

Wisconsin State Laboratory of Hygiene's Role in Clinical Laboratory Improvement

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ABSTRACT

The clinical laboratory at the beginning of the 21st century is a highly automated, multi-faceted entity, capable of turning out complex test results on a variety of samples in a relatively short period of time. These test results are used by physicians to diagnose illness, establish treatment strategies, and monitor therapies for patients. They must be of the highest quality and reliability to insure that the course of action taken by the health care provider will lead to the best possible outcome for the patient.

INTRODUCTION

The Wisconsin State Laboratory of Hygiene (WSLH) has long played a major role in providing training and outreach activities to management and staff in hospital and clinical laboratories in Wisconsin with the intent of improving their capabilities. While much has been accomplished through extensive teaching efforts, improvement has also occurred through the development of interlaboratory survey programs, often referred to as proficiency testing. In a proficiency testing (PT) program, unknown samples are sent to participating laboratories that analyze them and report their results. The results from each laboratory are then evaluated by comparison to the known correct result or against other laboratories performing the same test; a performance evaluation is then sent to the participating laboratory. A major motivation for the WSLH to expand these activities has been both federal and state laws that require clinical laboratories to participate in PT programs. An equally important factor for taking on this teaching role and developing training opportunities for laboratories in Wisconsin has been our unique position and location within the University of Wisconsin.

The WSLH has a distinctive history of information and technology transfer to other laboratories. While this has often resulted from legislative initiatives, the more driving force has been the desire to bring new technology to the increasing number of laboratories providing services to the medical community throughout Wisconsin. This article describes how the WSLH has taken an activity that was largely driven by regulatory mandate—proficiency testing and laboratory accreditation—and developed programs that not only would fulfill the order of the law, but also help laboratories in a much broader way. Proficiency testing has provided WSLH with the opportunity to collect data related to the analysis of clinical laboratory specimens. These data have been processed and analyzed, providing information and knowledge that enables laboratories to better evaluate and compare test methods, to become familiar with emerging technologies, to identify and resolve problems, and to share experiences that would eventually lead to more reliable testing.

Prior to the mid-1960s, clinical laboratories were largely unregulated entities. Inconsistencies between laboratories were identified and found to be sufficient to cause Congress to enact the Clinical Laboratory Improvement Act of 1967 (CLIA-67).¹ Along with the Medicare/Medicaid provisions under the Social Security Act of 1965,² CLIA-67 established quality requirements for clinical laboratories to meet certain criteria and standards. While clearly a step in the right direction, the regulations covered only 12,000 hospital and independent laboratories, or fewer than 10% of all clinical laboratories in existence at that time. It would take another 2 decades before federal legislation would address this shortcoming.

Prior to the time when the federal government first recognized a need for laboratory regulation, the Wisconsin State Board of Health (BOH) had identified a need for the WSLH to develop and carry out evaluation programs to test and certify laboratories in the specific areas of water and milk sanitation, syphilis serology, and enteric bacteriology. Driven by both federal and state

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initiatives and the fact that all individuals planning to marry in Wisconsin were required to be tested for syphilis, the BOH had developed an interlaboratory PT program, in cooperation with the WSLH, for laboratories performing this test. Other PT programs in chemistry, hematology, and bacteriology were developed later, becoming an integral component of Wisconsin's BOH Laboratory Certification Program.³ The state recognized that CLIA-67 covered only a small fraction of the clinical laboratories in the state at the time and legislation was passed to extend regulations to any laboratory in the state serving more than 2 physicians.⁴ Because state regulations were more comprehensive than the federal, the Wisconsin program grew to more than 500 laboratories throughout the 1970s, 4 times the number than would have been covered if only federal laws were in place. In 1979, management and operation of the PT component of the Laboratory Certification Program was transferred to the WSLH, where it remained relatively unchanged through the 1980s.

CLIA '88

The ever-increasing number of laboratories and the expanding menu of available tests (primarily in physician offices) caused concern over the quality of tests being performed in laboratories not subject to minimum quality standards. Studies demonstrated that laboratories subjected to minimum personnel and quality requirements performed better than those that were unregulated.⁵⁻⁷ Congressional hearings and public reaction resulted in the Clinical Laboratory Improvement Amendments of 1988, or CLIA '88.⁸ Under this new federal mandate, more than 150,000 US laboratories were now required to meet minimum standards, and, depending on the testing performed, required to participate in a federally approved PT program. Anticipating the need and opportunity, the WSLH began to develop new PT programs and to modify several existing programs. The WSLH applied for and obtained federal approval, and began to provide an expanded level of service to Wisconsin laboratories as well as those beyond the state's borders. During the early years of CLIA '88, WSLH Proficiency Testing (WSLH PT) grew to include participation by almost 800 laboratories in Wisconsin and 3000 nationwide. WSLH PT became one of fewer than 10 federally approved full-service PT providers in the United States.⁹ The 12 to 15 PT programs offered during the 1980s grew to more than 100 different programs in the 1990s. Table 1 lists the PT programs that are provided in 2003. Many of these programs are offered in multiple configurations covering

Table 1. Programs Provided by WSLH Proficiency Testing

Specialty Programs	
Microbiology	Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Enteric Pathogens, Blood Parasites, cerebral spinal fluid Bacterial Antigens, <i>Giardia</i> , <i>Cryptosporidium</i>
General Immunology	Syphilis Serology, Immunoproteins, antinuclear antibody, allele-specific oligonucleotide, Rubella, Infectious Mononucleosis, Rheumatoid Factor, Lyme Disease, <i>Helicobacter pylori</i> , HIV, Hepatitis, Sexually Transmitted Diseases
Chemistry Routine	Chemistry, Endocrinology, Therapeutic Drugs, Medical and Legal Alcohol, Cardiac Markers, Neonatal Bilirubin, Glycohemoglobin, Spinal Fluid Chemistry, Blood Gas, Co-oximetry, Special Chemistry, Urine Chemistry, Urine Drug Screening, Lead
Hematology	Hematology-Basic, Hematology with Automated Differential, Body Fluid Cell Count, Coagulation, D-dimer, Cell Identification, Sickle Cell, Reticulocytes, Sedimentation Rate
Microscopy	Urine Sediment, Provider Performed Microscopy Procedures, Body Fluid Cell Count, Urinalysis Immunohematology Basic, Comprehensive
Other	Semen Analysis, Fecal Occult Blood, Gastric Occult Blood, Rabies

from 1 procedure or analyte to a comprehensive program for the full-service laboratory. For example, a laboratory testing only for strep group A antigen would be in a bacteriology PT program that offered challenges only for that procedure, whereas a full-service laboratory would be in the comprehensive bacteriology program and be offered challenges to cover the full range of test procedures.

THE WISCONSIN PROFICIENCY TESTING PROGRAM

There are several reasons why Wisconsin was successful in expanding its PT services when nearly every other state that had a PT program eliminated or greatly reduced these services after CLIA '88 went into effect. During its history of providing interlaboratory testing service, there has always been significant interaction between the WSLH and laboratories and health care

providers in the state. Though largely regulatory in nature, the WSLH has always viewed proficiency testing as a vehicle to educate and inform the clinical laboratory community. Laboratorians quickly realized that participation in the WSLH PT program was an opportunity to learn, to share, to explore new methodologies, and to improve the quality of services provided to their physicians. Of utmost importance to WSLH success in this endeavor was finding the right balance between providing a service that would enable a laboratory to meet its regulatory/certification requirements, while at the same time being readily available for consultation and problem solving. Proficiency testing is the vehicle that has allowed WSLH to interact with many laboratories and to openly communicate with the laboratory professionals who perform the analyses. The following lists some of the unique programs and features that have enabled the WSLH to play a leadership role in clinical laboratory improvement over the past four decades.

- WSLH PT has benefited from being a part of a “working” laboratory and the accessibility to scores of highly trained professionals. These laboratory specialists are often called upon to lend their expertise to help solve myriad problems that emerge from both routine and specialized laboratory testing.
- In the early years of interlaboratory survey programs, WSLH developed and ran several voluntary programs that provided laboratories with feedback about a specific instrument or method used in their laboratories. These monthly programs (Wisconsin State Survey, Wisconsin RIA Survey, Wisconsin Blood Gas Survey), at no cost to participants, provided for rapid analysis and feedback of data, and were frequently a vehicle that led to improvement in a laboratory’s test performance. Because they were non-regulatory, problems that were identified through the comparative results and the statistical analysis often led to the resolution of a problem within the laboratory. As was often the case, many of these programs helped laboratories solve a problem that may not have been identified through their routine quality control.
- A wide variety of timely workshops and seminars, many held annually with support from manufacturers of laboratory diagnostics, were well attended and educated hundreds of laboratorians from around the state. The programs provided a forum for open discussions between the suppliers of laboratory-testing equipment and the end-users, with the WSLH often playing an important intermediary role.
- Unique samples were used on an episodic basis to challenge some of the special procedures carried out in mycobacteriology, parasitology, and bacteriology.
- A special program, using case-defined sera, was developed to evaluate new procedures required for the emergence of Lyme disease in Wisconsin and nationwide. This WSLH program was offered jointly with the College of American Pathologists Laboratory Accreditation Program for several years.
- When the Centers for Disease Control and Prevention (CDC) discontinued a lead PT program in the late 1980s, the WSLH added this analyte to its monthly erythrocyte protoporphyrin program to ensure continuation of this valuable service to laboratories nationwide. The activity, supported by the United States Bureau of Maternal and Child Health, has been administered by the WSLH since 1989. The program has noted continuous improvement in the level of laboratory performance through the years and serves as a model for voluntary PT programs. The program has developed an international reputation and has partnered with other laboratories and the laboratory industry to establish testing standards for new instrumentation and test methods. As such, it has played a key role in helping laboratories provide accurate testing in support of the critical activity of lead screening in children.
- The implied consent alcohol PT program was developed to provide an external quality assurance mechanism for Wisconsin laboratories and individuals performing legal alcohol testing. Reliable test results from these laboratories are important to Wisconsin law enforcement agencies and an important component of operating while intoxicated (OWI) investigation and successful litigation.
- WSLH provides the only PT program in the country for rabies; results from this program have identified the need for standardizing testing protocols for laboratories, clearly addressing an important public health issue.
- Under a contract with the CDC, the WSLH has developed a special PT program for laboratories performing tuberculosis testing using nucleic acid amplification technology. By carefully selecting and preparing unknown specimens to use as challenges, the program has helped to evaluate the limits of a test that has become an important tool in the rapid diagnosis of TB.
- In 2000, the WSLH PT program applied to the College of American Pathologists to have its PT program accepted for use by clinical laboratories accredited through the CAP. As a result of a very ex-

tensive evaluation and review, the WSLH became the first full-service PT provider to be accepted by the College, thus allowing many CAP-accredited laboratories in Wisconsin and nationwide to participate in the Wisconsin PT program for their CLIA '88 licensure requirements.

FUTURE ROLE OF WSLH PROFICIENCY TESTING

What role lies ahead for the WSLH in the area of laboratory improvement? As long as WSLH is a part of the University of Wisconsin, education and service to the laboratories in Wisconsin will continue to be primary activities. As new technology continues to evolve (e.g., molecular methods) and more specialized testing is developed, and with the emergence of new diseases, the PT program will be challenged to develop survey programs that will assess test methodologies in these areas. Similarly, with more complex testing being placed in the hands of individuals who have not had the benefit of professional or formal laboratory training, the need to provide evaluations that assess both test performance and operator competency will receive state and national attention. The need for rapid test assessment will further challenge the dissemination of this information. Issues arising in the 21st century (such as the threat of terrorism) will require the use of newly developed tools and resources to help educate and prepare local laboratories in a more timely manner for their evolving role. The post-2003 version of the WSLH will strongly emphasize the use of information transfer and distance learning through the Internet and satellite broadcasts. Providing support and education to laboratories has been a major role of the WSLH PT Program in the past, and there is every indication that it will continue to be an important activity in the future.

SUMMARY

For 100 years, the Wisconsin State Laboratory of Hygiene has taken a leadership role with respect to working with laboratories throughout the state. WSLH has provided quality leadership and support in the areas of training and education as new challenges are presented. The WSLH PT program has helped laboratories provide the most reliable testing services to health care providers. The laboratories in Wisconsin have come to rely on the support and services provided through WSLH proficiency testing. The foundation that has been established over the past 40 years will serve the state well into the future, further ensuring that the laboratory services provided to the medical com-

munity in Wisconsin by all laboratories continue to be of the highest quality and providing the greatest benefit to its citizens.

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