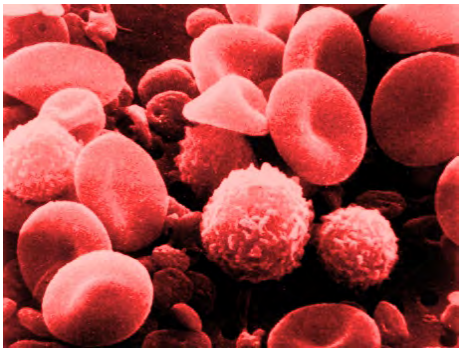
MINNESOTA MDH DEPARTMENT OF HEALTH



Public Health Laboratory

2010 Annual Report

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Message from the Director

According to the Greek philosopher Heraclitus, nothing is permanent except change. This first ever annual report from Minnesota's Public Health Laboratory comes at a time of great change: not only is there a new governor and new legislators, but there is much change ahead in healthcare as well as in science.

In the midst of all this change, the need that will remain constant is that of the Minnesota Department of Health to address issues that impact the health of the public. The Public Health Laboratory Division and its staff will need to continue to provide the high quality data that will guide the public health interventions and policy that are vital to the MDH mission of improving the health of all Minnesotans.

In its report entitled "The Future of the Public's Health in the 21st Century", The Institute of Medicine states: "Public health laboratories are a critical component of the disease surveillance resources of the public health infrastructure, providing essential capacity to detect, identify, and monitor the presence of infectious or toxic agents in populations and the environments in which those populations live."

The dedication of Minnesota's Public Health Laboratory staff was never more evident than during the H1N1 (2009) influenza pandemic response. Staff from the Environmental Laboratory, Newborn Screening Laboratory, Environmental Laboratory Accreditation, and Laboratory Support areas of the laboratory lent their time and expertise to assist their colleagues in the Clinical Laboratory with the surge of samples that arrived daily. As laboratory director, it was satisfying to see staff pulling together and working as a team and to know that planning for emergency preparedness resulted in an effective and coordinated response. Even more satisfying was that all other routine laboratory work continued during our response to the pandemic.

It is my hope that this annual report will serve not only as an accounting of PHL activities during fiscal year 2010, but that it will also double as an informational tool for our newly elected and appointed officials as well as for the general public so that they may come to understand and appreciate the fine work done by our dedicated staff. This document comes also with an invitation to visit our St. Paul laboratory and see the work done by public health professionals.

Joanne M. Bartkus

Joanne Bartkus, Ph.D.
Public Health Laboratory Director

Public Health Laboratory History and Overview

The Minnesota Department of Health's Public Health Laboratory (PHL) was established more than 100 years ago. At that time in history, the germ theory of infectious disease was being established in Europe and little was known about the impact of environmental contamination on the public's health. In the early 1900s, with the development of more sophisticated testing methods and instruments, the PHL became the premier laboratory in Minnesota with the ability to identify environmental hazards and diagnose epidemic infectious diseases. Today, the laboratory focuses on statewide surveillance for early detection of emerging public health threats; identification of rare infectious diseases, chemical, radiological and biological hazards; emergency preparedness and response; public health education; and assurance of quality laboratory practices through collaborative partnerships with clinical and environmental laboratories throughout the state.

The lab coordinates with local, state, and federal public health, environmental protection, and law enforcement officials to detect, investigate, prevent, and control public health threats.

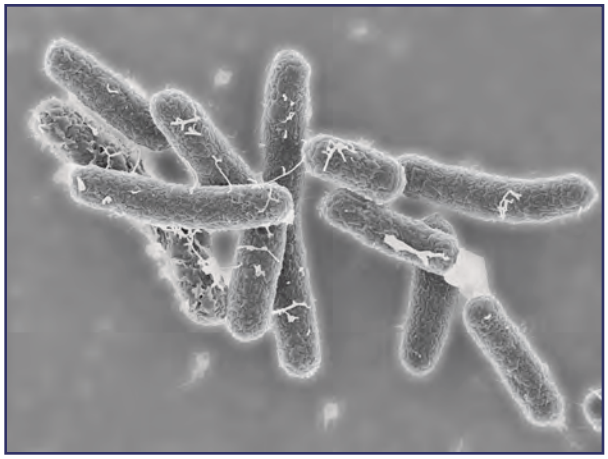
The laboratory performs a wide array of public health testing activities and cultivates public and private partnerships at the local, state, and national levels. In collaboration with environmental health programs, the lab develops testing methods and analyzes samples of air, water, wastewater, sludge, soil, wildlife, vegetation, and hazardous waste for the presence of toxins. The lab works closely with acute disease epidemiology programs to detect possible infectious disease outbreaks, provide information to focus disease outbreak investigations, and provide data to support the planning and implementation of effective public health interventions. The lab partners with hospitals, clinics, and other clinical laboratories to screen newborns for treatable congenital and heritable diseases. Through training, consultation, reference, and confirmatory testing, the lab increases the testing capacity of Minnesota hospitals and clinics. The lab coordinates with local, state, and federal public health, environmental protection, and law enforcement officials to detect, investigate, prevent, and control public health threats.

In October of 2005, the laboratory moved into a new energy efficient and secure facility. The building contains large open laboratory areas, a training laboratory, biosafety level 3 areas, administrative offices, and conference rooms. The new laboratory was designed and built to safely handle potentially hazardous biological, chemical, and radiological agents of known and unknown origin, including emerging infectious disease pathogens of public health significance.

The core laboratory activities are supported by a laboratory services section that receives, logs, and processes 165,000 total clinical, newborn, and environmental samples per year. The services group also handles routine laboratory communications, report distribution, purchasing, and database development.

During Fiscal Year (FY) 2010, the laboratory performed 70,020 tests on clinical specimens for infectious bacteria, viruses, fungi, and parasites for assessment of infectious disease trends and investigation of food and water borne disease outbreaks; analyzed 43,595 samples to detect chemical and bacterial contaminants in water, soil, and air for threats to human health; screened 69,363 infants for more than 50 treatable, life-threatening congenital and heritable disorders; and accredited 142 environmental laboratories.

Clinical Laboratory



Overview

The Clinical Section of the PHL is staffed by 40 professionals with expertise in microbiology, molecular biology, virology, immunology, and clinical laboratory science. The main functions of the Clinical Section are surveillance testing, diagnostic testing, and reference testing for bacteria, viruses, fungi, parasites, and toxins of public health importance. This amounts to over 70,000 tests per year for nearly 200 infectious agents.

Surveillance for communicable diseases is a critical component of assessing and maintaining the health of a population. The Clinical Section provides laboratory data in support of MDH's Infectious Disease Epidemiology Prevention and Control Division (IDEPC). Disease reporting and surveillance are centralized at the state level and guided by Minnesota Rules Governing Communicable Diseases. Designated pathogens must be submitted to PHL for additional testing (http://www.health.state.mn.us/divs/idepc/dtopics/reportable/rule/poster.html). The Clinical Section uses genetic fingerprinting to link pathogens to one another, searching for clusters or common sources of infection. Other testing allows the Clinical Section to monitor trends in pathogen characteristics such as antibiotic resistance.

The Clinical Section uses genetic fingerprinting to link pathogens to one another, searching for clusters or common sources of infection.

While diagnostic testing is best performed in hospital and clinic based private laboratories close to the patient, the Clinical Section maintains the capability to diagnose certain diseases when testing is not available in private laboratories.

The Clinical Section also functions as a reference laboratory to assist private laboratories throughout the state with identification of unusual pathogens or confirmation of test results. Staff is available to consult by phone and to provide educational opportunities for laboratory and other appropriate healthcare partners.

Foodborne Diseases

One of the more visible activities of the Clinical Section is foodborne disease detection and surveillance. Recently, routine testing of Minnesotans with *Salmonella* led to a national recall of contaminated eggs. The following story illustrates the Clinical Section's role and the many partnerships required during a foodborne disease investigation.

MDH PHL Instrumental in Detecting National Outbreak

From May – July 2010, MDH identified three *Salmonella* Enteritidis outbreaks associated with consumption of eggs at three separate restaurants. To identify these outbreaks: 1) clinical laboratories performed stool cultures on 111 patients to search for pathogens such as *Salmonella* and *E. coli,* then sent positive cultures, in this case *Salmonella*, to MDH in accordance with the disease reporting rule. 2) PHL identified the pathogen and performed subtyping to further differentiate the bacteria. Isolates with the same subtype, or fingerprint, are more likely to have come from a common source such as a food product. 3) As is routine in Minnesota, IDEPC conducted extensive food history interviews of all cases, which led to detecting the source of the three outbreaks and preventing foodborne illness in Minnesota. MDH collaborated with the Minnesota Department of Agriculture (MDA) to trace the eggs to the company that produced them and stopped distribution.

In August, the California Department of Public Health (DPH) announced that they had traced several clusters of *S.* Enteritidis to one egg producer. Egg tracebacks conducted by MDA based on the MDH outbreak investigations led to the same producer. MDH collaborated with MDA, Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Colorado DPH and California DPH to determine that eggs from this producer were responsible for several outbreaks and resulted in the recall of over 500 million eggs, thus preventing additional human illness.

Unexplained Death (UNEX) Program Utilizes Cutting Edge Technology

Surveillance testing like that performed for UNEX provides new awareness and can lead to practice changes in clinical, epidemiology, and laboratory arenas.

The Clinical Laboratory Section's highly skilled staff are capable of developing new test methods when new diseases emerge or disease trends change. Surveillance for unexplained deaths and critical illness of possible infectious cause began in September 1995. Cases are reported by clinicians and medical examiners, evaluated by MDH epidemiologists, and testing is performed by the Clinical Section in collaboration with the CDC. This program played an important role in identifying deaths due to H1N1 influenza in 2009.

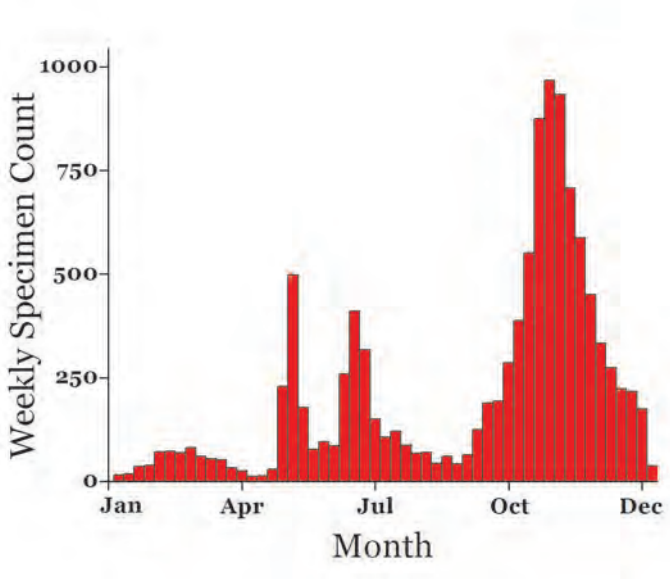
The surveillance now includes Sudden Infant Death Syndrome (SIDS) Infectious Disease Surveillance. The laboratory is testing Minnesota SIDS cases for an array of viral pathogens; most of these tests were developed on site. Surveillance testing like that performed for UNEX provides awareness of new diseases and can lead to practice changes in clinical, epidemiology, and laboratory arenas.

New Tick-Borne Virus Identified in Minnesota

Due to the UNEX program, the Clinical Section identified a virus previously not detected in Minnesota. In 2008, a 10 year-old male developed severe rash, fever, difficulty speaking, and partial paralysis following a tick bite. Testing at MDH revealed infection with Powassan (POW), an extremely rare virus. This was the western-most case of POW ever identified in the United States. Because POW is an emerging cause of serious human illness in Minnesota, MDH began a surveillance program to identify POW in ticks and in humans. In 2009 and 2010, MDH detected four Minnesota and two Wisconsin cases of POW, and determined that POW is present in specific tick species in certain regions of Minnesota. MDH will continue to monitor ticks and acute human illness for this serious and emerging pathogen.

Pandemic Influenza Response

In April 2009, one day after a novel strain of influenza was identified in Texas, MDH began planning a response to a potential influenza pandemic in Minnesota. MDH PHL, in collaboration with MDH IDEPC, began notifying hospitals, clinicians, Minnesota Laboratory System (MLS) labs, and other health care providers of the need for heightened surveillance. Through this enhanced surveillance, MDH identified the first Minnesota case of novel H1N1 (2009 H1N1) within days of the Texas identification. This newly emerging strain of 2009 H1N1 could not be identified by normal diagnostic laboratory tests, leaving PHL to provide the only diagnostic testing in the state. Rapid diagnostic influenza testing was a change from the Clinical Section's usual surveillance monitoring for the vaccine strains of influenza. The Clinical Section rapidly implemented a new CDC approved assay for 2009 H1N1 detection. During 2009, PHL staff tested 11,158 specimens from hospitalized patients, helping characterize the spread of disease throughout Minnesota.



Through the MLS, the Clinical Section provided laboratories in the state with up-to-date information on specimen collection, transport, submission requirements, testing, and results reporting. Daily and weekly summaries of specimen volumes were provided to IDEPC and Command and General Staff. PHL staff was cross-trained to provide surge capacity for the many responsibilities involved with the influenza testing and results delivery processes. PHL increased testing capacity and expanded capabilities to include antiviral drug resistance determination. Throughout the response, PHL sent 2009 H1N1 isolates to CDC to help characterize the pandemic nationally. In addition, PHL provided support for several general response functions, such as staffing for hotline operations and Command and General Staff roles. All of these efforts helped determine risk factors, severity of disease, and priority for vaccine distribution when in limited supply.

Testing for a Wide Spectrum of Diseases and Public Health Threats

Pathogens are studied for changes in virulence, changes in serotype that may decrease vaccine effectiveness, and for emergence of antibiotic resistance.

The Clinical Laboratory also performs surveillance testing to characterize invasive pathogens. Pathogens are studied for changes in virulence, changes in serotype that may decrease vaccine effectiveness, and for emergence of antibiotic resistance. Results of this testing are shared with Minnesota clinicians in MDH's annual antibiogram. This provides valuable information as to the susceptibility and resistence patterns to assist in treatment. The laboratory has responded to emergence of antibiotic resistance in bacteria by implementing screening and confirmatory tests to assist clinical laboratories and support surveillance for already existing and emerging mechanisms.

During FY 2010, the Clinical Laboratory analyzed the following samples:

9,260	Syphilis
8,720	Influenza
5,475	Routine air samples for biothreat agents
5,355	Tuberculosis
2,783	HIV
2,427	Rabies
794	Blood or intestinal parisites
373	Pertussis
218	West Nile Virus

Communication, Outreach, and Education

The Clinical Section's activities rely on strong relationships with many partners. Several programs and tools have been developed that assist in communication, outreach, and education to our partners. Below are several examples of the outreach programs and the impact they have on providing quality laboratory practice for the State of Minnesota.

Regional Clinical Laboratory Conferences

Through the Sixth Annual Regional Emergency Preparedness Laboratory Conference, Clinical Section Emergency Preparedness staff brought training to the eight Healthcare System Preparedness Program regions in the state. Topics included bioterrorism agents, how to identify them and who to call, and an update on public health issues. With more than 230 participants from more than 130 facilities statewide, attendance has remained steady over the years.

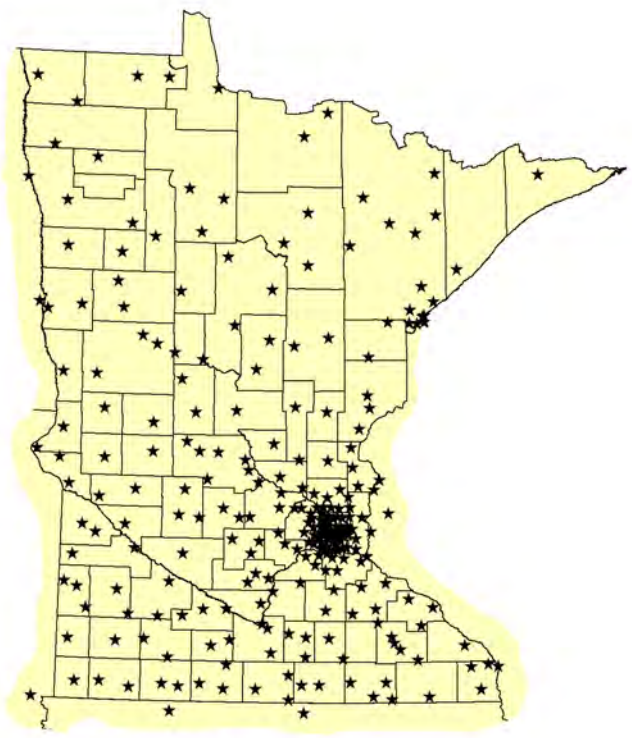
Clinical Laboratory Science Internships

As the overall number of laboratory education programs continues to decline nationwide, the national shortage of trained professionals in public health and clinical laboratory science continues to grow. In contrast, Minnesota is experiencing increasing enrollment in clinical laboratory science programs with a subsequent increase in demand for clinical training sites. In 2009, the University of Minnesota Clinical Laboratory Science program (UM-CLS) expressed to PHL a critical need for clinical microbiology training sites. In response, PHL partnered with UM-

CLS to provide a comprehensive clinical laboratory experience. The internship allows students to gain hands-on microbiology training from a unique public health perspective. As the UM-CLS program continues to expand and the need for clinical training sites grows, the PHL program has expanded to eight students.

Minnesota Laboratory System

The MLS is a statewide, voluntary network established over 10 years ago and maintained by PHL to facilitate inter-laboratory communication, collaboration, and cooperation. Its members include MDH PHL, over 400 public and private clinical laboratories, and veterinary and agriculture laboratories. A vital component of this system is electronic connectivity among members. In addition to providing a laboratory network essential for statewide emergency preparedness and response, the MLS also plays a key role in detecting and investigating common and emerging infectious disease outbreaks, monitoring trends in antibiotic resistance, providing and receiving continuing education and training, establishing safe transport of specimens, and promoting quality laboratory practice.



★ MLS Laboratory

Environmental Laboratory

Overview

The Environmental Section is a full service chemistry laboratory collaborating with multiple state and federal partners to carry out environmental projects in support of public health issues. The laboratory tests for organic and inorganic chemicals, as well as radioactive and microbiological contaminants. In FY 2010, the Environmental Section performed over 95,000 analyses on 43,595 samples. Data generated are used to support drinking water protection, groundwater and surface water monitoring, and the characterization of hazardous waste sites and their impact on public health and the environment. Sources of samples include drinking and surface water, air, soil, hazardous waste, vegetation, blood, urine, and workplace environments.

The chemistry laboratory has state-of-the-art instrumentation which enables it to actively develop analytical methods for emerging environmental contaminants (e.g., perfluorochemcials, pharmaceuticals, ethanol) and to provide biomonitoring (determining presence in the human body) of environmental chemical contamination.

The Section is an integral element of an all-hazards 24/7 response for public health and environmental emergencies in Minnesota. In partnership with the MDH Well Management Section, the Environmental Section takes a proactive role in preparing for emergency response to annual spring and unexpectded flooding. They coordinate to assist private well flood victims by offering well testing for Total Coliform at no cost to the owner. In 2010, the lab prepared 1,000 flooded well kits for distribution in anticipation of flooding, and then received and analyzed 122 samples.

The majority of the Section's test results are used by MDH or Minnesota Pollution Control Agency (MPCA) to demonstrate compliance or non-compliance with Environmental Protection Agency's (EPA) drinking water or MPCA's surface water, hazardous waste site, and effluent rules. Testing also provides comparisons of pollutant loading in comparable waters in different locations across the state. The Environmental Section also participates in innovative projects such as those described below.

Current Environmental Laboratory Projects

Mercury

Mercury is a potent neurotoxin found throughout the environment due to atmospheric deposition. Methyl mercury is of particular concern because it can enter the food chain and accumulate in game fish, such as bass and walleye, at levels that become dangerous for human consumption. Methyl mercury is typically a small fraction of the mercury that is present in surface waters. Even at low levels, consuming too much contaminated fish can cause problems including increased irritability, impaired memory, slurred speech, blurred vision, and impaired gait. The standard drinking water method for determining mercury is not sensitive enough (ug/L or parts per billion) to detect mercury at environmentally relevant levels (ng/L or parts per trillion), so this analysis requires additional care not to inadvertently contaminate the sample once it arrives at the lab.

The mercury data produced at the MDH lab is used by the Minnesota Department of Natural Resources (DNR) and multiple groups at the MPCA. The DNR is investigating whether sulfate loading from mining activities impacts mercury methylation (conversion of inorganic mercury to methyl mercury). One group at MPCA is using the data to define the occurrence and distribution of mercury in Minnesota's groundwater. Another MPCA group is working to compare mercury results to the water quality standards, assess the methylation efficiency of waters in the state, relate bioaccumulation factors of mercury levels in fish to the mercury levels in the waters where they are found, and establish maximum contaminant levels. A third group is working to address ambient trace metal levels statewide to determine if any sampling points exceed the water quality standards, detect statewide spatial trends, and support water assessment and research programs.

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Biomonitoring

In 2007, the Minnesota legislature directed MDH to develop and implement a biomonitoring pilot program. Biomonitoring is the measurement of the body burden of toxic chemical compounds, elements, or their metabolites in biological substances. The directive prescribed pilot projects for four separate chemicals: arsenic, perfluorochemicals (PFCs), mercury, and one that was yet to be determined. Pilot projects resulting from that legislation include the Minneapolis Children's Arsenic Study, the East Metro PFC Biomonitoring Study, the Lake Superior Mercury Biomonitoring Study, and the Riverside Birth Study in which environmental phenols and cotinine are measured.

The Minneapolis Children's Arsenic Study measured arsenic exposure of children living in specific contaminated neighborhoods of south Minneapolis. The analyses are able to determine if the arsenic present in the children's urine is derived from dietary sources (relatively non-toxic) or from environmental sources (more toxic). The above-normal levels of total arsenic found were predominately the organic, or relatively non-toxic, arsenic species.

The East Metro PFC Biomonitoring Study is measuring the exposure of adults who currently have or have had drinking water with PFC contamination. The contamination was the result of infiltration of a drinking water aquifer by PFCs from a nearby landfill. PFC levels found in subjects' urine were moderately elevated in comparison with results reported for the US general population. Concentrations were much lower than levels found in occupational studies of PFC manufacturing workers. A follow-up study with the same population has just been initiated for the purpose of understanding more about PFC exposures and for tracking the efficacy of drinking water interventions that are now in place.

The Lake Superior Mercury Biomonitoring Study is conducted in collaboration with the Wisconsin and Michigan state newborn screening programs and is designed to assess population-level exposure to mercury by measuring the level of mercury in newborn dried bloodspots. The level of mercury found in the newborns'

blood is indicative of the mothers' exposure to mercury during pregnancy. This study is currently analyzing bloodspots from Wisconsin, Michigan, and Minnesota. The Riverside Birth Study (RBS), conducted by the University of Minnesota, enrolls women from prenatal clinics to measure the correlation between maternal exposures during pregnancy and presence of specific chemicals in neonatal infant specimens. The MDH pilot study is ancillary to the larger RBS and measures exposure to environmental phenols and environmental tobacco smoke. This study is in the process of analyzing the samples. Data should be available in early 2011.

Emerging Contaminants

Pharmaceuticals and personal care product compounds are chemicals of emerging concern. The use and disposal of products containing these compounds can result in the contamination of surface waters, as wastewater treatment plants are not designed to remove these types of chemicals from an effluent. Likewise, drinking water treatment plants are not designed to remove pharmaceuticals and personal care products. This has resulted in the low level detection of many compounds including caffeine, hormones, pesticides and various pharmaceuticals in drinking water throughout the United States. MDH PHL has been working with MPCA to develop a method for the analysis of pharmaceutical and personal care products in surface water. This project has just begun with research and method development in 2010, with samples to be collected and analyzed beginning in early 2011.

Unregulated Contaminant Monitoring Rule

The 1996 amendments to the Safe Drinking Water Act (SDWA) required the EPA to establish criteria for state drinking water programs to monitor unregulated chemical contaminants in drinking water and to publish a list of contaminants to be monitored every five years. MDH processed samples for two of the analytical methods and tested for two pesticides, five flame retardants, and three explosive compounds. After successfully validating those methods, the lab analyzed samples over a two and a half year period

beginning in 2008. The results were all negative. The Unregulated Contaminants Monitoring Rule program provides information on the occurrence of these unregulated contaminants to permit an assessment of the number of people exposed and at what levels they are exposed. This data is the primary source of occurrence and exposure information the EPA uses to determine whether to regulate these contaminants.

Educational Outreach

The Environmental Laboratory staff frequently provide training to data users. At a training session for the Minnesota Wastewater Operator's Association, lab staff presented information demonstrating how even the smallest laboratory could relatively easily meet State accreditation requirements in a microbiological laboratory.

The lab also provides training to the MPCA and MDH Environmental Health Division including direct training, lab tours, one-on-one training, and conference calls. The lab is currently working on a collaborative training effort with MPCA to conduct training in Spring 2011 that will follow the process of an MPCA project from conception to completion, pinpointing issues along the way that need to be addressed to improve overall processing and data quality. The lab also collaborates with the University of Minnesota and provides student tours to encourage workforce development.

New Laboratory Information Management System

Until 2010, the Environmental Lab was supported by an environmental Laboratory Information Management System (LIMS) that was developed in-house. The system was not optimal for supporting efficient internal operations, meeting client requirements, or fulfilling federal regulations for documentation. In June 2009, the laboratory purchased Element Data System® from Promium, LLC to addresses these needs. Element® is a configurable, off-the-shelf, production-oriented LIMS system that significantly reduces costs (estimated annual savings of 65%) and increases analytical output through improved efficiency. After completing configuration, the new LIMS was put into use in May 2010.

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Newborn Screening Program

Overview

Newborn screening is a cornerstone of public health practice in Minnesota. It gives the 70,000 infants born annually access to early diagnosis, follow-up, and treatment for over 50 serious or life-threatening disorders. Testing is performed by staff members at the PHL and by a contract lab at the Mayo Clinic on a few drops of blood collected from the heel of the newborn onto special filter paper. Additional program staff alert physicians to abnormal results, assure all screening recommendations are followed, and educate parents and professionals about screening.

The disorders on the screening panel are determined by the Commissioner of Health with guidance from the Newborn Screening Advisory Committee. Newborn screening enjoys broad support among health care professionals, parent groups, public health professionals and policy makers. However, concerns about some screening practices have been raised and discussion of these concerns is ongoing at both the state and national level.

During FY 2010, there were:

69,257	Births registered
69,363	Infants screened
71,896	Specimens tested
152	Infants identified with metabolic, endocrine, or hematologic disorders
220	Infants identified with hearing loss
100	Number of refusals for screening
427	Number of requests for specimen destruction

Newborn Screening Laboratory

Approximately 200 dried blood spot specimens are screened each day, Monday through Saturday, for galactosemia, biotinidase deficiency, congenital adrenal hyperplasia, congenital hypothyroidism, cystic fibrosis, sickle cell disease, and other hemoglobinopathies. The lab partners with Mayo Clinic for metabolic screening to detect amino acidemias, fatty acid oxidation disorders, and organic acidemias. The laboratory identifies infants at risk for these disorders and communicates testing results to genetic counselors, who report results to the infant's primary care physician.

As part of its ongoing commitment to improved testing quality, the laboratory implemented a new method for detecting biotinidase deficiency. Biotinidase deficiency is an autosomal recessive disorder that results from the defective activity of the biotinidase enzyme. Newborns are asymptomatic. If an infant is not screened and/or left untreated, symptoms begin to appear later in infancy and can include seizures, developmental delay, facial rash, ataxia, and progressive vision and hearing loss. Affected children require lifelong treatment and monitoring by both primary care and specialty providers. This new method allows more precise and accurate results.

Babies affected with SCID are healthy at first but die of recurrent severe infections in their first year of life. There is an exceptional outcome when detected and treated in early infancy.

The laboratory has been working since December of 2009 to develop a complex method to detect severe combined immunodeficiency (SCID) in dried blood spot specimens. Babies affected with SCID are healthy at first, but die of recurrent severe infections in their first year of life. There is an exceptional outcome when detected and treated in early infancy. Currently, Wisconsin and Massachusetts screen for SCID in newborns. Minnesota's Newborn Screening Advisory Committee recommended SCID to the Minnesota Commissioner of Health for addition to Minnesota's screening panel in October of 2010.

Given the essential nature of newborn screening it is important to make contingency plans to continue screening in the event of an emergency. The laboratory participated in four drills with newborn screening programs in Iowa and Missouri through the Emergency Management Assistance Compact (EMAC). This series of successful exercises demonstrated how Minnesota's infants could be screened in a real disaster and provided guidance to the PHL for supporting neighboring states in distress.

Newborn Screening Offers Hope to Premature Infants

The Newborn Screening Program collects three specimens in the first month of life from infants weighing less than four pounds to get accurate results on these sick and premature Minnesotans. In the course of reporting abnormal results in cystic fibrosis (CF) screening, one of the genetic counselors noted that some infants had initial specimens that were normal for CF but whose second tests had elevated levels of the analyzed enzyme. This was odd, but not alarming, until conversations with neonatologists revealed that many of these infants were sick or dying because of perforated intestines.

With the support of the State Epidemiologist, a group of neonatologists and MDH staff confirmed the association between elevated enzyme and serious neonatal complications. With cooperation from the University of Minnesota Amplatz Children's Hospital and Children's Hospitals and Clinics of Minnesota, PHL is now testing specially collected samples from babies weighing less than two pounds who are at high risk for intestinal perforation. Collaborators hope to use this assay for pre-symptomatic detection (currently unavailable) so these tiny babies can receive life-saving treatment.

Newborn Screening Short Term Follow-up

The Newborn Screening Short Term Follow-Up Unit (STFU) is charged with ensuring that all children identified with positive, abnormal, or REFER (non-passing) results by newborn screening and newborn hearing screening receive timely follow-up and diagnostic evaluations. The STFU Unit partners with Minnesota birth hospitals and clinics as well as specialists to provide timely and effective follow-up of newborn screening results.

The STFU Unit continues to develop novel follow-up processes. Continuous quality improvement has greatly enhanced follow-up in the state over the last four years, and has resulted in a seamless screening process for Minnesota infants and families. Examples of follow-up work are outlined below.

Because children begin to learn language from the moment they are born, identifying children with hearing loss as soon as possible is pivotal to their communication and

lifelong achievements. Since newborn hearing screening became mandatory in September 2007, the STFU Unit has worked with health care providers to decrease the number of children who fail their newborn hearing screen and yet do not get appropriate medical follow-up (are lost to follow-up). National lost to follow-up rates approach 50%, while in Minnesota this number is approximately 16%. The STFU Unit is one of the first hearing screening follow-up units in the country to utilize an approach which integrates the active processes used in regular newborn screening follow-up with hearing follow-up. Newborn Screening strives to identify all children with congenital hearing loss as early as possible, but ideally before three months of age.

The STFU unit is one of the first hearing screening follow-up units in the country to utilize an approach which integrates the active processes used in regular newborn screening follow-up with hearing follow-up.

During FY 2010, a gap was recognized in follow-up efforts for children identified as having sickle cell disease or other significant hemoglobinopathies. These disorders are more common in minority populations where infants and their families were often unable to coordinate their follow-up visits and were thus falling through the cracks of the medical system. MDH worked with the specialty clinics serving these infants to help identify areas of improvement in follow-up and services. The Newborn Screening Program now provides staff expertise to attend these clinics and provide much-needed support and coordination for these families.

Newborn Screening Communication and Education

The Communication and Education Unit in Newborn Screening works to educate providers, facilities, expectant parents, and the general public on all facets of newborn screening. The Unit provides education through in-person trainings, conferences/events, audience-specific print pieces, routine upkeep of our website, and by providing one-on-one 'just-in-time' informational training. MDH staff reports positive screening results to primary care providers and ensures connections with specialty care providers. Audiologists work with providers and facilities to work towards best practices regarding newborn hearing screening.

The Role of MDH Follow-Up

Sarah was born deaf in one ear, but her family and doctor didn't notice. Research has shown that unrecognized unilateral hearing loss like Sarah's can lead to delayed speech, school problems, and even behavioral problems.

Sarah failed her hearing screen at birth, and, as is now required by law, the result was reported to MDH. Unfortunately, Sarah's mom left the hospital thinking that Sarah's hearing was fine and that the testing equipment malfunctioned. The MDH STFU staff contacted the clinic and urged them to do more sophisticated testing on Sarah's hearing. Because of the initial misinformation, Sarah's mom was reluctant to make the testing appointment, but after more information was provided from the Newborn Screening Program, the testing was done and Sarah's hearing loss was identified. She is now getting help, and because of the comprehensive nature of the NBS program, will avoid many challenges she could have faced.

The Communication and Education Unit has worked diligently to expand education regarding newborn screening, not only for providers, but for expectant parents. During FY 2010, staff members provided 30 trainings to more than 600 clinicians, laboratorians, nurses, birth registrars, audiologists, administrators, and local public health staff. Staff created a number of new educational pieces including a very successful "coupon" promoting educational training sessions and a number of pieces to address challenges related to hearing screening outcomes. The "Latest News" section of the website at www.health.state.mn.us/newbornscreening is routinely updated with pertinent stories and information relevant to screening in Minnesota.

During FY 2010, Newborn Screening staff engaged in significant planning around prenatal education. A prenatal awareness "print" piece was finalized and a survey was created to assess pre- and post-awareness of newborn screening among expectant parents. The Newborn Screening Program continues to work toward integrating prenatal education into healthcare systems across the state.

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A Rare Amino Acid Disorder: A Life-Saving Partnership

Two days after Sanna was born, the NBS lab received her newborn screening specimen. Analysis began immediately at PHL and Mayo. The next morning the genetic counselor received a call from the Mayo metabolic geneticist. Initial analysis of Sanna's specimen was consistent with a rare abnormality of amino acid metabolism that is usually fatal in the first week of life if not treated. Confirmation of the result would take another hour, but MDH staff began the process of finding the baby. The first call was made to alert the metabolic specialist at the University of Minnesota who would coordinate the baby's care.

Sanna's clinic was unaware that she had been admitted to Children's Hospital the night before because her parents noticed she was lethargic and not feeding well. The treating neonatologist sought guidance from the metabolic specialist in evaluating the baby. Because of newborn screening, the specialist knew that it was very likely that Sanna's symptoms were caused by the disorder. Sanna was transferred to the University and received intensive treatment for her metabolic abnormalities. The baby was discharged home in just a few days. Although she will need ongoing medical care, Sanna and her family will have many happy years together because of newborn screening and timely connection to services.

Environmental Laboratory Accreditation Program

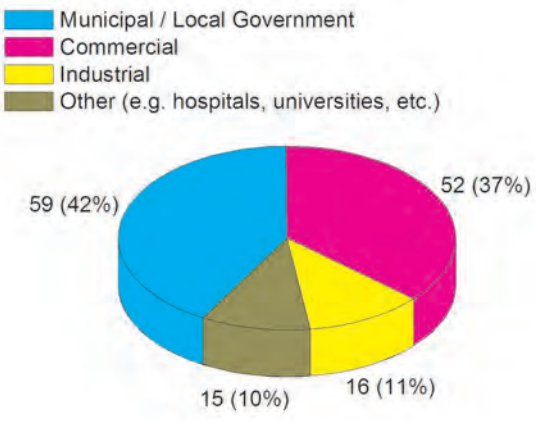
Protecting Public Health by Ensuring Validity of Environmental Data

The Minnesota Department of Health Environmental Laboratory Accreditation Program (MN-ELAP) was established in 1989 to help ensure laboratories submit reliable and consistent data to Minnesota's environmental programs. MN-ELAP offers accreditations designed to accommodate the needs of state and federal environmental programs including testing required by the Underground Storage Tank Program, Clean Water Act, Resource Conservation and Recovery Act, and the Safe Drinking Water Act.

MN-ELAP develops procedures and requirements to ensure accredited laboratories produce accurate and precise test results. Accreditation requires the laboratory's quality systems, staff, facilities, equipment, test methods, records, and reports be evaluated using objective and measurable criteria. The 2009 Minnesota Statutes require the Commissioner of Health to accredit laboratories against a national standard adopted by the National Environmental Laboratory Accreditation Program (NELAP) of The NELAC Institute (TNI). Effective July 1, 2009, laboratories accredited by the department must comply with the 2003 NELAC standard, the current adopted standard for NELAP.

The State of Minnesota's accredited laboratory community consists of 142 laboratories inclusive of wastewater treatment, drinking water, industrial, commercial, governmental, and tribal laboratories.

Minnesota's accredited laboratory community consists of 142 laboratories inclusive of wastewater treatment, drinking water, industrial, commercial, governmental, and tribal laboratories. Approximately twenty percent of the laboratories are out-of-state laboratories that seek and maintain laboratory accreditation with the State of Minnesota.



Promoting Excellence through National Participation

Environmental laboratory accreditation standards are developed by expert committees within the non-profit organization, TNI, using a consensus process required by the National Technology Transfer and Advancement Act administered through the U.S. Office of Management and Budget. Widely applicable standards have been used by nationally-recognized state accrediting agencies since 2001 and by MDH since October 2006 (Minn. Rules, Chapter 4740).

The national program establishes partnerships between participating states in the form of reciprocal agreements and aids in controlling cost for MDH and for the regulated community. By adopting a national standard that is accepted by a greater number of states, the department obtained an approximate seven-fold increase in the number of reciprocal agreements. These partnerships produce significant time and cost savings for the department.

On December 23, 2009, the Laboratory Accreditation Program submitted an application to be a nationally-recognized Accreditation Body under the National Environmental Laboratory Accreditation Program of TNI. Accreditation Bodies (AB) are state or federal agencies that have the legal authority to perform assessments and issue accreditations. The onsite evaluation occurred in May 2010. In August 2010, MN-ELAP became the 15th TNI Accreditation Body and the 14th state with an accreditation body recognized.

In 2009, the MN-ELAP assessors conducted 46 announced or unannounced onsite assessments. During an onsite assessment, the assessor reviews the laboratory's documentation, conducts lab staff interviews, and reviews laboratory practices to evaluate the laboratory's capability to perform analytical testing. Laboratories seeking or maintaining MN-ELAP accreditation are assessed at least once every two years to determine initial or continual compliance with State of Minnesota requirements for environmental laboratory accreditation.

The MN-ELAP staff offers compliance assistance to all laboratories through scheduled training events, web conferences, and onsite visits. The training events for 2009-2010 included topics regarding technical compliance with methods as well as implementation of the national standards.

Community Outreach: Kids' Groundwater Festival Makes a Big Splash

As a means to reaching out to the community, MN-ELAP staff volunteered at the 17th Annual Douglas County Kids' Groundwater Festival. The Kids' Groundwater Festival is an annual event where fourth graders can learn about ground and surface water, the importance of good water quality, ways to protect water quality, and ways to improve contaminated water. Volunteers with expertise in environmental sciences come together to do presentations, demonstrations, and hands on activities. Participating kids have fun while learning how to protect water resources.

Improving Performance through Better Technology

The ELDO (Environmental Laboratory Data Online) system is an innovative, user-friendly system that streamlines laboratory applications, documentation, and proficiency testing results for both the program staff and the regulated community. Minnesota leads the nation in the development and use of a comprehensive environmental laboratory online accreditation system.

The MN-ELAP attributes a portion of the user-friendly features of the online database to the great feedback received during design meetings held with the MN-ELAP Advisory Committee. In April 2010, the program began beta-testing the new application with volunteers from the accredited laboratory community. The beta-testing resulted in very few changes and received positive remarks from the testers. The program expects an implementation date within FY 2011.

Minnesota leads the nation in the development and use of a comprehensive environmental laboratory online accreditation system.

As a result of ELDO's streamlined design, online access, and easy-to-use interfaces, many other states have expressed interest in using the accreditation system. The cutting-edge ELDO system will be shared with counterparts in other states across the nation.

Quality Improvement

Minnesota's Laboratory System Improvement Program

In June 2010, PHL conducted a Laboratory System Improvement Program (L-SIP) assessment as part of a national initiative of the Association of Public Health Laboratories (APHL). The focus of the assessment was the Minnesota PHL "system", which includes all partners that contribute to the State's ability to meet the laboratory needs for assuring the health and well-being of all Minnesotans. Over 60 partners and stakeholders involved in all facets of the PHL were present. The ultimate goal was continuous quality improvement of these laboratory-affected programs.

Participants in the L-SIP assessment assessed Minnesota's Laboratory System against national model standards developed under each of the ten essential services of Public Health. An overarching theme that emerged was that although the Minnesota Public Health Laboratory System has many strengths, the following steps could sustain and improve the system for the future:

The ultimate goal of the assessment was continuous quality improvement of these laboratory-affected programs.

- Inventory stakeholders and services in the system and identify gaps;
- Formalize the state laboratory system, clarifying roles and responsibilities;
- Once the system is formalized, engage in ongoing quality improvement processes, including regular assessments with clear follow-up actions and accountabilities;
- Establish clear and effective communication across the system;
- Assure that the system maintains "forums", such as a research committee, that foster collaboration and innovation; and
- Promote the state public health laboratory system and career advancement for laboratory professionals.

The L-SIP assessment process provides a strong foundation for future efforts to improve the "system". To this end, the PHL received a grant to continue improvement efforts to develop a blueprint for an ideal public health laboratory system for Minnesota and establish an implementation work plan.

PHL Preparedness & Emergency Response

A key function of PHL is to provide emergency sample analysis of biological, chemical, and radiological materials that may result from an act of terrorism or other public health emergency. PHL is a member of several nationwide laboratory networks including the Laboratory Response Network (LRN), managed through the CDC; the Emergency Response Laboratory Network, managed through the EPA; and the Food Emergency Response Network, collaboratively managed by the FDA and the USDA. These laboratory networks are designed to wage a coordinated response in the event of a large scale emergency event.

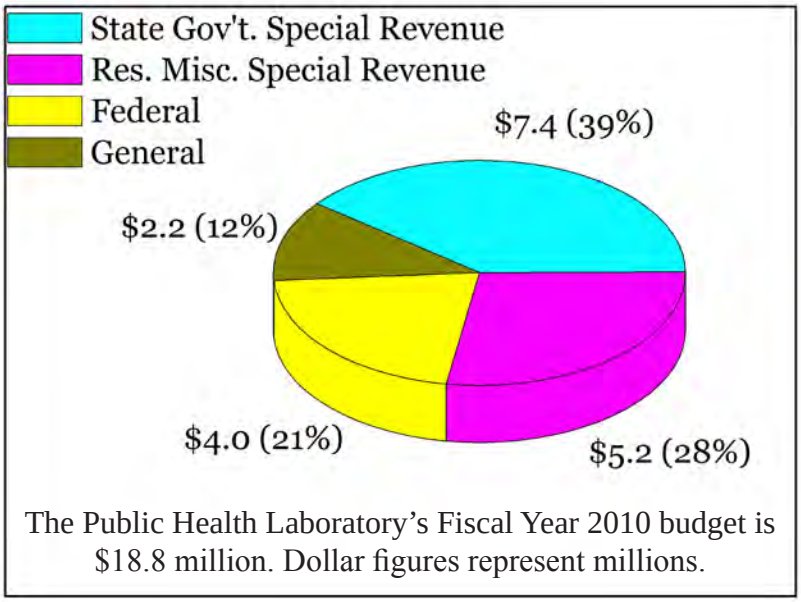
The Clinical Section of PHL serves as an LRN-B Reference level laboratory. Staff from the Emergency Preparedness and Response Unit provide statewide diagnostic and reference testing for the agents of highest concern, participate in test development studies in collaboration with the CDC, and provide training to Advanced Sentinel level laboratories in the Minnesota Laboratory System on the early detection and identification of biological agents of concern. As a LRN-C laboratory, PHL Environmental Section functions as a national resource for analysis of human specimens following exposure to chemical warfare agents, a responsibility shared with nine other laboratories across the country. PHL also plays a lead role in responding to radiological contamination events which may be the result of a release from a nuclear power plant or radiological dispersal device.

PHL screens unknown environmental materials that may be associated with a threatening correspondence or event. When such an event occurs in Minnesota, PHL works with the FBI, first responders, and MDH epidemiologists to assess the threat and identify the material.

PHL, Protecting Minnesota's Drinking Water

In 2010, Minnesota experienced an unprecedented string of break-ins at water treatment facilities throughout the state. Anytime a break-in occurs at a treatment facility there is concern that the water may have been tampered with. In coordination with MDH's Drinking Water Protection Section, local law enforcement, and the FBI, PHL played a lead role in ensuring the safety of the state's drinking water. To rule out the possibility of toxic chemicals, radiological agents and disease-causing organisms in the water supply, a coordinated response by many individuals throughout the laboratory was required. A vast array of tests were conducted and the data were analyzed quickly. In each of the break-in cases that occurred in 2010, PHL reported that the water was not contaminated within 24 hours of the samples arriving at the laboratory.

2010 Fiscal Year Budget



The Public Health Laboratory's Fiscal Year 2010 budget is $18.8 million. Dollar figures represent millions.

State Government Special Revenue Fund – The state government special revenue fund is a group of more than 20 accounts mostly in the Health and Human Services area. Money in the fund comes from fees and other charges. PHL collects fees for Newborn Screening and specimen handling that are managed in this fund.

Restricted Miscellaneous Special Revenue Fund – The special revenue fund includes numerous small accounts that have revenues dedicated to specific purposes. Most appropriations from special revenue fund accounts are statutory, but some are direct. Money in the fund comes from fees and charges administered by state agencies. The statute or law for special or dedicated purposes limits the expenditures of the fund so that receipts collected are appropriated for related expenditures.

Federal Fund – The federal fund accounts for federal money received by state agencies. The fund receives grant-in-aid from the federal government. Money in the fund is available for expenditure in accordance with the requirement of federal law. There is a statutory appropriation of federal funds subject to a legislative review process. Some expenditure of federal funds may be through direct legislative appropriations.

General Fund – The general fund is the state's largest fund with the most flexibility. It is the revenue that has been deposited in the treasury for the usual, ordinary, running, and incidental expenses of the state government and does not include money deposited in the treasury for a special or dedicated purpose. Major revenue sources include individual income tax, general sales tax, corporate income tax, and statewide property tax.

Public Health Laboratory Science and Policy: Bridging the Gap

Technological advances in science have occurred at a rapid pace over the past couple of decades. The sequence of the first entire human genome was completed in 2003 and took 13 years using robots that worked 24 hours a day. Now, sequencing of a human genome can be completed using a single machine in just 4 weeks. New analytical instrumentation and methodologies such as mass spectrometry and polymerase chain reaction have enabled scientists to detect multiple chemical contaminants and infectious disease agents at increasingly low levels. These technological innovations have enabled scientists to demonstrate an increasingly complex web of interactions between chemical contaminants, infection, and lifestyle choices that because of differences in genetic makeup may lead to an adverse health effect in some persons, but not in others.

While these technologies exist, not all of them can, or should, be implemented in public health laboratories. For example, public health laboratories do not perform whole genome sequencing because the information would not be useful to public health practice. In addition, the pace of technological development has sometimes outpaced our ability to interpret the information in a public health context. This in turn has limited our ability to provide policy makers with the information necessary to develop public health policy.

In order to better inform policy-making, it is important for us to be able to understand and communicate the public health implications of the data that we generate. As a rule, scientists are good at communicating with other scientists and not nearly as good at communicating with policy makers and the public. It is incumbent upon us to make every effort to bridge that communication gap. We can do this by finding ways to interact with non-scientists and to better communicate our data and to understand the needs and concerns of policy makers and the public. This may be accomplished in part through information forums, advisory groups, or via intermediaries or external organizations that can speak the languages of both science and policy makers. It will also be necessary for public health professionals and policy makers to communicate with academic researchers to help guide the research that will ultimately provide the answers that we need to inform public health policy.

Glossary of Acronyms

AB	Accreditation Bodies
CDC	Centers for Disease Control and Prvention
CF	Cystic Fibrosis
DNR	Minnesota Department of Natural Resources
DPH	California Department of Public Health
ELDO	Environmental Laboratory Data Online system
EMAC	Emergency Management Assistance Compact
EPA	United States Environmental Protection Agency
FDA	United States Food and Drug Administration
FY	Fiscal Year
HIV	Human Immunodeficiency Virus
IDEPC	Minnesota Department of Health Infectious Disease Epidemiology, Prevention and Control Division
IVD	In Vitro Diagnostic
LIMS	Laboratory Information Management System
LRN	Laboratory Response Network
MDA	Minnesota Department of Agriculture
MDH	Minnesota Department of Health
MN-ELAP	Minnesota Department of Health Environmental Laboratory Accreditation Program
MPCA	Minnesota Pollution Control Agency
MLS	Minnesota Laboratory System
NELAP	National Environmental Laboratory Accreditation Program
NBS	Minnesota Newborn Screening Program
PFC	Perfluorochemical
PHL	Minnesota Department of Health Public Health Laboratory Division
POW	Powassan virus
RBS	Riverside Birth Study
SCID	Severe Combined Immunodeficiency
SDWA	Safe Water Drinking Act
SIDS	Sudden Infant Death Syndrome
STFU	Short Term Follow-Up
TNI	The NELAC Institute
UM-CLS	University of Minnesota Clinical Laboratory Science program
UNEX	Unexplained Death program

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