UNMET NEEDS

• Provide $25 million in FY 2010 to fund CDC’s National Biomonitoring Program
  > $15M to fund states to build laboratory capacity and capability to monitor chemicals in people.
  > $10M to fund CDC to support state programs, develop methods, conduct studies and issue reports on monitoring disease and chemical exposures in people.

BACKGROUND

Every day we come in contact with thousands of chemicals. Though you would not knowingly breathe in air polluted with sulfur dioxide or drink water containing arsenic, chemicals in the environment often go unnoticed. While poor air quality has been linked with asthma, and asbestos with cancer, many other chemical exposure-health relationships are not known. Approximately 100,000 chemicals are currently registered for use in the US, yet we know very little about their effects on human health.

As part of its National Biomonitoring Program, CDC’s Environmental Health Laboratory has measured levels of chemicals in people for the last 30 years. The data are used to assess exposure to environmental chemicals in the US population and provide valuable information when analyzed in conjunction with health outcome data.

CDC currently has biomonitoring data available for hundreds of chemicals including perchlorate, bisphenol A (BPA) cotinine (a measure of secondhand tobacco smoke), flame retardants, certain pesticides and other complex chemicals.

Biomonitoring data are critical in assessing people’s exposure to chemicals following both unintentional and intentional chemical events by identifying the chemical agent and determining which people were and were not exposed. Additionally, information from CDC about background levels of exposure can be used as a reference to determine when people have elevated levels of chemicals in their bodies. Ongoing monitoring of exposed populations by CDC ensures people receive proper care and treatment and helps decision makers determine which chemicals need regulation.

PROGRAM

APHL supports funding for the National Biomonitoring Program at CDC. Currently, the National Center for Environmental Health at CDC uses biomonitoring to measure specimens from participants in the National Health and Nutrition...
Examination Survey. New funding would be used to provide adequate technical assistance and training to states, support studies to investigate the health impacts of chemical exposures and develop laboratory methods that are readily transferrable to states.

At the state level, this funding would expand state laboratories’ abilities to conduct targeted population-based biomonitoring studies, upgrade facilities and equipment and bolster their workforce to ensure proficiency in laboratory techniques.

**BIOMONITORING AND ENVIRONMENTAL PUBLIC HEALTH TRACKING**

Rates of chronic diseases such as allergies, asthma, obesity, diabetes, heart disease and metabolic syndrome are all on the rise in the US. Although there are many theories with regard to cause, there are no definitive answers explaining these alarming rates. Past research has linked some environmental exposures with specific diseases, such as benzene exposure to leukemia. However, much work remains to determine whether or not exposure to certain chemicals, such as flame retardants, causes illness or disease.

The Environmental Public Health Tracking (EPHT) Network will allow existing environmental hazard, exposure and disease tracking systems to be linked together. Biomonitoring is essential to such linkages since it is the most accurate method of determining human exposure to environmental hazards and is a better way to assess the impact of an environmental hazard on human health.

State laboratories should play an important role in the EPHT Network. The Connecticut EPHT Program, for example, is working closely with the state’s public health laboratory, the Maine Health and Environmental Testing Laboratory and the Vermont Department of Health Laboratory to examine umbilical cord blood from newborns for mercury, lead, cadmium and related biomarkers.

Although some states have made tremendous strides in biomonitoring, currently there are no systems that exist at the state or national level to track many of the exposures and health effects that may be related to environmental hazards.

APHL supports the expansion of the Environmental Public Health Tracking program to link environmental data with biomonitoring and health data in all states. Funding should increase the number of state laboratories doing biomonitoring and develop their ability to share data electronically with other agencies.
UNMET NEEDS

• Fund the programs authorized in the Newborn Screening Saves Lives Act of 2007 (S. 1858/H.R. 3825) to build the necessary infrastructure and workforce needed for education, outreach, follow-up care, laboratory quality assurance and contingency planning.

• Provide $10 million to the CDC Environmental Health Laboratory’s Newborn Screening Quality Assurance Program to ensure that laboratory tests used to screen newborns are high quality and that new ones are developed constantly.

BACKGROUND

Newborn screening is a vital responsibility with profound and lifelong consequences for the thousands of infants diagnosed each year with heritable and genetic conditions, such as sickle cell anemia and cystic fibrosis. In many cases, early intervention can mean the difference between relative health and severe impairment… or even between life and death.

APHL and its members are acutely aware of the importance of newborn screening (NBS) and the elements of a high-quality screening program. State public health laboratories are accountable for the NBS test results of 97% of all babies born in the United States—more than 4 million babies each year.

In the past decade, the environment for newborn screening underwent drastic change. On the one hand, new technologies and genetic discoveries led to a major expansion of the NBS testing panel, creating greater opportunity for intervention and also a pressing need for technical training.

On the other hand, unforeseen catastrophes—including hurricane Katrina—demonstrated the vulnerability of state newborn screening programs, which are almost always single-site operations.

One of the major milestones in newborn screening last year was the passing of the “Newborn Screening Saves Lives Act of 2007,” which was signed into public law by President Bush on April 24, 2008, without any appropriated funds.

Newborn screening is an essential, life-saving and effective preventive public health program for early identification of medical conditions that can lead to catastrophic health problems. It identifies thousands of babies born in the US each year with a genetic or metabolic disorder. The cost of these conditions if left untreated is enormous, both in terms of human suffering and in economic terms.

Worldwide, CDC’s Newborn Screening Quality Assurance Program Laboratory is the only

CDC FUNDING

Environmental Health Laboratory
(Dollars in millions)

FY 2009 $8 (Enacted)
FY 2010 $10 (APHL Required Amount)
newBorn screening
promoting the health of America’s future

A comprehensive source for ensuring the accuracy of newborn screening tests. Funding the Newborn Screening Quality Assurance Program at $8 million will allow for:

1) The research and development of new laboratory screening methods that expand the number of disorders babies can be screened for.

2) Population-based pilot testing for conditions (e.g., Severe Combined Immune Deficiency, Pompe Disease, Metachromatic Leukodystrophy, etc.) not presently included in test panels.

3) The provision of technical assistance and technology transfer to state newborn screening laboratories, particularly with regard to promising and sophisticated techniques capable of identifying a host of disorders currently not diagnosable in newborns.

4) The testing of new screening tools to ensure the highest possible analytic validity and utility.

COLLABORATION WITH STATE AND LOCAL HEALTH DEPARTMENTS

During the past several years, states have experienced newborn screening service interruptions due to both natural disasters and manufacturer inability to provide testing materials. Contingency planning is needed to lessen the effect of disasters that involve newborn screening program operations. APHL continues to support the funding for newborn screening contingency planning activities that were outlined in the Newborn Screening Saves Lives Act to ensure the availability of newborn screening during an emergency.

OTHER CRITICAL FUNCTIONS

The Newborn Screening Quality Assurance Program Laboratory at CDC:

- Trains state laboratorians on the latest technologies and provides proficiency standards for new materials.
- Supports state laboratories during newborn screening emergency situations, such as the aftermath of hurricanes Katrina and Rita.
LABORATORIES MUST BE ABLE TO TRANSMIT TEST AND RESULT DATA ELECTRONICALLY

UNMET NEEDS

• Provide $112 million in annual CDC funding for public health informatics initiatives.
• Provide $200 million annually to directly impact the state and local laboratories’ ability to develop and deploy Electronic Laboratory Messaging capability.
• Increase long-term funding to state and local public health laboratories to ensure purchase and maintenance of a standards-compliant, interoperable laboratory information system.
• Increase funding for the CDC’s National Center for Public Health Informatics to support state and federal efforts for electronic data exchange.
• Provide funding to support community-building and collaboration initiatives among all nationally-organized public health laboratory networks.

BACKGROUND

Public health laboratories are key providers of population-based disease data that can be used to protect the health of all Americans. They provide the means to recognize and alert officials to outbreaks of newly-emergent and recurrent disease by serving as testing sites for private physicians, hospitals and clinics, as well as serving as a direct interface between state and federal epidemiologists. Public health laboratories safeguard entire communities.

Without the ability to manage laboratory data themselves, labs cannot disseminate information timely and accurately to those responsible for managing, controlling and responding to an event. We need sustained funding to ensure our nation’s laboratories have access to technologically-advanced information systems in times of crisis.

A Laboratory Information Management System (LIMS) is a vital component of the laboratory and supports all of its functions—from specimen processing through subsequent testing and test result reporting. However, a LIMS is only one component of the daily work and functions of the laboratory to produce disease data. The other component is the electronic exchange of the patient’s test orders and test results among the laboratory and its private, local, state and federal partners, which is known as Electronic Laboratory Messaging (ELM). To implement one without the other would be to implement a marginally useful system.

ELM would promote rapid information dissemination and mitigation of exposure. Test orders and results can no longer be inefficiently reported by telephone, fax and
email. Improvements in health information technology must include the laboratories that perform testing of public health significance.

Virtually every government agency has created an information network within the past five years to try and support web-based exchange of laboratory data. The problem is that these efforts have not been coordinated, nor adequately funded, resulting in the multitude of siloed, inefficient, often homegrown systems we have today.

Modernizing these systems and enabling interoperability is a huge challenge that APHL is striving to meet. The Public Health Laboratory Interoperability Project (PHLIP) is a collaboration among public health laboratory scientists and IT experts from APHL member laboratories and the Centers for Disease Control and Prevention. The PHLIP team is defining the necessary infrastructure and expertise that a public health laboratory must have to enable two-way electronic data transmission with public health and clinical partners in a recognized standard format.

As documented in a recent report from Analytic Services, Inc., a panel of subject matter experts identified a funding level of $200 million annually as essential to moving forward in a significant way. “Without this funding, the full breadth of public health laboratory responsibilities cannot be met.”

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ENSURING THE EARLY DETECTION OF FOODBORNE DISEASES

BACKGROUND
While significant, the recent national outbreaks of gastrointestinal disease associated with fresh peppers and peanut butter that captured national attention are merely the best-known examples of a far more extensive burden. Food is capable of transmitting more than 200 known diseases, and in 1999, the Centers for Disease Control and Prevention (CDC) estimated that foodborne disease caused approximately 76 million illnesses annually, including 5,000 deaths in the US. In the majority of outbreaks, the causes of the illnesses remain unidentified. The improved public health laboratory (PHL) capability that would result from enactment of Congresswoman Rosa DeLauro’s bill, H.R. 875, would allow food safety experts to link cases of illnesses more rapidly, identifying common causes earlier in an outbreak and potentially limiting exposures. Frenzen, et al. estimated in 2005 that the prevention of a single fatal case of hemolytic uremic syndrome in a patient infected with Shiga toxin-producing E. coli may save $6.2 million dollars.

PHLs form the backbone of the response by providing information that can assist epidemiologists and other food safety officials in their investigation. Laboratories respond to foodborne emergencies by detecting and identifying outbreaks through networks such as PulseNet, the national molecular subtyping network formed by PHLs and CDC. Without these networks, large national outbreaks, including the 2008 pepper outbreak and the 2008-09 peanut butter outbreak, might never be detected. As an example, during the national E. coli O157:H7 outbreak in 1993 that was the impetus for the development of PulseNet, it took 39 days to determine ground beef patties served at a national restaurant chain were the source of the illness. In 2006, during the national outbreak of E. coli O157:H7 linked to fresh spinach, it took only 14 days from the first case onset of illness until the product was recalled nationally, preventing an untold number of cases of illnesses.

PHLs serve a number of food safety functions:
• Disease Surveillance and PulseNet. Through PulseNet, PHLs routinely perform DNA fingerprinting on common foodborne bacteria and transmit those data electronically to a national database, allowing member laboratories to identify related bacterial strains across state borders in a timely manner. PulseNet continues to expand in scope and utility by engaging new federal partners and targeting emerging food pathogens.
• Outbreak Testing. When an outbreak related to food consumption occurs, PHLs receive

CDC FUNDING
Food Safety
(Dollars in millions)
FY 2009 $28 (Enacted)
FY 2010 $37* (APHL Required Amount)
(*additional $9 million necessary to improve food safety measures at the state level)
both human and food samples from public health nurses or health inspectors and analyze them to determine the chemical or biological contaminant. PHLs’ contributions allow for human illness to be linked to a food source by investigators. Food safety initiatives may then be promoted to help prevent future illness.

- **Confirmatory Testing.** PHLs also test samples to confirm the results of clinical and hospital laboratories. This routine testing is important to monitoring the incidence and type of foodborne disease in the population.

**PHL UNMET NEEDS**

Over the years, PHLs have brought their food safety laboratory capacity to a higher level based on APHL recommendations. These efforts have yielded tangible results: the national laboratory capacity for food testing has grown stronger. However, notable gaps remain:

- **Personnel.** Without steady funding for qualified personnel, states may lack the ability to use their resources fully. According to a recent APHL survey, 64% of states would like to hire more staff but do not have sufficient funding.

- **Training.** PHL personnel trained for a variety of test methodologies are the lynchpin for surge capacity. The knowledge gap in conventional laboratory methods is increasing, and states need sufficient resources to adequately train staff to perform classical microbiological and chemical testing on both food and human samples. However, 81% of state laboratories have cited inadequate funding as the primary barrier that restricts them from providing food safety training to staff.

- **Reagents/Equipment.** While most laboratories use or have access to highly technical equipment and software capable of rapidly detecting and differentiating strains of foodborne pathogens, maintenance of laboratory equipment is very costly. In addition, reagent costs are placing a significant financial burden on many of these laboratories.

- **Food Chemistry.** Every PHL should have the capability to perform food chemistry testing to detect the presence of environmental contaminants, natural toxins and other chemical agents in food. However, the average PHL has only 1.6 FTEs that routinely perform food chemistry testing.

**CDC FOOD SAFETY UNMET NEEDS**

- **PulseNet—**to allow immediate testing of samples, expand PulseNet to be able to detect additional pathogens, to evaluate and implement next-generation laboratory testing methods, to improve diagnostic methods and training and to support national foodborne disease surveillance efforts.

- **Improvements in sample shipping—**to provide states funding to combat rising costs of shipping clinical isolates and/or specimens to PHLs and assure timely submission of samples from healthcare providers and clinical laboratories to PHLs performing surveillance.

- **Calicivirus/Norovirus—**to expand the number of states that have capacity for molecular Norovirus detection and sequencing, train laboratorians in Norovirus sequencing methods and sequence analysis, improve Norovirus typing methods and support national Calicivirus/Norovirus surveillance.

- **Parasitic activities—**to develop new technologies to detect the presence of foodborne parasites such as Cyclospora cayetanensis and to provide molecular, conventional and tele-diagnostic tools to PHLs.
UNMET NEEDS

- Support $20 million in FY 2010 for EPA’s Homeland Security Laboratory Program to:
  > Build capacity and workforce in the states to analyze environmental samples for chemical, biological and radiological threats.
  > Expand the number of state laboratories participating in the environmental response laboratory network (ERLN).
  > Develop and validate methods for transfer to states.
  > Expand the state radiological grant program.
- Provide EPA with $10 million to build a nationwide laboratory network to protect our drinking water (Water Laboratory Alliance).

BACKGROUND

Every day our air, water and soil are under attack from the tens of thousands of chemicals pouring into them. Most people don’t think twice about the air they breathe or the water they drink; they depend on our government to keep them clean and safe. To ensure that this important infrastructure is indeed safe, we must ensure that laboratories conducting regular testing maintain certain quality requirements. Unfortunately, as documented in a recent GAO report, this is not the case. EPA must address laboratory quality issues through a national state environmental laboratory accreditation program.

Terrorist attacks endanger not only human life and health, but also the national economy due to the need for evacuation and later remediation of the affected environment. EPA is responsible for conducting the environmental sampling that feeds into the decision-making process following an incident of national significance involving the environment, as well as the remediation of affected areas. State and local laboratories, however, are typically the first receivers during an incident; therefore EPA must coordinate with environmental laboratories around the country.

HOMELAND SECURITY LABORATORY PROGRAM

Governmental laboratories receive white powders or other samples that may contain radiological, biological or chemical warfare agents every day. These laboratories test unknown samples to identify contaminants and assess dangers.

The majority of state and local environmental laboratories, however, lack the proper resources to adequately respond such events. They need federal guidance such as validated methods, standards and proficiency testing programs.
Without this support, states will be delayed in their response or unable to respond at all, putting the lives of millions in danger.

To meet this need, APHL requests funding for EPA to advance the developing Environmental Response Laboratory Network. This network should provide a mechanism for state and federal environmental laboratories to collaborate and leverage capabilities. The ERLN will also provide a mechanism to fund state environmental laboratories to increase capacity to respond to emergencies and ensure high-quality results to support decision making.

**RADIOLOGICAL PREPAREDNESS GAPS**

If a terrorist were to attack the US with a radiological agent, federal and state laboratories would be very limited in their ability to respond. During an October 2007 Congressional hearing on US laboratory capacity to effectively respond to a radiological attack, expert testimonies revealed that validated methods to test clinical specimens in a radiological emergency exist for only 6 of the 13 highest priority radioisotopes most likely to be used in a terrorist event. The screening of 100,000 clinical samples for isotopes (for which validated methods do exist) would take more than four years, while analysis of environmental samples could take as long as six years to complete.

According to a 2007 APHL survey, 55% of responding state environmental laboratories have the ability to test drinking water for the presence of radiation. In a large-scale event, these laboratories would be quickly overwhelmed due to the high sample count. The same is probably true for other sample types.

Funding is needed to enhance the capability and capacity of state and local environmental and radiochemistry laboratories by upgrading equipment, providing training and bolstering the workforce.

**WATER LABORATORY PREPAREDNESS**

Two hundred and fifty million Americans get their drinking water from public water systems. A terrorist attack on a large municipal water supply could endanger the lives of millions of Americans.

During a terrorist incident, state and local laboratories would be hard pressed to analyze the thousands of water samples for contaminants. Laboratories need a network of other laboratories to call on for help; otherwise, decisions affecting life and death may be disastrously delayed.

EPA has managed to partially meet this need through the Water Laboratory Alliance (WLA). Dedicated funding should be directed toward the WLA’s Drinking Water Laboratory Response Preparedness Project for coordination of state environmental laboratories’ planning and for building capacity in the states to analyze threats (for example as directed by HSPD-9).
LACK OF FUNDS JEOPARDIZES DISEASE DETECTION

UNMET NEEDS

• Enhance the nation’s ability to respond to emerging disease outbreaks by:
  > Increasing CDC’s capacity to test samples.
  > Developing and deploying diagnostic tests to state and local public health laboratories (PHLs).
  > Providing technical assistance and training to state and local PHL professionals.
• Increase support for the Epidemiology and Laboratory Capacity Program, a critical source of funding and technical assistance for infectious disease detection in state laboratories, providing:
  > Capacity to respond to emerging diseases.
  > Genetic fingerprinting for foodborne diseases through PulseNet, which makes rapid detection of outbreaks of foodborne illnesses (for example, Salmonella contamination in peanut butter) possible to expedite public health interventions.
  > Detection of viruses that cause serious intestinal distress in humans.
  > Laboratory detection of drug resistant bacteria (such as MRSA), viruses and parasites.
• Enhance influenza pandemic preparedness and expand early warning laboratory surveillance with year-round testing to rapidly detect variations of influenza viruses, especially the deadly avian influenza viruses, in accordance with the Department of Health and Human Services’ “Federal Guidance to Assist States In Improving State-Level Influenza Operating Plans.” Continued additional funds will enhance molecular detection capacity using CDC’s new protocol that received FDA 510(k) clearance, provide needed reagents, allow for staff recruitment and provide training.
• Develop and implement electronic laboratory messaging systems that can transfer appropriate data for better disease control.
• Prepare the next generation of laboratory leaders through education and management training programs.
• Enhance national capacity to detect and prevent outbreaks of new infectious diseases through the Emerging Infections Program.

CDC FUNDING
(Dollars in millions)

Preparedness, Detection and Control of Infectious Diseases
FY 2009 $157 (Enacted)
FY 2010 $167 (APHL Required Amount)
(additional $10 million for responding to emerging infectious diseases)

Pandemic Influenza
FY 2009 $156 (Enacted)
FY 2010 $166 (APHL Required Amount)
(additional $10 million for state and local surveillance capacity)

Vector-Borne Diseases, including West Nile Virus
FY 2009 $26 (Enacted)
FY 2010 $46 (APHL Required Amount)
(additional $20 million for surveillance and detection of vector-borne diseases, including West Nile Virus)
PREPAREDNESS, DETECTION AND CONTROL OF INFECTIOUS DISEASES

The CDC Infectious Diseases Control Program funds critical laboratory improvements that allow federal and state programs to maintain early warning detection capabilities for known diseases and provide quick identification of unknown diseases. Increased funding is essential to preserve existing capacity, enhance surveillance for new strains of influenza and provide improved responsiveness to the growing problem of emerging diseases. A recent outbreak of chikungunya virus in Italy demonstrates how one person can acquire the disease while traveling abroad and transmit the virus to mosquito vectors in their home country. The initial introduction into the mosquito population resulted in 334 suspected cases in a geographical region that had not previously been exposed to the disease. Laboratory capacity in Italy was critical to confirm infection in more than 200 people.

Recent domestic infectious disease threats include CA-MRSA and other antibiotic-resistant bacteria, Tamiflu-resistant and avian influenza, SARS, monkeypox, Hepatitis A, bacterial meningitis, West Nile Virus, malaria and dengue fever. The threat for pandemic influenza is at an unprecedented level due to highly pathogenic avian (H5N1) influenza co-circulating with human influenza in settings with high risk of exposure (bird markets), resulting in greater potential for adaptation to human hosts or re-assortment with circulating human viruses. There have been at least 360 confirmed cases of avian influenza resulting in 226 deaths worldwide. We must also be prepared for an unexpected strain of influenza to emerge as a pandemic strain. A recommendation from the “Federal Guidance to Assist States in Improving State-Level Influenza Operating Plans” (http://www.pandemicflu.gov/news/guidance031108.pdf) has identified “Pandemic Intervals, Triggers, and Actions” to assist states and locals in updating their pandemic plans. Laboratory testing to confirm introduction and spread of a novel strain is a crucial component to trigger appropriate mitigation and control strategies for each interval.

Over the past few years, there have been several large, multi-state outbreaks of pertussis (whooping cough), mumps and measles, diseases now re-emerging in children and adults. In addition to the human impact of these diseases, there is a tremendous economic impact. Estimates indicate that infectious diseases have an economic cost in the US of more than $120 billion each year. An influenza outbreak on the scale of 1918 would cause an estimated one million deaths in the US.

VECTOR-BORNE DISEASES, INCLUDING WEST NILE VIRUS

Federal West Nile Virus funding supports surveillance that determines the level of disease risk to people and gets this message out to providers, responders and the public to allow for implementation of appropriate interventions.

With this funding, many states are also able to perform the same activities for other viruses that cause encephalitis, which is important to monitor for outbreaks of St. Louis encephalitis or even dengue if it emerges in the US. Proposed funding reductions will force some states to choose between keeping laboratory staff to perform tests and the materials needed to conduct those tests. Other states may be required to fundamentally change the scope of their testing programs and reduce the information that is necessary for successful intervention strategies—which will lead to increased illness in humans and animals. ■
UNMET NEEDS

• Provide HIV/AIDS funding consistent with the Centers for Disease Control and Prevention (CDC) Professional Judgment Budget.
• Support HIV surveillance so that funds can be allocated where they are needed most.
• Provide resources so that new HIV diagnostic and screening technologies can be validated and implemented in public health laboratories.
• Enable laboratories to detect HIV infections in their earliest (and most infectious) stages by supporting the newest and most advanced testing technologies, including nucleic acid amplification testing and fourth-generation immunoassays.
• Improve laboratory capacity to monitor and confirm HIV-2 infections.
• Evaluate the newly proposed alternative HIV testing algorithms to improve the speed, accuracy and efficiency of HIV diagnosis and surveillance.
• Facilitate HIV disease management by enabling laboratories to conduct viral load testing, genotyping and antiretroviral resistance monitoring.

BACKGROUND

More than 25 years after the first documented cases, HIV/AIDS continues to be a major public health burden in the United States. There are more than one million people living with HIV in the US today, and this number is growing. While HIV affects all racial, socio-economic, regional and age groups, African-Americans, Latinos and men who have sex with men have been disproportionately affected by the epidemic.

Recent advances in surveillance technology have allowed CDC to more accurately estimate the incidence (or number of annual new infections) of HIV. There were 56,300 new HIV infections in 2006, 40% greater than the 40,000 that was previously estimated. CDC estimates that for every 100 people living with HIV, five new infections will occur per year. Early diagnosis of HIV is crucial to limiting the number of new infections.

CDC has developed an ambitious plan to combat HIV/AIDS in the US. By 2020, they hope to reduce the HIV transmission rate from 5% to 2.5% and to reduce the proportion of infected individuals who are unaware of their status. Current data show that in 2006, 21% of HIV-infected individuals (more
than 200,000 people) don’t know they are HIV positive, and CDC wants this number cut in half.

To achieve these goals, CDC developed a professional judgment budget that outlined the ideal approach to fighting HIV/AIDS in the US. A vital part of this plan includes scaling up HIV testing initiatives, improving HIV monitoring systems and developing new tools to aggressively fight HIV/AIDS. State and local public health laboratories would play a key role in this initiative, and an increase in laboratory resources would be necessary in order for it to succeed.

Currently, public health laboratories provide services crucial to the diagnosis of HIV infections. Public health laboratories serve as referral and reference laboratories for HIV testing and support the work of other public and private sector laboratories. These laboratories are instrumental in conducting disease surveillance and provide the data necessary to monitor trends in HIV infection. With the increasing number of people living with HIV/AIDS in the public healthcare system, public health laboratories will have an increasing role in disease management as well. Developing this capacity by providing viral load testing, antiretroviral resistance monitoring and CD4/CD8 cell counts, will improve both patient care and public health surveillance. HIV-2, a less common but closely related strain of HIV, poses another challenge to public health laboratories. At present, there is limited capacity for the confirmation and management of HIV-2 infections. Infections by this strain are mostly limited to West Africa, but this gap must be addressed to improve public health laboratory preparedness.

In recent years, new technologies have arisen that have greatly improved the speed and accuracy of HIV screening and diagnosis. Most HIV tests rely on the detection of antibodies against HIV, which can sometimes take months to develop. Unfortunately, it is during this same period that HIV-infected individuals are most infectious. New technology, such as nucleic acid amplification tests and fourth-generation immunoassays are capable of detecting infection much earlier than was previously possible and could be crucial in breaking the transmission cycle. While these tests are more expensive than traditional HIV tests, their ability to detect infection at the most transmissible stage could significantly improve our ability to prevent new infections.

APHL has been working with CDC and state and local public health laboratories to develop new testing algorithms that incorporate the most advanced HIV diagnostic tools.
TUBERCULOSIS
A SERIOUS RE-EMERGING THREAT

UNMET NEEDS

• Provide federal funding of $210 million as authorized in Public Law 110-392. HHS Secretary’s Advisory Council for the Elimination of Tuberculosis has recommended $252.4 million to meet the CDC goal of tuberculosis (TB) elimination in the US.
  > Develop government/private partnerships designed to encourage the development of new tuberculosis assays.
• Increase funding for laboratories to implement new and existing diagnostic tests that can identify tuberculosis and screen for drug resistance.
• Standardize drug susceptibility testing methods in the US for first- and second-line drugs used to treat TB patients to improve clinical outcome.
• Provide funding for CDC to conduct an assessment of laboratory tuberculosis testing capacity.
• Develop a plan of action that will address extensively drug resistant tuberculosis (XDR-TB) to prevent it from invading the US.
• Direct CDC to develop a strategic plan for implementing and maintaining a systems approach to TB control that includes laboratory systems.
• Assess the true costs of providing TB laboratory services because the cost to identify individual cases rises as the number of cases declines and the cost of services will vary from one jurisdiction to another.
• Develop recommended testing methods for different patient populations, as well as guidelines to help jurisdictions select the appropriate level of service.
• Improve laboratory staff proficiency in complex tuberculosis testing procedures in light of fewer specimens being tested in relation to the decline in tuberculosis.
• Train new laboratory staff in tuberculosis testing procedures in light of a rapidly aging workforce.

BACKGROUND

Tuberculosis is a serious re-emerging infectious disease that affects the lungs and respiratory system as well as other organs and can lead to death if left untreated. This illness is transmitted person-to-person via the air by coughing, sneezing and even talking. Tuberculosis has re-emerged as a co-infection with Human Immunodeficiency Virus (HIV) because HIV weakens the immune system and makes the patient more susceptible to infection and severe TB disease.

Today, despite an overall decline in cases, tuberculosis continues to incur significant social, public health and economic costs in the US.

CDC FUNDED
(Dollars in millions)
FY 2009 $143 (Enacted)
FY 2010 $210 (APHL Required Amount)
Approximately one-third of the world’s population is latently infected with the bacterium that causes tuberculosis. An estimated 10 million to 15 million US citizens have latent tuberculosis infection, and about 10% of these individuals will develop tuberculosis at some point in their lives. Approximately 13,500 new cases of tuberculosis disease were diagnosed in 2007 in the US. Costly tuberculosis outbreaks still occur, and multi-drug resistant tuberculosis continues to spread. Now the nation is facing a new tuberculosis threat, extensively drug resistant tuberculosis (XDR-TB), a form of tuberculosis that is resistant to the two most important first-line drugs and at least two of the most important second-line drugs available for treatment. XDR-TB is a deadly form of tuberculosis that can be incurable, especially to people with HIV/AIDS, and is swelling to epidemic proportions in southern Africa. A number of laboratories have already reported this deadly new form of tuberculosis in the US. The CDC provisionally estimates that the direct medical treatment costs of an XDR-TB patient ($132,000) are on average 2.5 times higher than those of a multi-drug resistant tuberculosis (MDR-TB) patient ($53,000) and may be much higher depending on hospitalization length and location of treatment. Altogether, tuberculosis-related costs approach $1 billion each year in the US.

To reach the goal of the elimination of tuberculosis in the US, improvements in laboratory testing must be maintained and translated into improvements in the treatment, prevention and control of tuberculosis. Despite advances in laboratory methods, lack of coordination for referral of specimens and cultures continues to lead to unnecessary delays in laboratory testing, reporting and initiation of treatment.

Currently all 50 state public health laboratories perform some level of tuberculosis testing and serve as referral and reference laboratories for culture identification and tuberculosis drug susceptibility testing in support of other public and private sector laboratories. State public health laboratories have used CDC funding over a period of many years to create modern laboratories with the latest diagnostic equipment approved for tuberculosis isolation and identification, biosafety equipment to protect laboratory staff and premises, personnel sufficient to meet the need for rapid laboratory confirmation of tuberculosis and ongoing staff training in the use of state-of-the-art diagnostic equipment and rapid testing procedures. As laboratories have become better equipped and personnel better trained, federal funds have been used less to upgrade tuberculosis laboratories and more to maintain core tuberculosis capabilities and infrastructure.

Of the $140 million allocated for tuberculosis control, only $8 million goes to supporting public health laboratory testing. This number has been stagnant at $8 million annually since 1995. With inflation factored in, the funding has experienced a 25% decrease in real dollars. Although it is tempting to think that funding can decrease in proportion to the decrease in the number of tuberculosis cases, below a certain point this reasoning falls apart, since a base level of funding (in real dollars) is necessary to maintain the tuberculosis control infrastructure.
UNMET NEEDS

• Ensure CDC receives funding comparable to the FY 2005 levels to expand programs, develop methods, provide training and ensure adequate staffing levels at state and local public health laboratories that are members of the Laboratory Response Network (LRN) for biological, chemical and radiological terrorism preparedness.

• Increase direct funding for CDC to support a rapidly deployable reagent stockpile for the LRN laboratories to assure that rapid and accurate laboratory testing can occur.

• Build safe and secure facilities for intake triage and testing of unknown samples and provide national guidelines on the triaging of unknown samples.

• Develop and improve methods for rapid confirmation of bioterrorism, chemical and radiological threat agents in human, food, animal and environmental samples.

• Expand public health laboratory outreach, training and coordination with hospital, veterinary, food and environmental laboratories where terrorism agents may first be detected.

• Provide a minimum of $10 million funding to the DHS Office of Health Affairs to coordinate with other federal agencies and partners to develop a robust validation process for handheld assays and other field assays.

Continued federal funding at appropriate levels will preserve the state and local capacity that has been built, which allows laboratories to:

• Respond rapidly and effectively to a terrorist event or public health emergency.

• Purchase new instrumentation, adopt new technologies and develop electronic data messaging.

• Recruit and retain highly skilled laboratory personnel.

• Maintain outreach programs to hospital and clinical laboratories and first responders.

• Assure a coordinated response effort with federal partners.

BACKGROUND

Formed in 1999 by the Centers for Disease Control and Prevention (CDC), the Federal Bureau of Investigation (FBI) and APHL, the LRN is the nation’s premier system for identifying, testing and characterizing potential agents of biological and chemical terrorism. State and local public health laboratories comprise approximately 70% of
the 165 LRN Biological Reference Laboratories and almost 100% of the LRN Chemical Laboratories. These laboratories produce high-confidence test results that are the basis for threat analysis and intervention by both public health and law enforcement authorities.

The LRN for Biological Terrorism preparedness is organized as a three-tiered pyramid. At the foundation are thousands of sentinel clinical laboratories, which perform initial screening for potential pathogens. When sentinel clinical laboratories cannot rule out the presence of a biological terrorism agent, they refer specimens and isolates to an LRN reference laboratory. More than 160 state and local public health, military, international, veterinary, agriculture, food and water testing laboratories serve as reference laboratories, performing complex analyses and providing support to law enforcement for threat investigations. In addition to laboratories located in the US, facilities located in Australia, Canada and the United Kingdom serve as reference laboratories. At the apex of the pyramid are national laboratories, such as those at the CDC and the Department of Defense (DoD). These laboratories test and characterize samples that pose challenges beyond the capabilities of reference laboratories, and provide support for other LRN members during a serious outbreak or terrorist event.

In 2001, the LRN performed more than 1 million anthrax tests. Since then, public health laboratories have been regularly testing samples to rule out bioterrorism in support of law enforcement and public health agencies. In a 12-month period (CDC Public Health Emergency Preparedness Cooperative Agreement FY 07), state public health laboratories received more than 5,000 unknown samples and performed more than 9,000 tests looking for suspected terrorism agents.

BIOLOGICAL TERRORISM

The public health laboratories of 50 states and the District of Columbia (DC) received about $49 million for bioterrorism preparedness in FY 2007, which is approximately $24 million less than FY05 funding and $56 million less than FY02 funding.

Due to these funding issues, several problems plague public health laboratories, including severe staffing shortages, lack of integrated laboratory information management systems for electronic data messaging and aging, non-secure facilities. Despite these constraints, expectations of LRN public health laboratories continue to expand due to the implementation of new technologies; addition of new tests for additional agents of bioterrorism and other infectious disease threats; increased coordination with food, veterinary and environmental laboratories; and an amplified demand of training for sentinel clinical and hospital laboratory partners.

LRN public health laboratories continue to reach out to sentinel laboratories and have trained thousands of laboratorians. From August 2007 to August 2008, state public health laboratories sponsored sentinel (clinical) laboratory training and offered 233 rule-out testing classes to more than 2,100 laboratorians; about 250 packaging and shipping classes to more than 3,500 laboratorians; about 530 biosafety guidelines classes to approximately 2,300 laboratories; and more than 250 classes on broad laboratory practices to more than 2,700 laboratorians. Increased funding for staff at the state public health laboratories is needed to ensure continuation of these critical training classes.
UNMET NEEDS

• Direct CDC to dedicate funding for all Laboratory Response Network laboratories in their Public Health Emergency Preparedness cooperative agreement.
• Restore funding to CDC’s chemical terrorism laboratory to FY 2007 levels to support method transfer to states for drugs of abuse, incapacitating agents and other toxicants.
• Provide $10 million to fully fund all 10 Level 1 chemical terrorism laboratories to ensure our nation’s ability to respond to large-scale chemical events.

BACKGROUND

When most people think of terrorism events, they think about bioterrorism, such as the anthrax attacks of 2001. However, chemical terrorism poses an equally significant threat, and there are tens of thousands of toxic chemicals that could fall into the wrong hands. Although the creation of the chemical side of the Laboratory Response Network (with 46 public health laboratories and CDC) in 2003 dramatically increased capability and capacity to respond to chemical terrorism incidents, many gaps and challenges remain today. A key barrier has been the steady downward spiral of funding. Of the $746 million enacted for preparedness activities in 2008, only about $24 million of this was directed to public health laboratories for chemical terrorism preparedness activities. If this continues, millions of dollars of the investments made in these unique laboratories will be wasted as the instruments sit idle because there is no trained staff to operate them. In addition, we will fall short in meeting critical chemical preparedness needs.

Through determination and dedication, often despite the lack of dedicated funding, chemical laboratories have made progress:

• In 2003, only eight state laboratories reported having a chemical terrorism response plan in place. By 2006, 35 reported having a written plan for a chemical incident.
• Public health laboratories not only drafted plans for a chemical incident, but they also practiced for one. In 2007, state public health laboratories conducted on average 3.5 drills or exercises for chemical terrorism preparedness. In 2008, CDC and the 10 Level 1 surge capacity laboratories conducted an exercise involving the rapid analysis of 5,000 samples, the same number as there were patients in the March 10, 1995, Tokyo

PREPAREDNESS

(Dollars in millions)

FY 2009 $700 (Enacted)
FY 2010 $919 (APHL Required Amount)
subway Sarin attack. More than half (56%) of laboratories with a continuity of operations plan included chemical threat preparedness activities in this plan.

- Most states (31) reported having a full-time staff person to coordinate the chemical terrorism laboratory in 2007, although this is a requirement of the Public Health Emergency Preparedness cooperative agreement.
- In 2007, 92% of state public health laboratories were capable of conducting some chemical threat agent analyses on clinical samples using standardized methods and trained, dedicated staff, an increase from 10% in 2003. However, major gaps still exist:
  - Workforce shortages persist. In 2003, five states had chemists dedicated to chemical emergency response on staff. In 2007, 46 laboratories had dedicated analysts but only had an average of 2.8 full-time chemists on staff. Laboratories with one or two chemists would not be able to maintain 24/7 response, which is often needed during a large event.
  - Although 36 SPHLs reported that they provided training to first responders in 2007, laboratories report a lack of staff and instrumentation to provide sufficient training and outreach. Furthermore, there is still a lack of national guidance for these trainings.
  - Laboratories received more than 5,200 threat samples in 2007 and tested more than 1,800 for a chemical threat. Of the 5,200, more than 1,200 were environmental samples that could have contained a chemical or radiological threat.

**CHEMICAL LABORATORY RESPONSE NETWORK**

The Chemical Laboratory Response Network (LRN-C) is a nationwide network of federal, state and local laboratories capable of confirming the presence of chemical terrorism agents and other toxic substances in clinical samples (blood and urine). These laboratories have designated “levels” that correlate with their capacity to perform certain tasks during emergency events.

Chemical laboratories in this network have made great strides in preparedness since they first received funding in 2003. However, both CDC and the states are no longer receiving the necessary funding to sustain the level of preparedness they have worked so hard to build. CDC has and is currently developing methods that will enable laboratories to test more samples in a shorter time. However, these methods require expertise, training courses and laboratorians’ time, all of which require adequate funding.

In 2006, five new laboratories were designated as Level 1, which is the level capable of providing surge capacity to CDC for more rapid detection of the most dangerous chemical agents. Studies by the Integrated Consortium of Laboratory Networks have shown that our nation needs at least 10 Level 1 laboratories in order to handle the number of samples anticipated during a chemical event of national significance. Yet, the funding for these national assets has not increased to reflect the increased number of laboratories and the increased number of samples that are projected to be needed to respond to a major incident.
UNMET NEEDS

• Provide $10 million to CDC, as requested by the FY09 proposed Presidential budget, to build a radiological component of the Laboratory Response Network.
• Direct CDC to include funding in the Public Health Emergency Preparedness grant for radiochemistry activities.
• Provide additional funding to CDC to develop methods and to provide technology transfer to state and local laboratorians.

Since the 1950s, the threat of a radiological event evokes fear in hearts around the world. However, radiological preparedness in laboratories has long been ignored. It was not until a recent hearing in the House Committee on Science and Technology that most people understood there is a complete lack of capacity to screen and test for radionuclides. During this hearing, members of Congress expressed concern about the lack of readiness for a radiological event. However, they have yet to appropriate funding to improve this.

CDC is developing unique laboratory measurements in urine to determine whether people have radionuclides in their bodies and, if so, how much. This information will identify exposed individuals, assess their health risk and determine effective treatment. With the exception of a few radionuclides, it is not possible to determine this exposure without these new techniques being developed at CDC.

CDC’s development of the Urine Radionuclide Screen (URS) will need this for identifying which radionuclide a person is exposed to and the level of exposure or contamination. The URS is targeting more than 20 high-priority radionuclides on the basis of likely radiologic terrorism scenarios. Currently, CDC is working to complete the URS, which would provide results within 24 hours of receiving a sample.

Almost all state public health laboratories lack the capability to test human samples for the presence of radionuclides. This is due to a lack of funding and the workforce shortage affecting the radiochemistry field. Few new scientists are being trained on radiological analytical methods. Most laboratories do not have support for a radiological program and, therefore, there are few jobs for future radio-analytical scientists.

• On average, state public health laboratories have fewer than two trained staff for radiological activities.
• No state public health laboratory had high-resolution equipment for radiological analyses and only five laboratories have one that could be used for measuring radionuclides in Fiscal Year 2007.
Only 15 state public health laboratories can measure human specimens for radionuclides. Seventy-five percent of those laboratories can only measure for one radionuclide (Uranium). The recent assassination of Alexander Litvinenko illustrates just how quickly a radiation event can escalate. Only one person, Litvinenko, was targeted, but tens of thousands of people were potentially exposed. More than 1,000 people needed to be tested, and several buildings in the UK will be sealed for the next five years, due to contamination.

**RADIOLOGICAL LABORATORY RESPONSE NETWORK**

After a radiological event, there will be a myriad of questions: who was exposed, to what substance and to what extent. Experts’ opinions vary as to medical treatment but, in general, the treatment window varies between one day to two weeks. The current laboratory methods can return results within 3–21 days, assuming a method even exists. In an effort to improve state public health laboratory capacity, CDC has proposed adding a radiological component to the Laboratory Response Network (LRN-R.) In this network, five state public health laboratories would provide surge capacity to CDC to analyze samples for priority radionuclides using the URS. Having this capability will drastically reduce response time for providing local, state and federal decision makers with high-quality, interpretable analytical results in the immediate response phase of a radiologic or nuclear attack. This essential national radioanalytical laboratory capacity should markedly reduce morbidity and mortality resulting from a radiological or nuclear event.

To help address gaps in the nation’s ability to respond to radiologic terrorism, APHL is requesting:

- **$6.3 million** for developing and expanding CDC’s URS to measure 22 high-priority radionuclides. This extensive research effort includes:
  - Research on the best measurement approaches for approximately 11 of the 22 targeted radionuclides in human urine.
  - Supporting essential extramural research with Department of Energy national laboratories.
  - Purchasing specialized equipment and supplies, including instruments capable of measuring alpha, beta and gamma radiation, in addition to two high-resolution mass spectrometers.
  - Developing radiologic reference materials for method validation and proficiency testing.
  - Developing and maintaining both a clinical radiological proficiency testing program and a training and technology-transfer program.

- **$4 million** for establishing and maintaining five LRN laboratories to create and maintain regional radiological LRN capability. Funding would be used to:
  - Purchase specialized instruments, including those that can measure alpha, beta and gamma radiation, and high-resolution mass spectrometers.
  - Hire radiologic laboratory staff in states.
  - Support training for the radiologic lab staff.
  - Support participation in CDC’s proficiency testing program.