Most important, waived blood-lead testing not only solves the problem of poor screening rates—the consolidation of testing, results, and education into one visit means more children can be reached, screened, and treated as necessary—it provides healthcare professionals and parents with the information they need to focus their attention on the children truly at risk. Studies show that this approach is the most effective way to stem the adverse effects of lead exposure and prevent permanent damage. A waived test educates and empowers the people who can make a difference.

References

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 shoes. Laboratory testing showed that the tin was 99 percent lead.

If there is any good news that can come out of one family’s tragedy, it is that this case has been a loud wake-up call to focus attention on the “silent epidemic” of lead poisoning. Reducing the levels of lead poisoning in children has been a major public health priority since the 1960s—and our progress to date has made it one of the greatest public health success stories in history. Efforts such as banning lead in paints and gasoline, incentives to eliminate lead in older housing stock, and mandatory screening programs have dramatically reduced the instances of childhood lead poisoning over the past 30 years.

Today, approximately 310,000 U.S. children aged 1-5 years have blood-lead levels greater than the CDC-limit of 10 micrograms of lead per deciliter (μg/dL), although the CDC states in its latest report that, in fact, there is no “safe” threshold for lead in blood. Recent studies suggest adverse health effects exist in children at blood-lead levels significantly lower than 10 μg/dL. Lead poisoning remains the number one environmental threat to children, particularly affecting low-income people of color living in poor, often urban, neighborhoods. For example, in Detroit during the last 10 years, a disproportionately small number of housing units—only 657 addresses—accounted for nearly 1,500 children with blood-lead levels greater than 20 μg/dL. In Louisville, Kentucky, 35 percent of children identified with elevated blood-lead levels during the last five years resided in 79 housing units; these units represent less than 0.3 percent of all housing units in the community. These experiences are typical of high-risk communities across the country.

Silent, but potentially deadly
Lead poisoning can affect nearly every system in the body. Called the silent epidemic because it often occurs without obvious symptoms, it frequently goes unrecognized. But lead poisoning is devastating to children and families, and has serious economic consequences for the nation. Lead poisoning can cause learning disabilities, behavioral problems, and, at very high levels as in the Minnesota case—seizures, coma, and even death. A 2002 study estimated the total economic impact of lead poisoning in the U.S. at $43 billion per year.
confirmed that one of the children had a blood-lead level of 74 μg/dL! In this case, on-site testing reduced the time of diagnosis and treatment from potentially weeks to hours.

While lead-based paints were banned for use in housing in 1978, lead paint and lead-contaminated dust found in older buildings are still the primary sources of lead exposure among U.S. children. According to the CDC’s website, approximately 24 million housing units in the U.S. have deteriorating lead paint and elevated levels of lead-contaminated dust and soil. More than four million of these dwellings are homes to one or more young children. However, older housing stock is not the only source. 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, ceramic dinnerware, and metallic toys and trinkets.9 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.10 In addition to construction workers and others who work with lead, police, military, and firing-range personnel can also be exposed to high lead levels, putting their young children at risk. Children under the age of six are particularly vulnerable because lead affects their rapidly growing brains and bodies, and they are more likely than older children to ingest lead by putting their hands and objects into their mouths.

Early detection + early intervention = healthy bodies + sharp minds

Lead poisoning is preventable – and treatable condition. The key is early detection through screening and immediate intervention when testing identifies elevated blood-lead levels. Studies show that in most cases, early detection and treatment of lead exposure can eliminate the potential for permanent damage. The United States has taken a targeted approach to lead screening, focusing on populations living in older homes and those eligible for Medicaid. Massachusetts, New York, and New Jersey require that all one- and two-year-olds be tested. (Massachusetts also requires testing at age three.) Many other states have initiatives to help fund lead-abatement in low-income, private housing, and other programs to reduce childhood lead poisoning. Federal mandates require that 100 percent of Medicaid children be tested for lead poisoning at age one- and two-years of age, however fewer than 25 percent receive these lead tests — a failure rate of 75 percent.

While funding availability varies from state to state, tests are reimbursable through Medicaid and through other public funding sources and private insurance. However, regardless of how well-funded a state’s lead-prevention program is, a major problem is getting to the targeted population. As Ruth Ann Norton, the executive director of the Coalition to End Childhood Lead Poisoning, put it: “On one level, lead is one of the most simple issues around, but the complexity of reaching the audiences it impacts is immense.”

The CDC’s strategic plan to eliminate lead poisoning by 2010 establishes a goal to increase screening to 80 percent of the target population, nearly three-times the current level of testing. It is not an easy task. Reaching at-risk children even once to collect a blood sample is challenging enough. Reaching them a second time to follow up and initiate treatment can sometimes be impossible. Estimates are that 50 percent of children enrolled in Medicaid move every six months.

While there are approximately 900 laboratories nationwide certified to perform lead testing, the experts agree that the only way to achieve the target screening rates and improve health outcomes is with a rapid test that can be performed in the community, where and when children receive healthcare and other social services – in doctors’ offices, community health centers, schools, hospitals, clinics, workplaces, and outreach programs. The best, and perhaps only way to accomplish this is with a CLIA-waived, point-of-care test.

Waived test gives new hope for the future of blood-lead screening

In 1997, the original LeadCare®, the first FDA-cleared, portable, point-of-care blood-lead-testing system was released. Today, LeadCare is the most widely used blood-lead-testing system in the world. In fact, nearly half of the laboratories and clinics that perform these tests use the LeadCare system. Over the years, LeadCare has been a vital tool in the effort to reduce lead poisoning, helping to identify thousands of children with elevated blood-lead levels. However, since many pediatricians, public health clinics, and others serving at-risk children lack the certification for moderately complex tests required by federal law through the Clinical Laboratory Improvement Amendments (CLIA), the CDC funded development of a compact, portable CLIA-waived device – LeadCare II.

CLIA-waived LeadCare II removes all the complications associated with blood-lead testing. It can be operated with- or without special training by any healthcare professional. No more waiting days for expensive lab analysis, or spending hours in vain trying to locate families for important education and follow-up testing or care. LeadCare II delivers quantitative blood-lead results equivalent to those reported by reference laboratories from only two drops of blood in just three minutes. More cost-effective than sending samples out to a lab, LeadCare II saves both financial and human resources: the cost per test is lower, and on-the-spot results reduce tracking and administrative time.

A point-of-care success story

In 2004, as part of an ambitious program consisting legislation and a statewide leadawareness 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 (Women, Infants and Children) 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 expected the positive feedback 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 was just how effective it would be as an educational tool. They use the visit, including the three minutes that it takes to run the test, to talk to the parent about the dangers of lead exposure and what the family can do to minimize the risk. They provided the same educational information before, when they sent samples out to the central lab. But there’s nothing quite as powerful as seeing the results pop up right then and there. Parents understand the importance, take action, and are more vigilant about following recommendations. Since the county implemented the point-of-care testing, the number of children with elevated blood-lead levels that are no-shows for follow-up care have decreased by 50 percent.

Statistics indicate that 50 percent of Medicaid families will move four times before a child reaches the age of two, so the only way to ensure that children aren’t continually reexposed in this most-critical time period is to make sure 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 critical 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. The children were sent to the hospital immediately, 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 of diagnosis and treatment from potentially weeks to hours.

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 patients?

- 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 CLIA-waived LeadCare II, there’s no compromise required. Test, educate, and intervene if required – instantly, on the spot, and all in one visit.