The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network
Final Report of the Findings of Questionnaire 4
Corrected Patient Reports

Kathleen M. LaBeau [1], Marianne Simon [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
206 361-2802

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

February 1997

Questionnaire 4 was mailed to all 256 network participants in July 1996. The intent of this questionnaire was to determine the rate at which patient laboratory reports are amended and to characterize the sources of problems, errors or occurrences associated with the issuing of corrected patient reports. In addition, we hoped to assess the network participants' willingness and capacity to conduct a prospective study and to share information about their laboratory related problems and errors.

Questionnaire 4

Between July and October 1996, eight laboratories were deleted from the network due to various reasons (too busy to contribute time to the network; office closed; no longer perform regulated testing), leaving a total of 248 laboratories. One hundred ten usable questionnaires were returned in time for analysis, a 44% response rate. The demographics of laboratories that responded to this questionnaire did not differ significantly from the non-responders for aspects of laboratory type, location, accreditation status or personnel background.

Table 1 - Laboratories that Did and Did Not Respond to Questionnaire 4

Demographic Characteristic	**Responders** (N=110 Labs)	**Non-Responders** (N=138 Labs)
	percent	percent
Physician Office Laboratory (POL)	61	56
Hospital	22	27
Independent	17	17
Urban	70	74
Rural	30	26
Annual Test Volumes:		
< 2000	17	23
2000 to 10000	29	27
10000 to 25000	12	14
25000 to 50000	10	7
50000 to 75000	5	3
75000 to 100000	0	4
> 100000	26	22

Table 1 - continued - Laboratories that Did and Did Not Respond to Questionnaire 4

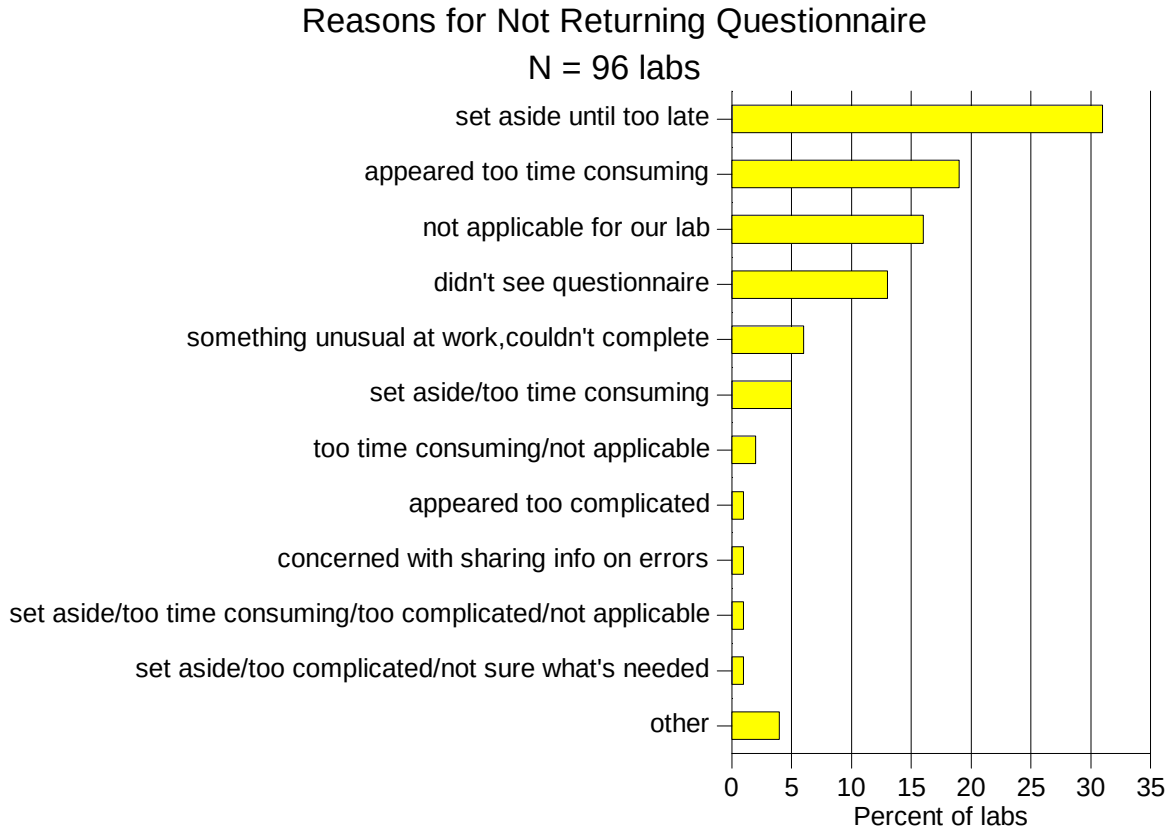
Demographic Characteristic	**Responders** (N=110 Labs)	**Non-Responders** (N=138 Labs)
	percent	percent
Accredited:		
Yes	27	28
No	73	72
Personnel with formal lab training (at least one medical technologist /technician on staff):		
Yes	66	75
No	34	25

Non-Responders

Since the format and content of Questionnaire 4 were quite different from what we had used in our previous questionnaires, we were very interested to learn why certain network participants did not return a completed questionnaire. To gather this information, a letter was sent to non-responders in October 1996. Using a list of seven possible reasons, participants were asked to select one to explain why they did not return a completed questionnaire. They were also given an opportunity to briefly specify a reason that did not appear among those listed. Ninety-six laboratories returned the form indicating their reasons for not completing a questionnaire.

The reason given most frequently was that the questionnaire was set aside and overlooked until too late. This was followed by: it appeared too time consuming to fit into our workload; it was not applicable for my type of facility; and I did not see Questionnaire 4. Only three laboratories thought it appeared too complicated and only one laboratory was unsure of what was needed. Two laboratories expressed a concern about sharing information on errors or sharing information with their government. Figure 1 illustrates the reasons given by the laboratories that chose not to respond to Questionnaire 4.

Figure 1



Corrected Reports

In this questionnaire, laboratories were asked "for the next eight (8) weeks, track the number of patient laboratory test reports that are corrected." For each corrected patient report, participants were asked to determine where the testing was performed and to tally each corrected report according to reasons listed, using separate forms for "testing performed on-site" and "testing performed by reference lab(s)". At the end of the eight-week period, tally marks were totaled to reflect the number of corrected reports detected for testing performed on-site and the number detected for testing performed by reference laboratories. The number of tests performed on-site and the number of tests sent out to reference laboratories for the same eight-week period were recorded. If network participants already tracked this information on an ongoing basis, they could complete these forms using existing data, as long as they selected data from an eight week period and provided test volumes for that time frame.

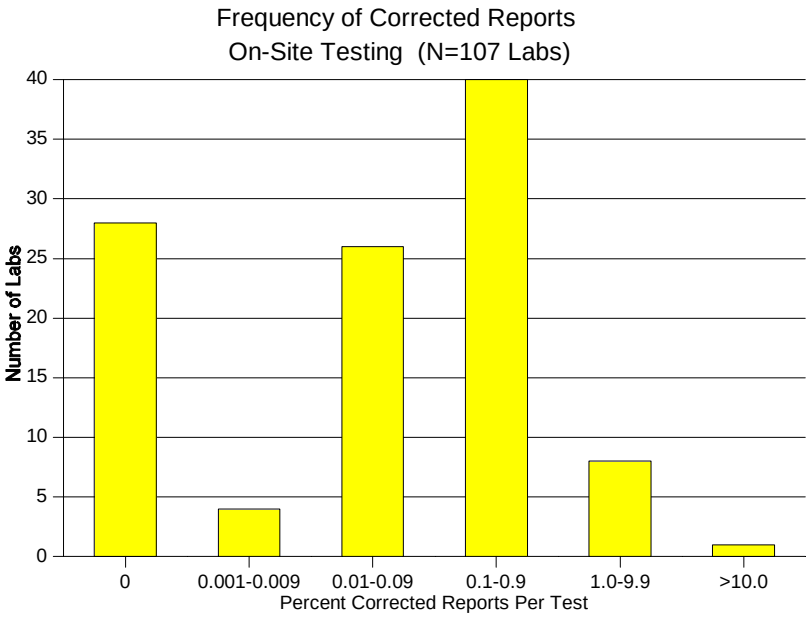
Corrected Reports - Testing Performed On-Site

One hundred ten laboratories provided usable data for this question. A total of 1804 patient reports were corrected in these laboratories during an eight-week study period. The number of corrected reports per laboratory ranged from 0 to 213. The total volume of on-site tests ranged from 2 to 528,754.

For an indication of the frequency at which test reports were corrected, the following calculation was made for each laboratory: Percent corrected reports per on-site test performed = number of corrected reports / 8 week on-site test volume x 100. One hundred seven laboratories provided data to calculate the frequency of corrected reports. The percent corrected reports per on-site test performed ranged from 0% to 17.85%. A mean frequency of 0.44% was calculated, reflecting 4 corrected reports per 1000 on-site tests performed. The median, which describes the midpoint in the data, was 0.07%. In a skewed distribution, the median value may be a more informative measure of central tendency, since it is less affected by extreme values than the mean.

We recognize that there are inaccuracies in the test volumes provided by respondents for this study. It is assumed that respondents used any number of approaches in counting and reflecting test volumes, including: counting each individual test; counting profiles as a single test; counting billable tests; counting all tests; using workload recording figures; using estimates; etc. Therefore, the frequency of corrected reports calculated in this report are to be used with the awareness of the limitations on the accuracy of the test volumes provided throughout this study. Figure 2 shows the distribution of laboratories according to rates of corrected reports per on-site test.

Figure 2



The rates of corrected reports are summarized in Table 2 according to eight-week test volumes and various laboratory characteristics.

Table 2 - Corrected Reports - On-Site Testing

Eight-Week On-Site Test Volume	Number of Labs	Percent Corrected Reports per Test	
		Mean	Median
< 100	12	1.93 (0.48 *)	0
>100 to < 1000	27	0.44	0.13
> 1000 < 10000	37	0.26	0.15
>10000 <100000	25	0.1	0.04
> 100000	6	0.06	0.05
POL	64	0.63 (0.36*)	0.06
Hospital	24	0.14	0.11
Independent	19	0.18	0.06
Urban	75	0.54 (0.30 *)	0.05
Rural	32	0.22	0.12
Accredited: Yes	30	0.2	0.08
No	77	0.54 (0.31 *)	0.07
Personnel with Formal Lab Training: Yes	70	0.19	0.07
No	37	0.92 (0.45 *)	0.1

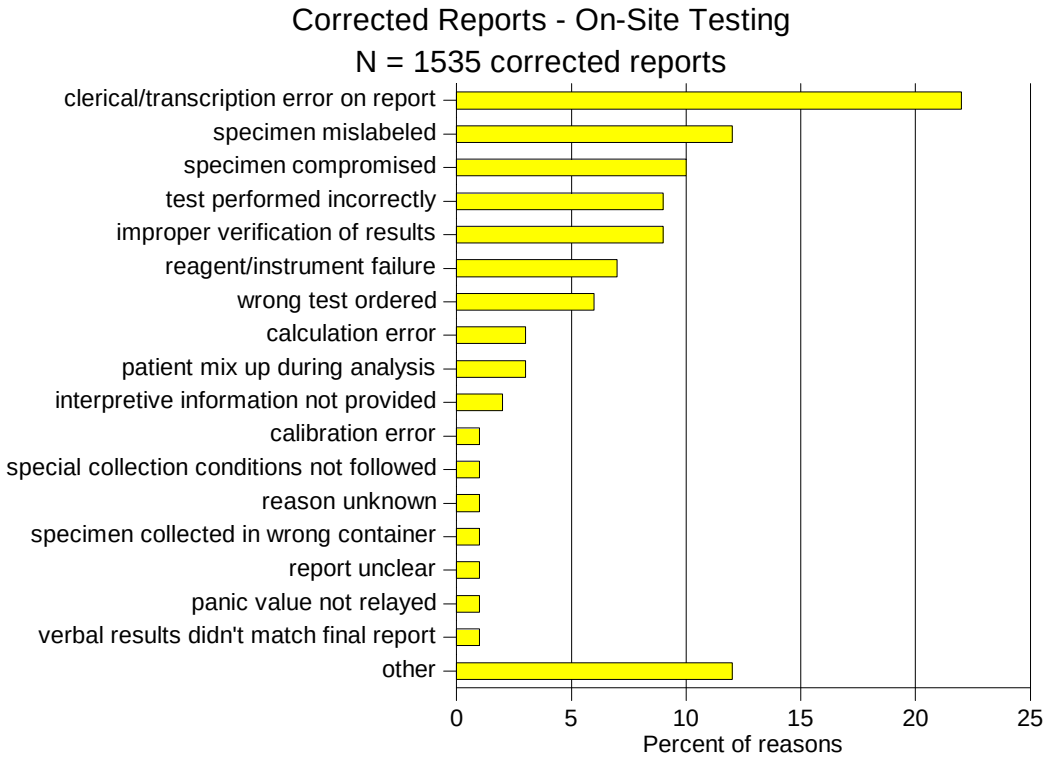
* mean when outlier value of 17.85% is removed

Reasons for Corrected Patient Reports

Using a list of 16 possible reasons, participants were asked to select one to describe the problem, error or occurrence associated with each corrected report detected. Any reason not listed could be described under "other" and if no reason could be determined, "reason unknown" could be selected.

Of the total 1804 corrected reports detected, 1535 were evaluated according to reasons. The remainder represent instances where the number of corrected reports detected by a laboratory did not match the number tallied by reasons, and were not included in this analysis. The most frequent reasons identified were due to: a clerical or transcription error related to reporting the test result (accounting for 22% of the reasons); the specimen being mislabeled, having no label, or insufficient patient information on the container (12%); and the specimen being compromised prior to analysis (10%).

Figure 3



When individual reasons were grouped according to categories of interest, problems associated with the test performance phase occurred most frequently (35% of all reasons), followed by problems occurring in the test reporting phase (29%).

Table 3 - Corrected Reports - On-Site Testing

Phase of Testing	**Percent of Reasons for Corrected Reports**
Specimen collection & handling	24
Test ordering	9
Test performance	35
Reporting test result	29
Other - reasons unclear, not categorized	3
Cause of error unknown	<1

POLs detected 299 corrected reports during the eight-week period - 283 were evaluated according to reasons. The most common reasons given were: specimen mislabeled, no label, insufficient patient information on container (16% of all reasons); clerical or transcription error related to reporting test result (14%); specimen compromised prior to analysis (13%); and reagent/ instrument/ equipment failure (13%).

Hospitals detected 992 corrected reports - 742 were evaluated according to reasons. The most common reasons given were: clerical or transcription error (17%); test performed incorrectly (16%); improper verification of results (14%); and specimen mislabeled, no label, insufficient patient information on container (10%).

Independent laboratories detected 513 corrected reports - 510 were evaluated according to reasons. The most common reasons given were: clerical or transcription error (33%); specimen compromised prior to analysis (11%); specimen mislabeled, no label, insufficient patient information on container (11%); and reagent/ instrument/ equipment failure (7%).

Corrected Reports - Testing Performed by Reference Laboratories

One hundred two laboratories provided usable data for this question. A total of 859 patient reports were corrected in these laboratories during the eight-week study period. The number of corrected reports per laboratory ranged from 0 to 147. The total volume of testing sent out to referral laboratories ranged from 16 to 202,938. Ninety-five laboratories provided data to calculate the percent of corrected reports per reference laboratory test performed. The percent ranged from 0 to 7.33%. A mean of 0.92% was calculated, reflecting 9 corrected reports per

1000 tests. The median frequency was 0.25% . Figure 4 shows the distribution of laboratories, according to the rates of corrected reports per reference laboratory test.

Figure 4

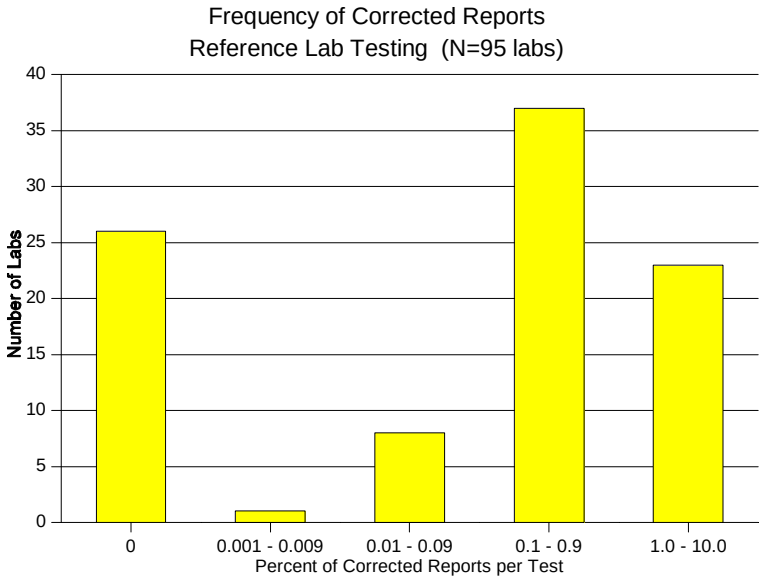


Table 4 summarizes the frequency of corrected reports according to various eight-week test volumes.

Table 4 - Corrected Reports - Testing Performed by Reference Labs

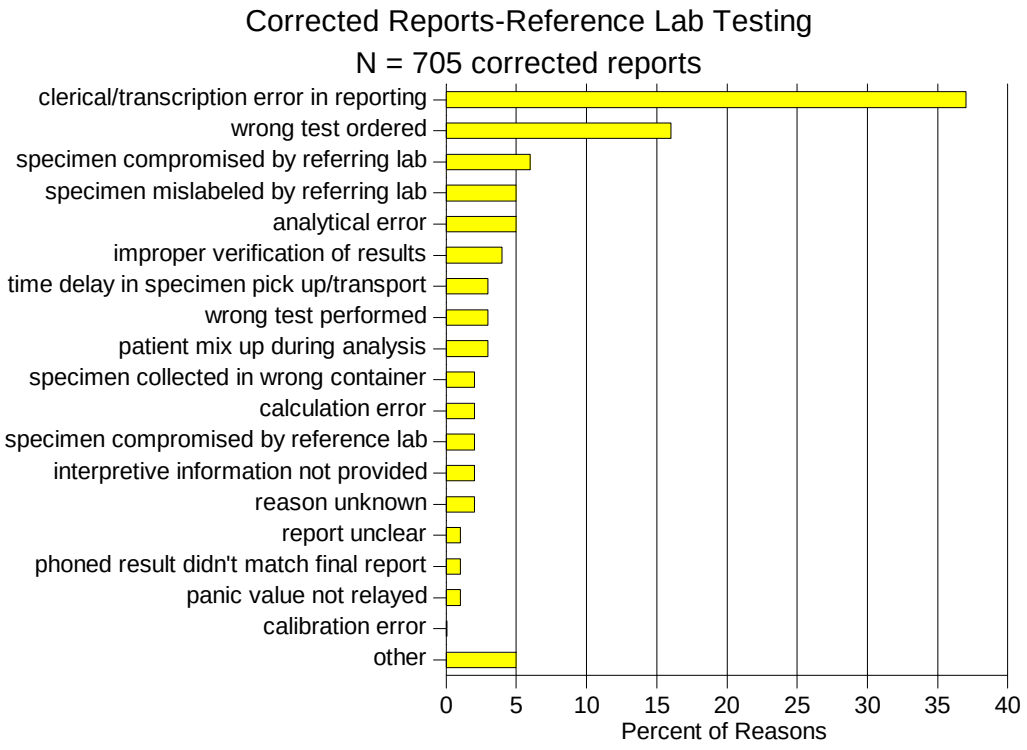
Eight-Week Reference Lab Test Volume	**Number of Labs**	**Percent Corrected Reports per Test**	
		Mean	Median
< 100	6	1.11	0
>100 < 1000	57	1.04	0.52
>1000 < 10000	27	0.79	0.2
>10000 <100000	4	0.04	0.03
>100000	1	0.07	0.07

Reasons for Corrected Patient Reports

Using a list of 17 possible reasons, participants were asked to select one to describe the problem, error or occurrence associated with each corrected report detected. Any reason not listed could be described under "other" and if no reason was detected "reason unknown" could be selected. Responses where the total number of corrected reports for a laboratory matched the number tallied by reason were evaluated.

Of the total 859 corrected reports issued, 705 were evaluated according to reasons. The most frequent reasons identified were due to: a clerical or transcription error related to reporting a test result (37% of all reasons given); wrong test ordered, order unclear, pertinent patient information not provided by the laboratory referring the specimen (16%); and specimen compromised prior to analysis by the laboratory referring the specimen (6%).

Figure 5



When individual reasons were grouped according to categories of interest, problems associated with the test reporting phase by the reference laboratory occurred most frequently (44% of the reasons), followed by problems associated with specimen collection, handling and submission by the laboratory referring the specimen (31%).

Table 5 - Corrected Reports - Reference Lab Testing

Phase of Testing	**Percent of Reasons for Corrected Reports**
Specimen collection / handling / test ordering by lab referring specimen	31
Specimen transport / accessioning / processing by reference lab	7
Test performance by reference lab	17
Reporting test result by reference lab	44
Cause of error unknown or not relayed by reference lab	2

POLs detected 375 corrected reports for tests performed by reference laboratories - 343 were evaluated according to reasons. The most common reason given were: clerical or transcription errors during reporting of results by the reference laboratory (33% of all reasons); wrong test ordered, order unclear, pertinent patient information not provided by the laboratory referring the specimen (13%); specimen mislabeled or incompletely labeled by the laboratory referring the specimen (10%).

Hospital laboratories detected 241 corrected reports - 120 were evaluated according to reasons. The most common reasons were: clerical or transcription errors during reporting of results by the reference laboratory (63%); and wrong test ordered by the laboratory referring the specimen (11%).

Independent laboratories detected 243 corrected reports - 242 were evaluated according to reasons. The most common were: clerical or transcription errors during reporting of results by the reference laboratory (30%); wrong test ordered by the laboratory referring the specimen (22%); and analytical errors by the reference laboratory (13%).

Corrected Reports - Total Testing Process

The intent of this study was to evaluate the entire testing process, for all laboratory test orders generated in a testing site during an eight-week period, regardless of whether testing was performed on-site or at alternate sites. The total number of corrected reports per laboratory was determined by summing the number of corrected reports from on-site testing and the number of corrected reports from reference laboratory testing. The total volume of tests ordered per laboratory was determined by summing the number of tests performed on-site and the number of

tests sent to reference laboratories.

One hundred one laboratories provided information about on-site and reference laboratory testing. A total of 2357 corrected reports were issued, with a mean of 23 total corrected reports per network laboratory and a range of 0 to 329 total corrected reports per laboratory. Ninety-eight laboratories provided data to calculate the percent of total corrected reports per total tests. The percent ranged from 0 to 7.96. A mean frequency of 0.47% was calculated, reflecting 5 corrected reports per 1000 tests. The median frequency was 0.18%.

Figure 6

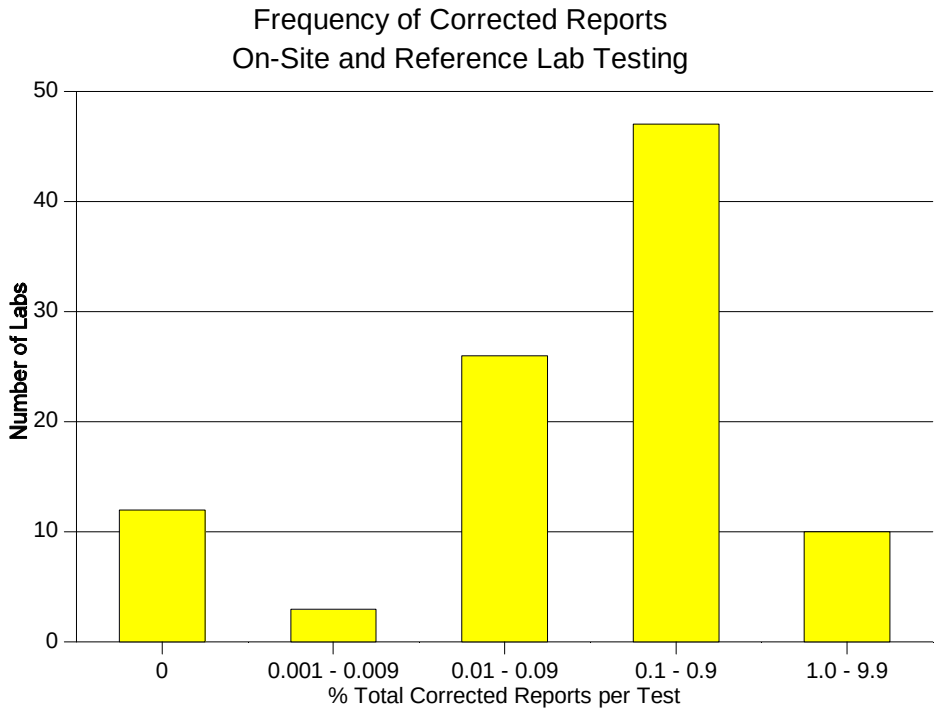


Table 6 categorizes all corrected reports according to phases of testing for all laboratories.

Table 6 - Corrected Reports - Total Testing Process - All Laboratories

Phase of Testing	**Percent of Reasons**
Specimen collection & handling	21
Test ordering	11
Specimen pick up, transport & processing by reference lab	2
Test performance	29
Test reporting	33
Other - reason unclear, not categorized	2
Reason unknown	1

Table 7 categorizes all corrected reports according to phases of testing for POLs, hospital and independent laboratories.

Table 7 - Corrected Reports - Total Testing Process - POL, Hospital and Independent Laboratories

	POL			**Hospital**			**Independent**		
	Number of Corrected Reports								
	total	on-site	reference	total	on-site	reference	total	on-site	reference
	626	283	343	862	742	120	752	510	242
Phase of Testing	Percent of Reasons for Corrected Reports								
Specimen collection, handling	28	33	23	19	21	9	18	24	7
Test ordering	11	9	13	11	11	11	12	8	22
Specimen pick up, transport,processing by reference lab	6	-	11	<1	-	3	<1	-	1
Test performance	18	29	8	38	44	6	27	24	35
Test reporting	35	26	41	30	24	71	36	37	33

Discussion

Evaluating the frequency of corrected reports gives an indication of laboratory related problems and errors, however corrected reports do not always occur as a result of a problem or error. Laboratories using computer generated reports may be obligated to label a report as "corrected" any time that additional information is added and a reprint is generated. These additions may be minor in nature and may not be related to an error in the original report. For this study, these types of reasons were categorized under "other", since they did not reflect a problem or error but reflected an "occurrence" prompting the generation of a corrected report.

As previously noted, we recognize that there are inaccuracies in the test volumes provided by respondents for this study. The frequency of corrected reports calculated in this report are to be used with the awareness of the limitations on the accuracy of the test volumes provided throughout this study.

Based on phone calls and completed questionnaires, we are aware that some laboratories tracked only errors that they attributed to being caused by "their" staff and excluded those attributed to "non-staff", such as ward nurses and clerks, outpatient client staff, etc. While the intent was to track errors from any source in the total testing process, some participants viewed their laboratory in somewhat different terms, distinguishing between "my" errors versus "their" errors.

Conclusions

While we hoped to get a general sense of the overall error rates, the most important issue in this study was for each participant laboratory to identify the areas in which improvements or changes could have the most impact in reducing their laboratory related problems or errors, regardless of the error rate determined. Laboratories can use the data about error rates to make broad comparisons about their own frequency of corrected reports. Laboratories with higher rates than average may use this information and take definite actions to reduce their frequency of errors.

In the first questionnaire that was disseminated to this network, we asked participants to indicate quality assurance monitors that they formally used. Thirty-eight percent of the respondents indicated they monitored the frequency of corrected reports as a formal quality assurance monitor. On that same questionnaire, 130 laboratories indicated that they did not monitor the frequency of corrected reports. Of those 130 laboratories, 49 (38%) completed the eight-week study, as outlined in Questionnaire 4. By participating in this study, these laboratories tried a new quality assurance activity and hopefully gained some useful information about the quality of their laboratory testing and their reference laboratory's testing. They also had the opportunity to learn about areas of improvement, unique to their setting. One POL respondent found this exercise to be "a great eye-opener", discovered a "surprising number of errors" and took actions to correct their problems. This underscores the real value of this study, in providing each participant with feedback on the quality of their own testing and on opportunities to further enhance their laboratory testing quality.