The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network Final Report of the Findings of Questionnaire 2 - Waived and PPMP Sites Access to Laboratory Testing

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EXECUTIVE SUMMARY

This study investigated access to on-site laboratory testing in clinical sites categorized as waived or provider-performed microscopic procedures (PPMP) by the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

In July 2000, a questionnaire was mailed to the 272 waived and PPMP testing sites that participate in the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network. A total of 187 network participants returned a completed questionnaire in time for analysis for a 69% response rate.

Eighteen percent of the respondents stated that in the past they had performed tests other than those categorized as waived or PPMP. Forty-seven percent of the reasons given for discontinuing moderate or high complexity testing related to laboratory regulations (regulations made testing too costly, too burdensome) and another 29% related to practice changes (test volumes were too low to be cost effective; due to a change in patient workload; decided test was not essential; could get timely results from another laboratory).

Six percent of the respondents stated they had stopped performing testing (waived, PPMP, moderate or high complexity) in the past two years. Among these sites, 57% of the reasons related to practice changes and 23% were due to costs (another laboratory could perform less expensively; reimbursement was too low).

Thirteen percent of the respondents stated there were laboratory tests they would like to perform or were essential to perform on-site that they currently did not perform. The majority of the responses (54%) for not performing the desired testing related to regulations (want to stay at waived or PPMP level, did not want to comply or could not afford to comply with the regulations associated with higher complexity testing). Among the tests they said they desired but did not perform because of regulations, 35% are currently available as waived tests and 14% can be performed as provider-performed microscopic procedures.

The majority of the network respondents were satisfied with their current test menus and had not made significant changes in their test menus in the past two years and longer. More education is needed to inform these clinical sites about the availability of waived tests and what is required to initiate new on-site testing.

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. Select microscopic examinations are categorized as "provider-performed microscopic procedures" (PPMP) when performed by a provider at the time of the patient's visit. PPMP tests fall into a special category of moderate complexity testing, where all applicable requirements for tests of moderate complexity must be met, with the exception of the requirements for an on-site inspection and participation in a proficiency testing program. Waived and PPMP sites pay significantly lower certificate/license fees than those performing higher complexity testing.

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 July 2000, the network comprised 650 clinical testing sites performing waived, PPMP, moderate and high complexity testing. To date, 16 questionnaires have been released to the network. [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.

METHODOLOGY

In July 2000, a questionnaire was sent to the 272 network participants categorized as waived or PPMP. One hundred eighty-seven participants returned a completed questionnaire in time for analysis, a 69% response rate.

Respondents

Using U.S. Census Bureau designations, 75% were characterized as urban and 25% as rural. The following types of clinical settings were represented: Physician office laboratories (POLs), clinics, nursing homes, pharmacies, health departments, community health clinics, home health agencies, hospital ancillary services, occupational health programs, surgical centers, student health clinics, rehabilitation centers, dental offices, Women, Infant and Children (WIC) programs.

FINDINGS

Waived and PPMP sites that had performed higher complexity testing

Participants were asked "Have you ever performed tests other than those categorized as waived or provider-performed microscopic procedures (PPMP)?"

Eighteen percent of the respondents answered "Yes." Of these, 31% changed to the waived or PPMP category because the tests they were performing became recategorized by CDC or the Food and Drug Administration (FDA) as waived, 59% discontinued all higher complexity testing to become a waived or PPMP site, and 9% did so due to both of those reasons. Of the sites that discontinued moderate or high complexity testing, the top primary reason given was "complying with laboratory regulations made testing too costly" (36% of all primary reasons). The top secondary reason was because "laboratory regulations were too burdensome" (27% of all secondary reasons given). When all primary and secondary reasons were combined into categories of interest, those related to regulations were most frequent, followed by those related to practice changes, Table 1.

Table 1 - Reasons for discontinuing moderate and/or high complexity testing (n=22 sites)

Reason	Number of responses	Percent of responses
Regulations:		**47**
Complying with laboratory regulations made testing too costly	15	
Laboratory regulations were too burdensome	13	
Practice changes:		**29**
Test volume was too low to be cost effective	10	
Determined that it was not essential to perform test on-site	5	
Due to a change in patient workload, case mix of patients	1	
Could get timely results from another laboratory	1	
Costs:		**17**
Reimbursement was too low	5	
Reimbursement was too difficult, complicated to obtain	3	
Another laboratory could perform tests less expensively	1	
Testing instruments, reagents were too expensive	1	
Test technology:		**3**
Tests were too complicated, problematic	1	
Test results did not match clinical impression, patient history, outcome	1	
Mandated by a managed care or insurance contract agreement	2	**3**

Discontinued testing in past two years

We asked participants "In the past two years, have you stopped performing any tests on-site and referred them to another laboratory?"

Six percent of the respondents answered "Yes." The top primary reason for discontinuing testing was because the "test volume was too low to be cost effective" (56% of all primary reasons given). The top secondary reason was "another laboratory could perform test less expensively" (50% of all secondary reasons). When all primary and secondary reasons were combined, practice changes ranked first and costs ranked second, Table 2.

Table 2 - Reasons for discontinuing any testing in the past two years (n=11 sites, 18 tests)

Reason	Number of responses	Percent of responses
Practice changes:		**57**
Test volume was too low to be cost effective	10	
Decided it was not essential to perform on-site	3	
Could get timely results from another laboratory	3	
Due to a change in patient workload, case mix of patients	1	
Costs:		**23**
Another laboratory could perform test less expensively	6	
Reimbursement was too low	1	
Regulations:		**7**
Regulations made testing too costly	1	
Regulations were too burdensome	1	
Due to a managed care or insurance contract agreement	1	**3**
Other: Due to an FDA recall of reagents	3	**10**

Eighteen tests were listed: 16 moderate complexity tests, 2 waived tests. Over half (61%) were tests used to diagnose an infectious disease. The following lists the tests discontinued in the past two years:

Chlamydia (2)
Mononucleosis (2)
Strep screen
Group B Strep culture
Gram stain
Sexually transmitted disease (STD) tests
ASO titer
Hepatitis B Surface antigen
Microbiology
CBC, differential, platelet count
Fecal fat
Magnesium
Ferritin
Vitamin B12, folate
Nasal smear for eosinophils
Semen analysis

Tests not currently performed that sites would like to perform

We asked participants "Are there any laboratory tests that you currently do not perform on-site but your practitioners would like to do or feel are essential to do on-site for optimal patient care?"

Thirteen percent of the respondents answered "Yes" and listed tests they would like to perform. The most common reasons given for not currently performing the desired tests related to laboratory regulations [want to stay at waived or PPMP level; do not want to undergo an inspection or comply with regulations; cannot afford to comply with regulatory requirements] (54% of reasons given) and cost issues [too expensive to initiate this test; reimbursement is too low; do not have adequate test volume to be cost effective] (26%). The following summarizes the

tests according to the reasons given.

Reason	Number of responses	Percent of responses	Would **like** to perform or is **essential** to perform on-site
Want to stay at waived or PPMP level	**18**	**33**	
Candida stool culture			like
CBC by machine			like
CBC with differential			essential
Chlamydia			like
Cholesterol *			essential
Easy H. pylori *			essential
Flu spot test			like
Gram stain			like
Hansel stain **			like
Hemoccult *			like
Influenza			essential
Microscopic analysis **			like
Monospot *			like
Quick Strep *			like
Rapid Strep A *			essential
Urine culture			like
Urine microscopic **			like
Vaginal microscopic **			like
* waived tests are available for this analyte ** this test can be categorized as PPMP if performed by a provider			

Too expensive to initiate this test	**8**	**15**	
Cholesterol screen			essential
Cyclosporin			like
Glucose tolerance			like
Hemoglobin			like
Hemoglobin A1C			like
Protime (2)			like
Tumor markers			like

Reason	Number of responses	Percent of responses	Would **like** to perform or is **essential** to perform on-site
Unsure what it entails to add this test	**8**	**15**	
Blood sugar *			like
Easy H. pylori *			essential
Gram stain			like
Hansel stain **			like
Protime *			like
Rapid Strep A *			essential
Sexually transmitted disease (STD) testing			essential
Vaginal microscopic **			like
* waived tests are available for this analyte ** this test can be categorized as PPMP if performed by a provider			

Do not want to undergo inspection or comply with regulations associated with this test	**6**	**11**	
Blood sugar *			like
CBC			essential
Cervical culture			like
Glucose *			essential
Urinalysis *			essential
Urine culture			like
* waived tests are available for this analyte			

Cannot afford to comply with regulatory requirements	**5**	**9**	
ABO blood type			essential
Candida stool culture			like
Cervical culture			like
Mono-spot *			like
Urine culture			like
* waived tests are available for this analyte			

Reason	Number of responses	Percent of responses	Would **like** to perform or is **essential** to perform on-site
Reimbursement is too low to justify performing this test on-site	**4**	**7**	
H. pylori stool antigen			like
Protime			like
Rheumatoid factor			like
Quick Strep			like
The quality of current test systems is not adequate for my needs	**2**	**4**	
Cholesterol screen			essential
Hepatitis A, B, C			like
Do not have adequate test volume to be cost-effective	**2**	**4**	
Free PSA			like
WBC			like

Other:

No space in laboratory	Protime	essential
No reason specified	Urine culture, Biggy culture, DTM culture	essential

Of the 29 tests they said they desired but did not perform because of regulations, 35% are currently available as waived tests and 14% can be performed as provider-performed microscopic procedures.

COMMENT

More education may be needed to inform testing sites about the availability of waived test systems and the regulatory requirements and fees associated with waived and PPMP testing.

[A current CLIA Waived Test List can be found on the CDC Website at: http://www.phppo.cdc.gov/dls/clia/testcat.asp]