The Physicians’ Office Laboratory

1988 and 1996 Survey of Illinois Pediatricians

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Objectives: To contrast practices of physicians’ office laboratories in the years 1988 and 1996 and ascertain physicians’ perception of the effect of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).


Subjects: There were 525 and 980 respondents in 1988 and 1996, respectively; analyses included 282 and 374 surveys representing offices where direct patient care was provided in a nonhospital setting. A paired analysis was also conducted on 101 offices that responded to both surveys.

Results: There was a decline from 1988 to 1996 in the percentage of offices doing in-office laboratory testing (93% to 84%, respectively; \( \chi^2 \) test; \( P < .01 \)) and median number of types of tests (6 tests vs 4 tests; Mann-Whitney U test; \( P < .001 \)). Decreases (\( \chi^2 \) test; \( P < .01 \)) were seen in the proportion of offices offering throat culture for group A streptococci (63% to 33%), urinalysis (54% to 33%), urine culture (53% to 22%), rapid hemagglutination slide test for mononucleosis (42% to 17%), theophylline level (27% to 4%), and total cholesterol (22% to 13%). The proportion of offices offering urine dipstick, hematocrit or hemoglobin, complete blood cell count, and stool occult blood tests remained stable. For solo practitioner offices only, streptococcal antigen detection testing decreased (66% to 39%; \( \chi^2 \) test; \( P < .001 \)). Findings in the paired analyses were similar. In 1996, more offices participated in a formal proficiency testing program (60% vs 11%; \( \chi^2 \) test; \( P < .001 \)). The CLIA guidelines were deemed responsible for increased documentation (58%), discontinuing 1 or more tests (56%), increased frequency of quality control (50%), joining a proficiency program (40%), and increased cost to patients (32%).

Conclusions: These surveys provide large-scale data concerning change in office-based laboratories of physicians serving children during an 8-year period. Office laboratories reduced their menu of tests and enhanced documentation and quality control for the tests that were done. Data like these in multiple specialties over time contribute to a comprehensive picture of the effects of CLIA on office laboratory practices.

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In response to reports of errors in laboratory testing, Congress updated the Clinical Laboratory Improvement Act of 1967 with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Related regulations classified tests by degree of complexity; waived (simple accurate tests, little risk of harm if performed incorrectly, or approved for home use) and provider-performed microscopy (PPM) (microscopy tests performed by physicians, dentists, nurse practitioners, nurse midwives, and physician assistants for their own patients in conjunction with a medical examination). All other tests are graded as either moderate or high complexity. At the time that CLIA became law, many physicians were concerned that the regulations would force closure of office laboratories, potentially changing how they provide patient care.

Deadlines for adherence to regulations developed in relation to test complexity. By September 1, 1994, laboratories performing tests of moderate complexity were required to have quality-control procedures in place. Many tests commonly needed in the practice of pediatrics (eg, most tests for streptococcal antigen detection or throat cultures for group A streptococci [GAS]) must be per-
RESPONDENTS, MATERIALS, AND METHODS

STUDY DESIGN AND SAMPLE

1988

The survey form regarding office laboratory practices was developed by the Illinois State Medical Society and sent to the PPRG for survey of Illinois pediatricians. After successful piloting to PPRG offices, survey forms were mailed in August 1988 to 1231 of the 1432 in-state members of the ICAAP, with a second survey to nonresponders 1 month later. Surveys were not sent to 201 members who were known to be either hospital-based practitioners or residents, or who were members of a PPRG practice in which a survey was directed to a practice representative. Eleven surveys were returned as undeliverable. Because the final survey design had not changed significantly from the pilot survey, 3 pilot responses—from those PPRG members answering only the pilot survey and not the surveys sent with the August or September 1988 mailings—were included among respondents; the response rate was 43% (523/1220).

1996

After a piloting, from January to March 1996, a survey regarding office laboratory practices was sent to 1674 in-state nonmerit members of the ICAAP, using a reminder postcard after the first mailing and up to 3 survey mailings to nonresponders. Of these, 47 were returned as undeliverable and 980 surveys were returned; the response rate was 60% (980/1627).

DATA INSTRUMENT

1988

All respondents were requested to categorize their practice location (hospital or nonhospital) and to provide information on the number of physicians in their group, the number of office sites in their practice, and the last 4 digits of their office telephone number. While the survey did not ask whether the physician was in active clinical care, a specialty practice, or residency or fellowship training, respondents indicating these statuses were noted. Nonhospital–based physicians were requested to complete the rest of the survey, which included questions about personnel performing laboratory tests and proficiency program participation. Three response categories for proficiency testing programs were listed: none, informal, and formal. Those participating in a formal program indicated whether they participated in 1 of 3 specified programs or an instrument/vendor program. For the larger of their office sites (if they had more than 1 site), respondents were requested to describe the tests performed at their office. Twelve commonly offered tests (hematocrit, complete blood cell count [CBC], urine dipstick, urinalysis, urine culture, stool occult blood test, streptococcal antigen detection test, throat culture for GAS, rapid hemagglutination slide test for mononucleosis, serum bilirubin, total cholesterol, and theophylline level) were listed. For each test performed, respondents were requested to list the kit or instrument they used, the average number of tests done per month, any quality assurance reference materials used (none, purchased, or office-prepared), and the patient charge for the test. Space was provided for respondents to list and describe additional tests.

1996

Each respondent was requested to categorize their practice locale (nonhospital or hospital only) and indicate if they were a resident, not currently in practice, or not in direct patient care. We added these questions to the 1996 survey, followed by an appeal to physicians who were hospital-based or not in primary care to return the survey; we believed that the absence of this request may have contributed to the lower 1988 response rate (ie, those to whom the survey did not pertain may have discarded it). Respondents who provided patient care in a nonhospital office and who were not residents completed additional questions regarding practice type; the number of physicians, pediatricians, and office sites in practice; whether they were a health maintenance organization (HMO) employee; the number of office sites performing any tests; the office ZIP code; and the last 4 digits of the office telephone number for the largest office site. Offices that performed any in-office laboratory tests were requested to complete the rest of the survey, which included queries about whether their laboratory regularly performed tests on adults also, the identity of office personnel performing laboratory tests, and proficiency program participation. Regarding the latter, respondents formed in laboratories able to handle tests of moderate complexity.

In 1988, the Illinois State Medical Society sought to survey Illinois physicians regarding office laboratory practices. The Pediatric Practice Research Group (PPRG)3 coordinated the survey of members of the Illinois chapter of the American Academy of Pediatrics (ICAAP). Results of this 1988 survey placed us in a unique position to document changes in the office laboratories of Illinois ICAAP members. To accomplish this we undertook a second survey in 1996. This article compares ICAAP physicians’ office laboratory practices regarding personnel, proficiency testing programs, and type of tests in 1988 and 1996. It also describes ICAAP members’ 1996 perceptions of the effects of CLIA on the office laboratory. This report is the first large-scale study to describe changes in office laboratory practices before and after necessary adherence to CLIA regulations.

RESULTS

SAMPLE CHARACTERISTICS

There were 525 respondents to the 1988 survey and 980 respondents to the 1996 survey. Two hundred eighty-two surveys (54% of cohort) from 1988 and 374 surveys (39% of cohort) from 1996 were analyzed. Survey respondents excluded from analyses in the 1988 and 1996 cohorts, respectively, included duplicate surveys from nonhospital practices (9% and 12%); hospital-based phy-
indicated whether they participated in none, informal, or formal proficiency testing programs. Those participating in formal programs indicated whether the program was 1 of 4 programs listed, an instrument or vendor program, or another program. For the larger of their office sites (if they had more than 1 site) respondents were requested to describe the tests performed at their office. The same 12 tests as in the 1988 survey were listed and respondents were requested to list the kit or instrument used and the average number of tests per month for each test offered. Space was provided for respondents to list and describe additional tests.

Additional questions dealt specifically with the effects of CLIA. These asked whether the respondent’s office laboratory had been inspected by CLIA or Commission of Office Laboratory Accreditation officials, and also asked about the CLIA complexity levels that applied to the tests performed at their office laboratory. A third question elicited respondent impression about the effects of CLIA:

Many factors may influence change in laboratory practices (eg, patient needs, managed care, new technology, and CLIA regulations). In the past 2 years, what changes have been made at your office laboratory for which the major reason for change was CLIA regulations?

The following answer options were provided for this question: discontinued test (specify which test); offered more laboratory tests; increased cost to patient for testing; new personnel hired to perform laboratory tests; joined a proficiency testing program; increased documentation of laboratory procedures; increased frequency of quality control for tests; other (specify); or none.

**ANALYSES**

Respondents who indicated only a hospital location for their practice or who were in nonhospital surgical practice or psychiatry were excluded from analyses. Respondents were matched by ZIP code and 4-digit telephone numbers to identify individual offices. Missing ZIP code and telephone number data were gathered using the American Academy of Pediatrics and local telephone directories. A single survey from each office (the one most thoroughly completed) was used in data analysis.

Offices were grouped for analyses by number of physicians in the practice: solo, 2 to 3 physicians, 4 to 7 physicians, or 8 or more physicians. Three 1988 and three 1996 respondents not specifying the number of physicians in their practice but indicating that they were part of large group practices were considered to be in groups of 8 or more physicians. For the four 1996 survey respondents from pediatric primary care practices who indicated the number of pediatricians and did not indicate number of physicians, the number of physicians was assumed to be the same.

Proficiency testing program participation was analyzed with regard to participation in a specified formal program. Instrument or vendor programs were not considered to be specified formal programs. The 6 respondents who indicated formal proficiency program participation but did not indicate if this was an instrument or vendor or specific formal program were classified as formal program participants.

Data was analyzed using SPSS for Windows, version 5.0.2 (SPSS Inc, Chicago, Ill). Because of the multiple tests performed, a significance level of $P<.01$ was used. Surveys were omitted from analyses if information was missing for the relevant variable. The $x^2$ statistic was used to test the significance of differences across categorical variables. The Mantel-Haenszel test for linear association was used to examine trends across the physician groupings for categorical variables.

There were 4 practices, 2 from each year and all with 8 physicians or more, who indicated that many more tests than were on the list were performed by their practice, but did not specify which additional tests were performed. For the nonparametric analyses related to the number of tests, these practices were classified as offering 82 tests; 1 more than the maximum number of tests reported by any practice. Mann-Whitney U or Kruskal-Wallis 1-way analysis of variance (ANOVA) tests were used to determine if the distribution of total number of tests per office differed significantly between the years or by number of physicians in the practice.

A paired analysis was conducted using the 101 offices that responded to the survey in both years to account for bias due to unequal response rates between years. Pairs were determined by comparing telephone numbers, ZIP codes, and mailing addresses. Variables were compared using the McNemar test for categorical data and the Wilcoxon matched-pairs signed rank test for ranked analyses.

Doctors (21% and 31%); physicians in residency or fellowship training (4% and 11%); physicians who were either retired or not in patient care (10% and 7%); and nonhospital physicians in the practice of surgery or psychiatry (0.4% and 1%). Also excluded from the 1988 analyses were 1% of respondents who had moved out of the state or who returned a blank survey.

The number of eligible surveys included in specific analyses varies owing to missing data. Of the 282 and 374 eligible surveys in 1988 and 1996, respectively, there were 99% and 99% of respondents who provided information on number of physicians in the practice and 99% and 93% who answered whether they did office laboratory testing. Of the 263 and 291 respondents from 1988 and 1996, respectively, whose offices performed laboratory tests, there were 99% and 95% who answered questions about testing personnel; 89% and 86% who answered questions about proficiency program participation; and 93% and 99% who answered questions about the types of tests performed. In 1996, among the 291 respondents whose offices performed tests, 85% provided information on CLIA complexity level, 89% on laboratory inspection, and 89% on perceived effects of CLIA.

There was a significant difference ($P<.001$) in the distribution of group size between the 1988 and 1996 respondents with fewer solo practitioners and more large group practices in 1996. These 1988 and 1996 samples included solo practitioners (42% and 27%, respectively), 2- to 3-physician groups (28% and 33%), 4- to 7-physician groups (15% and 19%), and groups of 8 or...
more physicians (15% and 22%). Eleven percent of the
1996 respondents (41 of 361 responding to this ques-
tion) were employed by an HMO; 25 of these HMO em-
employees (61%) were in groups of 8 or more physicians.

The paired analyses included 101 practices, many
of which had added physician staff between surveys. In
1988 and 1996, respectively, there were 41% and 27%
solo practitioners; 33% and 36% 2- to 3-physician prac-
tices; 14% and 22% 4- to 7-physician practices; and 13%
and 16% practices of 8 or more physicians. In 1996, 8
respondents indicated that they were HMO employees,
with 5 of those in groups of 8 or more physicians.

OFFICE LABORATORY TESTING

Significantly more offices performed laboratory tests in
the 1988 than in the 1996 sample (P<.01). In 1988, 93%
of offices performed laboratory tests and there was no
difference in the percentage of practices performing in-
office tests by group size. In 1996, this had changed; 84%
of offices performed tests, including 87% of offices with
2 or more physicians and only 73% of solo practitioner
offices (P<.01). Similarly, in 1988, 98% of paired sample
practices did in-office laboratory tests, while only 88%
of these same practices performed tests in 1996 (Mantel-
Haenszel statistic; P<.01).

Among offices that performed tests, the number of
types of tests performed varied significantly by year (1988
median, 6 tests; 1996 median, 4 tests; Mann-Whitney
U test; P<.001). In both survey years, offices with more phy-
sicians generally offered more types of tests than smaller
offices (Kruskal-Wallis ANOVA, P<.001). In 1988 and
1996, the median number of tests offered by solo prac-
titioners was 5 and 3, respectively, in contrast to a me-
dian of 9 and 5 tests offered by practices of 8 or more
physicians. In 1996, larger offices were more likely to be
performing tests for both children and adults, ranging
from 11% of solo practitioner offices to 81% of offices
with 8 or more physicians (Mantel-Haenszel statistic,
P<.001).

Ninety-eight of the paired practices answered ques-
tions about which tests were offered in both surveys. Over-
all, a reduced menu of tests was offered in 1996 (1988
median, 6 tests; 1996 median, 4 tests; Wilcoxon signed
rank test, P<.001).

TESTS PERFORMED

Frequently offered tests that remained stable across sur-
veys included urine dipstick, streptococcal antigen de-
tection test, hemoglobin level or hematocrit, CBC, and
stool occult blood test (Table 1). Differences between
surveys for other tests are also displayed in Table 1. Re-
ponses regarding these tests for the 98 practices in the
paired sample that answered questions about tests of-
ferred on both surveys were similar. Table 2 includes
tests commonly in a practice's laboratory profile and per-
centage of practices offering these tests by practice size
across surveys. Urinalysis, throat culture for GAS, CBC,
and some of the more complex tests (cholesterol, bili-
rubin, rapid hemagglutination slide test for mononucleo-
sis, theophylline level) were more commonly offered by
the larger practices (Mantel-Haenszel statistic, P<.001).

Although there was no reduction between 1988 and
1996 in the offering of a streptococcal antigen detection
test overall (Table 1), fewer solo practitioners offered a
streptococcal antigen detection test in 1996 (66% and 39%
in 1988 and 1996, respectively; P<.001). In 1996, only
27% of offices overall offered both streptococcal antigen
detection test and throat culture for GAS, down from 46%
in 1988 (P<.001).

CLIA COMPLEXITY LEVEL AND INSPECTION

The 1996 survey data regarding office laboratory com-
plexity level were analyzed by grouping offices by the most
complex level indicated. The majority (56%) of office lab-
atories were of a moderate complexity level, with 30%
waived and 8% categorized as PPM. Only 6% of offices
were of high complexity, with 80% of these in practices
of 8 or more physicians. The percentage of offices that
had been inspected increased with complexity level (29%
waved, 42% PPM, 88% moderate complexity, 100% high
complexity; Mantel-Haenszel statistic, P<.001). In con-

Table 1. Percentage of Practices Offering Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>1988 (n = 249)</th>
<th>1996 (n = 272)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy test</td>
<td>68</td>
<td>90</td>
<td>.36</td>
</tr>
<tr>
<td>Streptococcal antigen detection test</td>
<td>73</td>
<td>68</td>
<td>.07</td>
</tr>
<tr>
<td>Hemoglobin or hematocrit test</td>
<td>63</td>
<td>63</td>
<td>.82</td>
</tr>
<tr>
<td>Stool occult blood test</td>
<td>50</td>
<td>53</td>
<td>.50</td>
</tr>
<tr>
<td>Rapid hemagglutination slide test for mononucleosis</td>
<td>41</td>
<td>17</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Theophylline level</td>
<td>27</td>
<td>4</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>22</td>
<td>13</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>15</td>
<td>9</td>
<td>.02</td>
</tr>
<tr>
<td>Blood glucose</td>
<td>5</td>
<td>8</td>
<td>.25</td>
</tr>
<tr>
<td>Pregnancy test</td>
<td>3</td>
<td>14</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*χ² Test. †McNemar test.
PROFICIENCY PROGRAM PARTICIPATION

Between 1988 and 1996, there was a marked and significant change in reported formal proficiency program participation overall. By 1996, 60% of offices performing tests were in a formal program vs just 11% in 1988 (P < .001). Formal proficiency program participation did not change between surveys for practices with 8 or more physicians; in 1988, 61% participated in a formal program while 59% did so in 1996.

Of the 88 paired sample offices that performed tests in both 1988 and 1996, 77 (88%) answered the question about proficiency program participation in both years. An increase in formal program participation (9% in 1988 and 69% in 1996) was significant (Mantel-Haenszel statistic; P < .001) and consistent with findings for the entire sample.

PERSONNEL

The responsibility for performing laboratory tests may rest on several people within an office—physicians, nurses, medical technologists, and other staff. In 1988 and 1996, physicians performed office tests in more than half of the offices (55% and 59%, respectively), more frequently in solo practitioner offices than in larger offices (74% and 86% in solo practitioner offices in 1988 and 1996, respectively, vs 30% and 38% in offices with 8 or more physicians; Mantel-Haenszel statistic; P < .001 for each year). Nurses were more likely to perform tests in 1996 (50% in 1988 and 63% in 1996; P < .01). On the other hand, the percentage of offices employing a medical technologist or other staff to perform tests was similar in 1988 and 1996 (medical technologist, 24% and 18%; other staff, 39% and 46%, respectively). In both years, these personnel were more likely to be employed at the larger offices (Mantel-Haenszel statistic; P < .001).

Among the 86 offices in the paired sample that did in-office tests and indicated which personnel performed tests in both years, there were no significant changes between surveys in who performed tests. In 1988 and 1996, respectively, the percentage of offices with specified personnel performing tests were physicians, 64% and 53%; nurses, 60% and 64%; medical technologists, 19% and 20%; and other staff, 42% and 44%.

CLIA PERCEIVED EFFECTS

The CLIA regulations were perceived to have affected office laboratory practices, reportedly resulting in increased documentation (58%) and frequency of quality control (50%). Fifty percent of respondents reported joining a proficiency testing program. Most offices (56%) reported discontinuing 1 or more tests because of CLIA. About one third (32%) reported an increased cost to the patient for tests.

In the paired sample, responses to questions about CLIA effects were similar. The CLIA regulations reportedly resulted in increased documentation (65%), increased frequency of quality control (57%), joining a proficiency testing program (48%), discontinuing 1 or more tests (63%), and increased cost to the patient (37%).

MAJOR FINDINGS

The data, gathered in 2 surveys, document many changes in the office laboratories of physicians who serve children during the 8-year period that followed CLIA. Most salient was the fall in the percentage of offices that do laboratory testing—from 93% to 84%. Further, those who do testing now offer fewer tests. The availability in the office of key tests for pediatric practice (eg, throat culture for GAS and urinalysis) had declined. These results

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**Table 2. Percentage of Practices Offering Tests by Number of Physicians in Practice**

<table>
<thead>
<tr>
<th>No. of Physicians in Practice</th>
<th>Complete Blood Cell Count</th>
<th>Urinalysis</th>
<th>Urine Culture</th>
<th>Throat Culture for Group A Streptococci</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>19</td>
<td>11</td>
<td>39</td>
<td>20</td>
</tr>
<tr>
<td>2-3</td>
<td>38</td>
<td>23</td>
<td>57</td>
<td>29</td>
</tr>
<tr>
<td>4-7</td>
<td>52</td>
<td>39</td>
<td>70</td>
<td>32</td>
</tr>
<tr>
<td>≥8</td>
<td>71</td>
<td>44</td>
<td>77</td>
<td>56</td>
</tr>
<tr>
<td>Total sample</td>
<td>36</td>
<td>28</td>
<td>54‡</td>
<td>33</td>
</tr>
<tr>
<td>Paired sample</td>
<td>39§</td>
<td>27</td>
<td>53</td>
<td></td>
</tr>
</tbody>
</table>

*χ² Test, Mantel-Haenszel test for linear association, number of physicians in practice, P < .001.
†χ² Test, Mantel-Haenszel test for linear association, number of physicians in practice, P < .01.
‡McNemar test, 1988 vs 1996, P < .05.
§McNemar test, 1988 vs 1996, P < .01.
seem to bear out some physician worries that were expressed when CLIA was enacted.

However, the data also show positive changes. Between survey periods, enrollment in proficiency testing programs significantly increased. This, along with increased frequency of quality control and increased documentation, was attributed by the survey respondents to CLIA. Practices of 2 to 7 physicians seemed to have made the most changes to maintain testing and comply with CLIA, while the solo practitioner more frequently discontinued testing; offices with 8 or more physicians were less affected.

COMPARISON WITH OTHER STUDIES OF OFFICE LABORATORIES

Several smaller studies from the pre-CLIA era described laboratory testing availability in physicians’ offices. Data from a survey of 50 urban pediatricians in 1982 are similar to responses of the large offices in our 1988 sample. Nearly all respondents (94%) to a 1982 study of 188 North Carolina private practitioners, including 29% solo practitioners and 59% in groups of 2 to 4 physicians, collected and processed throat cultures for GAS in their offices, compared with 63% in our 1988 survey. Of respondents who processed throat cultures for GAS, 26% in 1982 subscribed to a formal proficiency testing program; more than twice as frequently as in our 1988 sample.

In the years between these studies and the 1988 survey, streptococcal antigen detection testing became available. Eighty-nine percent of our 1988 cohort offered at least 1 method of testing for GAS; 63% offered throat culture for GAS and 73% offered a streptococcal antigen detection test. This was quite similar to the findings of a 1992 survey of pediatricians in various clinical settings in 7 Western states, which found that a throat culture for GAS was offered in 61% of offices and a streptococcal antigen detection test in 57% of offices.

A study by Benjamin surveyed 25 midsized pediatric offices with laboratories performing tests of moderate complexity in 1990 and 27 similar offices in 1995 to ascertain changes related to CLIA. Among those offices, CLIA did not seem to limit the test menu. Our study findings are different, probably because our survey included more diverse practices.

EFFECTS OF CLIA

Previous studies have documented deficiencies in office testing procedures in the absence of regulation, improvement after state regulatory intervention, or no improvement after state regulation. Although the proficiency testing performance of physicians’ office laboratories is not yet on par with laboratories at hospitals and independent sites with a history of regulation, the encompassing nature of CLIA regulations and increased quality control, documentation, and proficiency testing in Illinois physicians’ office laboratories leads to the speculation that quality of testing has been enhanced in Illinois.

It is possible that inspections by CLIA officials in Illinois have contributed to the high rate of compliance with proficiency testing programs that we report; nearly all Illinois laboratories of moderate or high complexity had been inspected. Because inspection of waived and PPM laboratories is not required by CLIA, it was surprising that so many of these types of laboratories had been inspected. Possibly this is because of the frequency of laboratories changing their CLIA status after deficiencies were found at an initial inspection. With the increasing number of CLIA waived streptococcal antigen detection tests and rising CLIA registration costs, more offices may opt to change their certificate type.

Because we did not inquire about proficiency testing participation by test, it may be that practices are only complying with some tests and not others. A recent survey of California providers found that only 34% of private practices doing hemoglobin level testing that required proficiency testing program participation were in a program for that test.

Relatively few offices were of PPM (8%) or waived (30%) status, compared with data reported by the Health Care Financing Administration for all CLIA registered physicians’ office laboratories, of which 29% had PPM certification and 38% were waived (Division of Outcomes and Improvement, Family and Children’s Health Program Group, Health Care Financing Administration, written communication, October 1997). We speculate that PPM tests are of more use in the care of adults and, to accommodate the performance of streptococcal antigen detection tests, most offices caring for children established a laboratory of moderate complexity.

It is clear from this study that offices with fewer physicians have responded to regulations by limiting testing. It is likely that these practices have seen an increase in result turnaround time when specimens are sent out for processing. How this affects clinical care is unclear. The ability of the solo practitioner to provide laboratory services equivalent to those of larger practices has become more difficult.

Practices with 2 to 7 physicians have generally responded to CLIA with increased documentation, increased quality control, and increased participation in proficiency testing programs. A recent study indicates that the costs of tests are increased by CLIA compliance, especially for offices with low testing volume. A few of our 1996 survey respondents from larger practices commented that they have centralized their testing, sold office laboratory testing functions, or contracted with outside laboratories, and perform only waived tests, if any, at satellite offices.

Respondents attributed many changes in office laboratory procedures and testing to the effects of CLIA. It must be remembered that there have been many changes in office-based health care during the past 8 years (eg, increase in managed care and changes in accepted best practice) that may have subtly or overtly influenced changes that physicians attributed to CLIA.

In some locations, a consolidation of laboratories may have occurred among managed care offices in the absence of CLIA in an attempt to limit costs. However, few 1996 respondents were employed by an HMO and most HMO employees were in the larger practices, which we found were less subject to change. As of Janu-
January 1, 1996, the Illinois Association of HMOs reports that 24% of Illinois residents were HMO members (Stephanie O’Neill, Illinois Association of HMOs, oral communication, December 19, 1997). It is likely that most physicians are responding to multiple payors and the full effect of an HMO-driven marketplace has not yet been realized in Illinois.

Some changes in test offerings reflect changes in clinical care. Testing for theophylline levels is no longer necessary because of changes in asthma management. Consolidation of pediatric office laboratories with laboratories serving adults could have influenced the availability of a pregnancy test.

Some of the most interesting questions related to the application of CLIA are beyond the scope of this study and may never be completely answered owing to a lack of baseline data and reliable research methods. Data are needed regarding the influence of CLIA on changes in patterns of patient care and the relationship of changes to clinical outcomes (eg, diagnosis and treatment of streptococcal pharyngitis; timeliness of test results; test quality; and the costs of tests for patients, providers, and the health system.

CONSIDERATIONS

It is likely that some physicians neglected to indicate some of the tests performed in their office. However, the similarity in frequencies of commonly performed tests across years suggests that this did not affect the common tests or did so uniformly or minimally. Especially in the larger offices, some physicians did not provide responses about proficiency testing, CLIA effect, and specifics on laboratory tests performed. Some respondents wrote that they did not know answers to these questions because responsibility for CLIA compliance and office testing had been delegated to specific persons other than the respondent.

Extremely incomplete data made it impossible to do analyses related to test kit or instrument. Analyses related to testing volume were also deemed to be unreliable owing to missing data, wide ranges of volume estimates, and seasonal variation of some tests.

Members of ICAAP are not representative of all US physicians treating children. Tests offered at ICAAP offices’ laboratories are more likely to be focused on the needs of children than office laboratories of family physicians or generalists. Just prior to passage of CLIA, Illinois had enacted its own legislation regulating office laboratories; however, CLIA passage superseded development of Illinois guidelines. Knowledge of Illinois legislation may have increased Illinois physician response to federal legislation.

Although not all the same offices participated in both surveys and the response rate in 1988 was low, our analyses of a paired sample that did respond in both years lends credence to the analyses of the entire cohort. Because the same changes were seen in the twice-surveyed subsample, the study’s overall findings between the 2 years are less likely to be due to differences in sampling.

These surveys provide large-scale data concerning the effects of CLIA on office-based laboratories of physicians serving children. The CLIA regulations led to a reduced menu of tests in these office laboratories and more documentation and quality control for tests that were done. Data like these in multiple specialties over time will contribute to a comprehensive picture of the effects of CLIA on office laboratory practices.

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