The Impact of New Regulations on Laboratory Testing in Physicians' Offices

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The reaction of the clinician to the specter of regulation of any part of his or her practice mirrors the reaction of the laboratorian to the implementation of Medicare and Clinical Laboratory Improvement Amendments legislation in 1965 and 1967, respectively. Whether the regulatory burdens that will be visited upon these laboratories are justified or necessary is arguable; the fact of the upcoming regulation is not. The volume and breadth of testing in physicians' office laboratories (POLs) has increased exponentially since passage of the Diagnosis Related Group legislation by Congress in 1983, an increase made possible by remarkable developments in technology. State regulatory initiatives and private accrediting agencies have been perceived as being inadequate to prevent the proliferation of poorly controlled testing in the nontraditional laboratory environment. The testing menu of a given POL varies according to the scope of clinical services offered; the size of the practice group; the funding available for equipment and personnel acquisition; and the general availability of hospital, reference, and consultative laboratory services. Physicians who offer laboratory services as part of their practices must now prepare their laboratories to meet whatever requirements are mandated by regulation. This will include acquisition of trained personnel, improvement of instrumentation and methodologies, participation in proficiency testing, establishment of comprehensive quality-assurance programs, and adequate documentation of laboratory services. Organized medicine should devote its energies to assisting with needed educational processes to assure the survival of POLs.

In assessing the impact of new laboratory regulations on the practices of clinicians, one must be ever mindful of the fact that, except in a few states, the private practices of physicians in the United States have been largely spared any regulation by either the state or federal government. To be sure, many physicians have experienced at least rudimentary regulations in their offices by virtue of contractual agreements with managed health-care entities (e.g., HMOs and the like). Also, some states (most notably Pennsylvania and Idaho) have implemented rather sweeping regulations for laboratories in the physicians' office environment, and it is possible to draw upon the experiences in these states to a degree. However, until the passage of CLIA '88 (the Clinical Laboratory Improvement Amendments of 1988), the federal government has never involved itself in the day-to-day practice of medicine in private physicians' offices. Predictably, therefore, the reaction of most clinicians to regulation of any part of their practice is negative. In fact, one of the greatest problems confronting those who would attempt to help clinicians prepare for regulation is overcoming their anger and indignation. That is to say, most clinicians are reluctant to admit that there is a problem with the data generated by their laboratories, despite considerable evidence to the contrary.

It is also helpful to reflect upon the reaction of laboratorians to the idea that their practices should be regularly scrutinized and regulated. More-mature laboratorians will recall the hue and cry that occurred with the implementation of the initial Medicare legislation in 1965, and with the first CLIA legislation in 1967. There was considerable discussion among pathologists and other laboratorians at that time that such regulation of their practices was not only unnecessary but also intrusive, fiscally unsound, and counterproductive to good laboratory practice.

Many circumstances have contributed to the evolution of regulation of physicians' office laboratories (POLs). First, there has been a festering concern of laboratorians that POLs have an unfair competitive advantage in their unregulated utopian state. The fact that POLs have been largely free to perform whatever tests they desire, without the necessity of proficiency testing, unannounced inspections, and quality assurance and documentation requirements, etc., and can still charge the full amount for laboratory tests that they perform has not gone unnoticed by hospital and independent laboratories.

Some studies have shown rather conclusively that testing done in the POL environment by individuals without formal laboratory training is less well-controlled, and the data from this testing are thought to be less accurate and reproducible, than from similar testing in regulated hospital or independent laboratories (1). What has not been addressed with any degree of objectivity is whether or not this difference in test accuracy has resulted in patient harm, or in less-than-optimum care of patients. Laboratorians have difficulty in accepting the premise that in the day-to-day management of patients, clinicians often are required to rely on less-than-optimum data, whether such data are laboratory results, imaging information, or information obtained by history and physical examination of the patient. Laboratory testing is only one of many sources of information the clinician must utilize in his evaluation of patients, and the perspective of utility of data from laboratory testing is different for the clinician than for the more-academic laboratorian.

With the advent of prospective payment for hospitalized patients, the hospital laboratory, seemingly overnight, was changed from an income-generating activity

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to an expense activity, and the incentive to order as many tests as reasonably possible was similarly changed to an incentive to get by with as little laboratory testing as possible. At the same time, the evolution of microcomputers and the availability of this inexpensive technology made it possible for relatively sophisticated instrumentation to be adapted to the small-laboratory environment. Instrument manufacturers responded to these changes with a veritable explosion of technology designed for the office laboratory. These instruments have been marketed as requiring little or no formal laboratory training to operate. Never before has so much excellent laboratory service been so readily available to physicians in the daily management of their patients. Whether or not this availability of testing has improved the quality of patient management has not yet been adequately examined.

The result of all this has been an enormous increase in the amount of laboratory testing being done in physicians’ offices: expenditures for POL testing appear to have increased exponentially in the past several years (2). Many believe that this has created an additional incentive for the federal government to scrutinize more carefully the POL environment, and to discourage this proliferation of testing.

Some states could demonstrate an improvement in the performance of laboratory testing in physicians’ offices by virtue of regulatory and educational efforts (3). Another study has failed to show significant improvement, at least from the application of proficiency testing requirements to these laboratories (4). The regulatory efforts of most of the states have been too rudimentary to be of much value when one tries to extrapolate their experiences to a national perspective.

There has also been a concern that voluntary private credentialing programs for POLs have fallen short of making a significant impact on the quality of testing occurring in these sites. Although the Commission on Office Laboratory Accreditation (COLA) was incorporated in 1986—and to date, more than 1500 applications have been received by this organization—it still must be admitted that the single greatest incentive to applying for accreditation from this (or any other) voluntary accrediting agency will come with the implementation of either state or federal regulation. In other words, 1500 laboratories, although a respectable number, undoubtedly represents only the creme de la creme of POLs, and, at that, is only a small proportion of the estimated 150 000 testing sites in physicians’ offices nationwide. No other private accrediting agency exists for POLs, although a few laboratories are surveyed by the Joint Commission for Accreditation of Healthcare Organizations in accrediting ambulatory-health-care facilities.

In December 1987 and January 1988, a series of videos called “Deadly Mistakes” was aired in the Washington, DC, area. Although touted as an expose of offsite-testing laboratories, it was, in fact, an expose of pap-smear mills, and it documented several anecdotal cases of patient death from cervical carcinoma, despite repeatedly “normal” pap smears. Even though the series won awards for journalism, many researchers have faulted it as lacking in scientific objectivity, relying largely on unscientific anecdotal reports of laboratory and clinical impropery. Be that as it may, this video series was probably more responsible for the precipitous and impetuous passage of the CLIA ’88 legislation in October 1988 than any other single consideration.

Testing Currently Done in POLs

For you better to appreciate the breadth of testing currently being done in clinicians’ offices, I will review the results of four different surveys. Although these surveys sought to measure somewhat different parameters, the results are remarkably similar.

In March 1990, the American Academy of Family Physicians, as part of their annual survey of a statistical sampling of its membership, asked several questions regarding laboratory activities. Of the 4400 members surveyed, 92.6% responded that they did in-office testing. The Academy also found that 34.3% of these offices participated in some form of proficiency testing. Further, the survey revealed that 64.9% of these laboratories employed personnel who had no formal laboratory training.

The Nebraska Academy of Family Physicians surveyed its membership in a more complete questionnaire in June 1990 (one month after publication of the Proposed Rule for CLIA ’88 implementation in the Federal Register). They found that 95% of those responding did at least some laboratory testing in their offices. The types of testing done in the POLs in Nebraska is shown in more detail in Table 1. This survey also found that 61% of its laboratories employed personnel who had no formal laboratory training. Alarmingly, a full 31% of those Nebraska laboratories surveyed performed no daily quality control on their hematology tests.

Also in June 1990, the Florida Academy of Family Physicians surveyed their membership regarding their laboratory practices (5). The significant additional information obtained from this survey is that fully 80% of those respondents indicated that if they were required to pay as much as $2000 for a certificate to operate a laboratory, they would cease all laboratory testing.

Finally, in June 1990, Dr. A. Samuel Koenig of Fort Smith, AR, conducted a survey of ~100 primary-care physicians who were attending an educational seminar. The results of this survey were presented to the NCCLS Laboratory Seminar in Washington, DC, in November 1991 (6). This survey was taken in a pre- and post-seminar fashion. Of the physicians in this survey, all performed laboratory testing in their offices. Only 29% of them employed personnel with formal laboratory training; 55% employed “on-the-job” trainees. The level of confidence of these individuals was high: fully two-thirds considered their testing to be simple, easy to perform, and involving little chance for error. This survey was skewed toward rural clinicians, so it is important to note how they responded to the proposed regulations, particularly in regard to the continued
Table 1. Nebraska Academy of Family Physicians
Office Laboratory Services Survey

<table>
<thead>
<tr>
<th>Test</th>
<th>% of labs</th>
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<tbody>
<tr>
<td>Dipstick urinalysis</td>
<td>100</td>
</tr>
<tr>
<td>Urine pregnancy test</td>
<td>99</td>
</tr>
<tr>
<td>Microscopic urinalysis</td>
<td>96</td>
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<tr>
<td>Fecal occult blood</td>
<td>93</td>
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<tr>
<td>Vaginal wet mount</td>
<td>90</td>
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<tr>
<td>Glucose</td>
<td>86</td>
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<tr>
<td>Leukocyte count</td>
<td>81</td>
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<tr>
<td>Mono slide test</td>
<td>80</td>
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<tr>
<td>Hemoglobin</td>
<td>79</td>
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<tr>
<td>Sedimentation rate</td>
<td>75</td>
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<tr>
<td>KOH prep</td>
<td>73</td>
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<tr>
<td>Potassium</td>
<td>73</td>
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<tr>
<td>Total cholesterol</td>
<td>70</td>
</tr>
<tr>
<td>Microhematocrit</td>
<td>64</td>
</tr>
<tr>
<td>Direct strep antigen test</td>
<td>63</td>
</tr>
<tr>
<td>Uric acid</td>
<td>60</td>
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<tr>
<td>Platelet count</td>
<td>58</td>
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<tr>
<td>Erythrocyte count</td>
<td>56</td>
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<tr>
<td>Leukocyte differential</td>
<td>55</td>
</tr>
<tr>
<td>Pinworm prep</td>
<td>52</td>
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<tr>
<td>Semen analysis</td>
<td>52</td>
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<tr>
<td>Blood urea N</td>
<td>50</td>
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<tr>
<td>Gram stain (diesh, exud)</td>
<td>49</td>
</tr>
<tr>
<td>Cholesterol screen (qual)</td>
<td>49</td>
</tr>
<tr>
<td>Aspartate aminotransferase</td>
<td>46</td>
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<tr>
<td>Prothrombin time</td>
<td>46</td>
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<tr>
<td>Urine colony count</td>
<td>44</td>
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<tr>
<td>Hematocrit (automated)</td>
<td>44</td>
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<tr>
<td>Glucose (stick method)</td>
<td>42</td>
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<tr>
<td>Creatinine</td>
<td>41</td>
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<tr>
<td>High-density lipoprotein</td>
<td>37</td>
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<tr>
<td>Cholesterol</td>
<td>31</td>
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<tr>
<td>Bilirubin</td>
<td>31</td>
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<tr>
<td>Sodium</td>
<td>28</td>
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<tr>
<td>Reticulocyte count</td>
<td>24</td>
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<tr>
<td>Chlamydia slide test</td>
<td>24</td>
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<tr>
<td>γ-Glutamyltransferase</td>
<td>20</td>
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<tr>
<td>ASO screen (card test)</td>
<td>20</td>
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<tr>
<td>Rheumatoid factor (screen)</td>
<td>20</td>
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<tr>
<td>Ovulation tests (visual)</td>
<td>13</td>
</tr>
<tr>
<td>C-reactive protein</td>
<td>10</td>
</tr>
<tr>
<td>Sickle-cell screen</td>
<td>4</td>
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access to laboratory services for their patients. Fully 27% of those surveyed indicated that they would cease all testing if the NPRM were implemented as a final rule. It further indicated that in 37% of the communities represented, no laboratory services would be available at all if POLs were forced to cease testing. And 59% of them indicated that trained laboratory personnel were simply not available at any price. Most felt that they could meet the proficiency testing standards. This survey made clear the negative effect implementation of such punitive regulations might have on the recruitment and retention of medical personnel (most notably physicians) in rural areas.

State Government Initiatives

State government regulatory initiatives toward POLs have been well documented elsewhere (7, 8). Here, I will address the peculiar problems visited upon a state (Nebraska) attempting to implement its recently enacted laboratory legislation in the atmosphere of confusion caused by the oft-delayed implementation of CLIA ’88.

In 1990, the Nebraska legislature passed LB-551. Attempts by organized medicine to delay enactment of this legislation were foiled because of the continuing delays in the federal laboratory initiatives. At present, implementing regulations have been written for LB-551. To posture itself for "deemed status" under CLIA '88, the regulations to implement LB-551 were taken almost verbatim from the Final Rule of March 1990 for previously regulated laboratories.

It is now apparent that the Final Rule for CLIA '88 (expected in early 1992) will be substantially less stringent than that of March 1990. Now Nebraska is in the unhappy position of attempting to implement laboratory regulations that are much more rigorous and stringent than those for the rest of the country. Considering the manpower shortage of rural areas in general, and of Nebraska in particular, this situation presents a threat to access to care in this state. Although the Nebraska Medical Association (as well as other clinical organizations) will certainly seek legislative relief from this unintended state of affairs, it has created an atmosphere of suspicion, if not downright distrust, toward the State Health Department, as well as toward those individuals in the state who have worked hard to introduce laboratory control procedures that would not inordinately affect access to needed services.

This atmosphere of mistrust and confusion is not unique to Nebraska. Other states—including Illinois, California, and Washington—have been experiencing similar pains as they attempt to implement state regulations.

Private Accrediting Agencies

I know of only one private voluntary organization that currently is specifically addressing the issue of POL accreditation: the Commission on Office Laboratory Accreditation (COLA, 8701 Georgia Ave., Suite 610, Silver Spring, MD 20910). Others may come later, but the organizations founding COLA recognized even before federal regulatory initiatives directed to POLs that there was a need for an educational and accrediting agency for these laboratories, to assist those who were willing to bring their laboratories up to some standard of excellence, and thus to distinguish them from the poorly controlled laboratories that had been the foci of much criticism.

COLA is a program for assessment, education, and accreditation of office laboratories, initiated by the American Academy of Family Physicians, the American Society of Internal Medicine, the American Medical Association, and the College of American Pathologists. It is specifically designed for use by office laboratories serving one to five physicians (although many larger practices have been accredited). Its purpose is to educate these laboratories to improve the quality of the data
they generate, and thus make them eligible for accreditation by this organization. As soon as the Final Rule for the implementation of CLIA '88 is published, COLA will make whatever modifications necessary in its program to enable it to apply for "deemed" status with the Health Care Financing Administration (HCFA).

COLA emphasizes a nonpunitive approach to laboratory accreditation; it furnishes a checklist, personnel forms, and information relative to acceptable proficiency testing programs, along with a sophisticated educational support system for its applicant laboratories. It steers the laboratory through the accreditation process until all the criteria for full accreditation are met, at which time a certificate is issued. Application for COLA accreditation is an excellent tool that is available now for use by POLs in positioning themselves for CLIA certification. This is particularly important for laboratories that have heretofore not been exposed to regulatory activity.

Factors Determining the Testing Menu under CLIA '88

Apart from the regulatory issue, clinicians must consider several factors in determining the test menu for their laboratories. Not necessarily in order of importance, these include:

1. scope of clinical services offered
2. size of the practice group
3. funding available for equipment acquisition
4. commitment of the clinicians to laboratory quality
5. availability of trained personnel
6. availability of reference laboratory services
7. availability of hospital laboratory services
8. availability of laboratory consultative services
9. limitations of the facility

Scope of clinical services offered. If the practice served by the laboratory is a "typical" primary-care practice, with the wide range of services that a medical office connotes, the menu of tests offered by the laboratory might be expected to be similarly large. However, even in limited-service clinics, certain "basic" tests are needed in the laboratory's test menu, without which it is difficult to understand how day-to-day clinical medicine could be practiced. The following "generic" menu of tests for family-practice clinics probably should be immediately available to all clinicians:

- Dipstick urinalysis
- Microscopic urinalysis
- Urine pregnancy test
- Glucose
- Basic hematology (leukocyte count, hemoglobin, hematocrit)
- Erythrocyte sedimentation rate
- Fecal occult blood
- Vaginal wet mount
- Mono slide test

Depending on the services offered by the clinic, this menu may need to be expanded. For example, if obstetrics constitutes a large part of the practice, such things as semen analysis and ovulation tests may be required. If many hypertensive and CHF cases are followed, it will be necessary to offer serum potassium and prothrombin times. If there is a large black population, the sickle-cell screening test will be essential.

Size of the practice group. An economy of size is realized in determining a laboratory test menu. A larger number of clinicians will obviously generate a greater number of tests, often making it possible to retain better-trained personnel, obtain more-sophisticated testing equipment, and take advantage of volume purchase of reagents and control material.

If the group exceeds four or five physicians, "profiling" is often offered. Some of the desktop analyzers now available for use in office laboratories have multiple-test capability with a minimum of hands-on time.

With a larger group of physicians served by the laboratory, one physician is usually designated as the "laboratory director." This individual may not have any more laboratory acumen than other physicians in the clinic, but he or she acts as a conduit for information to flow between the laboratory and the other departments of the clinic, and he or she remains the advocate of the laboratory personnel when disputes arise between the laboratory and other physicians or other clinic departments.

Funding available for equipment acquisition. This is often closely a function of the number of physicians in the group. However, lease/purchase and reagent-rental options now available with instrument manufacturers, as well as the general availability of user-friendly microcomputer technology at a reasonable price, has put many rather sophisticated instruments well within the range of the smaller office laboratory.

Even so, the number of tests expected to be done by the laboratory plays a large part in deciding how much of the clinic resources are devoted to laboratory equipment. The per-test cost of procedures goes up dramatically for tests that are offered infrequently. Similarly, the cost of quality-control maneuvers, given as a percentage of tests billed, goes up dramatically with tests done infrequently.

Commitment of the clinicians to laboratory test quality. If the clinicians served by the laboratory are not willing to commit the required resources for a complete laboratory quality-assurance program, the clinic's testing menu will usually be quite small. All state and private accreditation programs require documentation of quality-assurance maneuvers, and this in turn requires a substantial financial commitment by the clinic.

Clinicians who are unwilling to agree to the necessity of implementing these quality-assurance procedures are constantly finding themselves at odds with the laboratory director and other laboratory personnel.

Availability of laboratory personnel. The unexpectedly rapid passage of CLIA '88 and its imminent implementation have produced a genuine shortage of trained personnel. Further, several training programs have been severely constricted in recent years, so that there are considerably fewer graduates than in the past. Many laboratorians will also soon be "snapped up" by government and private accreditation agencies to fulfill
the on-site inspection mandates of CLIA '88 and private accreditation programs. This will further attenuate the pool of laboratorians available for office laboratories.

This paucity of technical personnel and the personnel requirements for clinical laboratories that will be mandated by CLIA '88 have forced physicians to compete fiercely with independent and hospital laboratories for the available personnel. This is felt more acutely, of course, in rural areas, where fewer personnel have always been available.

Some POLs provide a substantial menu of tests by using "on-the-job trainees" in their laboratories. These laboratories often have an ongoing relationship with their reference laboratory, hospital laboratory, or a formal arrangement with a laboratory consultant to oversee the quality assurance program of the laboratory. In fact, such arrangements may be mandated by the Final Rule implementing CLIA '88.

Availability of reference laboratory services. The reference laboratory industry is also becoming fiercely competitive. This fact has put clinic laboratories in an enviable position. If the reference laboratory wants the business of the clinic for the completion of more esoteric tests, cytology, and gross and microscopic pathology, it is often willing to assist the clinic in securing personnel, initiating the quality-assurance program, selecting in-house test menus, selecting appropriate equipment, and setting up the safety and CME programs for the lab personnel. Unfortunately, such agreements between reference laboratories and POLs are currently in jeopardy, owing to the implementation of some of the provisions of OBRA-90 (the "Stark" amendment).

For those rural practices where there is no good access to a reference laboratory, the test menu is often larger, so as to be able to deliver quality health care. Indeed, for such tests as prothrombin times, where specimen management is critical, it frequently is not possible to ship specimens a large distance for analysis at a remote site.

Availability of hospital laboratory services. For those practices that are part of, or contiguous with, a hospital facility, the decision regarding a test menu in the office is often a simple one.

With the constraints on reimbursement for in-patient testing that were visited upon hospitals with the implementation of prospective payment, many hospitals began expanding the services they offered to physicians' offices. That is, they began acting more and more like independent (or reference) laboratories. A good relationship with a local hospital is often a reasonable alternative for those who practice in rural areas, and is in fact often mutually beneficial.

Availability of laboratory consultative services. The requirements of CLIA '88 (as well as some state and private accreditation programs) have spawned a relatively new industry—the laboratory consultant industry. This may be offered as part of a reference laboratory package to clinicians, but many laboratory technologists are becoming entrepreneurs in their own right, contracting directly with POLs; office laboratory personnel often relate better to technical people than to pathologists or doctorate-level laboratorians.

Consultants are invaluable to the clinician and his or her laboratory staff in deciding upon appropriate testing menus and equipment for the office laboratory. They also assist in setting up the quality-assurance program and the instrument-maintenance program, and interact with the proficiency testing program and in the acquisition and training of necessary laboratory personnel.

Limitations of the facility. The testing menu for the laboratory must take space and facility limitations into consideration. Here POLs often find it necessary to seek the assistance of laboratory consultants, as well as instrument vendors, to stay well within the guidelines for safe and optimum instrument operation. Consideration must also be given to adequate space for specimen collection, recording of laboratory results, and other administrative functions.

Recommendations for POLs under CLIA '88

Clearly, the utopian existence that laboratories in physicians' offices have enjoyed until now in most states will soon come rudely and abruptly to an end. Even the most optimistic of projections for the HCFA's Final Rule recognize that such fundamental laboratory exercises as proficiency testing and daily quality control will be required for all but a small number of "waivered" tests.

In September 1990 the final date passed for submission of comments on the Proposed Rule for the implementation of CLIA '88. The time has now come for physicians who offer laboratory services as part of their practices to recognize the necessity of preparing their laboratories to be in a position to meet whatever requirements are mandated. For those who have never executed formal quality-assurance practices in their laboratories, it will require a considerable amount of time to introduce these measures into their laboratories.

What follows here is a series of suggestions as they might be presented to clinicians who are striving to continue to be able to provide laboratory services in a regulated atmosphere. These clinicians will need to address five general areas of concern: personnel, instrumentation, proficiency testing, quality assurance, and documentation.

Personnel. Those laboratories that have any more than a rudimentary menu of tests and that have heretofore not hired formally trained technologists or technicians would be well advised to consider retaining such personnel if they are available. Whereas much of the instrumentation available to POLs has been designed for use by on-the-job trainees, other elements of CLIA '88 make degree personnel more of a necessity than a luxury in the day-to-day operation of the laboratory. Unless the physician laboratory director of a POL has formal training and is willing to spend much of his or her time otherwise spent in practice in hands-on supervision of quality-assurance procedures, he or she will be well advised to turn these functions over to a technically trained individual or to seek help from a laboratory consultant.
Instrumentation. A plethora of instruments is currently available for use in “nontraditional” testing sites such as the POL. Most of these instruments, if operated as directed, produce very satisfactory and utilitarian data. However, some do not. It is beyond the scope of this paper to specify which instruments should be considered by the clinician in his or her office laboratory. Many variables—including practice size, menu of testing, and personnel available—must be considered.

Some generalizations, however, are possible. First, there will be much narrower limits for acceptability of laboratory results than many clinicians have been willing to accept before regulation became a reality. Some instruments commonly used in POLs, no matter how well-trained the personnel using them, will simply not perform well enough to meet the accuracy requirements. A good way to determine exactly how a given instrument is performing in the POL setting, as well as how many POLs use a given instrument, is to obtain a copy of a recent surveys report document from any recognized proficiency testing program. This list, for each test performed, the number of laboratories using a given instrument and how well the instrument performed compared with other instruments and with the “referee” laboratories. What this document will not tell is the purchase price of the instrument, the sophistication required to use the instrument, and the per-test cost of using the instrument.

Another generalization for instrumentation is that laboratories performing any substantial number of hematology tests (e.g., hemoglobin, leukocyte count, erythrocyte count, platelets) would be well advised to consider acquiring an automated cell-counter, particularly if the laboratory does not utilize formally trained personnel. In the best of hands, manual cell-counting is poorly reproducible, and in the absence of (e.g.) excellent quality-control procedures the results are little better than estimates. Again, a quick glance at the proficiency testing report document will verify that the coefficients of variation of manual cell-count methods are always much higher than those of automated cell-count methods. Improved technology and competition have decreased the cost of these instruments so that they are well within the financial reach of almost all POLs.

Proficiency testing. Good laboratory practice dictates that all POL testing should be subjected to proficiency testing challenges. If a laboratory has never participated in a proficiency testing program, it would be well advised to do so immediately. Not only will this be mandated by the CLIA ’88 regulations for all but “waivered” tests, but there is some genuine concern as to whether the currently available programs will be able to gear up to accept all the laboratories that will apply. This should provide enough incentive for nearly all POLs to apply now to the proficiency testing program that most nearly meets the requirements for their level of testing.

Proficiency testing was originally intended as an educational tool for laboratories, to help them identify and correct deficiencies in their testing. However, with CLIA ’88, proficiency testing has become the single most important “outcome” monitoring device for evaluating laboratory performance. Whether or not a laboratory receives a certificate will depend in large measure on its performance in a proficiency testing program.

Quality assurance. The term “quality assurance” means the control of all elements of the testing system, including pre-analytical variables (test-ordering systems), post-analytical variables (test-reporting systems), other analytical variables (daily quality control, instrument maintenance, etc.), and the minimization of safety hazards within the laboratory. Demonstration of appropriate quality assurance includes documentation of all these elements.

A full discussion of the laboratory quality-assurance program is beyond the scope of this paper. It is incumbent upon the laboratory director to see that this component of laboratory function is in place—not an inexpensive proposition. Most laboratorians indicate that the average laboratory can expect 30% of its overhead to be spent on quality assurance. This figure may be higher for smaller laboratories, and it represents one of the “hidden” costs inherent in laboratory operation.

Because the physician laboratory director will usually be unable to spend the required time to set up and supervise this activity personally, it will need to be delegated to the technical personnel of the laboratory. However, the laboratory director still has the responsibility to ensure that this important function of the laboratory is carried out. If formally trained personnel are not available, it will be necessary to turn to consultant laboratorians to set up the program and to instruct the POL personnel in ongoing requirements for the program, including daily quality control and instrument maintenance, as well as control of the pre-analytical and post-analytical factors impacting on the testing process.

Documentation. Certain elements of documentation will be required by the HCFA (or other regulatory agency) before certification will be granted. Not only must all the requisite quality assurance be accomplished by the laboratory, but there must also be documentation that this has been done.

The following list of required documentation demonstrates the scope of these requirements:

- Procedure manual
- Laboratory safety manual
- Personnel file
- CME file
- Instrument-maintenance file
- Daily quality-control records
- Proficiency testing reports

Summary

To date, the reaction of clinicians to the specter of regulation of this portion of their practices has largely been one of outrage, and I have seen little inclination of most clinicians to accept the inevitable and prepare themselves for this eventuality. Even so, clinical organizations have been very active in the development of
educational programs for their members, to enable them to continue to provide quality laboratory services in a regulated environment.

Whereas many clinicians may opt to discontinue providing laboratory services rather than submit to regulation, presumably the majority will undertake to upgrade the laboratory services they provide and thus be able to meet the mandates of the regulatory environment that has been thrust upon them. Particularly in rural and underserved areas, there may simply be no alternative to the POL in the delivery of needed laboratory services.

Organized medicine should devote its energies to assisting with this educational process, rather than to attempting to reverse these regulatory mandates. The laboratorians of three decades ago were able to survive and thrive in spite of regulations, and clinicians should be able to do the same.

References