The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network
Final Report of the Findings of Questionnaire 1 - Waived and PPMP Sites
Training on Waived Test Systems

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EXECUTIVE SUMMARY

This study established baseline information about laboratory testing practices in clinical sites categorized as waived or provider-performed microscopic procedures (PPMP) by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). A total of 1263 waived tests were evaluated for 25 different analytes in 345 waived or PPMP testing locations.

In January 2000, letters were sent to 1709 waived testing sites in Washington State, inviting them to join an existing network of higher complexity laboratories in the Pacific Northwest and to complete a questionnaire about their experiences with waived test systems. As a result, 263 waived testing sites agreed to participate in our network and returned the first questionnaire. An additional 82 testing sites completed the questionnaire, choosing not to join the network.

Although we found a wide variety of tests being performed, the long standing tests were still the most popular - occult blood, urinalysis, glucose and pregnancy testing. With the availability of many new, easy-use, portable test systems for clinically important analytes, we expected to see more of these in use at waived testing sites. Only about one quarter of the respondents performed waived testing for Group A Streptococcus, and fewer than 10% performed waived testing for lipids, mononucleosis, glycated hemoglobin or Helicobacter pylori, despite recent attention given to these analytes.

Thirty-three different types of personnel were performing waived tests in these settings, with registered nurses, medical doctors and licensed practical nurses being the most common testing personnel.

The highest percentage of personnel are trained by another employee or trained themselves using the instructions provided with the waived test system. Relatively few respondents stated that they utilized manufacturers' representatives for their training, either initially or on an ongoing basis.

With this network in place, we hope to explore some of the following issues, as they relate to waived tests and test systems:

What test system features are important to these sites?
What factors influence their choices of on-site tests and specific test systems?
What problems are they encountering?
Are there quality, accuracy, reliability issues?

The information we gather can provide constructive feedback to manufacturers, laboratory scientists and regulators to potentially improve these test systems and make the technology more appropriate for and accessible to physician office laboratories and other near-patient testing sites. In addition, network participants can use the information to gauge their own practices and experiences with their peers.

BACKGROUND

Clinical Laboratory Improvement Amendments (CLIA) and waived test categorization

To improve the quality of clinical laboratory testing in all sites conducting the testing of human specimens for the assessment of health or the prevention, diagnosis or treatment of disease, the United States Congress passed the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Implemented in 1992, the CLIA regulations set minimum standards for clinical laboratory testing, taking into account different levels of testing technology complexity.

Tests categorized by CLIA as "moderate" or "high" complexity are subject to standards for: personnel qualifications and responsibilities; quality control; quality assurance; and record keeping. Laboratories that perform moderate and/or high complexity testing must undergo on-site inspections and participate in an approved proficiency testing program.

Under CLIA, a "waived" test is a simple laboratory examination or procedure that has an insignificant risk of an erroneous result. To be considered a waived test, it must: be approved by the Centers for Disease Control and Prevention (CDC) or the Food and Drug Administration (FDA), following a waiver review process; be approved by the FDA for home use; or be one of the original tests designated in the CLIA regulations to be a waived test. Testing sites that perform only waived tests must obtain a Certificate of Waiver and follow the manufacturer's instructions for performing the waived test, but are otherwise relieved of the regulatory requirements associated with tests of higher complexity.

The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network

With the passage of the CLIA regulations, studies were mandated to assess the quality, accuracy and reliability of laboratory testing results and the extent and nature of laboratory-related problems and errors. In 1995, in response to this mandate, the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network was created, through a cooperative agreement between the Washington State Department of Health and the CDC, to gather information about clinical laboratory testing practices in hospital, independent and physician office laboratories. As of January 2000, the network comprised 388 clinical testing sites performing moderate and high complexity testing.

This network has monitored clinical laboratory practices related to: quality assurance; access to laboratory testing services; laboratory-related errors; personnel training, changes and shortages; proficiency testing participation; and point of care testing. [Full text reports of the findings of these studies and references to published journal articles can be found on the CDC website at http//:www.phppo.cdc.gov/dls/mlp/pnlmsmn.asp] The network has provided interest groups (physicians, laboratorians, manufacturers, educators, consumers) and regulators with information on trends in the practice of laboratory medicine.

Recruitment of waived laboratories into the network

With recent advances in laboratory testing technology, there has been a rapidly increasing number

of test systems targeted for physician office, point of care and home health care settings. Manufacturers have developed testing devices that simplify the testing process and meet the CLIA criteria to qualify as waived testing. As of January 2000, tests for 25 different analytes can be performed using one or more waived test systems. [A current CLIA Waived Test List can be found on the CDC website at http//:www.phppo.cdc.gov/dls/clia/waived.asp] Despite the availability and popularity of waived test systems, there is little information about user experiences with waived tests in the clinical setting. To gather data about waived test system performance and other laboratory-related practices, we invited waived testing sites to join our existing network.

METHODOLOGY

On January 17, 2000, a letter was mailed to all 1709 testing sites in Washington State, categorized as performing waived testing only, or waived and provider-performed microscopic procedures (Appendix A). This letter introduced these sites to the existence of our network and our desire to include them as ongoing network participants. We encouraged them to learn more about the network by providing references about previous studies and reports. A week later, a second letter was sent to these sites, giving them an opportunity to: voluntarily join the network and complete the first questionnaire; complete the questionnaire only; or do neither (Appendices B and C).

During the recruitment process, we found a different perception about laboratory testing among some of these sites. Some denied performing any "laboratory" tests or were unclear about what "waived" tests were. Once they were prompted with names of common tests or testing systems (i.e., blood sugar, urine dipsticks, glucose meters, pregnancy tests) they readily realized that they were performing tests in the category of our interest. Manufacturers and regulators need to be aware that terminology common in the traditional laboratory setting may not completely translate to these near-patient testing areas.

Despite some initial anti-government sentiments by a few of the sites, we found that most of the concerns about joining this network related to a reluctance to add more paperwork or projects to their workload. Others wanted to know how they might benefit from their participation.

Respondents

As a result of these mailings, 263 testing sites agreed to participate and returned the first questionnaire. Using U.S. Census Bureau designations, 76% were characterized as urban and 24% as rural. The following types of clinical settings are represented: Physician office laboratories (POLs), clinics, nursing homes, pharmacies, health departments, home health agencies, hospital ancillary services, occupational health programs, surgical centers, student health clinics, rehabilitation centers, dialysis centers, dental offices, juvenile detention centers and Women, Infant and Children (WIC) programs. An additional 82 testing sites chose not to be ongoing participants in this network, but completed and returned the questionnaire.

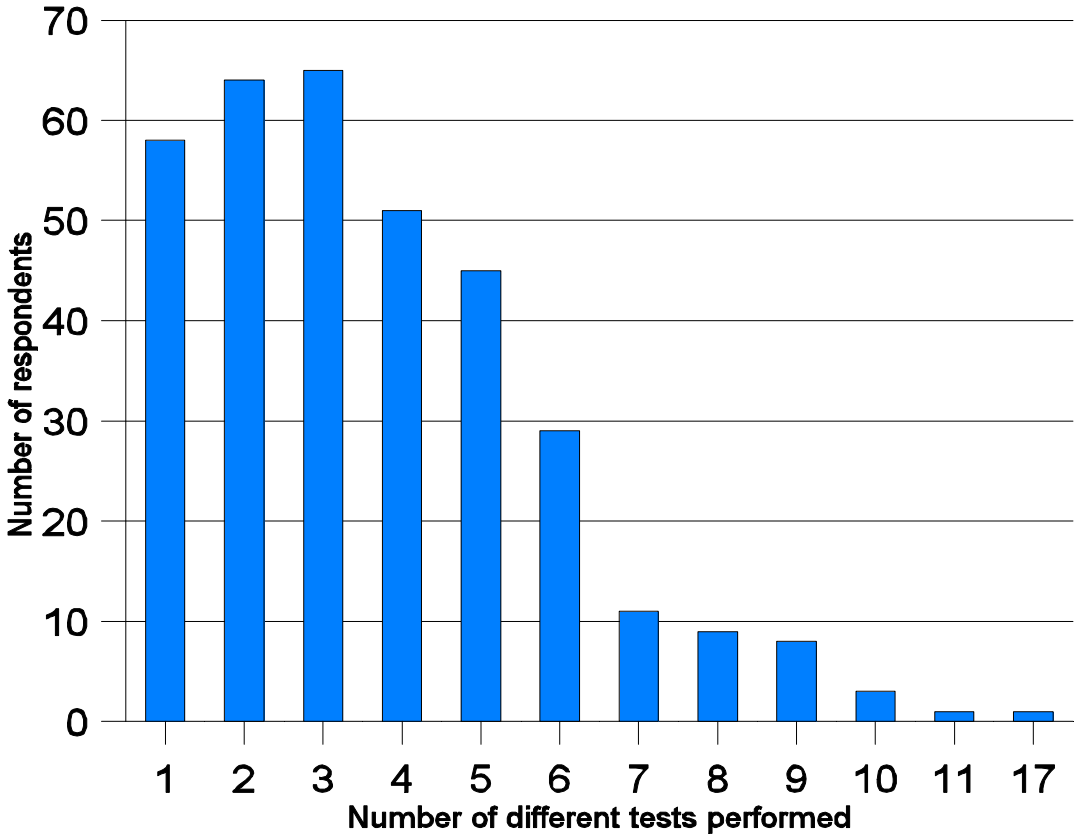
FINDINGS

Waived tests performed (N=1263 tests, 345 respondents)

Test	Percent of sites performing test		Test	Percent of sites performing test
Occult blood	65		HDL cholesterol	5
Urinalysis	64		Mononucleosis	4
Glucose	60		Microalbumin	4
Pregnancy test	43		Triglycerides	3
Strep antigen test	26		Hemoglobin A1C	2
Hematocrit	23		Creatinine	1
pH	19		Bladder tumor antigen	<1
Hemoglobin	11		Fructosamine	<1
Lipid panel	7		Ovulation test	<1
Helicobacter pylori	7		Catalase	<1
Cholesterol	7		Ethanol	0
Erythrocyte sedimentation rate	6		Nicotine	0
Prothrombin time	6			

One respondent listed a rapid influenza antigen test**,** which is not currently categorized as a waived test system. Several sites listed various provider-performed microscopic procedures, which was not the intent of this questionnaire.

Number of waived tests performed per site

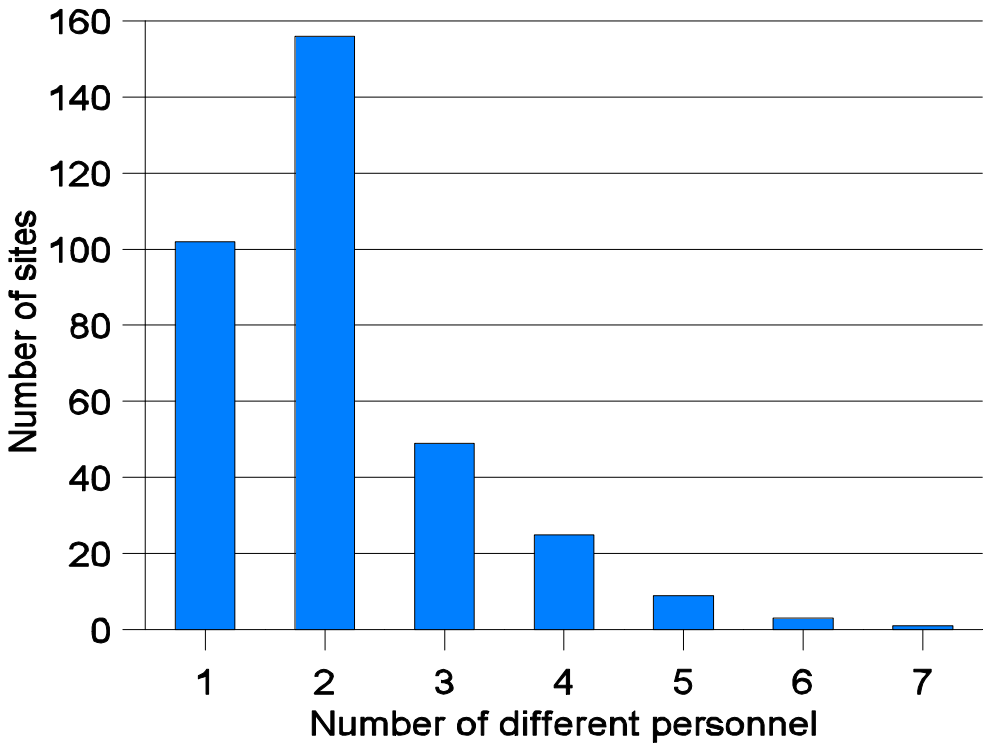


Who performs waived tests?

Background of personnel performing waived testing	Percent of responses (N=731)
Registered nurses	25
Medical doctors	19
Licensed practical nurses	18
Medical assistants	15
Advanced registered nurse practitioners	9
Physician assistants	2
Pharmacists	2
Medical laboratory technicians	2
Medical technologists	2
Health care assistants	1
Laboratory assistants/phlebotomists	<1
Nurse midwives	<1
Dieticians/nutritionists	<1
X-ray technologists/technicians	<1
Women, Infant and Children (WIC) certifier	<1
Other*	3

*Other personnel include: Certified nurse manager, certified nursing assistant, emergency medical technician, client under supervision, crisis pregnancy volunteer, dentist, dental hygienist, emergency room technician, hemodialysis technician, licensed to take X-rays, medical student, non-registered technician, patient care assistant, peer counselor, receptionist, technical assistant, trained volunteer, pharmacy technician.

Number of different types of testing personnel per site



Sources of initial training (N=485 responses)

Training source	**Percent of responses**
One on one training by another employee	25
Reading product inserts, instructions, directions	17
Formal training: Medical school; Nursing school; Fellowship program; Formal training; Medical laboratory technician program; Medical assistant program.	16
Specialized training: Written program; Quality assurance training; Classes; Inservice; State WIC training program; State Pharmacy Association training program.	14
By the manufacturer's representative	10
By a consultant: From: Reference laboratory; Hospital laboratory; Local health district; Another office; Clinical Laboratory Improvement Amendments (CLIA) staff; State Laboratory Quality Assurance office; Medical technologist; Pharmacist.	6
Other: Video; Training from previous job; Only done by practitioner; Have been doing for years; Continuing education course; Competency measures; Must pass a test; Tests are very simple-only need minimal training.	10
Not Applicable	2

Sources of ongoing training (N=463 responses)

Training source	Percent of responses
One on one training by another employee	51
Specialized training: Written program; Quality assurance training; Classes; Inservice; State WIC training program; State Pharmacy Association training program.	14
Reading product insert, instructions, directions	13
Formal training: Medical school; Nursing school; Fellowship program; Formal training; Medical laboratory technician program; Medical assistant program.	5
Video	2
Not Applicable: No new personnel; Perform all testing myself; Testing is only done by the doctor.	8
Other: Testing is only done by the doctor; Competency measures; Must pass a test; Periodically perform quality control; Ask manufacturer for help or information; Learned from others using the same equipment.	7