THE SILENT EPIDEMIC OF LEAD POISONING:

The Case for Point-of-Care Blood-Lead Testing

On March 23, 2006, the Centers for Disease Control and Prevention (CDC) issued a special edition of its Morbidity and Mortality Weekly Report (MMWR). It outlined the case of a four-year-old Minnesota boy, who died from acute lead poisoning after swallowing a heart-shaped charm. It had been part of a metal bracelet provided as a free gift with the purchase of Reebok shoes. Laboratory testing showed that the trinket was 99 percent lead. Since then, there have been countless news reports of lead found in everyday objects: from children’s toys, bibs, backpacks and jewelry to lunch boxes, candy wrappers, even artificial turf – a loud wake-up call to focus attention on the “silent epidemic” of lead poisoning.

The true cost of lead poisoning
Lead poisoning can affect nearly every system in the body. Called the silent epidemic because it often occurs without obvious symptoms, it frequently goes undiagnosed. Children under six are most at risk because they are more apt to be exposed to lead through hand-to-mouth activity than older children. They are also biologically more sensitive to lead. These years are a critical time in brain and organ development. The body readily takes up lead – mistaking it for calcium – which rapidly growing bodies need in abundance. This can cause lifelong disability.

While the CDC recommends public health actions be initiated when a child's blood-lead level is greater than 10 micrograms of lead per deciliter (μg/dL), there is increasing evidence that there is truly no safe level of lead for young children. The negative effects of even small amounts of lead exposure in those critical early years reverberate through an entire lifetime. Research shows a correlation between elevated

THE FACTS
There are typically no overt symptoms, but the consequences of lead exposure can be dire:

- IQ scores decline 2.5 to 3.0 points for every 1.0 μg/dL increase of lead in the blood
- 20-30% of the special education caseload in urban areas is due to lead poisoning
- 10% of juvenile delinquency is attributable to lead poisoning
- Kids with elevated blood-lead levels are 6x more likely to have a reading disability and 7x more likely to drop out of high school

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blood-lead levels and lowered IQ, behavior, and learning problems. And the decline in IQ attributable to lead takes the greatest toll on IQ early on; a one-point increase in lead levels below 10 μg/dL (for example, from five to six μg/dL) has a more negative effect than a one-point increase does at higher lead levels (e.g. from 28 to 29 μg/dL).3

Childhood lead exposure is also responsible for increased drug abuse and crime, and health problems in adulthood – from dental decay and osteoporosis – to cardiovascular disease and stroke. Recent studies even suggest that some of the mental decline associated with aging, losses in verbal and visual memory and language ability, may relate to lead exposure earlier in life.4 At very high levels, lead poisoning causes seizures, coma, and even death.

The human cost of lead poisoning is devastating to lead-poisoned children and their families. But the societal cost is also staggering to us all. Consider this: the CDC estimates that there are 6.8 million children with asthma versus 310,000 cases of children with elevated blood-lead levels. However, the total economic costs for asthma pale in comparison – $2 billion compared to $43 billion for lead.5

Still the #1 environmental threat to children
In 1971, President Richard Nixon signed the Lead-Based Paint Poisoning Prevention Act. Oil companies started phasing out the use of lead in gasoline in 1975. And subsequent legislation created the Consumer Product Safety Commission, which effectively banned leaded paint in 1978. Consequently, many in the public, and even some healthcare providers, mistakenly believe that lead poisoning is no longer a problem. While we have made significant progress, the scourge of lead poisoning persists: it remains the number one environmental threat to children.

But lead poisoning is entirely preventable! The key is early detection through effective screening and aggressive enforcement programs to eliminate lead contamination in housing, consumer products, and the environment. According to the U.S. Department of Housing and Urban Development (HUD), approximately 24 million housing units in the U.S. have lead paint hazards and elevated levels of lead-contaminated dust and soil. More than four million of these dwellings are homes to one or more young children. Older housing stock is not the only source of lead. One report determined that 34 percent of children under the age of six with lead poisoning in Los Angeles County had been exposed to items containing lead that had been brought into the home, including candy, folk and traditional medicines,

THE FACTS
The consequences of lead exposure reverberate through an entire lifetime:

› Children with even slightly elevated blood-lead levels do worse on math, reading, nonverbal reasoning, and short-term memory tests

› Studies show that infants and toddlers exposed to relatively low levels of lead in utero score lower on tests measuring neurobehavioral development

› Hypertension from childhood lead exposure contributes to adult cardiovascular disease

› Even though asthma affects many more children, the total economic costs pale in comparison – nationally, it is estimated at $2 billion for asthma versus $43 billion for lead
ceramic dinnerware, and metallic toys and trinkets. Children can also be exposed to lead from their parents’ clothes. A National Institute for Occupational Safety and Health (NIOSH) study found that children of lead-exposed construction workers were six times more likely to have blood-lead levels over the recommended limit than children whose parents did not work in lead-related industries. In addition to construction workers and people who work with lead directly, police, military, and firing-range personnel can also be exposed to high lead levels, putting their young children at risk.

Today approximately 310,000 U.S. children aged one to five years have blood-lead levels greater than 10 μg/dL. The General Accounting Office estimates that as many as 427,000 more young children have elevated blood-lead levels that go undetected. Most are poor, urban, and from minority and immigrant families – the hardest-to-reach populations. Eighty percent of children identified with

Point-of-care success story
Michigan County Health Department Teams Up With WIC to Screen At-Risk Children for Lead Poisoning

In 2004, as part of an ambitious program comprising legislation and a statewide lead-awareness campaign designed to eliminate lead poisoning in Michigan’s children, the lead-poisoning prevention program of one county health department took bold action. It moved all lead testing from its central laboratory, and placed LeadCare® analyzers in its eight WIC clinics. The reason: more than 40 percent of all babies born in the county receive WIC benefits, and each month, the WIC clinic serves more than 18,000 moms, babies, and kids under the age of five. Simply put, a WIC clinic is the ideal place to reach the at-risk population. The clear winners of this initiative are the families; the results of the WIC program prove that this approach works.

According to program leaders, they had expected the positive feedback that they received from parents and staff because LeadCare allows them to use finger-stick samples and gives parents real-time results. What they didn’t anticipate, however, was just how effective it would be as an educational tool. Now, they use the visit, including the three minutes it takes to run the test, to talk to parents about the dangers of lead exposure and what the family can do to minimize the risk. Previously, when the clinic sent samples out to the central lab, they provided the same educational information to parents, but it didn’t have the same power. When parents learn about lead poisoning at the same time their child’s blood-lead results pop up on the LeadCare II screen, they understand the importance, take action, and are more vigilant about following recommendations. Since the county implemented point-of-care testing, the number of children with elevated blood-lead levels that are no-shows for follow-up appointments has dropped by 75 percent!

Statistics indicate that 50 percent of Medicaid families will move four times before a child’s second birthday, so the only way to ensure that children aren’t continually re-exposed in this critical time period is to make sure that parents have the education they need to protect their children – wherever they go. Testing, intervention when necessary, and education: this county’s experience proves that all three are truly crucial when it comes to preventing lead poisoning in children.

The benefits of point-of-care testing really hit home the summer of 2005. The county screening program identified two siblings with very high blood-lead levels. They were taken straight to the hospital, where follow-up testing confirmed that one of the children had a blood-lead level of 74 μg/dL! In this case, on-site testing reduced the time from diagnosis to initiation of life-saving chelation therapy from potentially weeks to hours.
Elevated blood-lead levels are served by federal health programs, such as Medicaid and WIC, and the prevalence of elevated blood-lead levels for children served by these programs was nearly five-times higher than that of non-enrolled children!

The Centers for Medicare and Medicaid Services (CMS) has required universal screening of Medicaid-covered one- and two-year olds since the Medicaid Early and Periodic Screening, Diagnostic, and Treatment Services benefit (EPSDT) was defined as part of the Omnibus Budget Reconciliation Act of 1989. The same act requires that children ages 36 to 72 months receive a blood-lead test if they have not been previously tested. However, the GAO estimates that nationally, only about 20 percent of Medicaid children are receiving the mandated tests.

The CDC is also expected to recommend screening pregnant women for elevated blood-lead levels. New York State already has this requirement. Lead is transferred freely through the placenta as early as the 12th week of gestation, and studies show that infants and toddlers exposed to relatively low levels of lead in utero score lower on tests measuring neurobehavioral development.

Some states, including New York and New Jersey, require universal testing of all one- and two-year olds; Massachusetts also requires testing at age three. Legislation is pending elsewhere to expand mandated testing to more children. While funding availability varies from state to state, tests are typically reimbursable through Medicaid and through other public funding sources and private insurance. Many states also have initiatives to help fund lead-abatement in low-income housing.

HEDIS measures now include mandatory lead testing

With regular headlines about lead-contaminated toys and products, and new studies highlighting the dangers of lead, there is increasing scrutiny to ensure that states are testing all children as required by the Centers for Medicare and Medicaid Services. For example, the National Committee for Quality Assurance (NCQA) added lead testing to the Healthcare Effectiveness Data and Information Set (HEDIS) measures for EPSDT in 2008 on a first-year trial basis. While the 2008 results were not publicly released, knowledgeable sources indicate that about 100 self-selected plans from around the country provided data to NCQA for analysis; screening rates varied widely, from a low of about 17 percent to a high of more than 80 percent, with the average screening rate at about 50 percent. Based on the alarmingly low compliance, the NCQA committee voted overwhelmingly to adopt lead testing as a permanent measure, reportable for 2009. The HEDIS measure:

- Children must have at least one capillary or venous blood test on or before the child’s second birthday, as documented through either administrative data or medical record review.
- The medical record must indicate the date the test was performed and the actual finding (blood-lead level). It is not acceptable for physicians merely to write a prescription for lead testing, the child must actually receive the test.

In a separate action, the Office of the Inspector General at the U.S. Office of Health and Human Services has planned a 2009 review of the extent to which Medicaid-eligible children are receiving all mandated services, including lead testing, under the Medicaid EPSDT benefit.
Traditional prescription-based & send-out methods of testing miss those children most at risk

The traditional way of doing lead testing is for physicians to write a prescription for blood-lead testing and send children to an outside contracted lab. Parents want the best for their children, and usually have every intention of taking them for testing, but sometimes, life can get in the way. Socioeconomic and logistical barriers too often make it difficult, if not impossible, for families to follow through on written prescriptions for laboratory testing. Parents may be burdened with healthcare problems of their own, with transportation issues, or may have difficulty getting additional time off from work. For the general population there’s typically a 20 percent no-show rate for outside laboratory testing prescriptions, but that rate can be more than double in segments of the Medicaid population.

It can be costly and time-consuming for medical practices to determine which patients have or have not followed through on testing and to track down children who need follow-up. Sometimes, the latter can be impossible. Fifty percent of Medicaid children will move an average of four times by age two, and often there’s no forwarding address. Phone numbers change or are disconnected.

Losing track of a lead-poisoned child compounds the curse of lead poisoning too. Parents can’t protect their children when they don’t know there’s a problem. It also undermines federal, state, and local enforcement programs, which use elevated results tied to a specific address to target lead remediation and enforcement actions. Unfortunately, many children get poisoned at the same address. Experts agree that the best way to ensure that children receive mandated testing is to bring the test to the child, not the child to the test. That’s why the CDC funded the development of a portable device designed so children can be tested where they already receive healthcare or services.

Blood-lead testing has never been easier – waived test is convenient for patients & practitioners

In 1997, ESA, now a Magellan Biosciences business, introduced the first-generation LeadCare system – a moderately complex test. Although its CLIA status limited how many providers could adopt the test, where it was implemented, the LeadCare I system proved that point-of-care testing works to reach at-risk children who are missed by traditional prescription-based or send-out testing programs.

Wanting to expand the test to more community-based sites that serve at-risk

THE FACTS

Today, lead poisoning primarily affects poor, urban, minority children – the hardest-to-reach populations. National average prevalence of elevated blood-lead levels:8

- 1- and 2-year old non-Hispanic black children: 22%
- 1- to 5-year old children who are poor: 16%
- Children who live in large central cities: 21%
- Children who are poor, black, and live in urban areas: 36%

“The portable lead-testing system allows healthcare providers, as well as those of us who use that data, to react more quickly and comprehensively. With rapid, low-cost testing and more screening, we can find these homes, fix the hazards, and make sure no more children are poisoned by these properties.”

– Jon Gant, director of the U.S. Housing and Urban Development’s (HUD) Office of Healthy Homes and Lead Hazard Control, at the September 18, 2006, FDA press conference announcing clearance of the LeadCare II system
populations – from mobile health clinics and Head Start programs, to WIC clinics and Federally Qualified Health Centers – the CDC partnered with ESA to develop a CLIA-waived version. In September 2006, the FDA cleared LeadCare II.

The award-winning LeadCare II system removes all the complications formerly associated with blood-lead testing – waiting days for lab results, spending precious staff time and resources trying to contact patients for critical follow-up care, or tracking down lab results for record-keeping, reporting, or compliance purposes. Its CLIA-waived status enables a paradigm shift in lead testing: practitioners can test, educate, and initiate follow-up actions if necessary – instantly, on the spot, and all in one visit during the routine well-child check-up. This approach is convenient and easy for the child, parent, and healthcare provider, and thus, it is the most-effective way to ensure that those at greatest risk for lead poisoning actually receive mandated lead tests.

Far simpler to administer than traditional blood-lead tests, the LeadCare II device requires only a finger-stick sample, can be combined with other routine waived blood tests, and saves considerable administrative time spent on paperwork, tracking, and follow-up. Practitioners have even been able to do three different tests from a single lancet puncture – blood lead, hemoglobin, and ZPPH, a test for iron deficiency anemia.

**Early detection + early intervention = healthy bodies + sharp minds**

Where it has been implemented, providers serving at-risk children have found that using the point-of-care system provides a significant public health benefit in both the short- and long-term. When children are identified with significantly elevated lead levels, they are taken directly to the hospital for confirmation and follow-up, allowing life-saving treatment to start in a matter of hours, rather than days or weeks – a danger of prescription-based or send-out testing methods.

Significantly, educating parents on the hazards of lead at the same time they see their child’s lead levels come up on the LeadCare II screen dramatically improves overall compliance with follow-up visits and helps prevent future lead exposure. Parents understand the implications and take action to follow physician recommendations and ensure that their child’s surroundings remain lead-free. (See point-of-care success story on page three.) The immediate results from LeadCare II also bolster lead enforcement programs.

**How are children exposed to lead?**

From chipped or peeling paint & dust, water pipes, & soil in or around older housing, lead has also been found in mini blinds, home remedies, imported candy, makeup, ceramic-ware, toys & trinkets, backpacks, bibs, & lunch boxes – even artificial turf.

**www.LeadPoisonInfo.com**

for links to important recall information, articles, and lead-poisoning resources

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**Overcoming barriers to serving at-risk children**

The private pediatrician market has been quick to adopt the LeadCare II system. The rapid test is easier on the child, more convenient for parents, and cost-effective for physicians – the cost-per result can be half that of a send-out test, even before savings in staff time and resources made possible by the point-of-care test. Unfortunately, despite the promise of reaching more at-risk children, a variety of financial and bureaucratic obstacles prevent widespread implementation of the LeadCare II test in the public health arena across the nation. In the meantime, perhaps hundreds of thousands of children with elevated blood-lead levels are missed by current prescription-based and send-out testing practices.
The LeadCare II system is an innovative technological solution — developed at the behest of the CDC with taxpayer dollars — to improve screening rates, prevention education, and health outcomes by bringing the test directly to children, where they are already receiving health care or other services. But it is not enough to fund and develop the tool. The policies that prevent its easy adoption in public health need to be addressed as well. Recommendations can be found on the back page of this publication.

No more compromises!
Lead testing used to be a compromise, with tough choices for physicians and public-health professionals:

- Do I collect blood samples and send them out for analysis — or send patients directly to a lab, knowing that patient compliance will be very low?
- Do I collect a capillary sample (easier on patient, but requires another visit for a venous sample to confirm if high) — or do I go ahead and do venous samples for all?
- Do I get the laboratory accreditation necessary to do lead testing on-site — or do I send samples out, adding days or even weeks to the test cycle?

Now, the choice is easy: with the CLIA-waived LeadCare II system, there’s no need to compromise. LeadCare II is convenient for your patients and for your busy office too!

- In-office testing — 3-minute results
- Capillary (2 drops) sample — combine with other routine finger-stick tests using a single puncture
- Reimbursable: CPT code 83655 — why send revenues out the door?

For more information on LeadCare II, visit www.WaivedLeadCareDr.com
TAKE ACTION!

We can meet the Healthy People goal to eliminate childhood lead poisoning. But we all need to be advocates with city, state, and federal officials to help ensure that every at-risk child has access to rapid lead testing:

- State Medicaid plans must ensure that healthcare practitioners receive adequate reimbursement for blood-lead screening and follow-up services.
- Managed care contracts and state policies should be amended to require plans to offer point-of-care blood-lead testing to at-risk children outside of capitation fee schedules, if necessary.
- Federally Qualified Health Centers and others that serve low-income children need funding to ensure that all children can receive point-of-care blood-lead testing.
- Restrictive state regulations governing laboratories, blood-lead testing, and reporting need to be updated to support in-office and community-based testing made possible by the FDA clearance of the CLIA-waived blood-lead-testing device.

CLIA-waived LeadCare II changes everything:

- 3 minutes
- 2 drops of blood
- 1 visit
- 0 loose ends

for more information, visit www.WaivedLeadCareDr.com, or call +1 800.305.0197

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70-7052 Rev B

2 CDC FAQ. Why not change the blood lead level of concern at this time? http://www.cdc.gov/nceh/lead/faq/changeBLL.htm
6 CDC FAQ. http://www.cdc.gov/nceh/lead/faq/about.htm