Impact of CLIA on Physician Office Laboratories in Rural Washington State

Paula L. Roussel, MD
Tacoma, Washington

BACKGROUND. Despite physician concerns to the contrary, the United States Health Care Financing Administration (HCFA) estimated that its regulations implementing the Clinical Laboratory Improvements Act of 1988 (CLIA) would cause few physician office laboratories to either close or reduce testing.

METHODS. A survey requesting information about tests performed before and after the implementation of CLIA was developed and mailed to all members of the rural practice section of the Washington Academy of Family Physicians.

RESULTS. There were significant changes in the complexity of laboratory tests performed before and after implementation of CLIA. Among independent family physicians' office laboratories, waived-status laboratories (ie, those performing only the simplest and lowest risk tests) increased from 1% to 34%, laboratories performing tests of moderate complexity declined from 76% to 53%, and laboratories performing high-complexity tests declined from 23% to 13%. The shift to waived status was more pronounced among solo and small group physicians in smaller communities.

CONCLUSIONS. HCFA seriously underestimated the impact of CLIA on rural physician office laboratories.

KEY WORDS. CLIA (Clinical Laboratory Improvements Act); physicians' offices; laboratories; United States Health Care Financing Administration; physicians, family. *J Fam Pract 1996; 43:249-254)*

Regulations implementing the Clinical Laboratory Improvements Act of 1988 (CLIA)[1] were published by the Health Care Financing Administration (HCFA) on February 28, 1992. Those regulations imposed a licensing scheme on all clinical laboratories, including physician office laboratories (POLs). Prior to CLIA, most POLs were not federally licensed.[2]

CLIA divided laboratory tests into three categories of complexity: waived, moderate, and high.[3] Waived tests consisted of those that are so simple that errors are unlikely and for which there is little or no risk of harm.[2] Many tests routinely performed in POLs were classified as moderate.[3] Fees and other requirements, such as record keeping and required proficiency testing, increased substantially between waived and moderate status.

Approximately 14,470 comments were filed in response to the proposed classifications, with more than 95% in opposition.[4] Much of the opposition came from physicians—especially family physicians—and their representative organizations.[3] They argued that the regulations' costs and complexity would cause many POLs, especially those in rural areas, to close or downsize, thereby increasing patient costs and reducing access to health care.

While acknowledging that if the number of such labs is reduced, forcing patients to go elsewhere for testing could seriously impede access to care,[5] HCFA did not believe that this would occur. Instead, it estimated that CLIA would have little impact on the number or distribution of primary care POLs and thus would not compromise access to care. HCFA's estimate of post-CLIA distribution of POLs was 3% waived status, 87% moderate-complexity status, and 10% high-complexity status, essentially the same as that before CLIA (1%, 75%, and 23%, respectively).

CLIA regulations have remained controversial,

Submitted, revised, March 25, 1996.
This article was presented to the faculty, fellows, and residents of Tacoma Family Medicine, Tacoma, Washington, in June 1993.
From Tacoma Family Medicine, Tacoma, Washington.
Requests for reprints should be addressed to Paula Roussel, MD, Post International Box 76, 666 5th Ave, Suite 572, New York, NY 10103.

with legislative proposals during 1995 to exempt POLs from CLIA.[6] The purpose of this research was to determine what actually happened among family physicians' laboratories in rural Washington as a result of CLIA.

METHODS

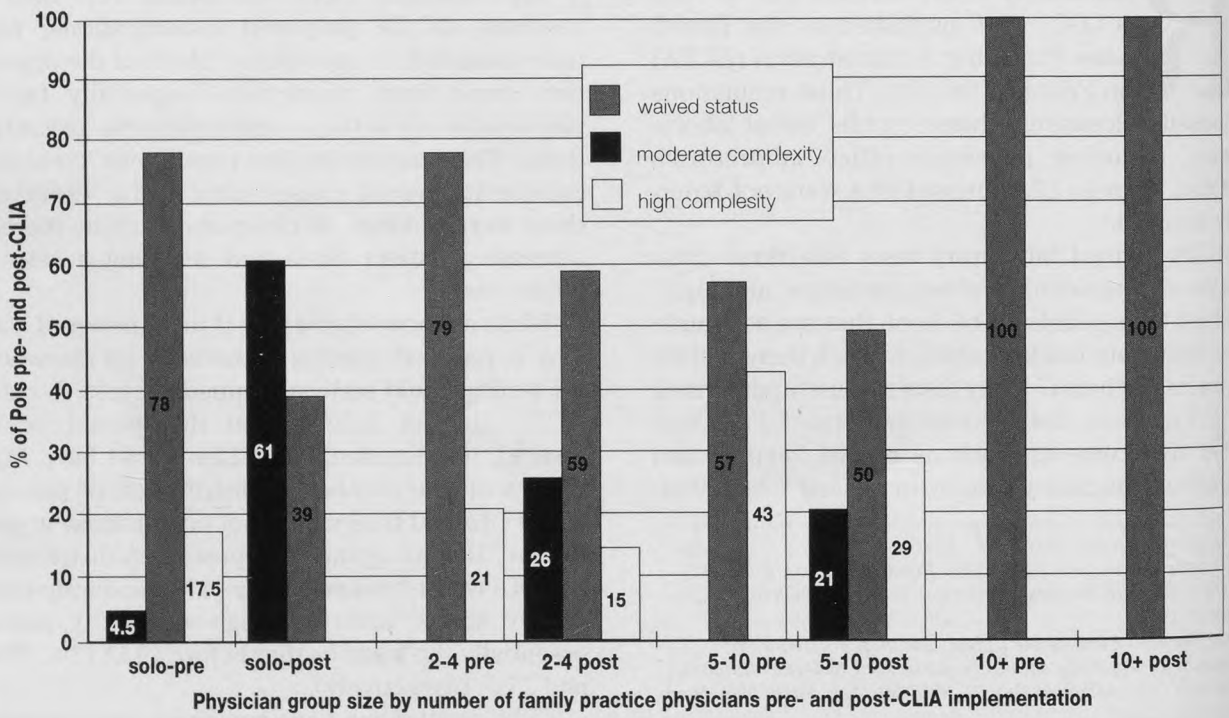
A survey was developed and mailed to all 414 members listed in the rural practice section of the Washington Academy of Family Physicians. According to the Academy, this mailing encompassed the overwhelming majority (approximately 85%) of all family physicians (FPs) practicing in rural areas of Washington State. The survey inquired about the performance of 15 tests before and after CLIA, and requested information on group size, community size, personnel, arrangements for other tests, and proficiency testing. The 15 tests were: complete blood count, hemoglobin, microscopic urinalysis, throat cultures, rapid streptococcal antigen tests, urine cultures, potassium, serum glucose, fingerstick glucose, cholesterol or lipid profiles or both, multichemistry panels, urine pregnancy, serum pregnancy, hematocrit, and total bilirubin. Physician groups were requested to return a single representative survey. Since responses were anonymous, questions on physician age, sex, and residency status were included for the purpose of identifying duplicate responses from larger groups.

Returned forms were classified by type of practice (family physicians only, independent; family physicians only, satellite office; multispecialty practice, independent; and multispecialty practice, satellite). Laboratory status pre- and post-CLIA was classified as waived, moderate complexity, or high complexity according to the CLIA regulations. A POL was considered waived if it performed only tests that met waived-status criteria, and moderate or high complexity if it performed at least one test in that level of complexity. Therefore, a shift from moderate or high complexity to waived status indicated that a POL no longer performed any moderate- or high-complexity tests.

Since a large percentage of the relevant universe of POLs and family physicians were contacted and responded, it was not necessary to conduct statis-

FIGURE 1

The impact of the Clinical Laboratory Improvements Act of 1988 (CLIA) on the distribution of waived, moderate-complexity, and high-complexity physician office laboratories (POLs) before and after CLIA implementation, by physician group size.



TABLE

The Impact of the Clinical Laboratory Improvements Act (CLIA) on the Level of Complexity of Tests Performed in Physicians' Office Laboratories

	Level of Test Complexity					
	Pre-CLIA, %			Post-CLIA, %		
Type of Office	Waived	Moderate	High	Waived	Moderate	High
Independent practice	1	76	23	34	53	13
Family practice satellite	8	77	15	31	62	7
Independent multispecialty group	0	33	67	0	25	75
Multispecialty satellite	7	36	57	7	50	43

tical tests of validity applicable to "samples" of a much larger universe.

RESULTS

Surveys were mailed to 414 individual family physicians. To eliminate duplicate responses, physicians were asked to return only a single survey for each practice, regardless of the number of physicians in the practice. Usable responses were received from practices representing approximately 315 physicians, or 76% of the physicians contacted. All physicians in FP-only groups were counted; conservatively, only one physician was counted for multispecialty groups. An additional 26 responses were excluded for various reasons, including retirement, no longer in practice, and missing data.

Categories and responses were as follows: 249 physicians representing the category FP only, independent; 40 physicians from FP only, satellite offices; 12 from multispecialty, independent; and 14 from multispecialty, satellite offices. Among independent family physicians, 23 respondents were in solo family practice; 39 in small groups (2 to 4 physicians), representing 111 physicians; and 14 large groups (5 to 10 physicians), representing 79 physicians.

Test complexity pre- and post-CLIA declined significantly for independent family physicians and family practice satellite offices, whereas multispecialty practices were only slightly affected (Table). Among independent family physicians' laboratories, there was a significant increase in waived status across all communities and all physician group sizes, except for the three groups with over 10 physicians. Among solo physicians' laboratories, waived status increased more than tenfold, while moderate status decreased by one half. A similar trend was seen for small groups (Figure 1).

As would be expected from the greater change to waived status by solo practitioners and small groups, the impact of CLIA increased as community size decreased. Among communities with a population of less than 2500, the percentage of POLs with waived status increased from 0% to 57%, while those of moderate status decreased by one half. Similar changes occurred in communities of 2500 to 5000. Even in larger communities (>20,000), there was an increase in the percentage of POLs with waived status, although the increase was less dramatic than in smaller communities (Figure 2).

Among independent family physicians, regardless of group or community size, the number of POLs performing only waived-status tests increased sharply after CLIA, whereas the number of moderate- and high-complexity POLs declined by more than one fourth and almost one half, respectively. Figure 3 contrasts these data with HCFA's post-CLIA estimates. Waived-status laboratories increased by more than 10 times HCFA's estimate, whereas moderate-status laboratories decreased by approximately one third rather than increasing, as estimated. Laboratories performing high-complexity tests decreased from 23% to 13%, closely approximating HCFA's estimate.

DISCUSSION

As with all research involving surveys, the likelihood of receiving a response from those surveyed can have an impact on results. In this case, such an impact might have been caused by a higher rate of responses from physicians unhappy with CLIA. Since responses were received from a high percentage (76%) of all physicians surveyed, however, this cause seems unlikely. Moreover, the shift to waived status is so pronounced that even if CLIA

had resulted in no change in laboratory status for all nonresponding physicians, the overall results would still indicate a change to waived status far in excess of HCFA's estimate.

A potential study limitation is that the survey sample was limited to members of the Washington Academy of Family Physicians. Results might be biased if members of the Washington Academy were dissimilar to physicians in rural Washington. This seems unlikely, however, since the Academy reports that its members account for approximately 85% of all FPs in rural Washington.

The survey sought to determine the impact of CLIA by measuring tests performed by POLs before and after the implementation of CLIA regulations. It is important to remember the limitations of this methodology. During the last several years, factors other than CLIA, such as the growth of managed care, have also had an impact on health care and may have affected POLs during the study period. No attempt was made to control for this potential impact. It would be appropriate to attempt to control for these factors in further research.[7]

According to HCFA's analysis, nonmetropolitan physician offices are more likely to provide laboratory services (54% compared with 34% for metropolitan areas) and, pre-CLIA, to have generated a larger percentage (10%) of total practice revenues from laboratory services. HCFA reasoned that this higher proportion of revenues from laboratory services would decrease the likelihood that rural physician offices already performing laboratory tests would discontinue providing these services. HCFA acknowledged, however, that if the number of such laboratories were reduced, forcing patients to go elsewhere for testing, access to care could be seriously impeded.[5] HCFA based its expectations in part on the experience of states, such as Pennsylvania, that have adopted their own regulatory programs that include proficiency testing. HCFA also recognized, however, that, compared with these state programs, CLIA would increase costs and place greater emphasis on sanctions rather than on provider education.

It appears that a significant number of

FIGURE 2

The impact of the Clinical Laboratory Improvements Act of 1988 (CLIA) on the distribution of waived, moderate-complexity, and high-complexity physician office laboratories (POLs) before and after CLIA implementation, by community size.

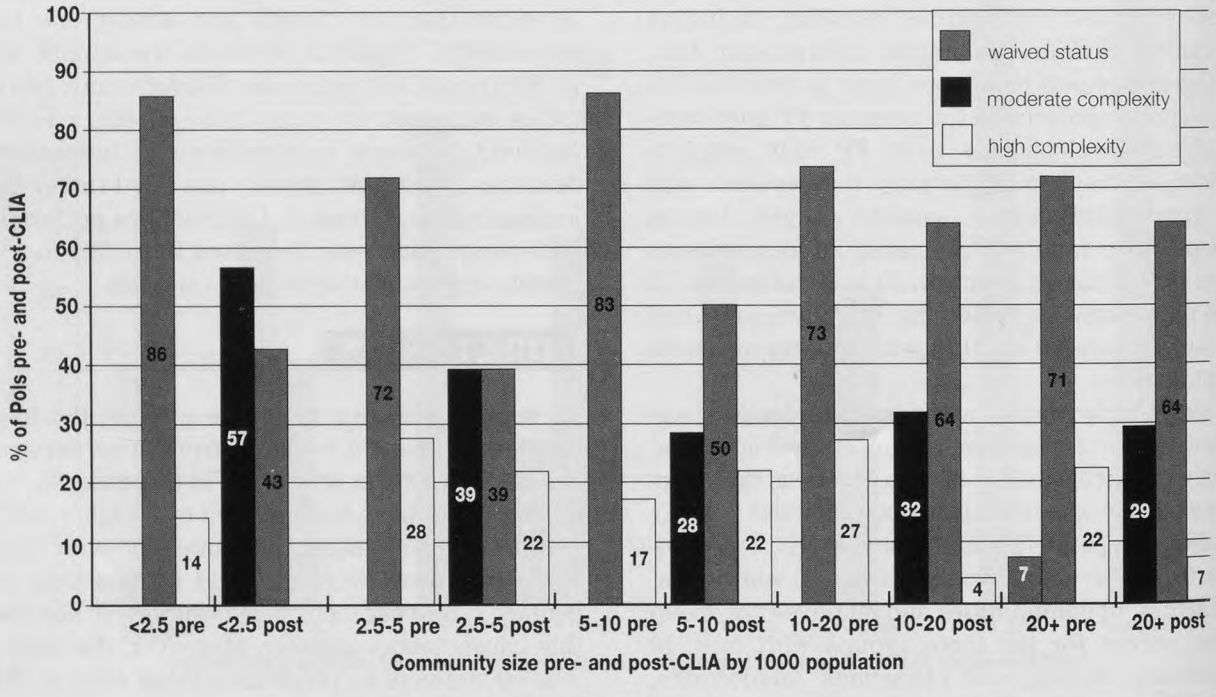
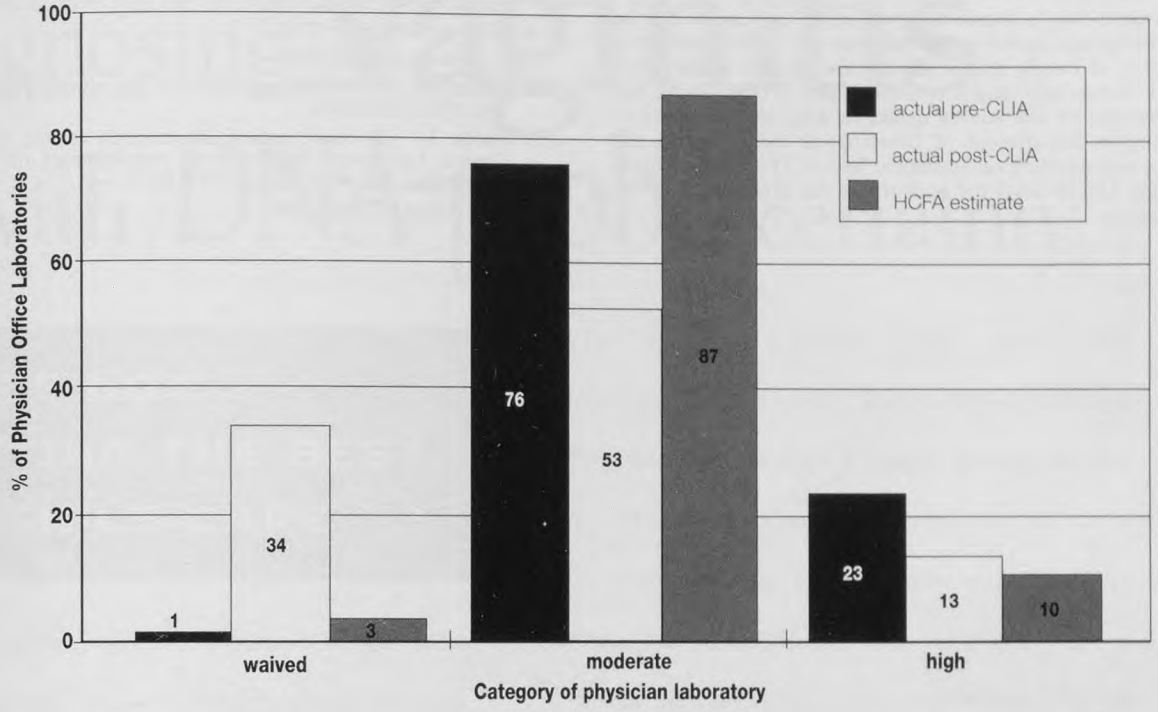


FIGURE 3

Figure 3. Changes in physician office laboratory status as a result of the Clinical Laboratory Improvements Act of 1988 (CLIA): changes estimated by the Health Care Financing Administration (HCFA) before implementation of CLIA and changes that occurred after implementation of CLIA.



Washington family physicians stopped offering many tests of moderate and high complexity as a result of CLIA. The greatest shift to waived status and the concomitant discontinuance of moderate- and high-complexity tests occurred in small physician groups and small communities, a result that is consistent with HCFA's conclusion that the impact of the regulations would be greatest for physician offices. HCFA had estimated that for many physician offices, laboratory costs would increase by 10% or more and the cost of an average test would rise by more than one dollar.[8]

There is some indication that simply looking at the classifying tests performed by POLs as waived, moderate, and high complexity before and after CLIA may understate the decline in physician office testing. Tabulation of the total number of test types offered by POLs that maintained the same complexity status indicates that these laboratories may have offered fewer types of tests after CLIA. Among independent family physicians, 34 POLs were classified as offering tests of moderate complexity both before and after CLIA. Before CLIA, they offered a combined total of 398 tests, or, on average, slightly more than 11 of the 15 tests surveyed per POL; after CLIA, these same laboratories reported a combined total of 312 tests, or, on average, slightly more than 9 of the tests surveyed per POL. This shift suggests that POLs whose complexity status stayed the same may have nevertheless reduced the types of tests they offered.

This study did not attempt to assess CLIA's impact on access to tests or quality of care. Those expressing opposition to the proposed CLIA regulations contended that a decrease in tests offered by POLs—particularly tests of moderate and high complexity—would reduce access to and quality of care. HCFA estimated that no significant reduction would occur and that few POLs would discontinue moderate- to high-complexity tests in favor of waived status. The data indicate, however, that at least in rural Washington, a significant move to waived status and a concomitant reduction in moderate- and high-complexity testing occurred after CLIA among POLs operated by independent family physicians.

ACKNOWLEDGMENTS

The research on which this article is based was performed as part of the Rural Family Medicine Fellowship at Tacoma Family Medicine, Tacoma, Washington, a program affiliate of the University of Washington.

I would like to thank the Fellowship and its faculty for supporting and assisting in this research; the Washington Academy of Family Physicians for use of their mailing list; Walter Henze, MD, and David Losh, MD, for reviewing and commenting on the survey questionnaire; the University of Washington Department of Biostatistics for reviewing the results and advising on statistical issues; Thomas E. Norris, MD; and Lee Roussel for assisting in the preparation of the manuscript.

REFERENCES

1. 57 Federal Register 7002 et seq (1992).
2. Stevens C. HCFA's new rules may shut down your office lab. Med Econ 1990; 18:28.
3. Losh DP, Geiger WJ. The practice and regulation of family practice residency laboratories. Fam Med 1993; 25:580-4.
4. 57 Federal Register 7016.
5. 57 Federal Register 7109.
6. Griffin GC. MD/DO jobs and incomes may shrink. Postgrad Med 1995; 97(5):13-6.
7. Boone DJ. Literature review of research related to the Clinical Laboratory Improvement Amendments of 1988. Arch Pathol Lab Med 1992; 119:681-93.
8. 57 Federal Register 7106.