Arkansas Laboratory Medicine Surveillance Network
Survey 4: Waived Testing
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Project Background

The Arkansas Department of Health was awarded a grant from the Centers for Disease Control and Prevention (CDC) to establish a data collection network of medical laboratories and survey them for information on the practice of laboratory medicine in hospitals, clinics, and independent laboratories. In meetings held with CDC personnel after the awarding of the grant, it was explained that a major goal of the project was to obtain non-anecdotal data on the operations and quality practices in medical laboratories. Data are needed to support further refinement of the regulations adopted under the Clinical Laboratory Improvement Act (CLIA).

Three other states are also conducting similar programs. The state of Washington was the first state to receive funding for this program, and has been conducting this research since 1996. The Arkansas Department of Health was selected for funding because of the network of county health units that are integrated into the state health agency and a significant rural, medically underserved population.

A Survey was sent to 600 facilities in the state of Arkansas. 169 responses were received for a response rate of 28%, approximately fifty percent higher the response rate from earlier surveys. In addition to laboratories who responded to the first set of surveys, surveys were sent to a new sample of physician's offices, nursing homes, and similar facilities which were less likely to have a formal laboratory, but likely to perform at least some waived testing.

Type of Facility

Forty-two respondents were either community health organizations or county health department clinics. Twenty-seven were hospital laboratories. Eighty four were physician office laboratories, five were nursing homes, and six were reference or independent laboratories.

Of the physician office laboratories, 49 were engaged in primary care practices. Nine were pediatric practices, two of which also indicated that they provided general primary care. Six were obstetric/gynecology practices, five practiced internal medicine, and three each oncology and urology. Three were engaged in dermatology, and two in surgery. The remaining disciplines included emergency medicine, gastroenterology, nephrology, and neurological rehabilitation.

Data Limitations

The small size and diverse nature of the sample set severely limits the ability to draw conclusions regarding specific tests or practice specialties. The sample set is notably deficient in non-traditional facilities which do medical testing at the “Waived” certification level – facilities such as nursing homes, hospices, emergency medical services, or pharmacies.

Tests Performed

The facilities were asked what waived tests were performed in their faciliy. The responses are described in Table 1.

Table 1. Waived tests performed in Arkansas Sample

Test	% Performing	Public Health Clinic	Physician Office	Nursing Home	Ind. Lab	Hospital
BTA	1	0	1	0	0	0
Catalase	5	0	0	0	0	31
Cholesterol	11	2	8	9	20	35
Creatinine	7	0	3	20	0	35
Erythrocyte Sedimentation Rate	33	0	37	20	60	77
Ethanol	5	0	1	0	0	31
Fructosamine	0	0	0	0	0	0
Glucose	61	63	55	80	80	77
Glycosolated Hemoglobin	8	0	7	20	20	19
HDL Cholesterol	6	0	2	0	0	31
Heliobacter Pylorii	19	2	22	40	0	38
Hematocrit	23	20	19	20	0	46
Hemoglobin	38	86	16	20	0	38
Lipid Profile	8	2	6	0	0	27
Microalbumin	8	2	10	0	0	11
Mononucleosis	23	0	24	40	0	58
Nicotine	0	0	0	0	0	0
Occult Blood	55	6	71	60	40	92
Ovulation	1	0	0	0	0	1
pH	12	9	7	0	0	38
Pregnancy	72	100	64	40	20	69
Prothrombin time	10	0	6	20	0	38
Strep antigen	37	2	52	40	0	54
Triglycerides	7	2	3	0	0	35
Urinalysis	74	84	77	40	20	65
Responses=	168	44	86	5	5	26

It should be noted that the low number of responses by independent laboratories and nursing homes rends any conclusions for these types of facilities unreliable from this data set.

A second caution is noted in the hematocrit and hemoglobin results. A number of Arkansas Department of Health county clinics reported performing hematocit when, in fact, they were performing the hemoglobin screen.

Desired Tests

Facilities were asked which moderate or high complexity tests that they wished to perform if available as a waived test (Table 2).

Table 2. Tests for which a "Waived" equilivent is desired

Test	Number of Responses	Test	Number of Responses
Complete Blood Count (CBC)	2	Capillary Blood Lead	1
Clotting ability to determine Heparin	1	Unspecified cultures	1
Fungal cultures &DTM media	1	Gram Stain	2
Hepatitis B Surface antigen	1	HIV – SUDS	1
Hemolytic Streptococci	1	Herpes	1
INH Secretion	1	Potassium	1
Semen Analysis	1	Serum pregnancy test	3
Sperm Count	1	Strep throat culture	1
Thyroid testing	1	Tzanck Smear	1
Urine culture	2	Viral culture	1
White blood count	1	Wet Prep	1

Additionally, a number of tests that are already waived were listed, indicating that some facilities are not fully educated as to the availability of waived tests. A notable exception was the response of cholesterol from 10 ADH county health clinics. Adding this test to their batteries has been discussed in the past, and the responses indicate that a real need is still felt for this test.

Tests that should not be waived

Facilities were asked which waived tests they felt should be reclassified as moderate or high complexity tests and why (Table 3). Respondents could choose more than one reason. 145/169 respondents did not list a test. One respondent answered "all" and listed as a reason "Low Standards = Low Quality." Although the sample is too small to draw conclusions as to the significance of the findings, the high level of concern for the accuracy of the HDL cholesterol test relative to the other tests warrants concern and further investigation.

Desired Services

Respondents were asked which tests that they desired to add, and why these tests were not currently offered. 166 responses were given, with 48 facilities indicating that they wished to offer a test they did not currently perform (Table 4). Sixty different tests were reported as desired. The facilities were asked whether these were tests that they would like to add and if they considered these tests essential to their practice. Respondents were also asked the reasons why these methods were not already initiated in their facility (Table 5, Table 6).

The two most common reasons given are related to the economics of the test, specifically that test volume is too low and that the test is too expensive to initiate. This is consistent with our earlier findings that the cost of the test is a factor in the decision to add a test to a facility's test menu (Lee *et al*, 2000).

Table 3. Tests that should not be waived but are classified as such.

Test	Reason	# Responses
Bladder Tumor Antigen	Results are difficult to interpret	2
	Too specialized for general use	1
Cholesterol	Waived Test is not accurate	2
	Too complicated for waived test	2
	No reason listed	1
Erythrocyte Sedimentation Rate	Waived test is not accurate	1
	No reason listed	1
Ethanol	No reason listed	1
Glucose	No reason listed	1
Glycosolated hemoglobin	Waived Test not accurate	1
	Does not match clinical observations	1
	No reason given	1
HDL Cholesterol	Waived test not Accurate	5
	Too specialized for general use	1
	No reason listed	1
Heliobacter Pylorii	Waived Test not accurate	1
	Waived Test is not reproducible	1
	Does not match clinical observations	1
	Too complicated for Waived	1
	No reason listed	1
Hematocrit	No reason listed	1
Hemoglobin	No reason listed	1
Lipid Profiles	Waived Test is not accurate	2
	Cost effective as a higher complexity battery	1
	Results are difficult to interpret	1
	Too complicated for Waived	1
	No reason given	1
Mononucleosis	No reason given	1
Pregnancy test	Waived Test is not accurate	1
	No reason given	1
Prothrombin time	Waived Test is not accurate	2
	Results are difficult to interpret	1
	Waived Test is not reproducible	1
	Too complicated for Waived	3
	No reason given	1
Strep Antigen	No reason given	1
Triglycerides	Too complicated for Waived	2
	No reason given	1
Urinalysis	No reason given	1

Table 4. Tests desired to be performed by respondents

Test	"Like" Responses	"Essential" Responses	Total Responses
250 hour Vitamin D	1	O	1
ACT	1	0	1
Antinuclear Antibody(ANA)	4	0	4
ATIC	0	1	1
Amylase	0	1	1
Bilirubin	2	2	2
Blood Lead	1	0	1
CBC and Differential	4	3	4
Chem 6/Chem 7	3	0	3
Cholesterol	3	1	3
Coagulation Studies	1	0	1
C-Reactive Peptide (CP)	3	0	3
Creatinine Kinase (CK)	0	1	1
Dextrostix/Glucose	0	0	2
Digoxin	1	0	1
Drug Screen	1	0	1
Drug levels	2	0	2
Erythrocyte Sedimentation Rate	0	1	1
Electrolytes	1	0	1
Ferritin	1	0	1
Folate/B-12	2	0	2
Free T4	1	0	1
Free Testosterone	1	0	1
Fungal Culture	0	0	1
Glucose	1	1	1
Gram Stain	0	3	3
Hemoglobin B A_1 ($HgBA_1C$)	4	1	5
Hepatitis B Surface Antigen	1	1	2
HIV	1	0	1
Heliobacter pylorii	2	1	2
Heliobacter pylorii by breath	1	0	1
Hematocrit	0	1	1
Liver Functions	2	0	2
INH Excretion	0	1	1
Interoperative PTH	1	0	1
Iron TIBC	1	0	1
Lipid Profile	2	0	2
Urine Microalbumin	1	1	1
Myoglobin	1	2	3
NTX Collagen Cross-link	1	0	1
P7	1	1	1
Prostrate Specific Antigen (PSA)	1	0	1
Parathyroid (PTH)	1	0	1
Prothrombin Time	1	2	5
Quantitative B HGG	0	1	1
Rapid Strep Screen	2	0	2
Reticulocytes	1	0	1
Semen Analysis	3	0	3
Spin Down Urinalysis	0	1	1
TSH	2	0	2
Thyroglobulin	1	0	1

Table 4. Tests desired to be performed by respondents (continued)

Test	"Like" Responses	"Essential" Responses	Total Responses
Total Testosterone	1	0	1
Triponin	0	1	1
Tzanck Smear	0	0	1
Urinalysis	1	0	1
Urine C&S	0	2	2
Vancomycin	2	2	2
Wet Prep	2	3	3

Table 5. Reasons not to add a desired test

Reason	Like	Essential	Total
Economic			
Too expensive to initiate	21	8	24
Reimbursement too low	5	4	6
Inadequate test volume to be cost effective	15	8	21
Currently evaluating cost/reimbursement issues and volume	2	0	2
Reference laboratory price too attractive	1	0	1
Regulatory			
Want to stay at the waived/PPPM level	6	2	7
Do not want to undergo inspection/comply with regulations	3	1	6
Cannot afford to comply with regulations	2	1	3
Complexity requires pathologist oversight	1	0	1
High Complexity, would perform if medium complexity	1	0	1
Test Technology			
Quality of current test system is inadequate	4	0	4
Too labor intensive, need a screen method	1	0	1
Lack equipment to perform the test	1	1	2
Lack qualified personnel to perform the test	0	1	1
Method not compatible with current instruments	0	2	2
Organizational Issues			
Required to outsource by managed care/insurance contract	1	0	1
Decision of parent organization	4	4	6
Want Pub. Health Nurses, not just RNP, to perform	1	1	1
Other			
Will add in near future	2	0	2
Unsure what it entails to add the test	2	0	2
Unsure what is available	5	2	7
Do not know	1	0	1

Table 6. Reasons for specific tests.

Response	*Test*	*# Responses*	*Total Responses*
Too expensive to initiate	Antinuclear antibody (ANA)	1	4
	Bilirubin	1	2
	CBC and Differential	2	4
	Chem 6/ Chem 7	1	3
	Digoxin	1	1
	Drug Levels	1	1
	Erythrocyte Sedimentation Rate	1	1
	Free T4	1	1
	Heliobacter pylorii by breath	1	1
	Liver Functions	1	2
	$HgBA_1C$	1	5
	Iron TIBC	1	1
	Lipid Profile	1	2
	Urine Microalbumin	1	1
	Myoglobin	2	2
	Prothrombin Time	2	5
	PTH	1	1
	Reticulocytes	1	1
	TSH	1	2
	Thyroglobulin	1	1
	Vancomycin	1	1
Quality of current test systems is inadequate	250H Vitamin D	1	1
	Coagulation Studies	1	1
	Free testosterone	1	1
	Total testosterone	1	1
Want to Stay at the Waived/ PPPM level	ACT	1	1
	Blood Lead	1	1
	Complete Blood Count	1	4
	Prothrombin Time	1	5
	Semen Analysis	1	3
	Strep Throat Culture	1	1
	Gram Stain	1	3
Cannot find or hire qualified Analysts	P7	1	1
Unsure what it entails to add this test/Unsure what is available	Drug Screen	1	1
	NTX Collagen Crosslink	1	1
	Chem 6/ Chem 7	1	3
	Cholesterol	1	3
	Dextrostix/Glucose	1	1
	Hematocrit	1	1
	Hepatitis B Surface Antigen	1	2
	Rapid Strep Screen	1	2
	Urinalysis	1	1
Do not want to undergo inspections or comply with regulations	Dextrostix/Glucose	1	1
	Fungal Cultures	1	1

Table 6. Reasons for specific tests. (Continued)

Response	*Test*	*# Responses*	*Total Responses*
Do not want to undergo inspections or comply with regulations	Prostate Specific Antigen (PSA)	1	1
	Rapid Strep Screen	1	2
	Tzanck Smear	1	1
	Urine C&S	1	2
Cannot afford to comply with regulations	Antinuclear antibody	1	4
	Semen Analysis	1	3
	Urine C&S	1	2
Reimbursement is too low	ATIC	1	1
	Coagulation Studies	1	1
	Heliobacter pylorii	1	2
	$HgBA_1C$	1	5
	Prothrombin Time	1	5
Required to send out by managed care or insurance contract	Progesterone	1	2
Inadequate volume to be cost effective	Amylase	1	1
	Bilirubin	1	2
	Chem 6/ Chem 7	1	3
	C-Reactive Peptide	1	1
	Creatinine Kinase	1	1
	Drug levels	1	2
	Electrolytes	1	1
	Ferritin	1	1
	Folate/B-12	2	2
	Gram Stain	1	3
	HIV	1	1
	Liver Functions	1	2
	Lipid Profile	1	2
	Myoglobin	1	3
	Progesterone	1	2
	Quantitative B HGG	1	1
	TSH	1	2
	Triponin	1	1
	Vancomycin	1	2
Decision of parent organization	Cholesterol	1	3
	Heliobacter pylorii	1	2
	INH Excretion	1	1
	P7	1	1
	Spin Down Urinalysis	1	1
	Wet Prep	1	1
Complexity of Test	Semen Analysis	1	3
	C-Reactive Peptide	1	3
	Hepatitis B Surface Antigen	1	2
Evaluating cost, reimbursement, and volume	Interoperative PTH	1	1

Table 6. Reasons for specific tests. (Continued)

Response	*Test*	*# Responses*	*Total Responses*
Lack proper equipment or personnel	Cholesterol	1	3
	Fungal Culture	1	1
	Gram Stain	1	3
	$HgBA_1C$	1	5
	Hepatitis B Surface Antigen	1	2
Not Reimbursed	Prothrombin Time	1	5
Reference Lab Price too attractive	Antinuclear antibody	1	4
Too labor intensive, need a screen method	Antinuclear antibody	1	4
Will perform in the near future	$HgBA_1C$	1	5

Tests Discontinued in the past two years

We asked participants "In the past two years, have you stopped performing any tests on-site and referred them to a laboratory?"

Forty-seven, or 28% of respondents, answered "Yes." This is significantly higher than the 6% of the respondents in Washington (LaBeau et al, 2000) who answered the question in the same manner. A total of 116 discontinued tests were reported, totaling from one to nineteen tests per facility.

The most common reason cited for discontinuing testing was that the volume was too low to justify performing the test on-site. Other significant (listed by more than 10% of respondents) economic reasons included the cost of regulations, cost of instruments and reagents, and that another lab could perform these tests less expensively. In our previous study, we found a weak link between cost and test offering decisions when controlled for patient mix. This study lacked sufficient data to make that determination. Besides these economic reasons, concerns about test accuracy and the perception that tests were too complicated were also significant. Tese reasons can be found in Table 7.

Seventy-one tests were reported, most with a single response. Tests receiving more than one response included:

Six Responses:

Gram Stain

Five Responses:

Creatinine Kinase (CK)
Lactate dehydrogenase (LDH)

Four Responses:

Amylase
Blood urea nitrogen (BUN)
Gamma-glutamyl transferase (GGT)

Three Responses:

High density lipoprotein (HDL)
Mononucleosis
Thyroid (TSH)
Potassium (K)
Triglycerides

Two Responses:

Alanine amino transferase (SGPT)
Aspartate aminotransferase (SGOT)
B-12/Folate
Complete Blood Count (CBC)
Heliobacter pylorii
Hemoglobin A_1 ($HgbA_1C$)
Lipid Panels
Lyme Disease
Microalbumin
Bilirubin
Semen analysis
Prostate specific antigen (PSA)
Reticulocyte counts
Salicylate

Table 7. Reasons for discontinuing a test

Reason	*Number of Responses*	*Percent of Responses*
Regulations		
Complying with regulations made testing too costly	16	14
Laboratory Regulations were too burdensome	4	3
Practice Changes		
Determined that it was not essential to perform the test on-site	7	6
Change in patient workload and case mix	2	2
Could get timely results from another laboratory	2	2
Changes in test panels	1	1
Mandated by a managed care or parent organization	5	4
Economics		
Reimbursement was too low	8	7
Reimbursement was too difficult to obtain	2	2
Another lab could perform this test less expensively	11	10
Test Instrument/reagents were too expensive	15	13
Test volume was too low to be cost effective	43	37
Test Technology		
Tests were too complicated	16	14
Concerns about test accuracy	16	14
Equipment malfunctions and breakdowns	9	8
Reagents recalled by manufacturer and FDA	1	1
Test strips had too short a shelf life	1	1

In addition, facilities were asked if they had discontinued ALL moderate or high complexity testing in the past two years (Table 8). Thirty-two respondents (19%) indicated that they, in fact, had done so. Twelve respondents indicated that they made the change because the tests that they performed had been reclassified as waived or PPMP tests, no longer necessitating a moderate or high complexity certificate. Nine indicated that they had discontinued moderate and high complexity testing explicitly to become a waived/PPMP site, and seven responded that they did not know why the changes was made. Four did not give an reason.

These facilities were asked what the motivating factors for the change was, and to list a primary and up to two secondary reasons (Table 8). As in the case of the decision not to add a test or to discontinue a test, the perception that test volume is inadequate is the most cited reason. Laboratories cite that the availability of a cheaper laboratory also plays a role in the decision. As in the case of discontinuing a test, the opportunity cost of complying with regulations is also a significant factor. Interestingly, this is not noticed in the case of a decision not to add a desired test. It is possible that this discrepency is due to the fact that a laboratory or clinic decides to adopt a level of quality assurance consistent with the requirements of a CLIA complexity level, and

then adds tests that are consistent with that complexity level, and thus the decision to accept a regulatory burden is already established. A laboratory that finds the regulations too burdensome is more likely to drop the tests that create the burden than add new ones that add to it.

Table 8. Reasons for discontinuing moderate and/or high complexity testing

Reason	Total Responses (%)	Primary Reason (%)	Secondary Reason (%)
Test volume too low to be cost effective	42	22	20
Laboratory Regulations are too burdensome	28	8	20
Another laboratory could perform the tests less expensively	25	8	17
Complying with laboratory regulations made testing too costly	22	6	16
Could get timely results from another laboratory	17	11	6
Test instrument or reagents were too expensive	17	3	14
Required by superiors in the organization	14	8	6
Determined that it was not essential to perform the test on-site	11	3	8
Reimbursement was too low	11	3	8
Could not find qualified personnel	8	3	5
Due to a managed care or insurance contract	6	3	3
Reimbursement was too difficult or complicated to obtain	3	3	0
New Office- never started testing at moderate/high	3	3	0
Instrument Failure/breakdown	3	0	3

Comment and Discussion

The dataset proved insufficient to draw significant conclusions regarding which tests presents problems that might suggest reclassifying them as a higher complexity level than “Waived,” although a higher level of concern for the accuracy of the HDL cholesterol test may warrant further investigation.

The key motivating factors for decisions to add or subtract a test from a facilities menu appear to be based primarily on whether sufficient volume exists to make the test economically feasible. Sinjay and Campbell (1995) examined the question of economies of scale in hospitals, and found evidence suggesting that mergers are motivated by a desire to achieve savings through scale. This data suggests that laboratory mergers may be motivated by a similar mechanism.

These decisions do not appear to be strongly motivated by responses to regulations, except for the decision to discontinue a test or testing. The decision to add a test does not show a relationship to regulatory burden. This difference may be modeled by conceiving the laboratory as not considering to add a test unless the decision has already been made to adopt a “Moderate”/”High” complexity quality system, whereas a laboratory seeking to avoid the ensuing burden has to discontinue testing to do so.

References

Labeau KM, Simon M, and Steindel SJ, **Waived and PPMP Test Sites: Access to Testing**,
Available at: http://www.phppo.cdc.gov/DLS/pdf/mlp/pnwsmn/report2w.pdf

Lee J, Falk S, Avery G, and Holmes T; (2000**) Laboratory Community and Quality Assurance** (ADH/PHL-LSMN-00/02) Little Rock, Arkansas Department of Health.
Available at: http://www.phppo.cdc.gov/DLS/pdf/mlp/asmn/report1&2.pdf

Sinjay UA and Campbell CR; (1995) "Scope and Scale Economies in Merging Hospitals Prior to Merger," **Journal of Economics and Finance** 19: 107-123.

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