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Laboratory Management

Clinical laboratory test menu changes in the Pacific Northwest: 1994 to 1996

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Laboratory testing services are presently undergoing dynamic changes in response to a wide range of external factors. Government regulations, reimbursement, and managed care are only a few of the influences affecting the availability of testing services and on-site testing capabilities in hospital, independent, and physician office laboratories. Medical practice changes, marketplace influences, test technologies, and costs also play a role in determining where testing is being performed. To better understand the factors influencing clinical laboratory test volumes and menus and to identify on-site testing deemed essential in physician office laboratories, we gathered information from a network of clinical laboratories in the Pacific Northwest. Questionnaires were sent to 257 Laboratory Medicine Sentinel Monitoring Network participants in March 1996. In the past 2 years, changes in on-site test volumes and test menus have been primarily due to medical practice changes and marketplace influences. When laboratories had a decrease in test volumes or test menu choices, the size of the patient workload and the volumes of test orders have had the greatest impact. Laboratory regulations and managed care contracts have played a role in shifting on-site testing to outside sources; however, these factors did not appear to be primary influences. Only 5% of physician office laboratories identified tests that they believed were essential for optimal patient care but did not perform on-site.

Laboratory testing services are presently undergoing dynamic changes in response to a wide range of external factors. Government regulations, reimbursement, and managed care are only a few of the influences that impact access to laboratory testing. Medical practice changes, marketplace influences, test technologies, and costs also play a role in determining laboratory testing menus.

When the Clinical Laboratory Improvement Amendments of 1988 (CLIA) were implemented in 1992, federal regulation was extended to previously unregulated laboratories, many of which were physician office laboratories (POLs). Since then, considerable attention has been focused on the perceived limitations of POLs to perform laboratory testing on-site and the adverse impact these regulations may have had on patient access to laboratory testing. As a result, legislation has been introduced into the US House of Representatives and Senate to exempt POLs from the majority of current laboratory testing regulations *(1, 2)*.

Recent studies on patient and physician access to laboratory testing and changes in testing capabilities have produced conflicting results. Some studies have indicated that on-site testing has been reduced or discontinued as a result of CLIA *(3, 4)*, whereas one study showed no significant ($P \leq 0.05$) differences in test menus or volumes before and after CLIA was implemented *(5)*.

A 1995 report by the US Department of Health and Human Services identified the nongovernmental factors that impact testing capabilities in POLs *(6)*. Mergers and acquisitions are on the rise, the number of managed care contracts are increasing rapidly *(7)*, capitation is replacing fee-for-service, and reimbursement is on the decline; therefore, nonregulatory issues must also be considered when studying changes in on-site laboratory testing menus.

The Laboratory Medicine Sentinel Monitoring Network

CLIA regulations provide authority to conduct studies related to the quality of clinical laboratory testing, to identify factors that may influence the accuracy and reliability of test results, and to characterize present and future trends in the practice of clinical laboratory medicine *(8)*. To address these issues, the Washington State Office of Laboratory Quality Assurance and the Centers for Disease Control and Prevention collaborated to de

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velop a data collection network in the Pacific Northwest and to provide ongoing information about practices in hospital, independent laboratories, and POLs. Through a series of surveys, which have been useful as screening tools, the network provides a clearer understanding of current issues related to laboratory testing quality, the extent and nature of laboratory problems, and factors affecting access to laboratory testing.

The Laboratory Medicine Sentinel Monitoring Network was created in January 1995. A letter soliciting voluntary participation was mailed to laboratory directors in all 950 licensed laboratories performing moderate and high complexity testing, as defined by CLIA, in Washington state, and 90 randomly selected laboratories in Alaska, Idaho, and Oregon. At the time of this study, the network included 257 laboratories. Demographic information for network laboratories was obtained through the Washington State Medical Test Site and CLIA databases and from a questionnaire mailed to all participants in June 1995. Characteristics of the network laboratories are described in Table 1. Investigators primarily targeted laboratories in Washington, where enrollment was expected to be optimal because of previous interactions between the state agency staff and those testing sites. A sampling of laboratories in the other three states was made to determine the potential response rate of testing sites unfamiliar with Washington state agency staff. The network was subsequently expanded in 1997 by the addition of more than 200 laboratories from these Pacific Northwest states and presently includes 436 participants.

We recognize that there are some inherent biases in our population because participants voluntarily joined the network and are limited to one geographic location. Most of the laboratories are in Washington state, which has a unique history with respect to the regulation of medical testing sites. Washington was the first state to regulate laboratories under a state program exempt from CLIA. Inspections of previously unregulated laboratories began in February 1991, under a state law enacted in November 1990 *(9)*. This preceded the implementation of CLIA inspections, which began nationwide in September 1992.

This study evaluated changes in on-site testing capabilities between March 1994 and March 1996, thereby assessing the impact of regulations that had been in effect for several years rather than the impact of initial implementation. This network consists of laboratories that perform at least moderate or high complexity testing. Because the network does not include sites performing only waived testing, laboratories that discontinued all moderate and high complexity testing before this time period would not be included in the study.

Table 1. Demographic characteristics.

Demographic characteristics	Percentage of laboratories: Monitoring network (n = 257)	Percentage of laboratories: Questionnaire respondents (n = 193)
Location		
Washington	90	91
Alaska, Idaho, Oregon	10	9
Census Bureau designation		
Urban	72	70
Rural	28	30
Laboratory type		
POL[a]	58	59
Hospital	25	23
Independent	17	18
Accreditation status		
Yes	26	26
Testing personnel		
At least one medical technologist or medical laboratory technician	68	72

[a] POLs are composed of the following subtypes: POL, clinic; community health clinic; health department; student health department; health maintenance organization; rural health clinic; and other.

Materials and Methods

In March 1996, a questionnaire was mailed to the director (or a director-specified contact person) of each network laboratory. This questionnaire was designed to learn about specific laboratory tests that were added or deleted from on-site testing menus and the various factors respondents perceived as influencing their on-site testing menus. We also asked POLs to indicate which tests they felt must be performed on-site for optimal patient care. To optimize the response rate, the questionnaire, consisting of five multiple-choice questions, was designed to be completed in ~20 min. The questionnaire was not field-tested before use.

One hundred ninety-three laboratories returned completed questionnaires (75% response rate). The demographic characteristics of respondent laboratories are described in Table 1. Nonrespondent laboratories were not contacted to determine their reasons for not returning the questionnaire. Significant ($P \leq 0.05$) differences were not found between the responders and the nonresponders with respect to location, type of laboratory, or accreditation status. A significantly higher percentage of respondent laboratories (72%) employed personnel with formal laboratory training (at least one medical technologist or medical laboratory technician) than did the nonrespondent laboratories (55%).

Tests of significance were performed using Student's *t*-test at 95% confidence limits ($P = 0.05$). Final reports of the survey findings were mailed to network participants in June 1996.

Findings

CHANGES IN ON-SITE TEST VOLUMES

Network laboratories were asked, "In the past two years, has the total number of patient tests performed on-site increased, decreased, or remained the same?" In this question, the total patient test volume was considered essentially the same if it remained within ± 10%. Total patient test volume remained essentially the same at 46%

of the respondent laboratories. The total test volume had increased at 35% of the respondent laboratories and had decreased at 18%. No significant differences were found in test volume increases or decreases between POLs, hospital, and independent laboratories or between urban and rural laboratories ($P \leq 0.05$).

Reasons for test volume increases. Laboratories that recorded an increase or decrease in test volume were asked to choose one primary and up to three secondary reasons for the change from a list of 18 possible reasons. The primary reasons given most frequently for a test volume increase were changes in the practice (the number of providers, the number of patients seen, or the case mix of patients seen; 69%) and as a result of mergers/acquisitions (10%).

When individual reasons were grouped into categories of interest, those related to practice changes and marketplace issues accounted for 95% of the primary reasons given. When all secondary reasons given were grouped, marketplace issues comprised 36% of the responses, test technology-related issues accounted for 16%, and practice changes accounted for 13% of the reasons (Fig. 1).

Reasons for test volume decreases. Of the 18% of laboratories that had a decrease in total test volume in the last 2 years, the primary reasons given most frequently were changes in practice (number of providers, number of patients seen, and case mix of patients seen; 37%); because of mergers/acquisitions (14%); and changes in reimbursement for on-site testing (11%). The most common secondary reasons given were changes in overall efficiency (overhead costs or billable procedures; 11%), changes in reimbursement for on-site testing (11%), compliance with laboratory regulations (CLIA or state regulations; 11%), testing sent out because of managed care or insurance contract agreements (11%), and changes in managed care guidelines (11%). When individual reasons were grouped into categories of interest, practice changes and marketplace issues accounted for 60% of all primary reasons given. Issues related to costs comprised 30% of the secondary reasons given, with marketplace issues and regulatory issues comprising an additional 17% each (Fig. 2).

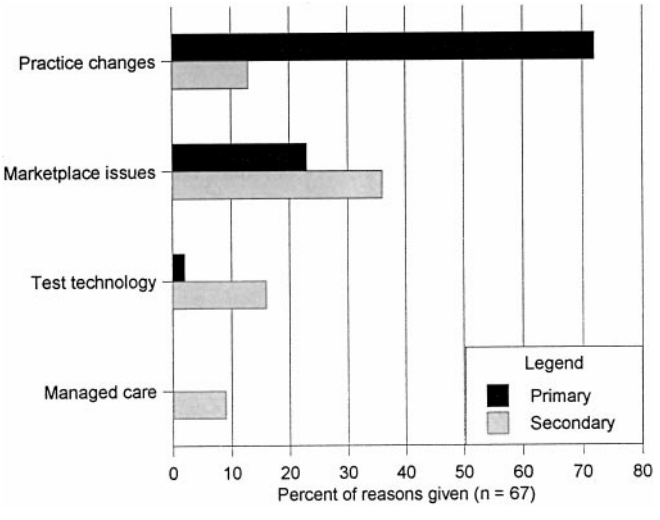

Fig. 1. Reasons for test volume increases.

Practice changes, number of providers, number of patients seen, case mix of patients; *Marketplace issues*, changes to meet community needs, changes in marketing efforts, result of mergers/acquisitions, better able to compete in marketplace; *Test technology*, availability of new testing technologies; *Managed care*, testing performed on site due to a managed care or insurance contract agreement.

CHANGES IN ON-SITE TESTING MENUS

Laboratories were asked to indicate which tests on a list of tests categorized by test specialties, as defined by CLIA, had been discontinued in the last 2 years. The test list consisted of individual analytes, except for "chemistry profile or panel" and "complete blood count," which could be chosen as one test. If laboratories discontinued any test that did not appear on this list, they could write in the name of the test.

Discontinued tests. Over the last 2 years, 107 laboratories (55%) discontinued at least one test. Chemistry tests were discontinued by the highest percentage of laboratories, followed in decreasing order by those dropping tests from diagnostic immunology, microbiology, hematology, waived, and immunohematology. Forty-five percent of laboratories had discontinued testing from more than one specialty. No significant differences were observed between the percentages of POLs, hospital, or independent

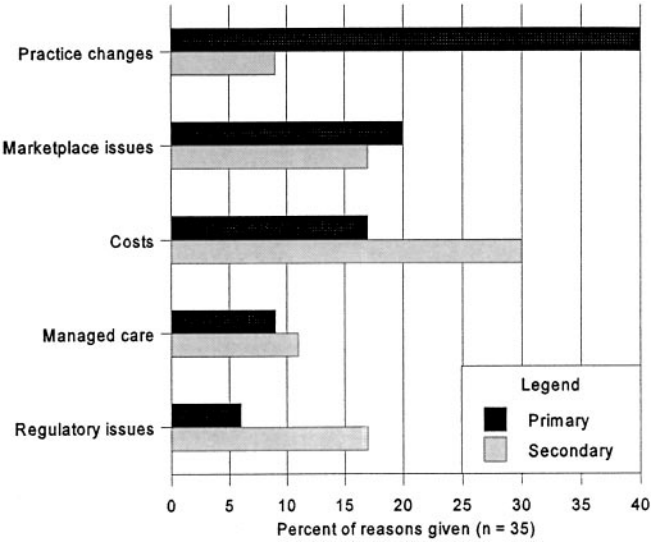

Fig. 2. Reasons for test volume decreases.

Practice changes, number of providers, number of patients seen, case mix of patients; *Marketplace issues*, to meet community needs, changes in marketing efforts, result of mergers/acquisitions, less able to compete in marketplace; *Costs*, changes in reimbursement for on-site testing, changes in overall efficiency (overhead costs, billable procedures), changes in cost of testing equipment, reagents, supplies; *Managed care*, testing sent out due to a managed care or insurance contract agreement; *Regulatory issues*, complying with laboratory regulations (CLIA, state), complying with Occupational Safety and Health Administration regulations, complying with physician self-referral regulations, proficiency testing too expensive.

laboratories that discontinued testing nor between urban and rural laboratories ($P \leq 0.05$). The tests that were discontinued are summarized in Table 2.

For each test listed, laboratories were asked to give one primary reason and up to three secondary reasons for discontinuing the test. When individual reasons for discontinuing testing were grouped by categories of interest, those related to practice changes and to test technology/accuracy issues accounted for 75% of all primary reasons. Of the secondary reasons, 31% were related to regulatory issues. Practice-related issues and nonregulatory cost issues each comprised another 30% of the secondary reasons (Fig. 3).

Added tests. In the last 2 years, 75 laboratories (39%) added at least one test to their on-site testing menu. Chemistry tests were added by the highest percentage of laboratories, followed by those laboratories adding tests for diagnostic immunology, hematology, microbiology, waived, and immunohematology. Thirty-seven percent of all laboratories added testing from more than one specialty. Hospital (70%) and independent laboratories (47%) added testing at significantly higher frequencies ($P = 0.002$ and $P = 0.01$, respectively) than did POLs (24%). Rural laboratories (53%) added tests more frequently than did urban laboratories (33%; $P = 0.01$). The tests that were added are summarized in Table 3.

The most common primary reasons for adding tests were as follows: test is deemed necessary to perform on-site for optimal patient management (22%); meets the needs of the community/clients (19%); better technology available, improved quality of kits or instruments (13%); and new medical knowledge that test is appropriate (11%). The most frequent secondary reasons given were as follows: patient convenience is enhanced (13%), patient outcomes are improved (12%), and meets the needs of the community/clients (11%). When individual primary reasons were grouped according to categories of interest, 30% related to patient outcome/convenience. When all secondary reasons were grouped, the highest percentage (34%) related to patient outcome/convenience. Issues related to testing costs/revenue ranked next, comprising 24% of all secondary reasons (Fig. 4).

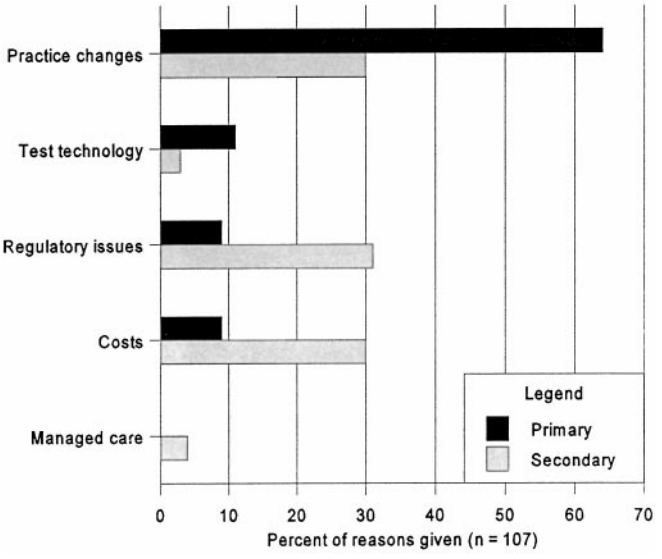

Fig. 3. Reasons that tests were discontinued.

Practice changes, change in patient load or case mix, test volume was too low to be cost effective, determined that it was not essential to perform test on site, another laboratory could perform test on a STAT basis; *Test technology*, method was too complicated or problematic, results do not match an outside laboratory, could not achieve acceptable scores on proficiency testing, results did not agree with clinical impression, patient history or outcome, replaced with better technology; *Regulatory issues*, quality control requirements made test too costly, laboratory license fees were too costly, proficiency testing was too costly, could not find personnel with necessary training or qualification, concerned with meeting Occupational Safety and Health Administration requirements; *Costs*, reimbursement was too low to justify doing on site, instrument or reagent costs were too high, another laboratory could perform less expensively; *Managed care*, mandated by a managed care or insurance contract agreement.

TESTS PERFORMED BY POLs

Network participants (excluding those in hospital and independent laboratories) were asked to indicate which tests, on a list of 45 tests commonly performed in POLs, they presently performed on-site. Participants were also asked to indicate the tests, from the same list of tests, whose performance on-site they considered essential for optimal patient management and/or care. Responses

Table 2. Tests discontinued, categorized by test specialty.

Test specialty	Laboratories that discontinued tests, % (n = 107)	No. of tests that were discontinued (n = 276)	Tests most commonly discontinued, %
Chemistry	64	144	Routine chemistries and profiles (55) Thyroid testing (13) Therapeutic drug monitoring (12)
Diagnostic immunology	30	46	Mononucleosis screen (24) Rheumatoid arthritis screen (17) Hepatitis testing (9)
Microbiology	28	37	Direct Strep antigen (19) Chlamydia (16) Cultures, other than throat or urine (16) Parasitology (14)
Hematology	28	34	Reticulocyte count (38) Coagulation (18) Complete blood count (12)

Table 3. Tests added, categorized by test specialty.

Test specialty	Laboratories that added tests (n = 75), %	No. of tests that were added (n = 172)	Tests most commonly added (%)
Chemistry	61	80	Routine chemistry and profiles (25) Thyroid testing (13) Therapeutic drug monitoring (13) Drugs of abuse testing (11)
Diagnostic immunology	33	34	*Helicobacter pylori* antibody (38) Hepatitis testing (12) Prostate-specific antigen (9) HIV antibody (9)
Hematology	25	21	Hemoglobin A1C (33) Coagulation (24) Complete blood count (19) Reticulocyte count (10)
Microbiology	20	23	*Clostridium difficile* antigen (22) Chlamydia (13) Urine culture (13)

from 93 laboratories (categorized as POL, clinic, or health maintenance organization) were evaluated.

The most common tests, performed by >75% of these laboratories, were urinalysis, fecal occult blood, and urine sediment and other direct microscopic examinations. Between 50% and 75% perform urine pregnancy tests, microhematocrits, erythrocyte sedimentation rates, direct Strep antigen tests, complete blood counts, and leukocyte differentials. The following tests were deemed essential for optimal patient management by >90% of the laboratories that performed them on-site: urinalysis, urine sediment and other direct microscopic examinations; urine pregnancy tests; microhematocrits; complete blood counts; whole blood glucose concentrations; leukocyte counts; and hemoglobin concentrations and/or hematocrits.

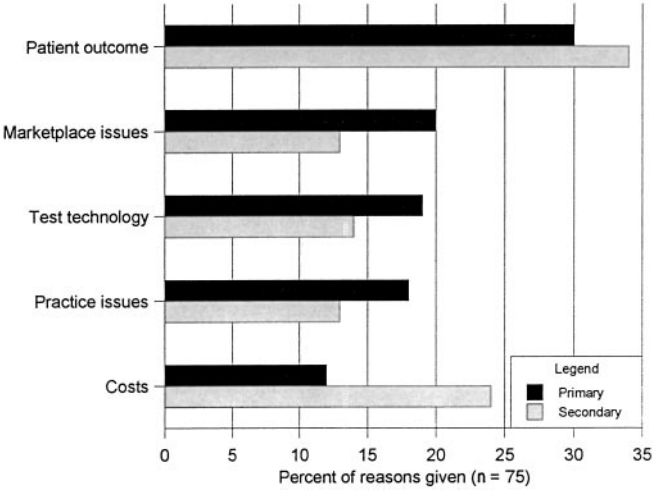

Fig. 4. Reasons that tests were added.

Patient outcome, patient convenience is enhanced, patient outcomes are improved, test is deemed necessary for optimal patient management; *Marketplace issues*, meets the needs of the community or clients, marketing efforts, marketing agreement/consolidation; *Test technology*, improved quality of kits or instruments, kits or instruments are easier to use; *Practice issues*, change in patient workload or case mix of patients, office efficiency is enhanced, new medical knowledge that test is appropriate; *Costs*, cost of kits or instruments are less expensive, cost to patient is reduced when performed on site, reimbursement is better when performed on site, provides a source of revenue for the practice.

Tests deemed essential but not performed. In addition to determining which tests are performed in these POLs, we also hoped to determine which tests they consider essential for optimal patient care but do not perform. Laboratories were asked to indicate any tests that they do not presently perform but that they felt were essential to be done on site. For any tests listed, assumptions could be made that some barrier existed that prevented the POL from performing the tests on-site. The data gathered from this question indicated that this was not occurring at a high frequency. Only five laboratories (5%) listed tests that they were not presently performing but believed were essential for optimal patient care. Four of the five laboratories had, in the last 2 years, discontinued some of the tests listed as essential. The reasons given for discontinuing these tests were that the test volume was too low to be cost effective, that instruments needed parts or repairs, and that proficiency testing was too costly.

Discussion

We investigated a wide range of factors believed to influence recent changes in laboratory testing capabilities. This study illustrates the basic reasons why network laboratories changed testing services. We found that, in most cases, they do so for business reasons or in response to changes in medical practice needs. In instances where laboratories had a decrease in test volumes or test menu choices, the size of the patient workload and volumes of test orders had the largest impact. In addition, marketplace competition, testing costs, and reimbursement appear to have further eroded the capabilities of laboratories to retain and perform testing on site. Laboratory regulations and managed care contracts did not feature prominently among the primary reasons given for these changes. Only rarely could a POL not do tests considered essential for the medical practice served.

We also note that laboratories have responded in a positive fashion to changes in medical practice guidelines, trends in appropriate test ordering patterns, and improvements in testing technologies by adding to their test menus. One example is the change in thyroid testing in response to presently recognized guidelines: network laboratories shifted from T_3 uptake and thyroxine (T_4) tests to thyroid-stimulating hormone, free T_3, and free T_4 tests *(10)*. We also found laboratories adding the glycohemoglobin (hemoglobin A1C) test, an addition that parallels the present emphasis on including this as a quality indicator for optimal management of diabetes mellitus *(11)*. Network laboratories added *Helicobacter pylori* antibody testing at the same time that diagnostic kits became readily available, providing a simple, minimally invasive, cost-effective screening device for this organism.

We have shown the utility of this network as a data collection mechanism. It has allowed us to conclude that, at present, the primary agents for changes in testing are factors that have always existed within the practice of laboratory medicine. We have used the network to undertake additional studies on issues related to quality assurance practices, laboratory-related problems and errors, personnel changes, and proficiency testing participation. The network successfully provides an insight into the dynamics of change in laboratory medicine and identifies areas for more rigorous studies.

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