lead Guidelines for Childhood Screening (2000), Pregnant Women Screening (2004), Case

Management (2001; revised in 2006), and Clinical Treatment (2001) have all been reviewed and endorsed by the Minnesota Medical Association and other applicable medical professional organizations.

Study Topics

There are three primary topics related to the testing of blood for lead exposure included in the present study. Specifically, the topics examine accuracy and methods for performing capillary blood lead testing and gather existing state and federal guidelines to provide perspective to decision makers. The information presented in the topic areas then forms the basis for generating recommendations later in the report.

Topic #1. False positive rate of capillary tests for children < 72 months old

Two main types of blood specimens are used for childhood blood lead testing, capillary and venous. Capillary specimens are drawn from a finger or heel stick, or rarely from the earlobe. Blood is pooled on the skin and either drawn into a glass capillary tube or dropped onto lead-free filter paper for collection. The filter paper method is not a separate type of blood lead specimen, but rather a different technique for collecting blood specimens for analysis. Capillary specimens are considered "screening" tests because they are prone to falsely high results due to surface contamination when the patient's hands are not properly washed with soap and water. Capillary tests tend to be more acceptable to parents and may be performed in a wider range of settings. Venous specimens are considered diagnostic tests because they are drawn directly from a vein into a collection device, thereby avoiding skin surface contamination, but they can be less acceptable to some parents due to discomfort for the child. Venous specimens also necessitate greater expertise in drawing the blood.

Two main sources of data are available for determining the rate of false positive capillary results due to contamination, (1) simultaneous sampling of capillary and venous specimens in the same individuals, and (2) surveillance or clinical data. Throughout this report, "false positive" will be defined as an initial result above the cutoff level (i.e. the level that delineates an elevated blood lead level, whether for medical or environmental intervention) followed by a second test below the cutoff level.

Simultaneous sampling of capillary and venous specimens

Several studies have used simultaneous paired venous and capillary specimens to investigate the rate of false positive tests for capillary specimens. Summaries of each study are presented below.

Holtrop et al. (1998) used the filter paper method for collection of capillary blood paired with venous specimens in 120 infants and children. Staff received a 20-30 minute training on filter paper technique and the children's hands were thoroughly scrubbed with soap and water. The researchers observed only 1 false positive capillary result, and a concordance of 0.96 between the capillary and venous specimens.

Parsons et al. (1997) studied 499 children with paired capillary (glass capillary tube) and venous specimens. They observed a positive bias for capillary specimens, with a false positive rate of 17 percent using a cutoff level of 15 μg/dL. They observed one false negative at 15 μg/dL. The researchers analyzed data for individual staff members and found only a 1-9 percent false positive rate for capillary tests if all procedures were followed, including hand washing, but the rate was 27-58 percent if there were lapses in cleaning technique. Vigilant oversight of the full collection procedure was recommended.

Schlenker et al. (1994) studied three methods of reducing contamination using paired specimens in 295 children. The methods used were hand washing, alcohol wipes, and a silicone barrier spray. Using a cutoff level of 20 μg/dL, the researchers observed a false positive rate of 0-5 percent for the three methods, with generally close agreement between the means of venous and capillary tests.

Sargent et al. (1996) studied paired venous and capillary specimens in 513 children. Prior to the capillary specimen collection, the finger area was washed three times with an alcohol wipe. The researchers observed a false positive rate of 23 percent using a cutoff level of 10 μg/dL.

Taylor et al. (2004) studied paired earlobe and venous specimens in a population of adults working in battery manufacturing or lead smelting. The researchers first took a venous sample, then an earlobe sample with preparation using two alcohol wipes, one for removing contamination and one for sanitizing. They also took an alcohol wipe of the earlobe surface for measuring the contamination left on the skin. The study observed a mean venous level of 25.2 μg/dL and a mean capillary level of 64.0 μg/dL, with a mean difference of 38.8 μg/dL. In more than half the participants the capillary result was more than twice as high as the venous result. Despite the use of a cleansing alcohol wipe and visibly clean earlobes, 94 percent of participants had 1 μg or more lead in the test wipe, with a mean amount of 38.6 μg lead per wipe, even after the first two cleansing alcohol wipes were performed. The difference between the capillary and venous specimens was significantly correlated with the amount of lead in the test wipe. The authors calculated that contamination of just 0.3 μg lead in a 200 μL blood sample would cause a 150 μg/dL rise in measured lead level.

Johnson et al. (1997) also studied paired specimens in adults. The authors took paired venous and capillary specimens with and without hand washing. The authors first took the venous specimen, and then deposited soil on a finger of each hand. One hand was washed, fingers of both hands were wiped with alcohol, and the specimens were taken. The mean blood levels observed were 1.3 μg/dL for venous, 4.27 μg/dL for capillary specimens with hand washing, and 168.6 μg/dL for capillary specimens with only an alcohol wipe.

As described below under the filter paper section (p. 10 below), both Yee et al. (1995) and Srivuthana et al. (1996) found the filter paper capillary method to be accurate (a correlation coefficient of 0.97 and 0.96, respectively, between capillary and venous specimens) if hand washing procedures were strictly followed. Although methods and venues varied, the consistent conclusion from all studies reviewed was that proper hand washing with soap and water was critical to limiting false positive results in capillary tests.

Surveillance and clinical data

Surveillance and clinical practice data have also been used to study the rate of false positives for capillary blood lead specimens. These types of studies have the disadvantage that the capillary and venous tests were not drawn at the same time. Since blood lead levels may naturally decrease over time, some of the initial elevated capillary tests may not be true false positives, but may be a result of the natural decline in lead levels in a child. However, an advantage of the studies described below is that they use data that are more relevant to the practice of blood lead testing in Minnesota statewide, across a range of clinics, rather than the strictly controlled laboratory conditions used in the studies described above. This gives an indication of the magnitude of the false positive problem that would be faced if capillary tests were used in place of venous tests for diagnosis of lead poisoning in Minnesota.

Shonfeld et al. (1995) studied the rate of false positive capillary tests in 1,085 children seen in clinical practice in suburban New Haven, CT. Clinic staff members were used for collections, and were provided a training session with a video on capillary blood lead specimen collection. This procedure included washing the hands with soap and water plus an alcohol wipe. Children received a venous follow-up test if the initial capillary test was elevated. The study observed 30 children with elevated capillary tests (15 μg/dL or greater) and follow-up venous tests. Nine of these were true positives, for a false positive rate of 70 percent.

In another study, Sargent et al. (1999) used both clinical practice data from Massachusetts and surveillance data for a county in Rhode Island. The study used data for 1,278 children with elevated capillary tests and follow-up venous results. The researchers observed a striking positive bias for capillary tests, with a correlation coefficient of 0.29 between venous and capillary tests. In the 10-14.9 μg/dL range, the false positive rate for capillary tests was 77 percent. The false positive rate for capillary tests dropped as the lead level range increased.

In a 2007 study (Anderson et al. 2007), researchers used statewide surveillance data from Maine. Using several years of data, the researchers identified 464 children with elevated initial capillary tests and venous follow-up tests. The false positive rate for capillary tests was highest in the 10-14 μg/dL range, at 81 percent. False positives were seen for higher blood lead levels as well; 57 percent of children with a capillary test of 20 μg/dL or greater had a follow-up venous test of 10-14 μg/dL. The length of time between initial capillary test and follow-up venous test was not significantly related to false positive results, suggesting that a natural decline in blood lead level was not responsible for false positive findings. The study observed a positive bias for false positive capillary results, with a median of 7 μg/dL difference between capillary and venous tests for false positive results. Of the false positives, 20 percent had a difference of 15 μg/dL or greater. Only 28 percent of false positives differed by 4 μg/dL or less; these may have been caused by potential laboratory error in chemical analysis. Five of the capillary specimen collection sites accounted for 50 percent of false positives although they did only 29 percent of tests. The combination of these finding led the authors to conclude that contamination was the most likely source of positive bias and false positives for capillary tests, rather than laboratory error or the time delay between tests.

Minnesota-specific surveillance data

Data from the Minnesota blood lead surveillance system were analyzed in a similar manner to the Maine study described above. All data described here consist of children less than six years of age with initial tests in 2006. There were 371 children identified with elevated capillary tests (10 µg/dL or higher) and venous confirmatory tests. Of these, 157 had an initial capillary result of 15 µg/dL or greater.

Using a cutoff of 10 µg/dL (the Centers for Disease Control and Prevention and MDH level of concern), the false positive rate was 68 percent for elevated capillary tests (i.e. 68 percent were not elevated upon follow-up venous testing). As was the case with the Maine data described above, follow-up time was not significantly associated with being a false high capillary result. The fact that the length of time between tests was not related to false high capillary results gives evidence that surface contamination is the problem. If a natural decline in blood lead levels were responsible for lower follow-up venous tests, one would expect that as the length of follow-up time increased the percentage of elevated initial tests with low follow-up tests would increase. Using a cutoff of 15 µg/dL (the mandatory environmental intervention level), 69 percent of elevated initial capillary tests were not elevated upon follow-up. As above, follow-up time was not significantly associated with being a false high capillary test. For elevated (15 µg/dL or greater) capillary initial tests, the mean drop in blood lead level upon follow-up venous testing was 14.9 µg/dL, with a median drop of 12.0 µg/dL.

The rate of "false positive" results for initial capillary tests may be compared with the rate of non-elevated follow-up tests for initial elevated venous tests. However, since venous tests are the diagnostic standard in blood lead measurement, a low follow-up test after an initial elevated venous test does not indicate a "false positive" initial test. Rather it indicates that the blood lead level has dropped over time. For elevated venous initial tests, 37 percent were not elevated upon follow-up testing, in comparison to 68 percent as described above for capillary tests. The mean time of venous follow-up for elevated capillary tests was 20 days, with a median of 7 days. The mean follow-up time for venous initial tests was 73 days, with a median of 50 days. The follow-up time is significantly longer for venous initial tests than capillary initial tests since venous tests are considered diagnostic results. Confirmation of the venous result is not necessary; therefore follow-up is only necessary to track the effectiveness of interventions to lower the blood lead level. In contrast, venous follow-up tests after capillary initial tests are done relatively quickly as confirmatory tests. The fact that the follow-up time was significantly less for capillary initial tests compared with venous initial tests gives additional evidence that a natural decline in blood lead levels is not responsible for the high rate of false positive capillary tests. If capillary tests were not susceptible to contamination, this shorter follow-up time should lead to a lower percentage of false positives for capillary tests, rather than a higher percentage, as seen in the data.

The discrepancy in blood lead level for false positive capillary tests can be large. There were 54 instances of an elevated capillary test with a follow-up venous that was at least 15 µg/dL lower. Most (83 percent) of the venous follow-up tests for these significantly elevated capillary tests were less than 5 µg/dL and nearly all (94 percent) were less than 10 µg/dL, strongly suggesting contamination as the source of the elevated result.

Topic #2. Current protocols for conducting capillary testing, including filter paper

The following information is available from federal agencies, professional medical associations and individual laboratories on collection of capillary blood specimens.

Centers for Disease Control and Prevention (CDC) protocol:

In their 2005 statement "Preventing Lead Poisoning in Young Children" (CDC 2005), CDC's Advisory Committee for Lead Poisoning Prevention (ACLPP) described the use of capillary and venous specimens: "…although venous blood is preferable for epidemiologic studies of environmental lead exposure, use of capillary blood is acceptable if collected by staff specially trained in the technique using devices certified as 'lead-free.' Data should be provided showing an acceptably low rate of contamination errors and low mean bias in the capillary BLLs as collected using the study protocol." The 2005 statement advised that stringent precautions for preventing contamination must include rigorous hand washing, and agreed with the National Committee for Clinical Laboratory Standards that venous blood is the most appropriate specimen for blood lead measurements.

CDC's guidance regarding blood lead screening, published in 1997, "Screening Young Children for Lead Poisoning: Guidance for State and Local Public Health Officials" (CDC 1997), included Appendix C., "Capillary Blood Sampling Protocol." This appendix recommended that the procedure must include thorough hand washing with soap and water and lead-free collection devices. Appendix C.1, "The Lead Laboratory," from the 1997 document describes proficiency testing programs: "The Health Care Financing Agency (HCFA), operating under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), regulates all aspects of laboratory operation, including determining the qualities of a laboratory director and establishing protocols for quality assurance and quality control activities, method validation, specimen collection, storage, analysis and reporting of results (42 CFR Part 493). For blood lead laboratories specifically, successful participation in an approved proficiency testing program is required."

American Academy of Pediatrics (AAP) protocol:

AAP does not provide specific recommendations for capillary sample collection, however in a 1998 statement in *Pediatrics* (AAP 1998), AAP stated that any elevated capillary result must be confirmed with a venous specimen. Also, AAP stated that when feasible, venous blood specimens should be used for initial screening.

Individual laboratory protocols:

The four largest laboratories in the Minnesota blood lead surveillance database, Labcorp, Mayo Laboratory, Medtox, and Quest Diagnostics, which collectively analyze approximately 63 percent of the blood lead test specimens for Minnesota citizens, were asked about their policies and educational efforts for capillary specimens.

Labcorp (Burlington, NC): No response was received from telephone and email inquiries.

Mayo Laboratory (Rochester, MN): The Mayo laboratory collects only venous specimens from their internal patients. However the laboratory does accept capillary specimens from their external clients for laboratory analysis. Mayo does not provide capillary collection procedures to these clients. The specimens must be marked either "capillary" or "venous", and Mayo recommends that any child with an elevated capillary test receive a confirmatory venous test.

Medtox (New Brighton, MN): Medtox (the major laboratory providing filter paper blood lead testing in Minnesota) includes collection procedure instructions (including thorough hand washing with soap and water) when collection materials are provided to clinics and other clients. This information includes written and video materials. Collection instructions are also available on Medtox's Web site (www.medtox.com).

Quest (Wood Dale, IL): No response was received from telephone and email inquiries.

In addition to conventional laboratories for analysis of blood specimens, an increasing number of health care clinics in Minnesota use the ESA Biosciences, Inc. "LeadCare" and "LeadCare II" instruments to analyze blood lead specimens. These products allow the analysis of blood lead specimens at the same time as collection, with immediate availability of test results. Materials provided with the instruments do not specifically describe hand washing for specimen collection, but an appendix is included that does contain hand washing information: CDC's "Steps for Collecting Fingerstick Blood Samples in Micro-Vials for Lead Testing."

Filter paper protocols:

There are two main methods for collection of capillary blood lead test specimens, glass capillary tubes and filter paper. The type of collection device (filter paper or glass capillary tubes) is not reportable to MDH according to statute; therefore this information is not provided by laboratories. Collecting specimens on filter paper generally is easier for non-phlebotomist staff to use in comparison with glass tubes. Also, since filter paper specimens are dried on the filter paper prior to storage and are stable for analysis up to six months, this method negates coagulation of the blood as a problem for analysis. Coagulation is an occasional cause of inability to analyze a specimen when glass capillary tubes are used. The use of the filter paper method may increase the ease of storage and shipping of specimens since they do not need to be refrigerated and may be shipped in the regular mail.

The use of filter paper for collection of capillary specimens does not fundamentally lessen the chance of specimen contamination in comparison to glass capillary tubes since both methods allow blood to pool on the finger surface. This pooling greatly increases susceptibility to contamination compared with venous specimens. However, during analysis, the filter paper method allows some assessment of finger surface contamination because non-homogeneous samples may be taken from different areas of the collection device (i.e., different blood drops), in comparison with glass capillary tubes. If one sample is significantly different from the other, contamination is a strong likelihood. When the filter paper method was first developed, there were concerns regarding contamination of the collection paper with lead. However, those

problems were resolved, and in February 1999 CDC approved the use of the filter paper method by CLIA-certified laboratories following appropriate procedures.

In addition to proficiency testing programs, published studies have also confirmed the accuracy of the filter paper method when hand washing and other collection procedures are strictly adhered to. Yee et al. (1995) and Srivuthana et al. (1996) found correlations of 0.97 and 0.96, respectively, between filter paper capillary and conventional venous specimens when procedures were strictly followed.

General Considerations for Capillary Testing Protocols:

All the published capillary blood lead collection protocols described above include thorough hand washing with soap and water. However, the extent to which this practice is followed in Minnesota is unknown. Some laboratories (specifically filter paper laboratories) may include collection information in mailings of supplies. However, for the glass capillary tube method, clinics use their own supplies; therefore supplies are not routinely mailed out from laboratories and collection procedures are not available. Even when educational materials and training are provided from the laboratory to the clinics, it is unknown whether clinics provide this information to staff, and clinic staff members may change. Since most other analyses (other than blood lead measurement) using fingerstick blood specimens do not require washing with soap and water, clinic staff members may not be aware of the crucial need for hand washing for blood lead specimens.

Topic #3. Existing guidelines and regulations from other states and federal agencies regarding lead testing.

The following are guidelines from a variety of sources. MDH documents are posted under the "Publications and Reports" sidebar at: www.health.state.mn.us/divs/eh/lead .

MDH:

Screening Guidelines: The MDH Childhood Blood Lead Screening Guidelines direct physicians to order blood lead tests for children residing in Minneapolis and St. Paul and those recently arriving from other major metropolitan areas or other countries. Testing is also recommended for children receiving Medicaid and those living in a home built before 1950, or built before 1978 with ongoing remodeling or damage. All other children should be screened using a risk questionnaire, and if any answer is yes or don't know, the blood lead test should be performed. The test is typically performed when the child is one and two years old, but may be done at any time if the parent is concerned or if a high-risk activity (e.g. remodeling a home built before 1950) has recently occurred. These guidelines will be evaluated and reissued by MDH in 2008.

Case Management Guidelines: The Minnesota case management guidelines generally follow CDC's guidelines from their 2002 report, "Managing Elevated Blood Lead Levels among Young Children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention" (ACLPP 2002). The MDH Childhood Blood Lead Case Management Guidelines are intended to establish standardized, minimum levels of care for providing services to children

with EBLLs. However, those local public health agencies that have greater resources available may wish to take a more rigorous approach to case management. These guidelines were evaluated and updated in 2006.

Environmental Management Regulations: Minnesota statute section 144.9504 mandates environmental assessment and intervention for venous blood lead levels of 15 µg/dL or greater in children less than six years old and 10 µg/dL or greater in pregnant women. The time frame in which the assessing agencies must investigate depends on the confirmed venous blood level, and ranges from 48 hours to 10 working days. State law mandates that cities of the first class perform these risk assessments. Currently the agencies performing risk assessments are city of Minneapolis Healthy Homes and Lead Hazard Control, Hennepin County Environmental Health (for suburban Hennepin County, excluding Edina, Bloomington, and Richfield), St. Paul - Ramsey County Department of Public Health, St. Louis County Public Health and Human Services, Bloomington Division of Health (for the cities of Bloomington and Richfield), Stearns County Human Services (for the city of St. Cloud), and Dakota County Department of Public Health. The remainder of the state is covered by the MDH Asbestos and Lead Compliance Unit.

CDC:

Screening: In their 1997 publication, "Screening Young Children for Lead Poisoning: Guidance for State and Local Public Health Officials," CDC moved from its recommendation of universal testing of U.S. children toward targeted screening (CDC 1997). CDC recommended universal screening in areas with 27 percent or more of the housing being older than 1950, and in areas with a prevalence of EBLLs (among those tested) of 12 percent or greater. CDC also recommended testing all Medicaid children in accordance with federal Medicaid law. In 2005, CDC increased their emphasis on primary prevention (CDC 2005).

Case management: CDC's case management guidelines were set by the ACLPP in 2002 (CDC 2002). Those guidelines specify a level of 10 µg/dL to be of concern. At levels of 10-14 µg/dL, CDC recommended follow-up testing, education and environmental changes such as thorough cleaning. Persistent confirmed levels of 15 µg/dL and up, or one venous test of 20 µg/dL or higher require environmental assessment. Elevated capillary tests should be confirmed with venous specimens. The ACLPP reiterated the need for diagnostic confirmation of elevated capillary tests in 2007 (Binns et al. 2007).

Environmental management: CDC's 2002 report recommended environmental assessment at a single venous level of 20 µg/dL, or two venous tests at least three months apart of 15-19 µg/dL (CDC 2002).

CDC maintains a national database containing de-identified records from all states participating in the Childhood Lead Poisoning Prevention Program (CLPPP), including Minnesota. In the past CDC has accepted two sequential elevated capillary results as a confirmed elevated blood lead level case for the purpose of data analysis. However, CDC stresses (in the documents cited above and in personal communication with MDH staff) that the national database is not used for enforcement or medical case management, and that venous confirmation is required to initiate these interventions.

AAP: In their 1998 statement in *Pediatrics* (AAP 1998), AAP stated that any elevated capillary test must be confirmed with a venous specimen and that when feasible, venous blood samples should be used for initial screening. If no guidance is available from the state or local government, AAP recommended that clinics consider testing all children. From their 2005 statement in *Pediatrics* (AAP 2005), AAP's recommendations for case management were the same as those from CDC (CDC 2002).

Other state guidelines and laws:

State health department web sites and published material were searched to obtain their current guidelines or recommendations for blood lead testing and case management, and their regulations or guidelines regarding environmental assessment and intervention. In addition, a query was posted to two national email groups regarding state regulations and policies for blood lead testing.

Screening guidelines: Most other states follow CDC guidance (CDC 1997) for screening of at-risk children. Universal testing is generally recommended for areas with a high percentage of pre-1950 homes and EBLL rates. Connecticut has mandatory screening of all children less than three years of age, and Iowa has a mandate to test all children before entering school.

Case Management: Most states were found to follow the 2002 CDC guidelines as described above. Eighteen states did not have published guidelines (thirteen of those have no CDC-funded lead poisoning prevention program). Vermont recently lowered their level of environmental concern to 5 µg/dL. Their mandatory environmental investigation level is still the same as CDC guidelines (a single level of 20 µg/dL, or two tests of 15-19 µg/dL). The cities of Cleveland and Cincinnati also have a level of concern of 5 µg/dL, but use the state of Ohio's mandated environmental investigation level of 20 µg/dL, or two tests of 15-19 µg/dL. New York City has a level of 5 µg/dL for educational intervention, but uses a single level of 15 µg/dL for environmental intervention.

Environmental Management: Most state regulations were found to follow CDC recommendations for the level at which environmental assessment and intervention is recommended or required. However, states have a large variation in their ability to enforce lead hazard reduction. For example, Rhode Island requires lead hazard inspections in rental property when tenants change. New Hampshire, Maryland and Kansas have a level of 10 µg/dL for environmental action. Minnesota, Oregon, Washington state, and New York City have a single level of 15 µg/dL for environmental intervention. Georgia and Maine have a level of 20 µg/dL, with no persistent 15-19 µg/dL requirement. Environmental guidelines could not be found for 21 states. The remaining 21 states follow CDC recommendations for environmental action (a single 20 µg/dL result, or two or more 15-19 µg/dL tests). The city of Cincinnati has a recommended environmental level of 10 µg/dL, but it is not mandatory.

Recommendations

The Commissioner was required to make recommendations on possible changes to two lead program enforcement areas currently authorized through statute. The two proposed changes are:

1) The use of capillary tests to initiate environmental investigations and case management, including number and timing of tests and fiscal implications for state and local lead programs; and

2) Reducing the state mandatory intervention to 10 µg/dL.

Recommendations were generated based on information gathered relating to the topic areas above and applying professional expertise gathered over years of working with lead poisoning prevention and a range of partners.

Recommendation Focus Area 1: The use of capillary tests to initiate environmental investigations and case management, including number and timing of tests and fiscal implications for state and local lead programs

As stated in Topic Area #3 above, Minnesota statute section 144.9504 currently mandates environmental assessment and intervention for venous blood lead levels of 15 µg/dL or greater in children less than six years old and 10 µg/dL or greater in pregnant women. Capillary tests are not currently recognized for mandatory environmental investigations or medical case management.

Advantages of Capillary Testing

Capillary specimens have several advantages over venous specimens for use as screening tests. Phlebotomy in young children can be especially difficult and requires experienced clinical staff. Capillary specimens are easier to collect for relatively untrained staff members, and therefore do not require a trained phlebotomist. This reduces staff costs. If the filter paper collection method is used, capillary testing can be brought into a wider variety of settings since the specimens need not be refrigerated. Capillary tests are less feared by parents and children, and their use as screening tests can avoid phlebotomy for a large number of children. For example, in Minnesota in 2006 the use of capillary tests as a screening tool avoided phlebotomy for 49,788 children (i.e., children with non-elevated capillary tests). The capillary collection of blood lead specimens can be accurate when hand washing procedures are strictly followed. Because of these advantages, the percentage of tests received by MDH that are capillary specimens has been increasing. In Minnesota in 2006, 83 percent of children's first tests were capillary specimens.

Due to all of the advantages listed above, when MDH has conducted screening efforts in the recent past the preferred collection method has been capillary samples using filter paper. These efforts included the Countryside Lead Prevalence Study conducted in 2001-2002 (Zabel, et al, 2005) and testing at WIC clinics across the state (2003-2005). Strict attention to hand washing technique helped minimize false positive results in each of these efforts. It should be noted,

however, that in all of these situations provisions were in place to provide follow-up venous testing to any elevated capillary result. Clearly, capillary testing is an important part of ongoing efforts to identify and eliminate lead exposure and should continue to be used in appropriate circumstances.

Disadvantages of Capillary Testing

Unfortunately, contamination is a major problem for capillary blood lead specimens. While paint is the most frequent source of elevated blood lead levels in children, lead is a ubiquitous environmental contaminant in the U.S., due to its many uses, lax environmental controls in the past, and its use in gasoline from the 1920s through the early 1990s. As a result, lead has been distributed throughout the upper soil, especially near major roads. This soil contamination can end up on finger surfaces where lead gets into capillary blood samples. Another source of finger contamination may be handling of objects that contain lead. As several of the above studies demonstrate, even with strict adherence to procedure, capillary tests may still be biased high. When hand washing procedures are not followed, contamination can cause severe bias in the measurement of blood lead concentration. For that reason, federal and state agencies, professional medical organizations and laboratories recommend that any elevated capillary test be confirmed with a venous test prior to initiation of environmental and medical intervention.

Using a capillary result for initiation of environmental investigation would lead to many investigations when there is not an elevated level of lead in the child's body. Assuming the error rate for a second capillary test is the same as the first capillary tests that were confirmed with a venous follow-up test (69 percent), there would have been 137 false positive cases in Minnesota in 2006 where the children actually did not have EBLLs. This assumes all first elevated capillary tests had second capillary tests and were used for environmental interventions. This would lead to 137 environmental investigations where there is likely to be no lead exposure. In addition, if the second capillary test is performed by the same clinic that performed the first false positive test, the second capillary test is even more likely to be falsely elevated since the clinic staff will likely continue to use poor technique in collection of capillary specimens. The Maine study described above (Anderson et al. 2007) observed a similar result, "There were 115 capillary tests of 20 µg/dL or above, a blood lead level that, if confirmed, would have prompted an environmental investigation to identify the source of lead exposure. However, only 18 (16 percent) of these capillary tests were confirmed by a venous test of 20 µg/dL or above, avoiding 97 environmental investigations."

Use of Limited Resources

The MDH report to the legislature for the 2004 study (available at www.health.state.mn.us/divs/eh/lead/reports/legislative/2004legreport.pdf) calculated a total cost of $12,000 per environmental case based upon the consensus of the group, which included maintaining the state lead database, screening, public health follow-up, risk assessment and lead hazard reduction and clearance on the child's residence. The cost was broken down as follows: $7,500 for lead hazard reduction, $500 for general education and outreach, $1,200 for environmental case management, $1,000 for medical case management, $750 for surveillance

activities, $500 for risk assessment, $200 for monitoring and evaluation, $200 for clearance testing, and $150 for relocation and medical costs.

Using the Minnesota surveillance data described above, if there were 137 false positive capillary follow-up tests used for initiation of environmental investigations, at a cost of $4,000 per investigation (investigation costs only) this would cost $548,000 statewide for investigating children with no actual blood lead elevation. State and local programs would incur significant increased costs at a time when federal, state, and local funds for lead poisoning prevention and investigation are level or decreasing. In addition, using risk assessment resources when there is likely to be no source, certainly not an identifiable or correctable source, would deflect resources from other children's health needs at both the state and local levels. It is possible that by chance the homes of some of the children with false positive capillary results would be found to have lead hazards, but this would come at a cost of $4,000 per investigation that might be used for prevention of hazards in known high-risk housing. This increased spending on investigating false positive capillary results would divert resources from true EBLL cases and primary prevention of exposure due to high-risk housing.

Additional Considerations

Testing of children should not be the primary means of detecting homes with lead contamination. Primary prevention should concentrate on homes that are at-risk for containing deteriorated lead paint. Therefore the focus of lead poisoning prevention stakeholders in Minnesota should be primary prevention programs, including systematic evaluation of housing conditions and lead hazard reduction before any child has an EBLL. Routine inspection of high-risk housing combined with programs such as window replacement may identify a greater number of children at risk for lead poisoning than relying on falsely high capillary testing.

In addition to financial costs, investigation of homes for children who do not actually have elevated blood lead levels will cause distress for families. By default, using false positive capillary results for environmental investigation would tell parents that their child is lead poisoned, when 68 percent of the time they are not. Parents may worry needlessly about a toxic exposure to their child. If confirmatory venous tests are never obtained, the family will continue to believe that their child is lead poisoned.

Providers collecting capillary blood lead specimens should be familiar with, and follow, proper collection procedures, including thorough hand washing. In all cases, any elevated capillary test must be confirmed with a follow-up venous test before beginning environmental or medical intervention. If it is suspected that it will be difficult to obtain a follow-up venous test, providers should obtain an initial venous test when possible. Using venous specimens as the initial screening tests would avoid follow-up efforts for falsely elevated capillary tests.

Summary

While capillary specimens are very useful for screening tests and play a very important role in the overall scheme of addressing lead poisoning in Minnesota, the use of capillary specimens for initiation of environmental or medical intervention cannot be recommended. This is based on the

high rate of false positive results (68 percent), preponderance of expert medical opinion as expressed in national and state guidelines, uncertainty in the statewide use of proper hand washing technique, unnecessary costs that would be incurred, and need to continue to focus program efforts on primary prevention (rather than screening, which is secondary prevention). Overall, it is not clear that using capillary tests to trigger statutory/medical thresholds will significantly help achieve the goal that all parties involved in lead poisoning prevention in Minnesota share, which is to eliminate exposure and protect children from lead.

MDH recommendation: *Based on the data presented above, MDH does not recommend that the legislature change Minnesota Statutes §144.9504 to allow capillary testing for initiation of environmental investigations; the statute should continue to require venous confirmation specimens for initiation of mandated environmental investigations.*

Recommendation Focus Area 2: Reducing the state mandatory intervention to 10 µg/dL

Minnesota's environmental investigation level of 15 µg/dL is currently lower than most states' and CDC's recommendations as described above. Also, enforceable environmental intervention at 10 µg/dL is currently allowed for state and local programs where resources are available. From Minnesota Statutes §144.9504, Subd. 2: "… (b) Within the limits of available local, state, and federal appropriations, an assessing agency may also conduct a lead risk assessment for children with any elevated blood lead level." In Minnesota Statutes §144.9501, Subd. 9 "elevated blood lead level" is defined as "a diagnostic blood lead test with a result that is equal to or greater than ten micrograms of lead per deciliter of whole blood in any person, unless the commissioner finds that a lower concentration is necessary to protect public health."

In general, the MDH Lead Program and Cities of the First Class currently respond to blood lead test results for children less than 6 years old as shown below:

Blood lead result	Response
Less than 10 ug/dL	Reports entered into MDH database
10 – 15 ug/dL	Same as previous, plus: MDH also notifies local health agency, which contacts the family and provides education on hazard reduction. Environmental intervention may be ordered, at discretion of assessing agency.
15 – 45 ug/dL	Same as previous, plus: environmental intervention mandatory
Greater than 45 ug/dL	Same as previous, plus: child is recommended for chelation therapy to reduce level
Greater than 60 ug/dL	Same as previous, plus: considered a medical emergency. Immediate action is taken

There are both benefits and costs associated with lowering the mandatory intervention level to 10 µg/dL. The benefits tend to be relatively long-term and generally are much more difficult to quantify. Long term benefits typically include things like improved population health (e.g. IQ), avoided morbidity (e.g. children not exposed to lead), reduced costs for social service programs, and increased lifetime earning potential. The costs tend to be relatively short term, and generally consist of agency/program costs associated with investigating additional cases and costs to homeowners for performing lead hazard reduction. Short term costs tend to be relatively easy to quantify. In addition to financial consideration, there are issues related to intervention

effectiveness for an individual child at lower exposure levels, duplication of currently available authority, and analytical uncertainty. These issues are explored in further detail below.

Availability of effective interventions:

A significant public health concern for changing the environmental intervention level to 10 µg/dL is whether there are effective interventions to reduce a child's BLL once a case of 10-14 µg/dL is identified. Several studies have investigated the effectiveness of environmental interventions. Aschengrau et al. (1998) studied education and cleaning interventions for Boston children living in homes with lead paint who had venous BLLs of 10-24 µg/dL. In the homes with the most severe hazards, BLLs dropped 2.5 µg/dL compared with controls, and BLLs dropped 0.3 µg/dL for children in homes with moderate hazards. Schultz et al. (1999) also found that educational intervention reduced BLLs about 3 µg/dL more than controls when children started with BLLs of 20-24 µg/dL. In a non-randomized study, Leighton et al. (2003) observed an 11 percent larger drop in BLL after one year in remediated homes compared with those not remediated, after adjustment for confounding factors. All the children in that study lived in homes with identified lead hazards and correction orders.

In a Minnesota study, Jordan et al. (2003) conducted a randomized preventive educational intervention for children aged zero through age 36 months in the Phillips neighborhood of Minneapolis. Intervention participants had a 19 percent risk of developing a BLL of 10 µg/dL or greater, compared with a 23 percent risk for controls. In a more recent study, Dugbatey et al. (2005) found no effect of educational intervention on BLLs at follow-up. Campbell et al. (2003) found that intensive cleaning reduced dust lead levels initially, but the lead dust levels came back to baseline levels at 3-6 months. BLLs were found to be no different for children with or without the cleaning efforts.

Neimuth et al. (2001) found that there is a natural decline in BLLs (approximately 9 percent) over an average one year period, even in children receiving no environmental or educational intervention to lower their BLL. This natural decline makes it difficult to notice any effect of environmental interventions. Another reason for the lack of effectiveness for environmental interventions in children with moderately elevated blood lead levels may be the lead stored in bone from long-term exposure (Rust et al. 1999). Even if lead exposure is stopped, the lead in bone may come out into the blood, leading to continued elevated blood lead levels. Lead hazard control work is not risk free; it may occasionally cause elevation in BLL if not done safely. Clark et al. (2004) observed an overall average reduction in BLL of approximately 1 µg/dL after lead hazard reduction activities. However, 9 percent of study participants had increases in BLL of 5 µg/dL or more.

The above published studies have shown limited effectiveness of interventions in reducing moderately elevated blood lead levels in children living in homes with lead hazards. Even the most successful studies in homes with identified lead hazards show a reduction in blood lead level of only approximately 3 µg/dL more than controls who did not receive the intervention. The outcomes of interventions in newer homes or homes with no identified hazards are likely to be even more uncertain. Unfortunately data on identified lead hazards in homes of children with BLLs above and below 10 µg/dL are not kept on a routine basis in Minnesota. Data such as the

findings of the above studies have led the AAP to state that "In children with BLLs of 10-14 µg/dL, a point source of lead exposure is not usually found" (AAP 1998) and "tactics that decrease blood lead concentrations might be expected to be less and less effective as they are applied to children with lower and lower blood lead concentrations" (AAP 2005).

When describing the findings of the controlled intervention studies above, it is important to note that MDH does not wish to imply that environmental interventions are not useful. To the contrary, we agree that environmental intervention is a necessary and effective strategy for primary prevention of lead poisoning. In the case of a child with an elevated blood lead level, environmental intervention is likely to prevent exposure of other family members or future residents of the home, and should prevent a child's elevated blood lead level from going higher. However, data do not support the contention that environmental intervention is an entirely effective way to lower a child's blood lead level once it is elevated. The limited effectiveness of environmental interventions in reducing EBLLs suggests that environmental investigations are most effective when used for prevention. Efforts to prevent children from developing EBLLs (e.g. primary prevention) should be the main strategy to eliminate childhood lead poisoning.

Benefits:

One benefit of lowering the mandatory environmental intervention level is that the level would then agree with the "level of health concern" recommended by both MDH and CDC. In addition, it would be the same as the environmental investigation level mandated for pregnant women in Minnesota. This may help reduce potential confusion in the health care community regarding interventions to specific lead levels.

In addition, given the recent published reports indicating that lead has no "safe" threshold of exposure, another benefit of lowering the intervention level (and therefore including more children) would be to keep lead poisoning prevention in the forefront of public health agency goals, health care provider efforts, and legislative funding priorities.

If lead hazard reduction is performed in a lead-safe manner, a lower environmental investigation level may provide primary prevention of higher exposures for the lead poisoned child in some cases, and may also prevent exposure of siblings and children living in the home in the future. This benefit could also be accomplished, however, by a comprehensive primary prevention program for all at-risk housing independent of blood lead testing.

While there is published literature on the long-term, societal costs of lead poisoning (e.g. Landrigan et al. 2002, Grosse et al. 2002), a detailed cost-benefit analysis of these issues is beyond the scope of the report.

Costs:

There would be significant costs involved with mandating a lower environmental investigation level. The number of cases would increase significantly. In 2006 there were 116 new children with venous results of 15 µg/dL or higher who were not a case in a previous year. In contrast there were 291 new children with venous results of 10 µg/dL or higher. The numbers reported by

MDH in the 2006 Blood Lead Surveillance Report are slightly higher than these figures because they include children who were cases in previous years. Using these 2006 numbers, the change in environmental case definition from 15 µg/dL to 10 µg/dL would have led to 175 additional environmental cases (2.5 fold more cases). As with current cases of 15 µg/dL or higher, most of the new cases would likely be found in the jurisdictions of city of Minneapolis Healthy Homes and Lead Hazard Control, St. Paul - Ramsey County Department of Public Health, and MDH Asbestos and Lead Compliance. However the remaining assessing agencies would also see an increase in case load.

In the past several years EBLL cases in Minnesota have been split in the following way: approximately 40 percent for Minneapolis, 26 percent for St. Paul - Ramsey County, and 23 percent for MDH, with the remaining 11% for the remaining assessing agencies. This means Minneapolis, St. Paul – Ramsey, and MDH would have seen 70, 46, and 40 additional new cases, respectively. New costs would also be borne by the local assessing agencies of Hennepin County Environmental Health, St. Louis County Public Health and Human Services, Bloomington Division of Health, Stearns County Human Services, and Dakota County Department of Public Health for dealing with a lower intervention level.

The primary cost for conducting environmental investigations includes staff time for inspectors and nurse case managers. Identifying lead risks at lower exposure levels often requires significantly more time and investigation compared to a normal EBLL case. If additional dust samples or X-Ray Fluorescence (XRF) readings are needed to characterize the exposure route, the laboratory analysis and XRF expenses will lead to additional time and resource costs. Additional visits to the home will burden the family and assessment staff in reconstructing the potential exposure, which may have come from any number of sources at varying times and durations. Because federal, state, and local funds for lead poisoning prevention activities have stagnated or decreased, funds to conduct additional environmental investigations would have to be redirected from other activities.

Other considerations:

One reason for lowering the environmental intervention level to 10 µg/dL is that children with EBLLs would be prevented from developing even higher BLLs. Using Minnesota surveillance data from 2006, there were 106 children with initial venous BLLs of 10-14.9 µg/dL, seven of which developed BLLs of 20 µg/dL or greater. Sargent et al. (1999) found that neither a venous nor capillary result in the 10-14.9 µg/dL range was predictive of a follow-up venous test in the 20 µg/dL or greater range. These data suggest that children with levels of 10-14.9 µg/dL do not frequently develop blood lead levels of 20 µg/dL or greater. However, performing lead hazard reduction in homes of children with BLLs of 10-14.9 µg/dL would undoubtedly prevent some of them from developing more serious EBLLs, and may help prevent future occupants from developing EBLLs.

If the mandatory environmental investigation level were changed to 10 µg/dL, the legislature would have to change the statutory reporting level for laboratories in addition to the secondary prevention section of statute. Laboratories are currently required to report results of 15 µg/dL or greater within two days. Even though most laboratories fax blood lead results of 10 µg/dL or

higher as soon as possible, not all follow this procedure. In addition to changing the statute, there would need to be a significant educational effort to ensure laboratories comply with the new law.

When considering a lower intervention level, another area of concern is the margin of error for laboratory analysis of blood lead specimens. Through national proficiency testing and certification programs, laboratories are required to maintain a margin of error of $\pm$ 4 µg/dL, although most laboratories are able to achieve a margin of error of $\pm$ 2 µg/dL. For example, a measured blood lead level of 12 µg/dL for a child may actually be a level of 8 µg/dL, or vice versa. If the intervention level is lowered, the margin of error in chemical measurement will become larger as a percentage of the measured level. There also are concerns over uncertainty as regulatory thresholds approach analytical detection limits, which can be as high as 5 µg/dL.

The secondary prevention statute already gives authority to assessing agencies to write lead hazard correction orders at BLLs of 10-14 µg/dL when the local agency finds reason to do so. The 2004 MDH Report to the Legislature reviewed this same issue (available at www.health.state.mn.us/divs/eh/lead/reports/legislative/2004legreport.pdf) and stated "It is not feasible to drop the level lower because of funding restraints at both state and local levels. There was consensus that lowering the mandatory environmental intervention level to 10 µg/dL would be most consistent with current public health research. However, the associated costs of that change cannot be supported by current budgets and would seriously disrupt current efforts toward primary prevention." MDH believes that if state funding for childhood lead poisoning activities were to be increased, primary prevention efforts would be the most effective way to achieve Minnesota's plan to eliminate childhood lead poisoning by 2010.

In addition to public health threats from lead, there are a variety of environmental health and safety concerns in the indoor home environment. These concerns have been shown to include mold, allergens, asthma triggers, carbon monoxide, home safety, pesticides, and radon (US HUD, 1999). As national, state, and local programs strive to provide healthy home environments, conflicting priorities compete for limited resources. Rather than focusing solely on lead issues, a more sustainable positive public health impact could be gained by working towards a comprehensive statewide healthy housing plan. Such a plan could work collaboratively with federal, state, and local programs that touch housing, health, and building sciences so that resources will be better focused to provide the greatest impact. The costs of implementing multiple housing-based interventions are far lower than if they are implemented one at a time. Success in pursuing an integrated "healthy homes" approach in Minnesota will require insights and assistance from a broad range of experts and practitioners in a variety of fields and disciplines, including housing, building science, medicine, epidemiology, toxicology, environmental science, asthma, lead poisoning prevention, pulmonary medicine, and many others.

Summary

Environmental investigation of lead exposure is a key step in protecting Minnesota residents from additional harm due to exposure to lead. Due to the prevalence of lead in the environment and the complexity of modern life, however, it does not automatically follow that lowering the intervention level will lead to additional protection. While environmental intervention is likely to

prevent exposure of other family members or future residents of the home, data do not support the contention that environmental intervention is an entirely effective way to lower a child's blood lead level once it is elevated. Lead hazard reduction as a primary prevention strategy can (and should) be targeted to high risk housing without relying on a blood lead test.

Current authority already allows an assessing agency to perform an enforceable environmental assessment as needed on any case above 10 µg/dL. However, the observation in the 2004 MDH Report to the Legislature indicating that costs associated with a mandated response to all cases above 10 µg/dL cannot be supported by current budgets and would seriously disrupt current efforts toward primary prevention remains valid. A lowered intervention level also would disrupt efforts seeking to implement a more comprehensive approach to housing-based health threats by targeting a single source (lead) at the expense of other issues (e.g. radon, mold, carbon monoxide, asthma, safety).

MDH recommendation: *While there are both benefits and costs involved, MDH's recommendation to the legislature is to not change the secondary prevention statute (Minnesota Statutes §144.9504) to lower the environmental investigation level to 10 µg/dL. More effective and sustainable positive public health impacts could be gained by working towards a comprehensive statewide healthy housing plan.*

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Comments Received and MDH Responses

A draft of the report, along with a solicitation for comments, was emailed to the full Minnesota Collaborative for Lead Education and Assessment Network (MCLEAN) attendee list on October 19, 2007. Responses were received through email from Sue Gunderson (ClearCorps USA), Jack Brondum (Hennepin County Community Health Department), The Minneapolis/Hennepin County Childhood Lead Poisoning Prevention Work Group, and the Minneapolis Department of Health and Family Services. A comment period was also provided during the October 24, 2007 meeting of MCLEAN.

Sue Gunderson (ClearCorps USA), email:
An email was received from Ms. Gunderson on October 22, 2007. The main concern expressed in that email was that the report makes it seem as though it is not worth it to do environmental investigations for EBLLs under 15 ug/dL due to the ineffectiveness of environmental and educational interventions for children with EBLLs in that range. Secondly, it was recommended that MDH study the original premise that a house-by-house approach does work.

MDH Response:
In the report we do not generally state that environmental interventions are not worth it. We believe the fact that interventions are generally not effective in bringing elevated blood lead levels (EBLLs) down supports the emphasis on housing-based primary prevention. The inability to quickly reduce BLLs suggests that we must prevent the exposure in the first place, by making homes lead-safe before children are exposed and preferably before children even live there. In addition, we do mention in the report that interventions for EBLL cases may prevent higher EBLLs and prevent future occupants or siblings from developing EBLLs. Our main point is to question whether this is the most cost-effective way to prevent EBLLs, or would a broader system, based on at-risk housing be more effective. While there is published literature on costs of lead poisoning (e.g. Landrigan et al. 2002, Grosse et al. 2002), a detailed cost-benefit analysis of these issues is beyond the scope of the report. In response to this comment, an emphasis on the effectiveness of environmental interventions as a primary prevention strategy rather than lowering of EBLLs was added to Recommendation #2.

Jack Brondum (Hennepin County Community Health Department):
Numerous comments were provided directly on the draft manuscript.

MDH Response: Due to the large number of comments, and the fact that most of them were editing changes, the comments will not be addressed individually. Many of the comments were incorporated into the final document during editing.

The Minneapolis/Hennepin County Childhood Lead Poisoning Prevention Work Group:

The following text, in italics, was submitted to MDH by the Minneapolis/Hennepin County childhood Lead Poisoning Prevention Work Group:

November 14, 2007

To: Erik Zabel
Dan Symonik

From: The Minneapolis/Hennepin County Childhood Lead Poisoning Prevention Work Group

Re: Comments of the Draft Legislative Report – Blood Lead Testing Methods

In response to the MDH draft legislative report on lead testing, the Minneapolis/Hennepin County Lead Work Group has the following comments.

1. The Work Group supports requiring a venous test to trigger a state-mandated environmental intervention, however capillary testing if done properly is a valuable screening method.

2. The Work Group requests that language in the MDH report reflect that:
a. Capillary testing is an effective and accessible screening test that is a key component of reaching all at-risk children with lead testing.
b. That clinics choosing to use capillary testing focus on doing the tests following proper techniques (hand washing prior to testing, etc.), and have a plan for providing accessible venous testing services either on-site or through a referral process.
c. That elevated capillary tests should be followed-up with education about lead and its sources, and about the need for venous follow-up testing.

3. The Work Group supports that idea that lowering the state-mandated environmental intervention level to 10 mcg/dL is consistent with CDC standards and is consistent with the MDH 2010 report. However, local public health authorities are unable to support lowering the level without identification of funding sources to pay for this change.

4. The Work Group requests that language in the MDH report reflect that:
a. Lowering the mandated environmental intervention level to 10 mcg/dL is a key component of the state's overall goal being lead-safe state by 2010.
b. Environmental intervention is the number one most effective and necessary strategy for both primary prevention of lead poisoning and for intervention once a child is poisoned.
The report should describe more fully the benefits of lowering the intervention level.

5. The Department of Health should recommend that the legislature fund the state and local government costs incurred to lower the intervention level.

MDH Response:

1. The utility of capillary tests as a screening method is already described in the report. The entire first section in Recommendation #1 describes this.
2. a. See #1 above.
   b. This is already recommended, however MDH has no way of measuring or assuring compliance with proper techniques. Also, MDH has no way of assuring venous testing capacity. MDH believes that venous testing capacity is generally sufficient overall in Minnesota. However, for a variety of reasons, the effort to bring children back in for re-testing is not performed as often as needed.
   c. Venous retesting is already recommended by MDH and CDC. Education strategies for families of children with elevated capillary tests will be assessed during the re-evaluation of the MDH case management guidelines in 2008.
3. This concept is already in the report.
4. a. Unfortunately, reducing the intervention level would not prevent children from developing EBLLs. Only programs that prevent children from ever being exposed to lead will achieve Minnesota's 2010 goals. While lowering the blood lead level for mandated environmental investigations is not a documented part of the Minnesota plan to eliminate childhood lead poisoning by 2010, it would likely help increase the number of lead-safe homes. However, it is unknown whether this is a cost-effective strategy in comparison with broad-based primary prevention programs.
   b. We agree that environmental intervention is a necessary and effective strategy for primary prevention of lead poisoning. In the case of a child with an elevated blood lead level environmental intervention is also likely to prevent exposure of other family members or future residents of the home, and should prevent a child's blood lead level from going higher. These concepts are already described in the report under Recommendation #2. However, data do not support the contention that environmental intervention is an entirely effective way to lower a child's blood lead level once it is elevated. This finding gives even more importance to preventing elevated blood lead levels in the first place, through primary prevention of exposure. In response to this comment, further emphasis on primary prevention was added to Recommendation #2.
5. While increased local government funding for investigation of elevated blood lead cases is necessary to implement a lower intervention level, MDH is not in a position to make that type of recommendation to the legislature as part of this report.

<u>Minneapolis Department of Health and Family Services</u>:

The following text, in italics, was submitted to MDH by the Minnapolis Department of Health and Family Services. MDH reponses to the comments follow the text.

> *MDH Blood Lead Testing Method Report to Legislature*
> *Comments on DRAFT from MDHFS*
>
> *1. The report seems to include contradictory information for people less familiar with the lead issue. As one example, environmental housing interventions are recommended as the best form of primary prevention but are cited as an ineffective strategy once a child is poisoned. And this despite the fact that the state-mandated*

intervention for an EBL is an environmental housing intervention. As a result, we are concerned that legislators may be confused and may not understand best practice approaches in prevention childhood lead poisoning.

2. The CDC defines lead poisoning as a level of 10 or greater and there are national goals to eliminate lead poisoning by 2010. This statement is in the opening paragraph of the report: the state's goal is "to create a lead-safe MN where all children have blood lead levels below 10 mcg/dL by the year 2010", but it is never addressed in the report.

3. Include what the public health value is of addressing lead poisoning, and express it both in terms of the impact on people and the financial cost to society. Separate the cost of interventions from the science of their effectiveness. What would we recommend based on the science? And then what would it cost to do it? As an example, perhaps spending the estimated $700,000 to reduce the level to 10 is worth it (even if we don't have an identified funding source).

4. The goal of environmental intervention is stated as "reduction" of lead levels throughout the report. It is more accurate to say environmental intervention prevents further increases in lead levels, and prevents poisoning in other children in the household.

5. Capillary Testing

a. Capillary testing is an effective and accessible screening tool in various settings. 97.5% of children do not have lead poisoning (assuming a prevalence of 2.5% in the population). Capillary testing properly identifies 90% of the children who are not poisoned without the need for phlebotomy. This leaves only 10% of children, identified through elevated cap tests, requiring more invasive phlebotomy. Capillary testing should more clearly be supported as a widespread screening tool.

b. Capillary tests are very accurate, but conducting them properly can be difficult. This needs to be stated clearly each time it is mentioned.

c. The capillary test section is based on "contamination," which is another way of saying "there's lead on the child's fingertip." Identifying the source of that lead could be an effective means of primary prevention for children with lead on their fingertips but not in their blood. Appropriate interventions with this in mind should be included in the report.

d. The 69% false positive rate for capillary testing is cited using MN surveillance data as a reason to discredit the test. However the gold standard test, the venous test, has a 45% false positive rate looking at the data in the same way. Because we know venous testing is essentially accurate, it's misleading to use these statistics to describe the accuracy or usefulness of either of the tests. Using these data also has the effect of having the reader think there is little reason to do either test, when we know each test serves an important purpose in reaching the elimination goal.

6. The report states that dedicating resources to intervening with two capillary tests and/or lowering the mandatory intervention level to 10 detracts from primary prevention efforts. This statement is not substantiated and perhaps should be removed. What are the specific primary prevention efforts MDH wants to see more of that are jeopardized? The report says generally "systematic evaluation of housing conditions and lead hazard reduction before any child has an EBLL" but doesn't say specifically what these are, who's doing them, who funds them, and how these proposed changes detract from them.

7. The report mentions funding stabilizing or decreasing being a reason to not support the two issues. But, the problem of lead poisoning is getting smaller each year. Including information in the report on the amount of resources each year compared to the number of cases of 10 or greater in the state each year would be a way to see how funding compares to the size of the problem.

In addition to the above text, comments were also received directly on the draft document; however, these changes generally were also addressed in the comments in the above referenced memo.

MDH Response:

1. See response to Sue Gunderson above.
2. While the 2010 goal is mentioned in the introduction, it is not a focus of the report as mandated by the legislature. In addition, achieving the goal of no blood lead levels of 10 µg/dL or greater is different from performing environmental interventions at 10 µg/dL or greater. For further explanation please see the response above for the Minneapolis/Hennepin County Childhood Lead Poisoning Prevention Work Group comment #4.
3. We agree that in absolute terms it is unknown whether a systematic way to identify and clean up at-risk housing would be more effective than using children's EBLLs to identify at-risk housing. However, there are many unknowns that stand in the way of doing a cost-benefit analysis in a scientific manner; and that is beyond the scope of the document.
4. These concepts are already in the report. However, most lead professionals would agree that even if preventing higher levels is the main goal of environmental interventions, lowering elevated blood lead levels is desirable.
5. Capillary testing:
    a. These concepts are already in the report; and capillary tests are already mentioned several times as effective for screening, not for initiating intervention.
    b. We must emphasize the distinction between specimens and analysis. Blood lead laboratory analysis is very accurate whether performed on either capillary or venous specimens. However, capillary specimens are highly prone to contamination during collection, especially when not conducted with proper technique. This concept is already described in the report; doing it each time would add unnecessary text.
    c. It is true that a child with an elevated capillary test may be getting lead on his or her finger. The lead contamination could also come from analytical error, or contamination of specimen collection devices or collection environment. Even if the child is getting lead on his or her hands from his or her environment, the lead source could be anywhere, deteriorated paint, soil at a friend's house, an unknown toy or

household object, something they touched on the way to the clinic, etc. With that in mind, proposing interventions is impossible, other than general education about lead and sanitation. Fully investigating these cases of fingertip contamination would likely be more extensive and costly than home investigations for confirmed cases. In addition, children with non-elevated capillary levels might have the same problem, but happen to have providers who are doing a better job of washing the child's hands. A program to address lead in the environment of all children would be better than using children's hand contamination as the detection method.

d. We agree that comparing venous follow-up testing for venous initial tests with follow-up for capillary tests may be misleading. However, this was put into context in the report. The venous follow-ups for venous tests are generally performed much later than the capillary follow-up tests because they are being conducted as medical monitoring. In contrast, the venous follow-ups to capillary tests are done relatively quickly as confirmatory tests. This shorter time should lead to a lower percentage of false positives since there hasn't been much time for the level to decline. However we see that the false positive rate for cap tests is much higher than for venous initial tests. In combination with the data on simultaneous venous and capillary testing, this gives further evidence that capillaries are prone to false positive results in comparison with venous tests. In response to this comment, text was added to the capillary testing section of the report to better explain this concept.

6. We agree that statewide "systematic efforts" at identifying at-risk housing are not occurring now. However, MDH recommends them as a comprehensive way to reach at-risk housing rather than relying on blood lead testing and intervention only for elevated cases. Emphasis was added to the end of Recommendation #2 that if funding is expanded, primary prevention is the preferred place to spend it, rather than testing or lowering the environmental investigation level. If funding is not increased, the money for additional environmental investigations would have to come from somewhere. Even if funding is increased specifically for investigations, the money would likely be taken from other public health activities.
7. Cost-benefit analyses may help inform the decision to lower the intervention level to 10 µg/dL; however inflation projections and many other complex societal factors would confound the analysis and are needed for accurate analysis. MDH does not have access to all the details of lead funding available at the local level. In addition, a cost-benefit analysis is beyond the scope of this report.

MCLEAN verbal comments:

Comments and their respective MDH responses are listed for each MCLEAN attendee who provided comments.

Joe Jurisik, Hennepin County Community Health Department: The main points weren't described until the end. Joe suggested a summary of recommendations or abstract in the beginning. This could consist of two short paragraphs.

> **MDH Response:** In response to this comment, the Executive Summary has been significantly shorted and rearranged to provide the main points in a single page.

Mary Ellen Smith, St. Paul – Ramsey County Department of Public Health: There should be a focus on hand washing. Lead professionals overlook the learning curve of technicians and also need to be concerned about milking the finger. You can control protocol when you have the same person testing over and over, but not if there are a large number of clinics.

> **MDH Response:** These concepts are already in the report and hand washing and proper collection technique are emphasized. In response to this comment, a sentence was added to Recommendation #1 that providers should follow proper collection technique.

Megan Ellingson, Minneapolis Department of Health and Family Services: Keep in mind the 2010 goal. Guide people to these goals and the thought process for the 2010 plan when writing the report. It is helpful to keep the broader goal in mind. If we do this it will help us reach the 2010 elimination plan.

Megan wondered about the number of cases coming down in recent years (i.e., there are a lot less >10 cases than in 2000). See the data related to number of cases in relationship to the dollars.

Contamination means lead on a child's fingertip, this is an indication that there is lead in the child's environment. Ninety percent of children don't have lead on fingers.

> **MDH Response:** These issues are addressed above for the written comments received from Minneapolis Department of Health and Family Services.

Lisa Smested: When looking at data did you notice any clinics that you believe capillary only is working or should these clinics be using venous? Are there differences between clinics, i.e. a lot of false positives?

> **MDH Response:** These issues are important and will be addressed in future versions of the annual MDH surveillance report and will be included as part of annual grant applications to CDC.

Jack Horner: The number of children screened is increasing; therefore in fact more work is being done with the same amount of money.

> **MDH Response:** Funding for blood lead testing is generally separate from funding for environmental investigations; however it is true that more effort is being spent to test children while the number of cases has been dropping.

Becky Bernauer: The cost of handling cases has gone up and funding has gone down.

> **MDH Response:** A statement has been added to Recommendation #2 regarding this comment.