The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network
Final Report of the Findings of Questionnaire 7
Proficiency Testing Participation

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BACKGROUND

The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network was created in January 1995 to gather ongoing information about practices in hospital, independent and physician office laboratories (POLs). To date, seven questionnaires have been released to the network, exploring issues related to: testing quality; access to testing services; laboratory-related problems and errors; personnel training; personnel changes and proficiency testing participation. The data gathered thus far have provided network participants, interest groups and regulators with solid information about current trends in laboratory medicine, based on actual practices and experiences in testing facilities. Informed decisions can then be made about the impact of regulatory activities and health care reform measures on the practice of laboratory medicine.

QUESTIONNAIRE 7

Questionnaire 7 was mailed to 436 network laboratories in July 1997. The intent of this questionnaire was to determine how participants utilize proficiency testing (PT) challenges in their quality assurance programs and to assess the degree to which problems are encountered with participation in PT programs. Data from this questionnaire were analyzed using Microsoft ACCESS ™ and Raosoft SurveyFirst ™. Tests of significance were performed using Student's t-test, at 95% confidence limits (p=.05).

Three hundred nineteen laboratories returned a completed questionnaire in time for analysis, a 73% response rate. Demographic characteristics of the respondents are summarized in Table 1.

Table 1 - Questionnaire 7 respondents (N= 319 laboratories)

Demographic characteristic	Percent
STATE	
Alaska	8
Idaho	18
Oregon	25
Washington	49
LABORATORY TYPE	
Physician office laboratory (POL)	60
Hospital	28
Independent	12
CENSUS BUREAU DESIGNATION	
Urban	61
Rural	39
ACCREDITATION STATUS	
Yes	32
No	68

FINDINGS

Participation in proficiency testing

Network laboratories were asked "Current laboratory regulations specify that you successfully participate in an approved proficiency testing program. In the absence of such regulations, what changes would you make in your quality assurance practices with respect to participation in proficiency testing programs?" Laboratories were asked to select one of ten possible choices or to describe an alternate choice under "Other."

Sixty percent of all laboratories responded that they would continue to perform PT at the level specified in the current regulations or that they currently perform more PT challenges than specified in the regulations and would continue to do so. Thirty percent of laboratories would continue to perform PT on an ongoing basis, but would prefer fewer challenges. Seven percent of laboratories would perform PT on a very limited basis or not at all. Figure 1 summarizes the responses of all laboratories.

Figure 1 - Changes in participation in proficiency testing (N=319 laboratories)

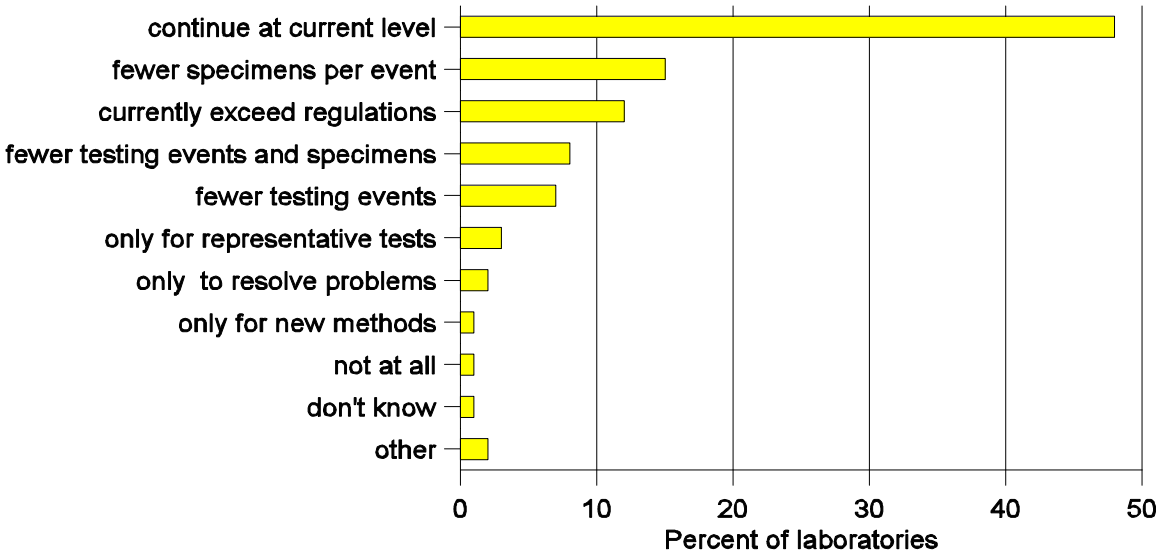

Table 2 summarizes the responses of the 96 laboratories that would continue to perform proficiency testing on an ongoing basis but would prefer fewer challenges per year.

Table 2 - Changes in proficiency testing participation

	Percent of labs
Fewer testing events (N=22 labs)	
1 event	18
2 events	77
3 events	5
Fewer specimens per testing event (N=48 labs)	
2 specimens	33
3 specimens	63
4 specimens	4
Fewer specimens and fewer testing events (N=26 labs)	
2 testing events	96
did not specify number of events	4
1 specimen	4
2 specimen	23
3 specimen	69
did not specify number of specimens	4

Laboratories that selected one of the following choices were asked how they would assess the accuracy of all tests on an ongoing basis: *Would analyze PT specimens for representative tests for each instrument, method or test specialty; Would participate only once when introducing a new method, instrument or test system; Would order only as deemed necessary to evaluate or resolve testing problems* or *Would not participate in PT at all*. Using a list of eight choices, participants were asked to select any that applied. Any additional possibilities could be described under "Other."

Twenty-one laboratories gave a total of 50 responses to this question. Forty-six percent of the responses related to the use of external quality control activities (comparison of control sample results with those of peer laboratories or comparison of patient sample results with those of another laboratory). Comparison of patient test results to other patient information (history, diagnosis, presentation or outcome) accounted for 24% of the responses. Sixteen percent of the responses related to the assessment of internal control sample results and 12% to the use of a biannual verification protocol. Figure 2 shows all individual responses given by this group of laboratories.

A significantly higher percent of independent laboratories (87%) indicated they would continue to meet or exceed current regulations compared with hospital laboratories (59%) and POLs (55%). Otherwise, changes in proficiency testing participation were not significantly different between subgroups of respondents based on location, size or accreditation status. Table 3 summarizes the responses of laboratories according to various demographic characteristics.

Figure 2 - Assessing test accuracy with limited proficiency testing participation (N=50 responses)

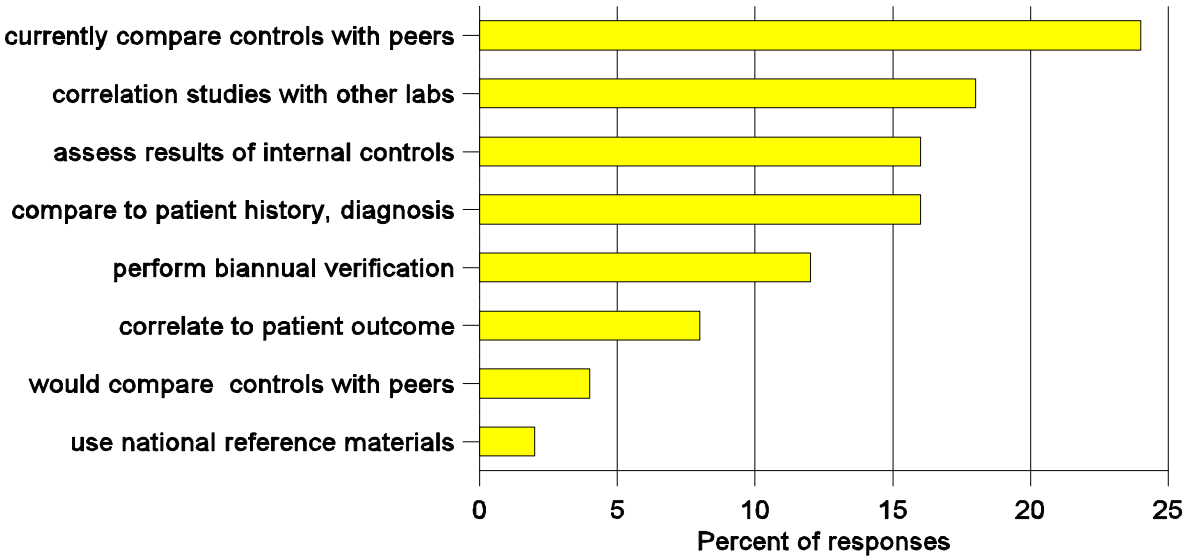

Table 3 - Proficiency testing participation (N=319 laboratories)

	Percent of laboratories				
	POL	**Hospital**	**Independent**	**Urban**	**Rural**
Continue to meet or exceed regulations	55	59	87	62	56
Continue on an ongoing basis but fewer challenges	33	33	8	26	36
Not for all tests, not on an ongoing basis or not at all	8	4	5	8	5

	Annual test volume (in thousands)				Accredited	
	<10	10 to 25	10 to 75	>75	Yes	No
Continue to meet or exceed regulations	57	59	64	63	59	61
Continue on an ongoing basis but fewer challenges	29	31	31	31	36	28
Not for all tests, not on an ongoing basis or not at all	9	3	6	5	3	6

Changing proficiency testing companies

Participants were asked “In the past five years, have you changed proficiency testing companies?” Laboratories that had changed companies were asked to indicate the number of times they changed and to select, from a list, any reasons for the changes.

Ninety-three of the respondents (29%) indicated that they had changed PT companies in the past five years, with the majority of these laboratories (79%) changing companies only one time. A total of 212 reasons were given for changing companies. The most common reasons related to costs (29% of all reasons given), test selection (18%), and attention to customer needs (14%).

Table 4 - Reasons for changing to a new proficiency testing company (N=93 labs)

Reasons related to:	Number of reasons	Percent of reasons
COSTS		
Chose a company that was less expensive	56	26
Chose a company that did not have registration fees	6	3
TEST SELECTION		
Chose a company that had a better selection of tests and test groups	39	18
ATTENTION TO CUSTOMER NEEDS		
Wanted a company that would be more responsive to my phone calls, letters	15	7
Wanted a company that could offer better technical assistance to my questions, problems	15	7
FORMS AND REPORTS		
Wanted a company that had forms that were easier to understand and complete	14	7
Wanted a company that had reports that were easier to understand and interpret	11	5
RETURN OF SCORES		
Wanted a company that returned my scores more quickly	24	11
PROGRAM NO LONGER AVAILABLE		
Used a manufacturer-sponsored program that is no longer available	2	1
Used a company that is no longer available	7	3
MEDICAL SPECIALTY AFFILIATION		
Chose a company that reflected my medical specialty affiliation	6	3

Using proficiency testing challenges in quality assurance activities

Network laboratories were asked "How often do you engage in quality assurance activities that utilize proficiency testing samples and/or reports?" Using a list of six possible activities, laboratories were asked to indicate the frequency at which they performed each activity using PT materials. If they performed additional activities not listed, these could be described under "Other." As a guide to answering this question, participants were instructed to choose one of the following for each of the activities listed: "never"; "rarely" if the activity was performed with less than 25% of the PT sample shipments or reports; "sometimes" if the activity was performed with 25-50% of the shipments or reports; "often"if the activity was performed with more than 50% of the shipments or reports; "always"; or "don't know."

For each of the quality assurance activities, the percent of laboratories ranking "often" or "always" was calculated. Using these criteria, the most frequent activities utilizing PT samples or reports were: *Review of proficiency testing summary reports or critiques* (93% of laboratories ranked often or always); *Follow up of all challenges scored as unacceptable, even though a passing score was achieved* (89%); and *Assess testing personnel competency* (69%).

Table 5 - Activities using proficiency testing samples and reports - All laboratories

Activity	**Frequency of activity**		
	Often or Always (more than 50% of shipments, reports)	**Sometimes** (25 to 50% of shipments, reports)	**Rarely or Never** (less than 25% of shipments, reports)
	Percent of laboratories		
Review summary report or critique	93	4	3
Follow up on all challenges that were scored as unacceptable, even though a passing score was achieved for the analyte	89	5	4
Assess testing personnel competency	69	18	12
Utilize summary reports / critiques as continuing education materials for staff	43	26	30
Utilize samples /challenges as continuing education events for staff	42	25	31
Select new test methods, reagents, instruments based on performance characteristics tabulated in summary reports	28	26	42

When comparing the percent of laboratories that ranked activities as "often" or "always," statistically significant differences were noted as follows: Independent laboratories used PT summary reports and critiques as continuing education materials at a higher rate than either POLs or hospital laboratories; A higher percentage of hospital laboratories selected new methods, reagents or instruments based on PT summary reports than POLs or independent laboratories; A lower percentage of POLs followed up on individual failed challenges (despite overall passing scores) than hospital or independent laboratories.

Table 6-Activities using proficiency testing samples and reports - POL, hospital and independent laboratories

Activity	Percent of laboratories that perform activity often or always		
	POL	Hospital	Independent
Review summary reports or critiques	91	95	100
Assess personnel competency	65	74	78
Utilize samples / challenges as continuing education events	39	47	46
Utilize reports / critiques as continuing education materials	40	41	59
Select new test methods, reagents, instruments based on summary reports	24	37	24
Follow up on all challenges that were scored as unacceptable, even though a passing score was achieved for the analyte	85	97	95

Proficiency testing participation problems

Participants were asked "What problems have you encountered in your participation in proficiency testing?" Using a list of 13 possible problems, laboratories were asked to indicate the frequency at which they encountered each problem. If they encountered additional problems not listed, those could be described under "Other." As a guide to answering this question, participants were instructed to choose one of the following for each of the problems listed: "never"; "rarely" if the problem was encountered with less than 25% of the PT testing events; "sometimes" if the problem was encountered with 25-50% of the events; "often" if the problem was encountered with more than 50% of the events; "always"; or "don't know."

Overall, problems appear to occur at low levels. For each problem listed, the percent of laboratories responding "never" or "rarely" ranged from 70% to 95%. To determine the issues that are most problematic for laboratories, responses that were ranked as "sometimes," "often" or "always" were combined for each problem. This would reflect a problem that occurred with more than 25% of the PT shipments or reports. Using these criteria, the following problems ranked highest: *My results are ungraded due to a non-consensus by participants or referees* (28% of laboratories ranked the frequency as sometimes, often or always); *The PT company mails my scores to me too late to take corrective actions before the next shipment arrives* (26%); *Handling PT samples is difficult or error-prone* (24%); and *Instructions for completing forms are difficult to understand* (24%).

Table 7 - Problems encountered with proficiency testing participation

Problem	**Frequency of the problem**		
	Often or Always (more than 50% of testing events)	**Sometimes** (25 to 50% of testing events)	**Rarely or Never** (less than 25% of testing events)
	Percent of laboratories		
My results are ungraded due to a non-consensus by participants or referees	6	22	70
The PT company mails my scores to me too late to take corrective actions before the next shipment	9	17	72
Handling PT samples is difficult or error-prone (dilutions, reconstitution, etc.)	6	18	75
Instructions for completing forms are difficult to understand	3	21	75
My results are ungraded due to lack of a peer group or other comparative group	5	16	77
Instructions for performing PT are difficult to understand	3	18	79
Instructions for completing forms are inconsistent from one event to the next	5	9	85
The PT company representatives are not helpful with technical questions, troubleshooting	4	8	74
The PT company representative are not helpful with clerical issues	4	7	81
There is a matrix problem with the PT sample	1	9	88
I do not understand the scoring information	1	6	93
The PT company doesn't acknowledge receipt of my results even though I mailed on time	4	2	94
The PT company enters my results incorrectly	1	3	95
Note: In some instances, percentages do not add to 100. In these cases, the remaining percentage reflects responses of "don't know" and/or "not applicable."			

When comparing the percent of laboratories that ranked problems as "sometimes," "often" or "always," hospitals demonstrated higher frequencies than POLs and independent laboratories for the following: receiving their scores too late; finding PT specimens difficult to handle; finding instructions for performing PT and completing forms difficult to understand or inconsistent among testing events or sets. This may be reflective of unique types of tests or specialties performed in the hospital setting as opposed to other types of laboratories.

Table 8 - Differences in frequency of PT problems encountered by hospital, POL and independent labs

Problem	**Percent of labs ranking frequency as sometimes, often or always**		
	Hospital	POL	Independent
Receiving scores too late	40	19*	25
Finding PT samples difficult to handle	39	19*	16*
Finding instructions for performing PT difficult to understand	34	15*	14*
Finding instructions for completing PT forms difficult to understand	35	18*	22
Finding instructions for completing PT forms inconsistent	24	9*	14
*denotes statistically significant difference from hospital laboratories (p=.05)			

Twenty-eight laboratories listed additional types of problems under "Other." Half of the problems listed (50%) related to proficiency testing samples. Problems with forms comprised 18% of the comments under "Other" and problems with reports, another 18%. The following are examples of these additional concerns:

PT samples
microscopy unknowns-don't match the real world
KOH, blood cell slides-are poor quality
ABG's-handling is difficult, not like human
difficulty with hemacytometer WBCs
hemolyzed samples
parasitology slides-are poor quality
specimens arrived improperly handled
Kodachromes-not optimal
shipment never came
wrong module mailed

PT forms
time consuming to complete
need to enter procedure codes each challenge
differ for each survey
inconsistent within same company
classification system difficult, unclear

PT reports
too long to get scores
company is changing report format
inadequate educational feedback on results
must send slides back before results are known

Cost burdens of proficiency testing participation

Laboratories were asked "From a cost standpoint, which aspect of proficiency testing participation is the most burdensome for your facility?" Using a list of four choices, participants were asked to select one.

The highest percentage of laboratories (59%) responded that *the costs of annual PT enrollment fees* were most burdensome. Twenty-two percent of laboratories chose *staff time to perform PT samples and complete result forms* and 11% chose *the use of reagents and disposables to analyze PT samples* as the most burdensome aspect of PT participation.

A significantly higher percent of hospital laboratories (33%) ranked staff time to perform PT samples as most burdensome, compared with POL (17%) and independent laboratories (19%). Large laboratories (annual test volumes > 75,000) also ranked this most burdensome at a significantly higher rate (33%) than smaller laboratories (18%).

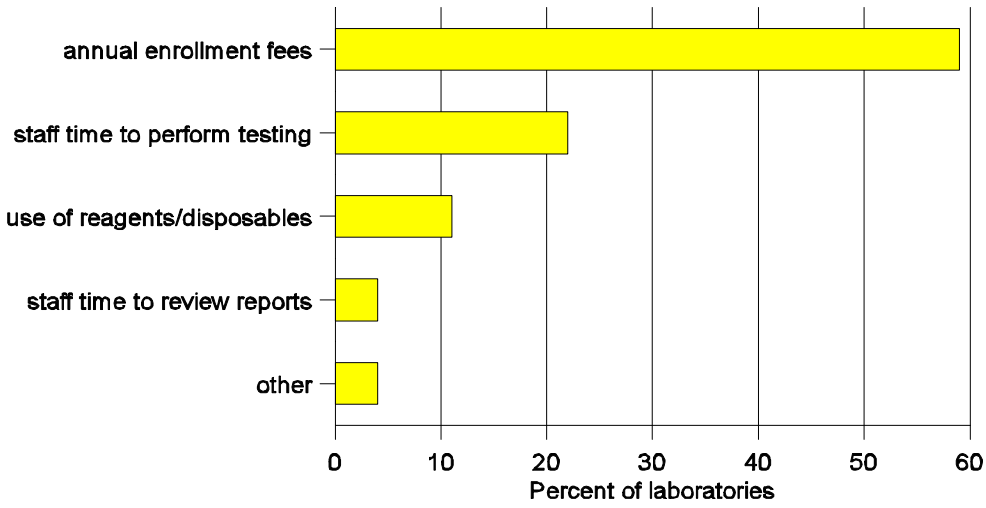

Figure 3 - Most costly aspect of participation in proficiency testing (N=303 laboratories)

Current enrollment in proficiency testing

Laboratories were asked to indicate the PT companies in which they were currently enrolled (for 1997). Three hundred thirteen laboratories answered this question as intended. Sixty-nine percent of laboratories were enrolled with one PT company and 31% were enrolled with multiple companies. Table 9 summarizes the number of network laboratories enrolled with each PT company. Table 10 shows the distribution of network laboratories subscribing to one or multiple PT companies.

Table 9 - Enrollment in proficiency testing companies in 1997

Proficiency testing company	Number of labs enrolled	Percent
Accutest	5	1
American Academy of Family Physicians (AAFP)	21	5
American Academy of Pediatrics (AAP)	5	1
American Association of Bioanalysts (AAB)	85	19
American Proficiency Institute (API)	25	6
American Society of Internal Medicine (ASIM - MLE)	20	5
American Thoracic Society	2	<1
College of American Pathologists (CAP)	129	29
EXCEL (CAP)	61	14
Idaho Bureau of Laboratories	45	10
Pacific Biometrics Research Foundation	6	1

Solomon Park Research Institute	1	<1
Wisconsin State Laboratory of Hygiene	20	5
Other programs	16	4

Table 10 - Enrollment in proficiency testing - 1997

Enrollment with:	**Number of labs**	**Percent**
1 company	215	69
2 companies	76	24
3 companies	15	5
4 companies	5	1
5 companies	2	1

DISCUSSION

Current laboratory regulations-the Clinical Laboratory Improvement Amendments of 1988 (CLIA)- require that laboratories performing moderate and/or high complexity testing must successfully participate in a PT program for each specialty, subspecialty and analyte or test in which the laboratory is certified. While PT results are reviewed by regulatory agencies and accrediting bodies to determine a laboratory's successful compliance with performance requirements, there is a current emphasis on the value of PT as an educational tool in the overall quality assurance scheme.

Data gathered from network participants on previous questionnaires revealed that proficiency testing is generally accepted as a valuable quality assurance activity. With Questionnaire 1 (Quality Assurance Practices - June 1995), 98% of the network respondents reviewed proficiency testing results as one of their formal quality assurance monitors and 88% ranked the activity as "valuable" or "very valuable." This is supported in our findings from Questionnaire 7. Ninety percent of respondents would continue to perform PT on an ongoing basis, with 48% remaining at current required levels, 12% at levels exceeding current requirements and 30% performing fewer challenges. Laboratories are using PT samples to engage in a variety of quality assurance and educational activities, beyond satisfying a regulatory requirement.

In order to determine how satisfied laboratories are with current PT programs, we approached this topic from several directions. The frequency with which laboratories change companies is one means of determining satisfaction with companies (or offerings) and provides insight into the features deemed most important. Only 29% of laboratories changed PT companies in the last five years. Costs, test selection and customer service issues were given most frequently as reasons for

a change in companies.

We asked specifically about problems encountered and found these to be generally low. For each problem listed, the percent of laboratories responding that the frequency of occurrence was "sometimes," "often" or "always" ranged from 4% to 28%. Ranking highest were problems related to participant scores (non-consensus among participants or referees and lengthy time frames for receipt of scores), difficulties handling PT samples and difficulties understanding instructions for completing PT forms.

Finally, we asked about burdens from a cost standpoint. Data gathered from a previous questionnaire (Questionnaire 3 - Access to Laboratory Testing - March 1996) showed that 14% of all secondary reasons given by laboratories that discontinued testing between 1994 and 1996 related to the cost of PT participation. Responses from Questionnaire 7 revealed that the highest percent of laboratories (59%) felt that the cost of annual enrollment fees was most burdensome, followed by 22% of laboratories citing the cost of staff time to perform PT testing.

CONCLUSIONS

Through this data gathering device, we evaluated the degree to which network laboratories regard PT as a valuable quality assurance activity. In addition, we investigated the ways that respondents might change the number and frequency of PT challenges, to balance quality benefits with cost constraints. We found that the majority of network respondents would continue to participate in PT at some level, regardless of regulatory mandates. We recognize, however, that the vast majority of individuals completing these questionnaires are laboratory supervisors, managers and testing personnel as opposed to laboratory directors, owners or administrators. The latter, or others directly responsible for laboratory expenditures, may have responded differently to this question.

We also found that network laboratories experience relatively few problems incorporating PT into their routine laboratory testing activities. PT providers may use this information to recognize issues that are most important to their subscribers to enhance the value of this participation.