The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network Final Report of the Findings of Questionnaire 3 - Waived and PPMP Sites Quality Assessment Activities

Kathleen M. LaBeau [1], Sharon Granade [2] and Steven J. Steindel [2]

1 Office of Laboratory Quality Assurance
Washington State Department of Health
1610 N.E. 150th Street
Seattle, Washington 98155

2 Centers for Disease Control and Prevention
Public Health Practice Program Office
Division of Laboratory Systems
Laboratory Practice Assessment Branch (MS G-23)
4770 Buford Highway N.E.
Atlanta, Georgia 30341

December 2000

EXECUTIVE SUMMARY

This study evaluated quality assessment activities performed on waived test systems used in clinical sites certified as waived or provider-performed microscopic procedures (PPMP) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. A total of 706 waived tests were evaluated for 22 analytes in 190 clinical sites.

In October 2000, a questionnaire was mailed to 267 waived and PPMP testing sites in Washington State. Using a list of waived tests by analyte and specific test system (brand name and manufacturer) participants were asked which tests they performed on-site and if they performed any of the following quality assessment activities:

- Test external liquid controls
- Observe built-in procedural control results
- Test electronic controls
- Test proficiency testing samples
- Correlate result with patient presentation, history, diagnosis
- Other activity

We found that patient test results were compared with the patient's clinical presentation, history, diagnosis with 72% of all the waived tests performed, making this the most common quality assessment activity used by the respondents.

The use of procedural controls and electronic controls were also relatively high: procedural controls were observed with 60% of the portion of tests where procedural controls are part of the test system; electronic control devices were tested with 77% of the portion of tests where these are available for use with the test system.

While other quality assessment reference materials are readily available, they were used by a smaller proportion of waived test sites in our network. External liquid controls were performed with 38% of all the waived tests performed and with 57% of the waived tests where the testing of liquid controls was required as part of the manufacturer's instructions. Proficiency testing samples were tested with 13% of the waived tests performed.

BACKGROUND

Clinical Laboratory Improvement Amendments (CLIA) and 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. 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 Centers for Disease Control and Prevention (CDC), to gather information about clinical laboratory practices in hospital, independent and physician office laboratories. As of October 2000, the network comprised 636 clinical testing sites performing waived, provider-performed microscopic procedures (PPMP), moderate- and high-complexity testing. To date, 18 questionnaires have been released to the network. The network has provided interest groups (physicians, laboratorians, manufacturers, educators, consumers) and regulators with information on trends in the practice of laboratory medicine.

[Full text reports of the findings of these studies and references to journal articles can be found on the CDC Website at: http://www.phppo.cdc.gov/dls/mlp/pnlmsmn.asp].

METHODOLOGY

To evaluate the extent to which waived and PPMP sites perform quality assessment activities for their waived test systems, a questionnaire was sent to the 267 network participants categorized as waived or PPMP (Appendix A). One hundred ninety participants returned a completed

questionnaire in time for analysis, a 71% response rate.

Respondents

Using U.S. Census Bureau designations, 76% were characterized as urban and 24% as rural. The following types of clinical settings were represented: Physician office laboratories (POLs), clinics, nursing homes, pharmacies, hospital ancillary services, home health agencies, rehabilitation centers, health departments, occupational health programs, family planning clinics, community health clinics, student health clinics, dental offices, and Women, Infant and Children (WIC) programs.

FINDINGS

Waived tests performed

Using a list of waived tests by analyte and specific test system (brand name and manufacturer), participants were asked to place a check-mark next to each specific test system or kit performed on-site.

Waived tests performed (N=706 tests, 190 respondents)

Test	Percent of sites performing test		Test	Percent of sites performing test
Glucose	73		*Helicobacter pylori* antibody	8
Urinalysis	72		Mononucleosis	7
Fecal occult blood	60		Erythrocyte sedimentation rate	6
Urine pregnancy	42		Prothrombin time	5
Strep antigen	26		Microalbumin	3
Hematocrit	25		*H. pylori* - gastric tissue	2
pH	14		Glycohemoglobin (A1C)	2
Hemoglobin	10		Fructosamine	1
Cholesterol, HDL, lipid profile	9		Ethanol	<1
Gastric occult blood	8		Nicotine	<1

Quality assessment activities

For each of the waived tests performed, participants were asked if they performed any of the following quality assessment activities:

- Test external liquid controls
- Observe built-in procedural control results
- Test electronic controls
- Test proficiency testing samples
- Correlate result with patient presentation, history, diagnosis
- Other activity

Definitions were provided for external liquid controls, procedural controls, electronic controls, and proficiency testing samples.

For each activity where they recorded "Yes", the participants were asked to indicate how often they performed the quality assessment activity.

External liquid controls

External liquid controls are reference solutions that are not built into the testing device (test pack, cartridge, cassette or strip) and are added in liquid form to the test reagent device in the same manner as the patient sample. Although liquid controls are sometimes included as part of the testing kit, they often must be purchased separately for quality control purposes.

Overall, liquid controls were tested with 38% of the waived tests that respondents performed. For individual waived tests or test systems, we found considerable variation in the proportion of sites running liquid controls and in the frequency with which they tested liquid controls.

Liquid controls were more commonly tested with quantitative tests (e.g., Lipids, prothrombin time, glucose and glycohemoglobin) and with qualitative tests where controls are either included in the kit or readily available (Strep antigen, mononucleosis and *Helicobacter pylori*). Liquid controls were less commonly tested with tests where there is no "kit" and controls must be purchased separately (e.g., Hematocrit, urinalysis, erythrocyte sedimentation rate).

Use of external liquid controls

Waived test	**Number of sites**	**Percent performing liquid controls**	**Frequency that liquid controls were tested *** (Number of testing sites)								
			E, D	W	M	K	KO	Q, S	A	NS	O
Cholesterol, HDL, lipid profile	17	76	1	1	2	6		2		1	
Prothrombin time	8	75		3		3					
Glucose	124	69	46	10	12	6	1	5	2	3	1
Glycohemoglobin (A1C)	3	67		1		1					
Strep antigen	44	64	3	1	2	19	1	1		1	
Mononucleosis	10	60	1			5					
Fructosamine	2	50				1					
Helicobacter pylori antibody	13	46				6					
Urine pregnancy test	68	29	2		2	11	1	1		3	
Fecal occult blood	90	23	16	1		1	1	1		1	
Hemoglobin	18	22	2	1	1						
Hematocrit	38	21	2	3	1					2	
pH	20	20	3	1							
Urinalysis	118	20	8	6		4	1			4	1
Erythrocyte sedimentation rate	9	11								1	
Gastric occult blood	12	8	1								
Microalbumin	3	0									
H. pylori gastric tissue	4	0									
Ethanol	1	0									

* E,D=each test or daily; W=weekly; M=monthly; K=each new kit, lot or shipment; KO=each new kit and each new operator; Q,S=quarterly or semiannually; A=annually; NS=not specified; O=Other frequency.

For many waived test systems, the manufacturer's instructions for test performance include **recommendations** for testing liquid quality control materials (e.g., "Good laboratory practice recommends the use of external controls to assure that the assay is performing properly. It is recommended that controls be tests once for each 25 tests and as otherwise required by your laboratory's standard quality control procedures").

For other waived test systems, the manufacturer's instructions include specific **requirements** for testing liquid controls (e.g., "A positive and negative external control must be tested when opening a new test kit. Each operator performing testing within a test kit must test a positive and negative external control once with each test kit"). Testing sites using waived tests with quality control requirements must perform the quality control as part of following the manufacturer's instructions for performing the test.

We found that liquid controls were tested with 57% of the waived tests where this was required in the manufacturer's instructions.

Waived test kits/systems with required quality control

Waived test system with required quality control	Manufacturer's requirements	Number of sites	Percent where liquid controls were tested
Glycohemoglobin (A1C) Bayer DCA 2000+	Test a normal and abnormal control with each new lot and 1 liquid control (alternating levels) with each 10 cartridges	3	67
H. pylori antibody Quidel QuickVue One-Step	Test 2 levels of liquid control with each kit and each new operator	12	50
Hematocrit Wampole STAT-CRIT	Test 2 levels of control once per week	1	0
pH Litmus Concepts	Test a pH and amine control with each new lot and each new operator	3	33
Prothrombin time Roche/Boehringer Manneheim Coagucheck	Each operator must test 2 levels of liquid controls weekly	7	86
Strep antigen test Quidel QuickVue In-Line One-Step Becton Dickinson LINK 2	Test 2 levels of liquid control with each kit and each new operator	28	64
Urinalysis Bayer Clinitek 50	Test a positive and negative control each day and each new bottle of strips	7	28

Procedural and electronic controls

Procedural controls are built into each test reagent device to ensure that reagents are active, that reagents and patient sample are added correctly and that the test system performs according to specifications. Procedural controls are common in qualitative waived test kits (e.g., Urine pregnancy, mononucleosis, Strep antigen and *H. pylori* tests). Respondents observed the results of procedural controls with 60% of the 235 tests where procedural controls are part of the waived test kit or test system.

Electronic controls are inert, reusable devices (test strips, cartridges, cassettes, etc.) that are used to check instrument performance specifications. Electronic controls are available for use with some quantitative waived test systems [e.g., Hemoglobin, lipids, prothrombin time, glycohemoglobin (A1C)]. Respondents tested electronic control devices with 77% of the 60 waived tests where electronic controls are available for quality assessment purposes.

Proficiency testing participation

Samples from a private proficiency testing company can be obtained and tested to provide a comparison of results with sites performing the same test and using the same test system. While not required for waived testing by the federal CLIA requirements or by the Washington State laboratory regulations, participation in a proficiency testing program can offer a means of assessing the accuracy of a particular test system and the competency of the testing personnel. The cost of participation in a proficiency testing program can vary greatly, depending on the company and the number of samples provided in the annual subscription. Some manufacturer's of waived test systems provide proficiency samples and case study critiques as a free service to their customers.

Overall, proficiency testing samples were performed with 13% of the waived tests performed by the respondents.

Performing proficiency testing samples

Waived test	Number of sites	Percent performing proficiency testing
Fructosamine	2	50
Cholesterol, HDL, lipid profile	17	47
Mononucleosis	10	40
Glycohemoglobin (A1C)	3	33
Helicobacter pylori antibody	13	31
Prothrombin time	8	25
Erythrocyte sedimentation rate	9	22
Strep antigen	44	21
Glucose	124	18
Hematocrit	38	11
Hemoglobin	18	11
Urine pregnancy test	68	10
Urinalysis	118	8
pH	20	5
Fecal occult blood	90	4

For 25 tests (4%), the respondents stated they performed proficiency testing samples with each patient test, three times daily, daily, monthly, or with each kit. These respondents may not have understood what was meant by proficiency testing samples, since the typical frequencies for testing events are three times per year for five sample programs and twice per year for two sample programs.

Correlation of patient result with patient presentation, history, diagnosis

In physician offices, clinics and other near-patient testing sites, it is common for testing personnel and health care providers to have the patient and their chart available at the time of the performance of the waived test. This allows for a comparison of the validity of the test result with the patient's current clinical findings and past history.

Patient test results were compared with clinical information for 72% of the waived tests performed.

Other quality assessment activities

Of the 49 responses given about other quality assessment activities, 39% related to correlation studies with another method or another laboratory. Twenty percent of the activities related to having a confirmatory test done. Other quality assessment activities included the performance of equipment maintenance, running the test in duplicate, and comparing patient results to other diagnostic test results.