The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network
Direct Access Testing

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July 2003

BACKGROUND

The Pacific Northwest Laboratory Medicine Sentinel Monitoring Network

With the passage of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 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). This network currently comprises 570 hospital, independent and physician office laboratories in Alaska, Idaho, Oregon and Washington. To date, 26 studies have been conducted which have provided interest groups (physicians, laboratorians, manufacturers, educators, consumers) and regulators with information on trends in the practice of laboratory medicine.

Full text reports of the findings of these studies and references to published journal articles can be found at: www.phppo.cdc.gov/dls/mlp/pnlmsmn.asp

Direct access (patient authorized) testing

With the proliferation of patient self-testing devices and increasing access to health care information, there has been a transformation of patients into direct consumers of products and services that bypass physicians and other health care practitioners. As a result, more and more laboratories are debating about whether to offer direct access (patient authorized) testing.

Under CLIA, direct access (patient authorized) testing is not prohibited unless it is prohibited by state law.

In Alaska and Washington State, there is no statute specifying who can order laboratory tests. Since the laws are silent on this issue, there is no restriction on a person ordering testing on him/ herself. And anyone who can order a test may also receive their own test result. In Alaska and Washington, the decision to provide direct access to testing falls to each laboratory.

Direct access testing is prohibited in Idaho and Oregon.

METHODS

Questionnaire about direct access testing

To gather information about direct access testing practices in Alaska and Washington, a questionnaire was developed to address the following:

- How widespread is direct access (patient authorized) testing?
- What tests are being offered?
- What tests are most commonly ordered?
- What percentage of total test volumes does direct access testing represent?
- How are the results of patient authorized tests given to the patient?

In a cover sheet that accompanied the questionnaire, direct access (patient authorized) testing was described as "Clinical laboratory testing that patients can order on themselves, without the request of a physician or other health care practitioner authorized to order such testing."

Target study group

Questionnaires were mailed to 320 clinical testing sites in Alaska and Washington in February 2003. Using the Washington Office of Laboratory Quality Assurance (LQA) Medical Test Site (MTS) database and the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network database, the following types of testing sites were targeted to receive the questionnaire:

- Hospitals
- Independent laboratories
- Clinics
- Community health clinics
- Health departments and districts
- Rural health clinics
- Health fairs
- Mobile testing

Pacific Northwest Network participants from Idaho and Oregon were not included in this study since direct access testing is prohibited in those states.

Although the mode of laboratory testing in pharmacies closely aligns with the description of direct access testing, they were not included in this study since testing characteristics of pharmacies in Washington State have been previously summarized.[1] (Pertinent findings from that study will be shared in the Discussion section of this report).

RESPONDENTS

One hundred eighty-five testing sites returned a completed questionnaire in time for analysis, a 58% response rate. Response rates from members of the Pacific Northwest Network were higher (69%) than the rates from laboratories that are not part of that Network (52%).

Demographic characteristics of the questionnaire respondents are summarized in the following table.

Table 1 - Questionnaire respondents

Demographic characteristic	Sites that were sent the questionnaire N=320	Respondents N=185	Non-responders N=135
	Percent		
State			
Alaska	5	5	4
Washington	95	95	96
US Census Bureau designation			
Urban	60	55	67
Rural	40	45	33
Test complexity category			
Waived/PPMP	33	28	39
Moderate/high	67	72	61
Laboratory type			
Hospital	30	36	21
Independent laboratory	10	10	9
Clinic	14	14	15
Community health clinic	20	17	23
Health department/district	10	9	11
Rural health clinic	9	10	7
Health fair	2	0	6
Mobile testing	5	3	9
PPMP=Provider performed microscopic procedures			

FINDINGS

Sites offering direct access testing

Participants were asked if they had a written policy that allows or prohibits direct access testing and whether they currently offer or have ever offered this type of testing.

Of the 185 respondents, 60 (32%) had a written policy that addressed direct access testing: 11 sites allowed it and 49 sites prohibited it. Higher proportions of hospital (39%) and independent laboratories (42%) had written policies than the other laboratory types (26%). A higher proportion of moderate/high complexity laboratories (38%) had written policies than sites categorized as waived or PPMP (20%).

Twenty-seven of the respondents (15%) currently offer or had offered direct access testing.

Table 2 - Laboratories that offer direct access testing (N=27)

Demographic characteristic	Respondents offering direct access testing	
	Number	Percent
Alaska	2	7
Washington	25	93
Urban	13	48
Rural	14	52
Waived/PPMP	7	26
Moderate/high	20	74
Hospital	14	52
Independent laboratory	1	4
Clinic	4	15
Community health clinic	1	4
Health department/district	1	4
Rural health clinic	2	7
Health fair	0	0
Mobile testing	4	15

Factors in choosing tests offered

Participants were asked "What factors were considered in choosing the tests you offer for direct access by patients?"

There were several common themes among the factors given by the respondents offering direct access testing: Public interest; Test results are easy to understand; Test method considerations; Patient education; and Costs.

Table 3 - Factors in choosing direct access testing menu

Public interest	What patients want Patient demand Public interest Most requested by patients Market demand High demand Tests with name recognition
Test results are easy to understand	Public understanding Results are easy to understand Limited interpretation issues Not requiring extensive clinical interpretation Low risk Not STD testing
Test method considerations	Automated testing Rapid turnaround times Machines are easy to use Instant results Fairly accurate Portable equipment Finger stick method Reliable Can be done in health fair setting
Patient education	Risk reduction Public awareness Coincide with "awareness months" Cardiac education General panels covering many body systems
Costs	Reasonable price Cost effective Tests not paid by Medicare Patients must pay cash

Two respondents mentioned that they did a customer survey or community questionnaire to help guide their selection of tests.

Tests offered

Participants were asked to list all tests offered for direct access by patients and to rank the top five patient authorized tests performed in 2002. (A ranking of 1 would be the most common).
The most common tests offered by the respondents fell into one of these categories:

- Lipids
- Drugs
- Diabetes
- Hepatitis
- Pregnancy
- Sexually transmitted diseases
- Thyroid
- Wellness screening

Table 4 - Direct access tests offered by hospitals (N=14)

	Laboratory complexity	Location	Tests offered (Ranking of top tests performed in 2002)
1	Moderate/high	Urban	Drugs of abuse (1); cholesterol (2); ABO/Rh (3); legal alcohol (4)
2	Moderate/high	Rural	Glucose (1); cholesterol (2)
3	Moderate/high	Rural	Pre-employment drug screen (1); DOT drug screen (2); legal alcohol (3)
4	Moderate/high	Rural	PSA(1); lipid profile(2); occult blood (3); glucose (4); urinalysis (5)
5	Moderate/high	Rural	Lipid panel + glucose
6	Moderate/high	Rural	CBC; CMP; lipid panel; TSH
7	Moderate/high	Urban	Lipid profile
8	Moderate/high	Rural	Any test we offer (Top tests: Drug tests (1); pregnancy test (2); alcohol (3)
9	Moderate/high	Rural	Drugs of abuse screen
10	Moderate/high	Urban	Lipid testing (1); allergy panel; food allergy panel; CBC; blood type; cardiac risk comprehensive panel; chemistry panel; glucose + A1C; glucose; men's health panel; women's health panel; hepatitis A; hepatitis B; hepatitis C; mononucleosis; occult blood; serum pregnancy; PSA; testosterone; thyroid panel; urinalysis; urine drug screen (take home); urine drug screen (central lab)
11	Moderate/high	Rural	HIV (1); pregnancy test (1); drug screen (2); cholesterol (4); alcohol (5)
12	Moderate/high	Rural	CMP + lipid + auto-hematology (1); TSH (2); PSA (3); blood type (4)
13	Moderate/high	Urban	Any test we offer except HIV, cultures, pathology, cytology
14	Moderate/high	Urban	Urine drug testing

DOT=Department of Transportation; PSA=prostate specific antigen; CBC=complete blood count; CMP=comprehensive metabolic panel; TSH=thyroid stimulating hormone; HIV=human immunodeficiency virus

Table 5 - Direct access tests offered by mobile testing (N=4)

	Laboratory complexity	Location	Tests offered (Ranking of top tests performed in 2002)
1	Waived/PPMP	Urban	Hemoglobin A1C (1); lipid panel (2)
2	Waived/PPMP	Urban	Glucose; cholesterol
3	Waived/PPMP	Rural	Lipid profile (1); cholesterol + HDL (2); glucose (3); cholesterol (4)
4	Moderate/high	Urban	Cholesterol; glucose; hemoglobin/hematocrit; occult blood; pregnancy test; triglycerides; HDL
PPMP=provider-performed microscopic procedures; HDL=high density lipoprotein			

Table 6 - Direct access tests offered by clinics and health departments (N=8)

	Laboratory type	Laboratory complexity	Location	Tests offered (Ranking of top tests performed in 2002)
1	Clinic	Moderate/high	Urban	Urine Chlamydia LCR (1); HIV (2); RPR (3); pregnancy test (4); hepatitis screen (5)
2	Clinic	Moderate/high	Urban	Lipid profile
3	Clinic	Moderate/high	Rural	Throat culture (1); glucose (2)
4	Clinic	Moderate/high	Urban	Pregnancy test (1); HIV (2); RPR (3)
5	Community Clinic	Waived/PPMP	Rural	CMP + lipid (1); PSA (2); TSH (3) (Note: work is sent out to reference laboratory)
6	Rural Health Clinic	Waived/PPMP	Rural	Health fair panel
7	Rural Health Clinic	Waived/PPMP	Rural	Strep antigen (1); urine/serum pregnancy test (2)
8	Health Department	Waived/PPMP	Urban	Urine pregnancy test
LCR=ligase chain reaction; HIV=human immunodeficiency virus; RPR=rapid plasma reagin; PPMP=provider-performed microscopic procedures; CMP=comprehensive metabolic panel; PSA=prostate specific antigen; TSH=thyroid stimulating hormone				

Table 7 - Direct access test offered by independent laboratories (N=1)

	Lab complexity	Location	Tests offered (Ranking of top tests performed in 2002)
1	Moderate/high	Urban	Lipid testing (1); allergy panel; food allergy panel; CBC; blood type; cardiac risk comprehensive panel; chemistry panel; glucose + A1C; glucose; men's health panel; women's health panel; hepatitis A; hepatitis B; hepatitis C; mononucleosis; occult blood; serum pregnancy; PSA; testosterone; thyroid panel; urinalysis; urine drug screen (take home); urine drug screen (central lab)
CBC=complete blood count; PSA=prostate specific antigen			

Advertising, marketing direct access services

Participants were asked "How do you advertise or market your direct access testing services?"

Of the 26 laboratories that answered this question, the most common methods of advertising were brochures, newspaper advertisements and mailings. Thirty-five percent of the respondents use multiple approaches to advertising.

Table 8 - Advertising direct access services (N=26 respondents)

Method of advertising	Respondents	
	Number	Percent
Brochures	9	35
Newspaper advertisements	7	27
Mailings	5	19
Website	4	15
Do not advertise	4	15
Walk-in, on demand	2	8
Other comments: Advertise at health clubs; Advertise at health fairs; Community education; Flyers, reader boards, cable TV; Signs in stores; Promoted by church, health van attracts people.		

One of the websites listed offered links to pharmaceuticals that could be ordered on-line.

Assisting customers in choosing the laboratory test

Participants were asked "Do you assist customers in choosing the laboratory tests they want to order?"

Of the 26 respondents that answered this question, 9 (35%) indicated that they assisted customers in test selection. Table 9 shows a summary of the types of information provided to the customers.

Table 9 - Information provided to assist customers in choosing tests (N=26 respondents)

Type of information	Respondents	
	Number	Percent
Indications for the test	8	31
Descriptions of diseases or conditions detected	6	23
Benefits of testing	5	19
Risks of testing	5	19
Other comments: Provide HIV pre-test counseling; We do not diagnose, offer medical advice. Provide health handouts from manufacturer; We do not diagnose, treat, cure any disease.		

Five respondents (19%) provide a contact person for the customer to call for assistance in selecting tests. Table 10 summarizes information about the contact people mentioned by these laboratories.

Table 10 - People who assist patients in test selection

	Credentials of contact person(s)	Part of staff or on contract by the laboratory?
1	Physician Disease intervention specialist	On contract On contract
2	Pathologist	On contract
3	Pathologist Ph.D. Client customer service representative	Part of staff Part of staff Part of staff
4	Laboratory administrator	Part of staff
5	HIV counselor	Part of staff

Release of test results

Participants were asked the following questions about the release of test results to the patient:

- "Do you release test results only to the patient?"
- "Can the patient specify someone else to whom results may be released?"
- "Is a pathologist or other physician involved in the review of results prior to release?"
- "Are there any conditions where you will not release results without a physician's involvement?"

The following summarize the responses given:

- 62% of the respondents stated they released test results *only* to the patient.
- 38% stated the patient could specify someone else to receive test results.
- 19% had a pathologist or other physician review test results prior to their release, under these special conditions: critical values; positive results; legal drug screens.
- 23% percent stated there were conditions where test results would not be released without a physician involvement: critical values; results that did not make sense or had unresolved issues; legal drug screens.

Participants were asked “Do you assist patients in the interpretation of their results?”

Seventy-seven percent of respondents stated that they assisted patients in the interpretation of their results. Table 11 summarizes their responses.

Table 11 - Assisting patient in interpreting test results (N=26 respondents)

Mode of assisting patients	**Respondents**	
	Number	**Percent**
Provide reference range or interpret as normal or abnormal	19	73
Provide an interpretive statement	12	46
Provide information about testing limitations	10	38
Provide information about the test method Sensitivity Specificity Accuracy False positives, false negatives	6 3 3 4 3	23 12 12 15 12
Allow patient to call for additional consultation	8	31
Provide disclaimer about the use of the results	9	35
Refer patient to their physician	17	65
Assist patient in obtaining a physician	8	31
Refer patient to another source of information (example: www. labtestsonline.org)	6	23
Other responses: Tell patient to go to hospital if cholesterol is dangerously high; Refer to website of laboratory; Community resources	3	12

Participants were asked "How do you handle test results that must be reported to public health authorities (i.e., conditions that are notifiable by state law, such as sexually transmitted diseases, hepatitis, HIV, etc.)?"

For 65% of the respondents, this question was not applicable. Seven of the 26 respondents (27%) answered this question, including the following comments:

- We would report result to the health department (2)
- Patients are notified of this requirement in our brochure and disclaimer with results
- Physicians are required to order any of these tests
- The health department has a representative on-site to do counseling, contact follow up
- We inform the patient at the time of collection and have an authorization form
- HIV results are presented to the patient by an HIV counselor

Experiences with offering testing directly to the public

Test volumes

Participants were asked "What was your volume of patient authorized testing for 2002?" and "What percentage of your total test volume for 2002 does this represent?"

Seventeen respondents gave their volume of direct access testing for 2002 and 18 gave the percentage of their total volume that direct access testing represented.

Of those responding, the range of direct access tests performed in 2002 was 0 to 8800. The average number of direct access tests per respondent was 802, with a median of 100. The percentages of total volumes ranged from 0 to 100. Most respondents indicated that their direct access testing was less than 1% of their total test volume.

Figures 1 and 2, and Table 12 summarize these responses.

Figure 1 - Direct access test volumes in 2002 (N=17 respondents)

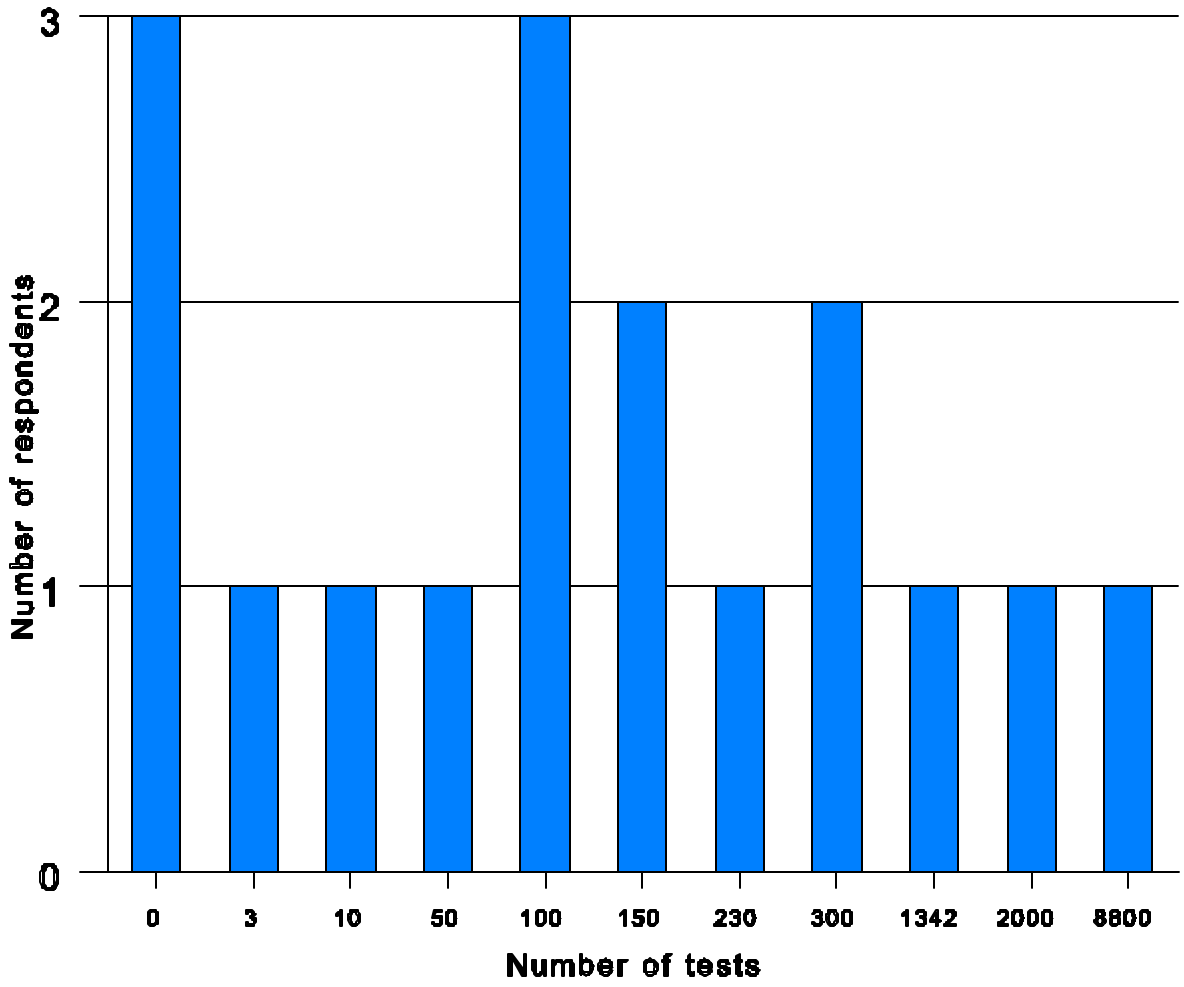

Figure 2 - Percent of total test volume that direct access testing represents (N=18 respondents)

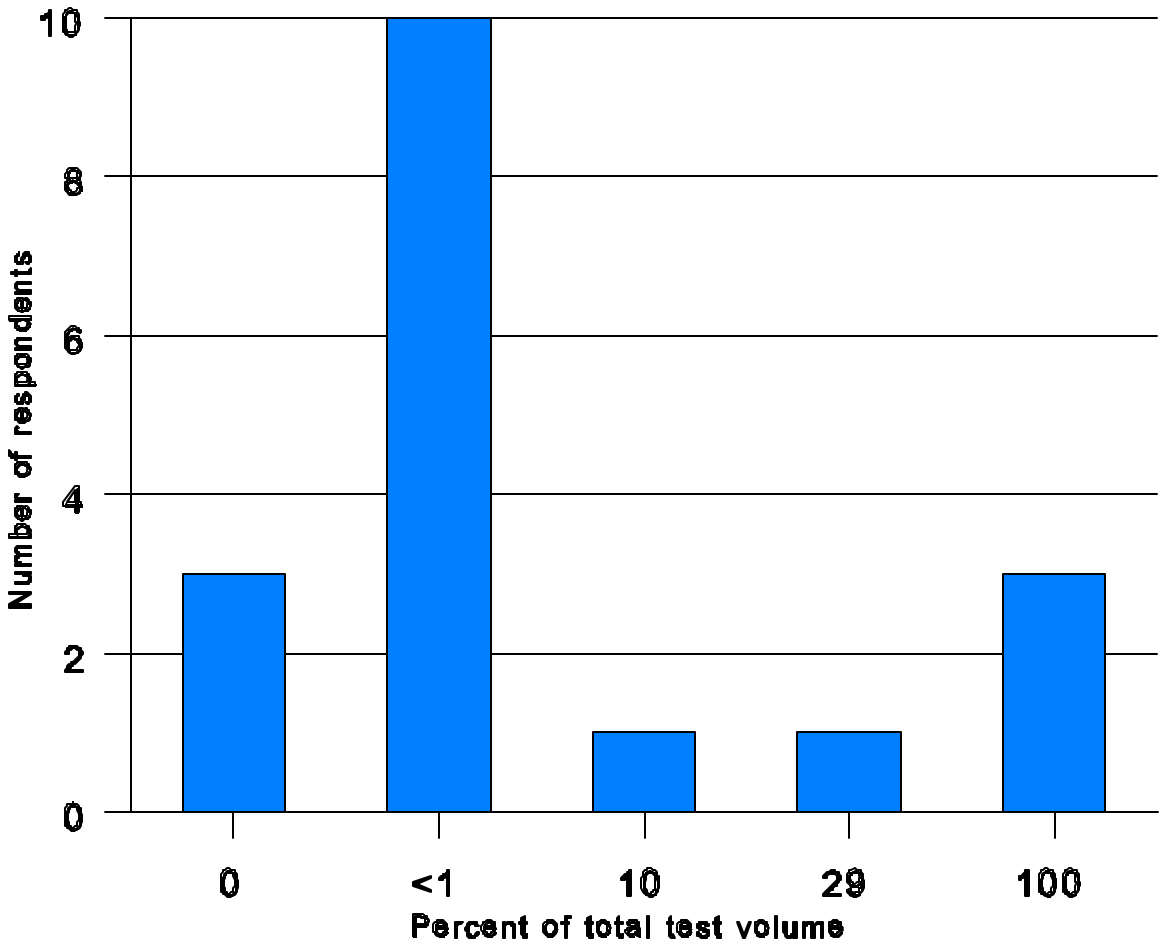

Table 12 - Test volumes by laboratory type (N=21 respondents)

Laboratory type	Location	Volume of direct access testing	Percent of total test volume
Hospital	Rural	100	<1
Hospital	Rural	230	<1
Hospital	Urban	-	<1
Hospital	Rural	100	<1
Hospital	Rural	10	<1
Hospital	Rural	3	<1
Hospital	Rural	0	0
Hospital	Rural	1342	-
Hospital	Rural	-	<1
Hospital	Urban	-	<1
Hospital	Rural	0	0
Hospital	Urban	150	<1
Clinic	Rural	0	0
Clinic	Urban	8800	29
Clinic	Urban	150	<1
Rural Health Clinic	Rural	100	-
Rural Health Clinic	Rural	300	10
Community Clinic	Rural	2000	-
Mobile	Urban	300	100
Mobile	Urban	-	100
Mobile	Urban	50	100

Experiences with direct access testing

Participants were asked "What have been your experiences (both positive and negative) with offering laboratory testing directly to the public?"

Positive responses:

"Good experiences. Patients are appreciative. Sends a good message in the community. Considering offering year round"

"Very positive to all that have used it. Only a very limited group of people use at this time"

"Would like to expand menu, simplify report format"

"Works pretty well in health fair setting"

"It's a joy. People appreciate it"

"Most people enjoy convenience, low cost, fast results. I often hear comments that doctors don't relate specific numbers on test results. They will just say something like "you're OK." From patient viewpoint, I believe all testing should be available on patient authorized basis"

"Public is very pleased. Seen as a community service as we offer reduced pricing. Patients pay cash or check. Not done as a profit"

"All positive due to cost"

"Very well received"

"Folks like to have control over their health and like results sent directly to them. They are hungry for medical knowledge. Show and tell on blood type builds trust in lab's expertise. Opportunity for interaction with "customers." Special pricing is much appreciated"

"Public liked to be able to have testing done without seeing a provider first"

"Very limited test menu, no problems"

"Limited experience. Positive for patients"

"Since there are only 2 tests there have been no problems"

Negative responses:

"Because we require cash, many people decide not to have test done"

"Found it more organized to have a triage nurse screen all calls and order tests when needed" (This respondent no longer offers direct access testing)

"Patients want you to do a complete physical and discuss all their ailments for free. They push for advice"

"Sometimes problematic if youth are released prior to getting lab results, difficult to contact them with positives" (Individuals may choose testing prior to being placed into detention)

"Direct access testing was discontinued 8-10 years ago"

"Folks like getting their test results but are very confused about what they mean and what the next step should be. We refer them to own health care provider and to our follow up session with a doctor and dietician"

DISCUSSION

The Washington State Office of Laboratory Quality Assurance frequently receives questions from laboratories about direct access testing: *Can* we offer it to patients who request it? Do we *have to* offer it to patients who request it? Is there a law that allows or disallows it?

Despite the apparent interest, this study shows that relatively few laboratories have a policy about direct access testing and even fewer offer it. Most of the respondents offering direct access testing are hospitals and clinics and are licensed to perform moderate and/or high complexity testing. Test volumes are low and test menus are limited in most cases. The most common tests offered are for screening for diseases that have high name recognition and public awareness (i.e., diabetes, heart disease, prostate cancer). Other popular offerings are for testing that the customer may not want their doctor's office or insurance company to know about (i.e., drugs of abuse or sexually transmitted diseases).

[In another study that inventoried all waived testing in all licensed laboratories in Washington State, pharmacies were recognized as a common setting for direct access testing. In 2002, 136 pharmacies in Washington were licensed to perform waived testing, that is offered directly to customers. All test site directors had degrees in pharmacy. The most common testing related to screening and monitoring for diabetes (glucose, glycohemoglobin, fructosamine) and lipid testing. In addition, these pharmacies commonly offered testing for *Helicobacter pylori* antibodies and for prothrombin times and International Normalized Ratios (INRs).[1]]

Meeting public demands was a common factor in deciding to offer direct access testing and in test menu selection. However, only two respondents said they actually polled their community to help determine interest, test menus, or levels of service.

When the "customer" of laboratory services is not a health care provider, laboratories depart from their normal practices in a number of ways. Only 35% of the laboratories offering direct access testing assist customers, in some way, in test selection, and only 19% provide a person for the customer to contact directly. While 73% provide either reference ranges or an interpretation of normal/abnormal, only 31% take calls from customers for further consultation about test results. More than a third of the respondents (35%) include a disclaimer with test results, letting customers know that they are not providing a diagnosis and/or referring customers to a physician for further interpretation of their test results.

Our study respondents' experiences with direct access testing are generally positive. They state that customers like the convenience, low cost and fast results. Laboratories like the opportunity to connect with customers and demonstrate what laboratorians do.

In an article about one direct access testing laboratory in San Antonio, Texas, testing was up 200% in 2002. Seventy thousand people used this laboratory's direct testing service in 2002.[2]
If this is any indicator, interest in direct access testing and the number of laboratories offering this service, can be expected to grow.

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