The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network
Final Report of the Findings of Questionnaire 12
Proficiency Testing and Quality Assurance Practices

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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. To date, 12 questionnaires have been released to the network, exploring issues related to: testing quality; access to testing services; laboratory-related problems and errors; personnel training and changes; proficiency testing participation; and point of care and waived test systems.

[Final reports of the findings of each questionnaire can be found on the Centers for Disease Control and Prevention (CDC) website: http://www.phppo.cdc.gov/dls/mlp/pnlmsmn/asp]

Proficiency testing

Current laboratory regulations (the Clinical Laboratory Improvement Amendments of 1988 [CLIA] and Washington and Oregon CLIA-exempt state regulations) require that laboratories performing moderate and/or high complexity testing successfully participate in an approved proficiency testing (PT) program for each specialty, subspecialty and regulated analyte or test in which the laboratory is certified. Although PT results are reviewed by regulatory agencies and accrediting organizations to determine a laboratory's compliance with performance requirements, there is a current emphasis on the value of PT as a key component of a laboratory's overall quality assurance scheme. Regulatory intervention does not occur until there are unacceptable scores for an analyte or test speciality on two consecutive or two of three PT events. However, laboratories are provided with information with each PT event, to identify potential analytical problems, adopt new quality control (QC) or quality assurance (QA) activities or monitors, enhance existing ones and prevent similar problems from occurring.

QUESTIONNAIRE 12

Questionnaire 12 was mailed to 381 laboratories in July 1999. The intent of this questionnaire was to focus on the reasons for less than acceptable PT scores and the QC and QA monitors or activities that best discover or identify the underlying reason for the unacceptable score. We did not intend to capture failure rates or focus on problems with PT companies, both of which have been previously studied and reported upon by many other researchers.

Two hundred twenty-seven laboratories returned a completed questionnaire in time for analysis, a 60% response rate. Demographic characteristics of the respondents are summarized in Table 1.

Table 1 - Questionnaire 12 respondents (N=227 laboratories)

Demographic characteristic	Percent of laboratories
Washington	51
Oregon	22
Idaho	19
Alaska	8
Physician office	59
Hospital	28
Independent	14
Urban	61
Rural	39

FINDINGS

Laboratories with less than 80% proficiency testing scores

One hundred five laboratories (48%) responded that they had at least one score of less than 80% for an analyte in the past two years (six testing events) (Table 2). Using multi variate analysis of variance, the only significant factor for having <80% PT scores was rural location ($p=0.02$), which may be acting as a surrogate for other factors.

Table 2 - Laboratories with at least one <80% score

	State				Lab type			Location	
	WA	OR	ID	AK	POL	Hospital	Independent	Urban	Rural
Total number responding	115	50	43	19	133	63	31	138	89
Percent with <80% score	47	40	49	53	34	73	45	33	66

	Accredited		MT or MLT		Annual test volume (x1000)				
	Yes	No	Yes	No	<2	2 to 10	10 to 25	25 to 100	>100
Total number responding	71	144	166	48	39	64	33	35	54
Percent with <80% score	63	40	55	23	21	31	55	71	59

Laboratories were asked to record the name of each test (analyte) for which they received a score of less than 80% (or less than 100% for ABO, Rh or compatibility testing). A total of 246 analytes were listed. The most common tests were categorized under chemistry (58%), followed by hematology (20%), microbiology (13%), immunology (5%), blood bank (1%) and urine sediment exams (1%). Appendix I shows all tests by test specialty, in order of frequency.

<u>Reasons for <80% scores</u>

For each test listed, participants were asked to select one reason, from a list of 19 possible choices, for the <80% score. Reasons were grouped into the following categories:

- Mix up of specimens prior to testing
- Problems with instrument/kit/testing materials
- Problems in test performance
- Problems unique to proficiency testing performance
- Reason unknown

If none of the choices applied, laboratories could describe their own particular reason.

The most common individual reasons given for a PT score <80% were:

- Problem with standard, calibrator, reagent, kit or media
- Misidentification of cell, organism, urine sediment element
- Instrument failure
- Incorrect completion of PT forms

When all reasons were grouped into our categories, they were almost equally distributed between the following:

- Problems with instrument/kit/testing materials (30%)
- Problems in test performance (28%)
- Problems unique to proficiency testing performance (26%)

Table 3 shows all the reason given for tests with <80% scores.

Table 3 - Reasons for <80% PT scores

Reasons	Percent
Mix up of specimens prior to testing	**2**
Problems with instrument/kit/testing materials	**30**
Instrument failure	9
Instrument maintenance problem	6
Problem with standard, calibrator, reagent, kit or media	15
Problems in test performance	**28**
Test performed incorrectly	4
Test result exceeded method linearity	<1
Controls were outside acceptable limits	2
Calibration performed incorrectly	3
Calculation error	1
Transcription or transposition error during test performance	4
Misidentification of cell, organism, urine sediment element	10
Misinterpretation of qualitative results	1
Improper techniques used or improper conditions for culturing or isolating organisms	2

Reasons	Percent
Problems unique to proficiency testing performance	**26**
Incorrect completion of PT forms	9
Incorrect reconstitution or dilution of PT samples	1
Matrix problems with PT samples	2
Shipping or stability problems with PT samples	4
Missed deadline for return of PT results	1
Misplaced PT samples, not tested, results not sent to PT agency	3
PT samples mishandled, tested wrong specimens	1
PT agency scored results in incorrect peer group, lost results	3
PT samples were poor, inadequate volume, handled differently than patient samples	2
Reason unknown	**10**
Other	**3**

Quality control / quality assurance monitors or activities

For each test listed, laboratories were asked "in hindsight, could this problem have been predicted or prevented from a routine quality control (QC) or quality assurance (QA) monitor or activity that you already had in place?" If yes, they were asked to select from a list of 14 general QC or QA monitors or activities, one that best described the activity or monitor they had in place.

For each test listed, laboratories were asked "did you implement a new QC or QA monitor or activity as a result of this problem?" If yes, they were asked to select from the same list of general QC or QA monitors or activities, one that best described the activity or monitor they implemented.

Respondents had at least one existing QC or QA monitor or activity in place for 56 (23%) of the analytes listed and implemented a new QC or QA monitor or activity as a result of their unacceptable PT scores for 79 (32%) analytes.

The following are reasons why existing QC or QA monitors or activities may not detect problems or errors. Examples, given by the respondents, are provided.

• A monitor or activity may not be performed or not performed frequently enough.

> "Monitor in place, internal compliance issue"
> "Reemphasis on instrument maintenance and accountability"
> "Increased frequency of daily calibrations"
> "QC/QA in place, didn't have time to investigate trend"

• Testing personnel may not understand how to interpret information or are not following protocols.

> "QC/QA in place, error in tech judgement"
> "Restated policy"
> "Staff inservice on acceptable calibrations"
> "Education and counseling provided to tech"

• The monitor may not be sensitive enough to detect errors.

> "We're more careful about subtle changes and documenting on problem log"
> "Assigned control range was too wide"
> "Instrument due for recalibration soon, QC starting to shift"
> "Set tighter constraints on QC for personnel"

Table 4 summarizes these QC and QA monitors or activities, according to the reasons given for the less than 80% score.

Table 4 - Quality control and quality assurance activities

Reason	Number of responses				
	Total	**Existing QC/QA**	**QC/QA monitor**	**New QC/QA**	**QC/QA monitor**
Mix up prior to testing	6	0		2	-Train personnel
Instrument failure	24	4	-Review control results -Perform instrument maintenance	6	-Check instrument function -Perform recalibration -Started using higher control than before
Instrument maintenance	15	5	-Review control results -Review problem log	10	-Perform instrument maintenance -Perform recalibration -Check instrument function -Revise procedure -Review control results
Problem with standard, calibrator, reagent, kit, media	37	11	-Review control results -Check out reagents -Check calculations -Perform instrument maintenance -Review problem log	12	-Review control results -Perform recalibration -Check out reagents -Perform calibration verification -Train personnel -Store reagents in cooler refrigerator
Test performed incorrectly	10	3	-Review procedure -Assess personnel competency	4	-Train personnel -Assess personnel competency -Check calculations -Review problem log -Review procedure
Result exceeded linearity	1	0		1	-Review control results -Check instrument function -Check calculations -Check out reagents
Controls exceeded acceptable limits	6	5	-Review control results -Perform recalibration	4	-Review control results -Check instrument function -Perform recalibration
Calibration performed incorrectly	7	7	-Perform recalibration -Review control results	1	-Revise procedure to perform more frequently
Calculation error	2	0		0	
Transcription or transposition error during test performance	11	2	-Review results for accuracy -Check calculations	4	-Review results for accuracy -Train personnel -Check calculations

Reason	**Total**	**Existing QA/QC**	**QC/QA monitor**	**New QA/QC**	**QC/QA monitor**
Misidentification of cell, organism, urine sediment element	26	5	-Review procedure -Assess personnel competency -Revise procedure -Train personnel	11	-Revise procedure -Train personnel -Assess personnel competency -Review results for accuracy -Have second tech review when direct exam results and stained results don't compare
Misinterpretation of qualitative results	3	0		1	-Train personnel -Assess personnel competency -Replace with new kit
Improper techniques used in culturing	5	3	-Review procedure -Revise procedure -Train personnel -Follow through on flowchart	4	-Revise procedure -Train personnel
Incorrect completion of PT forms	24	9	-Review test results for accuracy -Review procedure -Two techs review PT forms	6	-Review test results for accuracy -Review test method codes -Train personnel
Incorrect reconstitution or dilution of PT samples	2	0		1	-Train personnel

DISCUSSION

Our intent was to use the collective input of our network respondents to recognize the quality assurance and control activities that best identify laboratory problems and errors. The following summarize the most common responses of the network respondents (which are underlined) and some general comments on quality assessment practices for each category of reasons.

MIX UP OF SPECIMENS PRIOR TO TESTING

•Although errors of this type are usually random and non-systematic, an evaluation of systems for assuring positive specimen identification and the labeling of aliquots and instrument specimen vials may be useful.

PROBLEMS WITH INSTRUMENT/KIT/TESTING MATERIALS

<u>Review control results</u>
•Quality control values may be well documented but not critically reviewed on a regular basis. You may need to address more subtle changes in control values.

•Look at how your control ranges were derived. If you assayed your controls, your ranges may be mis-assigned or too broad to detect errors.

•Your selection of levels of controls may need revising. For example, choosing one near your upper limit of linearity, if your PT failures are in the high range.

•Your criteria to accept test runs may be too lenient or may be incorrectly interpreted on consecutive test runs. Some participants found that PT failures occurred when accepting test runs when one of two controls was within acceptable limits.

<u>Perform instrument maintenance</u>

<u>Verify calibration, check instrument function</u>

<u>Review problem log</u>
•Institute a problem log, encourage better documentation or review more frequently.

<u>Check out reagents, other testing materials</u>
•Participants discovered reagent stability/integrity issues and made simple practice changes:

Store reagents in a cooler refrigerator.
Standard gets contaminated so it is changed more often.
Alcohol fumes from cytology department were interfering with test for ethanol.

<u>Check calculations</u>

Revise procedure and train personnel

Replace instrument or drop testing

PROBLEMS IN TEST PERFORMANCE

Test performed incorrectly
Review procedure
•Compare your written procedure against the manufacturer's technical manual or product insert.

•Check abbreviated procedural work cards for accuracy.

•Have testing personnel review technical procedures to catch any omissions or subtle differences in their practices and the official procedure.

Assess personnel competency
•Observe personnel performing each procedure on a regular basis - especially for rarely performed tests, complicated procedures or ones with calculations.

Train personnel

Check calculations

Review problem log

Test result exceeded method linearity
•Determine or verify your linear reportable limits.

•Re-verify when there is any major change in reagents, critical instrument parts, significant shifts in control values.

•Are linear reportable limits available to testing personnel and is there a protocol for how to handle test results that exceed the limits?

Controls were outside acceptable limits
Review control results
•If you are using statistical rules to accept runs, they may be misunderstood or incorrectly applied.

•May need stricter rules for run acceptance.

Calibration performed incorrectly
Review and revise procedure
•Assure that testing personnel understand when calibration meets acceptable criteria

•Review quality control results critically after calibration

•Perform calibration verification after each calibration or more frequently

Calculation error
•Compare your written procedure against the manufacturer's technical manual or product insert.

•Check abbreviated procedural work cards for accuracy.

•Implement a check by a second testing personnel for any calculations.

Transcription or transposition error during test performance
Review result for accuracy
•Implement a check by a second testing personnel for all final test reports.

Check calculations

Train personnel

•Evaluate your reporting system: Do instrument tapes, result logs and report formats follow the same order? Can any of these improve with a redesign?

Misidentification of cell, organism, urine sediment element
Review and revise procedures
•Verify microbiology flow charts

•Assure that personnel adhere to procedures

Assess personnel competency

Train personnel

•For cell identification, assess written protocols for reporting abnormal cells - are testing personnel reporting results for PT unknowns beyond their skill levels?

•For microbiology, are testing personnel identifying organisms to an extent beyond the systems for identification you have available?

Misinterpretation of qualitative results
Assess personnel competency

Train personnel

Replace with new kit

•Use the PT summary report statistics to choose a kit with better performance characteristics (i.e., fewer false positives or false negatives)

Improper techniques used or improper conditions for culturing or isolating organisms
Review and revise procedures

Train personnel

PROBLEMS UNIQUE TO PROFICIENCY TESTING PERFORMANCE

Incorrect completion of PT forms
Review results for accuracy

•Many participants have an existing policy or adopted a new practice to have a second person review the PT forms prior to mailing the results to the PT agency.

Review procedures

Train personnel

•If this occurs frequently, it can indicate a lack of attention to detail and individual testing personnel may need an assessment.

Overall -

A good practice is to integrate your PT samples into your routine testing process as fully as possible. Although PT samples best identify analytical errors, you can also detect problems in accessioning, specimen identification and reporting issues as well. PT samples should be placed in perspective with the results of other patients, typical quality control samples, reagent lot changes, etc. to get the full impact of the testing conditions on the date of testing or the particular testing run. This type of practice allows the best chance to identify the source of a problem that may be affecting the quality of your patient testing.

Consider implementing an internal blind sample program, by introducing split samples into the routine workload. These programs are excellent in identifying problems that are sometimes difficult to detect otherwise.

CONCLUSIONS

In this questionnaire, we hoped to present an overview of quality assurance activities and monitors that best identify errors, especially those detected from an external source. In addition, we hope that by simply completing this questionnaire some laboratories may have learned some new ways to look at systems for problem identification and corrective activities.

Flaws in the design of a quality assurance program or in the establishment of testing performance criteria, or the lack of the assessment of personnel competency can all lead to some undetected testing errors. The introduction of proficiency testing unknowns balances a laboratory's ability to detect inadequacies in their internal quality assurance system. With good record keeping and detective skills, laboratories can use proficiency test scores to identify areas where corrective actions will have the most impact.

Proficiency testing results usually represent a laboratory's best practices, so any failure should warrant review. While random errors are also detected by the proficiency testing process, the exercises in investigating potential problems are usually worthwhile overall.

Other studies of proficiency testing scores show that single analyte failures are relatively common, however consecutive failure rates for the same analyte are quite rare. This demonstrates the capacity of laboratories to use this information to improve their testing performance.

Appendix i - Tests listed with <80% scores

Tests	Number	Percent
Chemistry	**142**	**58**
Sodium	15	
Thyroid	14	
Therapeutic drugs	12	
Arterial blood gases	9	
Creatinine	7	
Amylase	6	
Cholesterol	6	
HDL cholesterol	6	
HCG	6	
Albumin	5	
Bilirubin	5	
BUN	5	
Chloride	4	
Glucose	4	
AST	3	
Ethanol	3	
LD	3	
Uric acid	3	

Listed twice each: Alkaline phosphatase, ALT, CK-MB, Cortisol.
Listed once each: Calcium, Chemistry profile, DHEA sulfate, Electrolytes, GPT, Insulin, Iron, Lead, Magnesium, Myoglobin, Phosphorus, Prealbumin, Testosterone, Total protein, Urine glucose, Urine protein, Zinc, FSH.

Hematology	**49**	**20**
Coagulation	18	
Cell identification	10	
Hematocrit	10	
Reticulocyte count	2	
Red blood cell count	2	
White blood cell count	2	
Hemoglobin	1	
Hemoglobin A1C	1	
Centrifugal hematology (QBC)	1	
Erythrocyte sedimentation rate	1	
Platelet count	1	

Appendix i - continued

Microbiology	**33**	**13**
Bacteria identification	11	
Parasitology, Ova & parasites	4	
Throat culture	2	
Urine culture	2	
GC culture	2	
Wound culture	2	
Mycology	2	
Gram stain	2	
Strep antigen	2	
Mycobacteria	1	
Sensitivity	1	
Stool culture	1	
Antigen detection	1	
Immunology	**12**	**5**
Mononucleosis	5	
Prostate specific antigen	2	
Rheumatoid arthritis	2	
Helicobacter pylori	1	
HIV antibody	1	
IgE	1	
Immunohematology	**3**	**1**
ABO	1	
Antibody detection	1	
Compatibility test	1	
Urine sediment examination	**3**	**1**
Not specified	**4**	**2**