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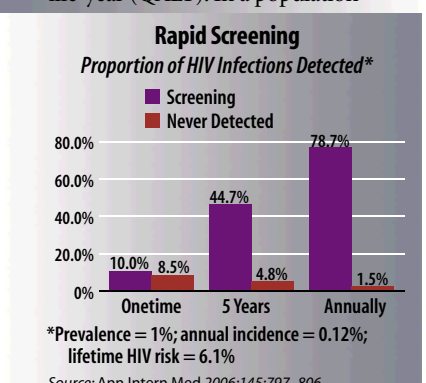
NEWS BRIEF

Routine HIV Screening Cost Effective But Challenging

In September 2006, when the CDC revised its HIV screening guidelines to include routine testing of all individuals age 13 to 64, the economic impact of such a program raised concerns. But a newly published study by researchers at Yale School of Medicine (*Ann Intern Med* 2006;145:797–806) indicates that routine, rapid HIV testing of all people in a population with an HIV prevalence as low as 0.2% is cost effective.

To estimate the cost benefits of routine HIV testing, the team used a computerized simulation model, and reviewed published randomized trials, observational cohorts, national cost and service utilization surveys, as well as previous modeling results. The new CDC recommendations urge health care providers to follow an opt-out screening protocol, unless the provider has documented evidence that the prevalence of undiagnosed HIV infection in their patients is less than 0.1%. But the authors of the *Annals* study concluded that where the prevalence of HIV is at least 0.2%, a one-time routine screening will cost less than $50,000 per quality-adjusted life-year (QALY). In a population with a prevalence of at least 0.45% and an annual incidence of 0.0075%, the study showed repeated screening every 5 years would also be valuable. Although there is no absolute standard in judging a medical intervention as cost effective, health care economists typically deem anything below $50,000 per QALY acceptable.



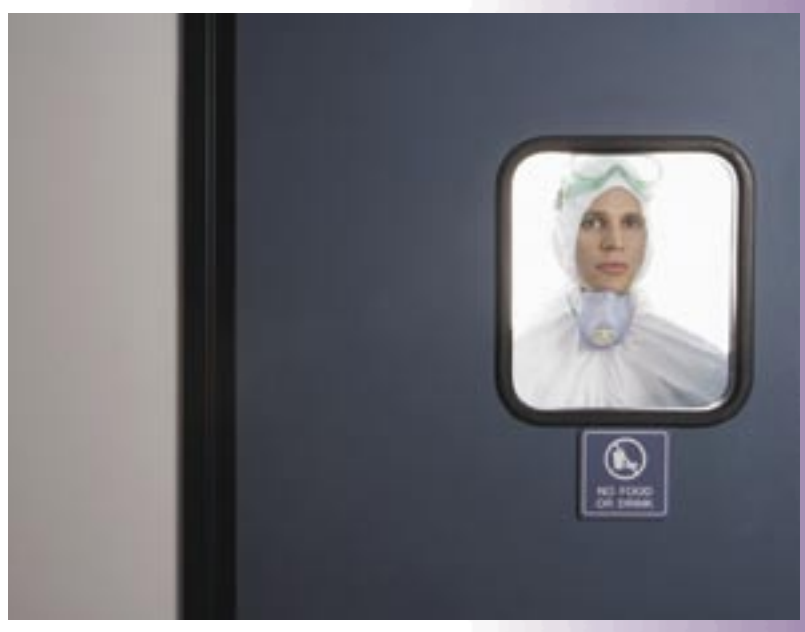
However, experts recently voiced their concerns about wider HIV screening, saying that that the associated costs of treating and counseling more individuals could overwhelm the health care system with new patients (See Graph). At a recent CDC-sponsored summit in Washington, D.C., Kevin Fenton, PhD, director of the CDC's National Center for HIV, Sexually Transmitted Diseases, and Tuberculosis Prevention, said that an additional 56,000 to 250,000 HIV-positive patients discovered by the routine testing would require over $900 million dollars in new funding for counseling and treatment.

Ready for Disaster?

Katrina's Lessons Can Strengthen Emergency, Disaster Planning for Labs

By Julie McDowell

Since Hurricane Katrina and the subsequent flooding killed over 1,500 people in August 2005, there has been intense pressure on the U.S. government to develop better strategies for delivering rapid medical care to the victims of all public health emergency situations—whether due to a natural disaster, a terrorist-related chemical agent attack, or a pandemic influenza outbreak. However, government officials have reiterated that emergency medical response is most effective when it is local and developed by a community-based network of health providers—including hospitals and clinical laboratories. Now, as those who experienced Katrina continue to analyze the breakdowns of medical care during and after the storm, federal officials are directing the clinical laboratory community to identify the vulnerabilities in their existing emergency and disaster management plans to ensure that labs can operate amidst the chaos of power outages, personnel shortages, and other disruptions that occur with public health emergencies.



Last May, the U.S. Homeland Security Council's Pandemic Influenza Implementation Plan stated that the "center of gravity of the pandemic response" is at the state and community level, and therefore hospitals and clinical laboratories should have a pandemic influenza plan in place to protect staff, transport suspect specimens to state public health laboratories, and handle routine testing. The Centers for Disease Control and Prevention (CDC) is also advising that the response to other

See **Disaster Planning**, *continued on page 3*

Lead Poisoning

Is Point-of-Care Testing the Answer?

By Kay Downer

Despite the elimination of many potential sources of exposure, lead poisoning remains a significant public health concern, particularly for children. The Centers for Disease Control and Prevention's (CDC) Lead Poisoning Prevention Program estimates that approximately 310,000 children ages 1–5 have blood lead levels above the 10 µg/dL recommended level. But in fact, more children may be adversely affected by lead exposure, since the CDC's 2005 statement on preventing lead poisoning in young children states that "no 'safe' threshold for blood lead levels in young children has been identified." Recent research also suggests that lead exposure can have significant health risks for adults, even at levels well below the 25 µg/dL threshold established as the Healthy People 2010 limit for adult occupational exposure.

To reduce the incidence of lead poisoning among adults and children, public health officials and other health care professionals must be able to identify individuals with elevated blood lead levels so that the source of exposure can be eliminated and medical treatment, if necessary, can begin promptly. However, with lead poisoning frequently occurring among children living in older housing in urban areas who may lack routine access to health care, clinicians serving these areas often encounter difficulties in testing patients and following up with their families if the test results show elevated lead levels. A new point-of-care (POC) test, the LeadCare II Analyzer, manufactured by ESA Biosciences, Inc. (Chelmsford, Mass.) could help to address this problem by allowing health care personnel to more easily provide testing in the communities where lead poisoning poses the greatest risks.

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FDA Approves First POC Lead Test

Lead Testing, *from page 1*

Designed to be portable and simple to operate, the LeadCare II analyzer was granted a CLIA waiver in September by the Food and Drug Administration (FDA), giving health care professionals the ability to perform testing in a variety of settings. By approving the device for widespread use, the FDA hopes to maximize the benefit of POC testing, a point several speakers emphasized during a press conference announcing the device's CLIA waiver. "We're using the science and technology to reach many, many more people for screening," said Andrew von Eschenbach, MD, Acting Commissioner of the FDA. "Broader access, broader availability with an easier access to implementation provides us the opportunity to have much more of a significant public health impact."

Effects of Lead Poisoning

Although lead poisoning can occur without easily recognizable symptoms, it nonetheless profoundly affects individuals and communities. In terms of childhood development, lead exposure results in learning disabilities and behavioral problems, with lead poisoning accounting for 20%–30% of the special education caseload in some urban areas according to a 2000 article in *US News and World Report*. Even lead exposure below the 10 µg/dL "level of concern" threshold established by the CDC can impact children's education, resulting in poorer performance on tests of math, reading, and other academic skills. Symptoms of lead poisoning can also include headaches, stomach cramps, fatigue, memory loss, and high blood pressure; severe exposure can even cause seizures, coma, and death.

"The big issue with lead is that it's a silent killer," said Judi Momber, Public Health Nurse Supervisor of Community Clinical Services in Kent County, Mich. "It doesn't necessarily kill the child, but it kills brain cells. So it kills what the child can become." Momber's agency serves the city of Grand Rapids and the surrounding communities in Western Michigan. Kent County has approximately 53,000 children under age six and identifies about 250 cases of lead poisoning each year.

Limitations of Current Lead Testing Programs

Today, lead poisoning poses the greatest risk to children whose families lack easy access to health care. "The primary sources of lead poisoning in the United States were gasoline and paint, and once lead was removed from both of those, the incidence of lead poisoning became more and more focused in poor neighborhoods where lead paint still exists," explained Robb Morse, Support and Marketing Manager of Blood Lead Products at ESA Biosciences, Inc. "As lead poisoning has become more concentrated in poor areas, it also has become further removed from access to central laboratory testing."

The lack of access to health care, including lab services, likely contributes to the low rates of lead testing among children enrolled in Medicaid. Despite the requirement that all Medicaid children receive lead testing at ages 1 and 2, only about 25% of Medicaid children in the 1–2 age range received a lead screening test in 2003, according to a 2005 report published by the Alliance for Healthy Homes (Washington, D.C.). While some states have relatively high lead testing rates—for example, a 2001 study showed that nearly 80% of Medicaid children in Rhode Island received at least one lead screening test—the testing rates in many states are much lower, and testing rates vary widely across the country (See Figure, p. 7).

In addition to the large percentage of children who don't receive blood lead testing, many parents whose children are tested never receive their child's test results. Traditionally, clinics draw blood for lead testing and send the samples out to a central lab, but when the clinic receives the results days or weeks later, clinic personnel often cannot find the family to inform them of the result. "Before [we implemented point-of-care testing], we did not receive the results of the capillary lead test for 3–10 days. If there was a child with a high lead result, we had to contact the family to refer the child for a venous draw, which is required for the confirmatory test. This proved difficult due to work schedules and because parents did not understand the need for the venous draw, or they had moved to another address," explained Joan Dyer, Program Supervisor of the Childhood Lead Poisoning Prevention Program in Kent County, Mich.

Point-of-Care Lead Testing

Moving lead testing to the point of care eliminates this problem, which was one of the reasons that ESA developed the LeadCare II system. The new device, which is the first POC instrument for lead testing, employs the same electrochemical method already used by some central lab analyzers and the instrument's predecessor, the ESA LeadCare I. The anodic stripping voltametry method works by exploiting the precise correspondence between the amount of metal involved in an electrochemical reaction and the size of the electric current the reaction generates (See figure above). "It's an incredibly simple, incredibly specific, and incredibly reproducible technique that is independent of what else is in the sample," said Morse.

Compared with central lab methods such as graphite furnace atomic absorption spectrometry (GFAAS), a 2002 study showed that the electrochemical method can produce comparable results under appropriate test conditions. The study, published in the *Journal of Trace Elements in Medicine and Biology*, compared GFAAS with the LeadCare I Blood Lead System and found that both methods had comparable results for between-run and within-run precision studies and that both methods had "quite satisfactory" performance in recovering lead from samples to which it was added. The authors noted, however, that samples should be tested on the LeadCare device within 24 hours of collection and that "care should be taken to double-check any result close or higher to the limit value." With the LeadCare II test, both of these concerns are easily addressed, since the normal operating procedure involves running a sample within minutes of collection and confirming results over 10 µg/dL with a central lab method.

Advantages for Lead Poisoning Prevention

While not a replacement for central lab testing, the LeadCare II test enhances clinicians' ability to screen children who may be at risk for lead poisoning, many of whom are currently not receiving testing. Because the LeadCare II test was granted a CLIA waiver, any health care provider can use the test, opening up the possibility of lead testing in public health clinics, physicians' offices,

A Look at Lead Testing

COURTESY ESA BIOSCIENCES, INC.

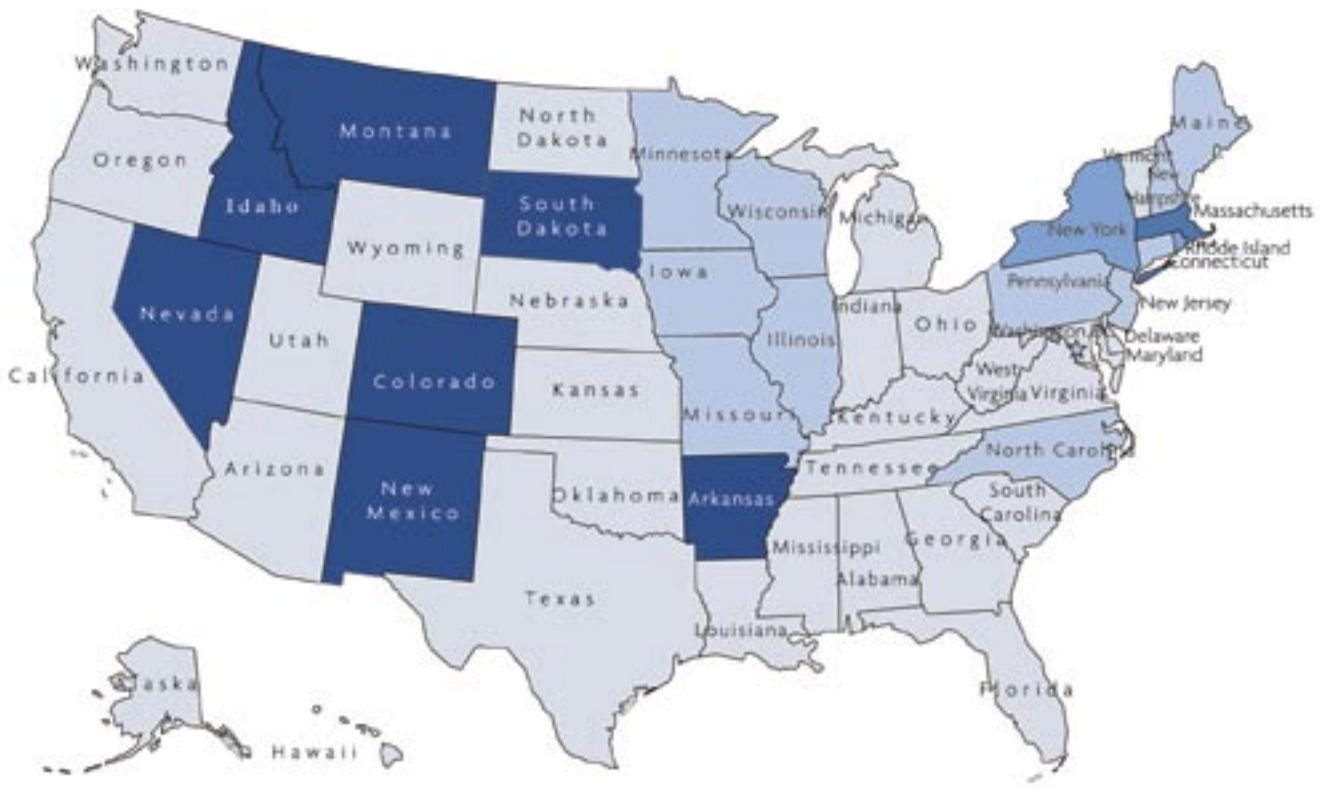
After a sample of whole blood is lysed to release the lead (steps 1–2), the LeadCare II test quantifies the amount of lead in the sample by plating the lead onto an electrode (step 3) and then applying a stripping voltage to the electrode and measuring the current generated as the lead is released (step 4). "The key to electrochemistry is that each element has a different potential at which it will release its electrons, so we can pick a potential where we're going to measure for just lead. We adjust the potential and all of the lead strips off the electrode, releasing two electrons [for each lead atom], which creates a current, and that current is directly proportional to the amount of lead in the sample," explained Robb Morse, Support and Marketing Manager of Blood Lead Products at ESA Biosciences, Inc.

and a variety of other settings. "The big two [applications] are going to be pediatricians' offices and through public health—community health centers, [Women, Infants, and Children (WIC)] clinics, mobile outreach programs, and Head Start programs," said Morse. Although the LeadCare II test still requires that a facility have a certificate of waiver, the FDA estimates that approximately 115,000 locations in the U.S. would be able to perform the new test.

In addition to expanding the number of locations where testing could be performed, the LeadCare II test embodies the advantages of a POC platform. Small and light enough to be portable, the analyzer returns results in only a couple of minutes and requires just a finger stick blood sample. Especially for clinicians working primarily with young children, the ability to avoid routine venipunctures presents a significant practical advantage. "For some parents, the issue [with lead testing] is the drawing of blood," said Laura Kelly, RN, owner and administrator of Tilman Community Health Clinic in Chicago, Ill. "Now with this being as easy as a finger prick, that's excellent…We can start having a conversation with the child and—boom—it's over."

In addition to ensuring that all patients who are tested receive their results, providing test results during the patient's initial appointment can also positively impact the lead poisoning education that many clinics provide. "We set up the testing in the WIC programs here…The advantage is that when children come into WIC, the clinic staff test for lead poisoning at the same time that they test for iron deficiency, which is a WIC requirement. While the LeadCare machine is actually bringing in the result, the clinic staff talk about why they're testing and give some general information about lead poisoning," said Dyer. "When we get an elevated result, at or above 10 µg/dL, the clinic nurse is called in to talk to the family, provide a brief [educational] intervention, and immediately either draw the venous confirmatory sample or refer that family to the local hospital lab. The impact is an immediate response to a high lead—a brief intervention, a recommendation, and a referral." According to Dyer, the number of children in Kent County with high screening results who failed to get a confirmatory test has dropped to 50% of previous levels since the implementation of POC lead testing.

U.S. Lead Screening Statistics



ALABAMA	6%	KANSAS	11%	NORTH CAROLINA	19%	Percentage of 6 year olds screened in 2003	
ALASKA	0%	KENTUCKY	9%	NORTH DAKOTA	2%		
ARIZONA	3%	LOUISIANA	16%	OHIO	13%		
ARKANSAS	?	MAINE	17%	OKLAHOMA	5%	0% to 15%	
CALIFORNIA	8%	MARYLAND	15%	OREGON	4%	16% to 30%	
COLORADO	?	MASSACHUSETTS	49%	PENNSYLVANIA	5%	31% to 45%	
CONNECTICUT	25%	MICHIGAN	11%	RHODE ISLAND	43%	46% to 60%	
DELAWARE	12%	MINNESOTA	16%	SOUTH CAROLINA	14%	Unknown ?	
DISTRICT OF COLUMBIA	24%	MISSISSIPPI	15%	SOUTH DAKOTA	?		
FLORIDA	9%	MISSOURI	16%	TENNESSEE	11%		
GEORGIA	8%	MONTANA	?	TEXAS	13%		
HAWAII	8%	NEBRASKA	12%	UTAH	13%		
IDAHO	?	NEVADA	?	VERMONT	16%		
ILLINOIS	18%	NEW HAMPSHIRE	16%	VIRGINIA	7%		
INDIANA	8%	NEW JERSEY	22%	WASHINGTON	1%		
IOWA	19%	NEW MEXICO	?	WEST VIRGINIA	12%		
		NEW YORK	31%	WISCONSIN	20%		
				WYOMING	5%		

Source: The Centers for Disease Control and Prevention Childhood Lead Poisoning Prevention Program Surveillance Data

More Testing Likely

With the availability of a CLIA-waived, POC test for lead, public health officials may now have the tools to expand testing further into the communities where lead poisoning poses the greatest risk. Screening more children, and possibly adults as well, will likely result in the identification of more elevated blood lead levels, which in turn could mean more confirmatory tests for reference and hospital labs. While the burden of running screening tests may shift to clinics, these facilities will likely continue to send samples to the central lab for confirmation of elevated results. "I think with this test being out there and being so available, and with lead being a health issue, that there's going to be a lot more testing done," said Cindy Overkamp, Regional Lab Manager of the Kent County Health Department and Technical Consultant for the moderate complexity CLIA certificate of Region 4 of the Michigan Regional Laboratory System.

And hopefully as the number of tests performed goes up, the results of those tests will also begin to come down, as continued efforts to reduce lead exposure and educate parents about the dangers of lead poisoning result in fewer elevated blood lead levels. "Point-of-care lead testing has been a good thing and hopefully it will continue to help us decrease the lead poisoned population in our community," said Momber. "This will come with time; you can find lead poisoning and you can teach about lead poisoning, but we are not going to see a true, lasting decline in lead poisoning until the community begins to hit the source of lead poisoning with housing remediation activity, property maintenance codes and enforcement, and other efforts aimed at prevention." CLN

Lead Poisoning—Not Just for Kids Anymore

Although much of the attention in lead poisoning prevention has focused on children, a recent study in *Circulation* showed that lead may also have significant adverse health effects on adults, even at relatively low levels. In an analysis of data from the Third National Health and Nutrition Examination Survey (NHANES III), researchers found that adults had increased risks of all-cause mortality and cardiovascular mortality beginning with blood lead levels of only 2 µg/dL. According to NHANES data from 1999–2002, 38% of adults in the U.S. had lead levels above this level, possibly making lead a more significant public health concern than was previously realized.

Also possibly raising concern about lead poisoning in adults, a recent publication from the CDC noted that in 2004, according to data from the 37 states that reported information to the CDC's Adult Blood Lead Epidemiology and Surveillance program, there were 9,170 adults with blood lead levels at or above 25 µg/dL. Of these cases, there were 1,425 individuals whose blood lead level was at or above 40 µg/dL, the level at which Occupational Safety and Health Administration (OSHA) regulations require an annual medical exam to evaluate adverse health effects.

Since lead poisoning in adults typically results from occupational exposure rather than household exposure, the methods for prevention will likely differ from those used to prevent childhood lead poisoning, but the benefits of point-of-care testing seems to extend to adults as well as children. "I think there are probably a lot of adults who perhaps haven't looked into having lead testing done, but who may end up being tested in their physician's office if the doctor asks about possible environmental exposure," said Cindy Overkamp, Regional Lab Manager of the Kent County Health Department in Michigan. "There are quite a few fields out there that are very risky for people being exposed to lead." Some of the occupations with the highest risks of lead exposure include manufacturing storage batteries, painting, and mining.