

COLA'S

inSights

INTO

The Cost Effective Laboratory

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FROM THE CHAIR



Richard A. Wherry, M.D.
Chair, COLA Board of Directors

In this issue of Insights, we look at strategies for containing costs, maintaining quality, and attaining a higher level of visibility and partnership within the healthcare community. We examine the differences between cost containment, operational efficiency, and cost effectiveness. The latter is of increasing importance to the future of laboratory medicine as it defines the value of our contribution to patient care.

We begin with a discussion of strategies for determining *optimum instrumentation and test menus*; “right-sizing” testing capacity for your laboratory as it is now operating, and as you plan for the future. This includes performing cost/benefit analyses to help determine which testing should be performed in-house, and which should be referred to an outside laboratory. An important part of your cost-benefit analysis is examining staffing needs, which comprise 50% - 70% of direct laboratory cost. *Staffing strategies* include not only looking at staff size, but the mix of qualifications and experience, and shift responsibilities. If revenue growth is not sufficient, despite all efforts, there will be a need to cut expenses below present minimums. We discuss strategies to *cut costs while maintaining quality*.

Competent management is a pre-requisite to achieve these operational efficiencies. We discuss how your laboratory director, and other professionals play key roles in moving the laboratory forward, by providing the resources, organizing the work, and ensuring accountability.

New strategies for increasing the visibility of the laboratory both within and outside its institutional setting is discussed. These include providing *value-added services*, such as consultation, team-building and partnerships with other healthcare providers, providing important clinical data for research projects, and providing laboratory services in non-traditional settings.

Finally, we examine in detail the concept of *“Cost-Effectiveness”*, which has become the key standard when evaluating the role of the clinical laboratory in the healthcare continuum. This is not just cost-containment; it is not just about efficiency; it is about *value*, defined as *quality per unit of cost*. This represents the total picture of the usefulness of each laboratory test in the care of the patient.

Finally, on a different note, our Feature Article, *Direct Access To Test Results*, takes a look at last year’s landmark decision by CMS to support a patient’s right to access their own test results directly. We also provide information to assist you when these requests come. This change reflects the continuing demand for increased control of their healthcare by the individual, and clinical laboratories are very much in the center of these changes.



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The Cost Effective Laboratory: Right-sizing Your Instrumentation and Test Menus

Whether you are planning a new, start-up laboratory operation, or performing a cost/benefit analysis of current testing, or thinking of purchasing a new or replacement instrument, you must do a realistic assessment of not only what you *want* to offer your patients, but what you *can* realistically offer your patients.

An important component of a cost –effective laboratory is assuring that you have “right-sized” your test menus and instrumentation to provide the highest quality service in the most economical manner. What do we mean by “right-sizing?”

This is the appropriateness and “do-ability” of the test menu. In fact, this is really such a fundamental aspect of the lab operation, that problems in this area affect everything else.

When your instrumentation and test menu create problems with staffing, time management; work overload, and expiration of unused reagents; when quality control, calibration and maintenance requirements exceed test time and budgeted expenses for infrequently utilized instruments....you’ve got problems!

Your decision making should first include a cost/benefit analysis of:

- Instrument capacity and present or proposed test menu
- Instrument cost (purchase or lease?)
- Reagent cost (are you obligated to purchase reagents from a particular manufacturer?)
- Reagent life (expiration dates: days, weeks, months before/after opening packages)
- Storage requirements for reagents (do you need to buy a new refrigerator or freezer?)
- Frequency and expense of Quality Controls, Calibration, and Maintenance
- Tests run singularly or in batch mode?

- Comparison of in-house testing with reference laboratory charges and turn-around time
- Staffing requirements: number, training expenses; qualifications and experience beyond present staffing; continuing education
- Proficiency Testing requirements
- Facility space, ventilation, electrical needs; hazardous disposal requirements
- Time and involvement of the Lab Director, and the Technical Consultant
- Document storage requirements / LIS capability
- Adjusting the front office staffing to handle additional pre and post analytical paperwork and communications

Include physician input when determining the optimal test menu; the laboratory’s test menu can help clinicians to select the correct test or panel of tests for diagnostic or monitoring purposes. Cooperation between the laboratory and physicians is recommended to develop and adopt utilization guidelines and protocols.

Of course, providing the highest level of service for your patients may justify costs associated with the above considerations, but you must right –size the instrumentation to meet the demand in terms of test volume capacity, variety of tests offered, operating times and staffing. Having a laboratory with excess capacity and operating requirements can ultimately bankrupt a practice. Investigate which instruments can meet your present needs, and for the near future, and be cost effective.

In today’s world, when compensation for laboratory testing is constantly under pressure, right-sizing your lab means better financial health; better resource utilization, and ultimately, better service for your patients. This spells Quality!

The Cost Effective Laboratory: Staffing Strategies

Labor accounts for 50% to 70% of direct clinical laboratory cost; thus the management of staffing levels is central to managing overall laboratory expenses¹. With too high a staffing level, a laboratory operates inefficiently; too low a staffing level increases the potential for errors or slow throughput. Determining optimum cost-effective staffing levels without compromising quality is a complex process, going beyond the laboratory industry's benchmarks that measure output per Full Time Employee (FTE).

Other considerations when determining optimum staffing include levels of experience, motivation, and the capabilities of your staff; the amount of labor-saving automation employed; any special labor-intensive testing or other demands not encountered by a "typical" laboratory; and the amount of "nonproductive" work that technical staff are expected to perform, such as ordering supplies or training. Decisions about how many managers to employ reflect many of these same considerations and are also influenced by personnel policies that managers are expected to administer, the amount of technical knowledge managers are expected to possess, and other work managers are expected to do beyond supervision of subordinates². A key determinant is the operating budget provided by your institution.

It is also helpful to include direct staff input when staffing levels are under consideration. This provides added insight: ask your staff how they feel about their present workload. Are they sufficiently challenged, but not overworked? How's your quality? Could you be as close to error-free as possible with fewer people working fewer hours?³ What suggestions do they have in regard to modifying staffing patterns?

If you determine that you can reduce staffing, first ask yourself what effect downsizing might have on morale, quality and productivity versus reduction by natural attrition.

The following recommendations for evaluating your staffing needs were derived from a study conducted by the College of American Pathologists Q-Probes Study of Staffing at 151 Institutions⁴:

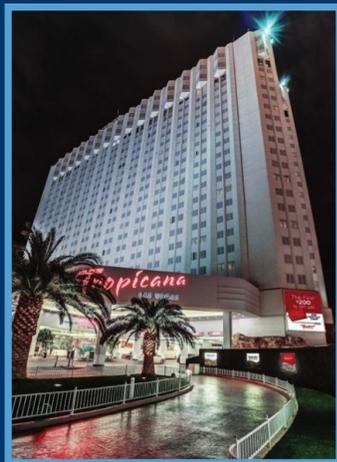
1. Laboratory staffing should be evaluated in the context of peer-group data. Smaller-volume laboratories should not compare their labor productivity with larger-volume institutions, except in histology.
2. Laboratory departments or specialties with lower labor productivity compared to their peer group generally require management attention. Some staff assigned to these areas might be redeployed elsewhere, or the section might be merged into a larger operation so as to bring laboratory productivity out of the bottom quartile.
3. Laboratory departments with high labor productivity may also require scrutiny. Staff in areas with particularly high productivity may be overworked and prone to error or slow throughput. Alternatively, the laboratory may have more experienced or able staff, may have more streamlined procedures, or may make better use of automation and not have an error rate or turnaround time any higher than that of other laboratories. We suggest that managers of high-productivity laboratory sections critically examine error rates and throughput and also, as an exercise, write down the reasons they believe the section is particularly productive. High error rates, slow throughput, or high productivity with no ready explanation may be a signal that a department is understaffed.
4. There is wide variability among laboratories in the number of staff each manager supervises. Managers who supervise few people might be assigned to perform more technical or "bench" tasks within the laboratory. Alternatively, sections might be combined so that staff operate with fewer total managers. In some cases, administrative tasks may need to be streamlined to allow managers to increase their span of control.

Thus, when strategizing how to achieve the most efficient staffing for your laboratory, it is important to go beyond relying on calculated productivity alone, and to take into account particular characteristics of your laboratory operation.

RESOURCES:

1. Paul N. Valenstein, Rhona Souers, and David S. Wilkinson (2005) Staffing Benchmarks for Clinical Laboratories: A College of American Pathologists Q-Probes Study of Staffing at 151 Institutions. Archives of Pathology & Laboratory Medicine: April 2005, Vol. 129, No. 4, pp. 467-473.
2. Paul N. Valenstein, Rhona Souers, and David S. Wilkinson (2005) Staffing Benchmarks for Clinical Laboratories: A College of American Pathologists Q-Probes Study of Staffing at 151 Institutions. Archives of Pathology & Laboratory Medicine: April 2005, Vol. 129, No. 4, pp. 467-473.
3. Lab Soft News. March 2015. Advice on Clinical Lab FTEs and Workload Units. Posted by Bruce Friedman.
4. Paul N. Valenstein, Rhona Souers, and David S. Wilkinson (2005) Staffing Benchmarks for Clinical Laboratories: A College of American Pathologists Q-Probes Study of Staffing at 151 Institutions. Archives of Pathology & Laboratory Medicine: April 2005, Vol. 129, No. 4, pp. 467-473.

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The Cost Effective Laboratory: The Key to Effective Strategies

Community laboratories have been under financial stress for some time, both from the changes Congress is making to the clinical laboratory fee schedule and from private payers seeking to contain costs. Most recently, Congress overhauled the lab fee schedule with the Protecting Access to Medicare Act of 2014 (PAMA). Experts anticipate that fees for routine, high-volume tests that are the bread and butter of community labs likely will be cut at least 20% under PAMA—if not more over time. How will community labs survive a steep decline in Medicare reimbursement, even as their nursing home and physician clients face cuts of their own?¹

Community labs are the small-to-medium-sized laboratories that serve physician offices, nursing homes, and assisted living facilities. While most of the testing that community labs perform consists of routine, high-volume tests—such as complete blood counts, metabolic panels, prothrombin time, and other essentials, a key characteristic of these labs is rapid turn around time, and proximity to the patient, in other words, service. These labs often have smaller staff size, interconnected to the office operation.

Before you can have major cost effective strategies in place, you've got to have competent management of the laboratory. It is through the application of management skills that you gain the confidence and loyalty of your staff, build a culture of teamwork, trust and quality, and can implement the (sometimes painful) changes necessary for the survival of the laboratory.

Laboratory management can be divided into four main categories²:

- 1. Planning:** the laboratory manager provides key information and direction for the continuing future development of the laboratory; involvement in the development of strategic plans.
- 2. Organizing:** the lab manager determines how the laboratory work gets done through job assignments, staffing levels, policies and procedures; management of timelines and budgets; and keeps current with changes in laboratory technology and regulation as it affects the laboratory operation
- 3. Leadership:** this goes beyond management as it often sets the environment (culture) and pace of the lab. Good leadership can inspire lab members toward greater productivity and creativity, teamwork and trust; and encourage feedback. This includes external communication as well, with physicians, institutions, and boards.
- 4. Directing:** establishing clear and firm lines of communication and accountability. This involves the evaluation of lab staff performance, including the ability to correct problems as they arise; and definitions of responsibilities.

A successful manager can motivate their staff to provide feedback about their workload, instruments and kits used; make suggestions for improvement of, and changes to, their test menu; and provide information about interactions with other offices, departments, physicians, and patients. These types of information play an important role when developing strategies for cost containment, re-alignment, and even repositioning of the lab in the community.

RESOURCES:

1. Community Labs- Can Community Labs Survive? By Bill Malone. September 2014. Clinical Laboratory News. Community Labs-AACC.org
2. How To become A Good Lab Manager by Elizabeth Sandquist. ASBMB Today. October 2013.

The Cost Effective Laboratory: Value-added Services¹

Cost effectiveness for clinical laboratories is defined in terms of increased operational efficiencies and reduced unit costs while maintaining quality. However, our frame of reference for achieving this is often limited to the traditional adjustments to present – day laboratory operations, including updating instrumentation and test menus; modifying staffing patterns; changing reagent suppliers, and even finding alternative venues for outsourcing tests.

However, the massive changes in information technology; biotechnology, and healthcare delivery have opened up new approaches for laboratories to deal with these challenges. Laboratory professionals can differentiate themselves not only by their technical skills but also by being involved in the creation, distribution, and application of knowledge related to laboratory aspects of patient care. This strategy is of competitive value for the laboratory by providing knowledge based services to clinicians related to in vitro diagnostics.

The laboratory test menu has expanded rapidly. Primary care physicians find it difficult to become familiar with the indications and result interpretation for the many tests available, as do specialized physicians for tests that are not specifically useful to their specialty. Thus, the complexity of laboratory investigations has increased and clinicians need more assistance in the use of new laboratory technology. This need will continue to increase as even more complex testing becomes available (e.g., genomic and proteomic testing). Therefore, laboratory professionals should optimize their professional relationships with the clinicians who order laboratory tests with those who serve as clinical consultants for appropriate test ordering and interpretation. The Academy of Clinical Laboratory Physicians and Scientists have recognized medical consultancy as a key competency of

clinical pathologists. Clinical consultancy may be practiced in several ways: implementing reflex testing and diagnostic algorithms, providing patient-specific narrative interpretation of complex testing, providing probabilistic data related to laboratory results, organizing clinical audits, participating in grand rounds in hospitals, eliminating obsolete tests, achieving consensus with clinicians on guidelines and standardization, and optimizing clinical pathways. We now have the IT tools to make this information easily accessible.

Another way that laboratories can more effectively utilize their testing capacity is to grow their test volume by external outreach: by offering services to other physician offices, nursing homes, assisted living facilities, and managed care organizations. This allows the existing fixed costs of plants and equipment to be spread over a larger base. Higher analysis volume lowers the unit cost and speeds up the diffusion of (expensive) state-of-the-art technology. Unit cost and quality should improve, as efficiency is boosted.

The mission of clinical laboratory medicine is to improve patient care through quality laboratory testing. To be positioned strategically for the future, it must enhance efficiency, but just as important is the enhanced value provided. To add value, the core competency of laboratory professionals must be refocused on providing additional knowledge services to clinicians.

RESOURCES:

1. Much of the information for this report was gleaned from “Laboratory Medicine: Challenges and Opportunities” by Xavier Bossuyt, Kurt Verweire, and Norbert Blankert. doi: 10.1373/clinchem.2007.093989 Clinical Chemistry October 2007 vol. 53 no. 10 1730-1733. <http://www.clinchem.org/content/53/10/1730.full>

The Cost Effective Laboratory: Sustaining Quality While Cutting Costs

While the mission of the laboratory will always be to provide the highest quality patient care, the environment within which the lab operates is undergoing rapid regulatory and technological change. These include changes to reimbursement, test utilization protocols based on patient outcomes, and new competition from non-traditional sources. All of these present new challenges to traditional budget planning.

Strategies for adjusting the laboratory operation to stay within your present and future budgets must not only include cutting costs, but maintaining quality. It is ironic that we sometimes equate maintaining or improving quality with increased operating costs, yet lack of quality performance actually results in net increased expenses.

To achieve the goal of cutting expenses, yet maintaining quality you must first understand how your laboratory operates. Here is a summary of steps to analyze your laboratory operation and determine where you can reduce expenses²:

- 1. Monitor all expenses:** This includes accounting for every expense, such as salaries and benefits paid, supplies, equipment, overhead, services, personal costs, fees, fines.
- 2. Determine which laboratory's costs are fixed, and which are variable (volume independent).**
- 3. Determine the cost per procedure.**
- 4. Determine the revenue or reimbursement per procedure.**
- 5. Limit the number of revenue negative tests:** careful consideration must be given as to whether to continue performing tests that cost more to perform than receive in reimbursement. Consult with the physicians who order these tests and decide if they can be sent out; or if alternative testing is available. This is part of the quality equation.
- 6. Discuss proper laboratory utilization with all staff and laboratory technicians.** Ensure that everyone understands when certain tests and procedures are indicated, and that all criteria for specimen submission, handling, processing, and reporting of results are observed. This is part of maintaining the quality of the laboratory service. Educate if necessary.

7. Update all laboratory workers on any changes in standard operating procedures: Discuss these changes during morning reports, staff meetings, and annual trainings, and post these changes. Ensuring adherence to all protocols will help reduce unnecessary costs. This is another place where quality can be maintained with proper education and follow up.

8. Batch tests whenever possible..

9. Order supplies in bulk to save money, if the supplies are unlikely to be outdated. For supplies that may expire or become obsolete, calculate the inventory turnover (cost of goods sold divided by inventory) and make sure the time to expiration/obsolescence is well below the period of time implied by the turnover. These are quality considerations as well.

10. Determine which tests to perform in-house and which to send out to a reference laboratory. Consider all costs associated with a specific test or procedure, including cost of quality control testing, cost of supplies, cost of proficiency testing and training, clerical time for record keeping, and mailing or transport costs to outside facilities. If a test requiring special technical skills or equipment is rarely requested, it may be cost-saving to have the test sent out rather than performed in-house. On the other hand, frequently performed tests, or those that require quick turn-around time, may be better performed in-house.

11. Monitor the effects of any cost-cutting strategies over time. An effective cost cutting strategy should lower the cost per procedure or the expense ratio of the laboratory, while maintaining the quality of testing performed.

Cutting costs is never a welcome task, but it can be achieved in a quality-effective way by careful analysis, conferring with all stakeholders, including physicians, institutional management and related departments. Internal communication must be thorough.

RESOURCES:

1. <http://www.wikihow.com/Cut-Costs-in-a-Laboratory>

The Cost Effective Laboratory

Introduction

The Changing Landscape of Laboratory Testing

The healthcare landscape is undergoing dramatic changes: hospitals are consolidating into regional networks with highly specialized medical care performed in core facilities, generalized medical care provided in satellite hospitals, and ambulatory services offered at point-of-care (POC) locations.

Diagnostic laboratory testing is undergoing a similar transformation. Complex, non-urgent tests are performed in core facility laboratories or in reference sites; routine, acute diagnostic tests are performed in core laboratories or in satellite hospital facilities; and point-of-care testing is performed in outpatient clinics, physician office laboratories, retail clinics, and in-home testing. With an increased effort to provide cost-effective, timely medical care for ambulatory patients, patients are seeking treatment at local physician offices and retail clinics at a rate higher than ever before¹. It is estimated that 70% or more of medical decisions are based on laboratory test results.

Today, it is no longer sufficient for laboratories to provide efficient quality testing. Increasingly, payers demand to know the value of the tests, with value equaling quality per unit of cost. Along with expenditures for imaging studies, laboratory testing accounts for a significant percentage of health care expenses, despite efforts by Medicare and commercial insurers to limit payments for laboratory testing. A savvy, health-conscious aging population wants access to the emerging technologies at an earlier stage. Payers, including Medicare, commercial insurers, and employers, want more accountability for both safety and quality². They want laboratories to prove that tests are cost-effective. The demand for proving the value of medical interventions, including laboratory testing grows stronger with each passing day.

In the past, laboratorians and pathologists believed that striving for maximum sensitivity, specificity, accuracy, and reliability was sufficient and that clinicians would not want anything more from the laboratory. Cost-effectiveness was viewed in terms of dealing with direct and indirect costs in the laboratory; with the terms “Cost-Effective” and “Cost-Containment” used interchangeably; applied to controlling

expenses with the goal of quality service within a balanced budget.

New Challenges

Today, with steadily increasing use of robotics, and computerized testing, the services offered by clinical laboratories are increasingly perceived as homogeneous. Many tests are performed on well known automated instruments using commercially available reagents, thus the analysis of patient specimens is becoming commoditized; and the questions are no longer whether testing can be performed, but rather, is the testing justified? Is there value to this test?

In their report “Laboratory Medicine: Challenges and Opportunities” Bossuyit, Verweir, and Blanckaert³. described two proactive responses to anticipate commoditization: a value-added strategy (increasing augmented services) and a price compression/product innovation strategy. They called for clinical pathologists to be prepared for future threats and opportunities by enhancing efficiency and providing value-added services. Enhanced efficiency, and as a consequence improved cost and quality, can be realized through increased “operational excellence”. More importantly, laboratory professionals should provide value-added knowledge services by providing comprehensive consultative support to clinicians and fostering evidence-based laboratory medicine. The enhanced interaction, “customer intimacy” with the physicians who order the laboratory tests should create additional value.

Laboratory Cost Containment

Perform a cost/benefit analysis of your laboratory operation:

- Instruments in use: right –sized for your test volume and level of staffing?
- Reagent cost , expiration life, storage requirements
- Tests run singly or in batch mode?
- Comparison of in-house testing with reference laboratory charges and turn-around time
- Staffing requirements: number, training expenses; qualifications and experience beyond present staffing; continuing education.

- Facility space, ventilation, electrical needs; hazardous disposal requirements
- Document storage requirements / LIS capacity

In addition:⁴

- Differentiate between:
 1. Billable vs. non-billable tests & activities
 2. Reimbursable vs. non-reimbursable tests & activities
- Understand the impact of “hidden” costs
- Measure and Rank Demand from all clinical users services by test volume/type
 1. Identify Low Value/High Cost tests using Activity Based Costing
 2. Identify High Value Tests & Services using clinical user input; find their cost per test
- Modify the lab’s technology footprint to use more efficient, Low Cost analyzers
- Identify & Remove Low Value, Obsolete, Duplicative & Wasteful Tests

Adding Value To Laboratory Services

The Definition of Value is: “Worth in usefulness or importance to the possessor of the information”.

1. Clinical Consultations with Physicians

To enhance the cost-effectiveness of the clinical laboratory, improve test utilization, improve trust with other healthcare professionals, and to differentiate itself from competitors, laboratory professionals should optimize their professional relationships with the clinicians who order laboratory tests, serving as clinical consultants for appropriate test ordering and interpretation and for point-of-care testing. The laboratory test menu has expanded rapidly. Primary care physicians find it difficult to become familiar with the indications and result interpretation for the many tests available, as do specialized physicians for tests that are not specifically useful to their specialty. This

need will increase as even more complex testing becomes available (e.g., genomic and proteomic testing). Clinical consultancy may be practiced in several ways: providing patient-specific narrative interpretation of complex testing, providing statistical data related to laboratory results, organizing clinical audits, participating in grand rounds in hospitals, eliminating obsolete tests, achieving consensus with clinicians on guidelines and standardization, and optimizing clinical pathways⁵.

2. Laboratory Leadership and Team Building for Cost-Effective Test Utilization⁶

A. Establishing The Laboratory Role in Disease Management

Disease and patient care process management means tapping the underutilized potential of Laboratory Medicine’s proven expertise in diagnostics to directly provide:

- Interpretive reporting for busy clinicians
- Pattern recognition & patient data integration capability
- Connectivity and messaging experience
- Measurement and analytic capability
- Trending and data mining capability

B. Actions needed to Initiate The Laboratory’s Participation in Patient Care Teams

- Actively solicit the support of the organization’s top management
- Participate in organization wide committees and focused teams for quality improvement; delegate lab department and section leaders to serve on hospitals quality improvement committees
- Gain the support of clinical department chiefs to use interdisciplinary lab expert teams on daily rounds and regular consultation to prevent medical errors before they happen

- Coordinate the agreement of mutually acceptable standards for reducing errors that meet the needs of clinical department/section chiefs with laboratory department/section chiefs

C. The Value-Added to Clinical Care Teams by Participation of the Laboratory

- Reducing uncertainty for clinical care decision-makers
- Managing risk when caregivers have limited time
- Promoting interconnectivity between the laboratory, clinical decision-makers and
- Therapeutic services
- Enabling disease management at the time of therapy
- Providing evidence-based support data about the patient's disease, condition or
- Therapeutic progress
- Providing trending and analysis of the patient's current and past lab data
- Recommending preventive medicine test protocols for at risk patients

as they evaluate a particular patient, but it is difficult, if not impossible, for any one individual to be proficient in all areas of medicine. In addition to providing guidance to clinicians, test utilization efforts may also be driven by financial realities as laboratories try to rein in laboratory costs or in response to payer programs and policies that reduce payments to providers⁷. Laboratories need to design their own strategies for test utilization based on the particular structure and culture of its institution.

RESOURCES:

1. Laboratory Strategies: meeting the increasing demand for point-of-care diagnostics. By Patrick Murry. October 2014. <http://www.mlo-online.com/articles/201410/laboratory-strategies-meeting-the-increasing-demand-for-point-of-care-diagnostics>.
2. James S. Hernandez (2003) Cost-Effectiveness of Laboratory Testing. Archives of Pathology & Laboratory Medicine: April 2003, Vol. 127, No. 4, pp. 440-445.
3. <http://www.clinchem.org/content/53/10/1730.full>
4. The Impact of Medicine on Laboratory Costs with Ideas to Reduce Utilization Eleanor M. Travers, MD, MHA, FCAP. <http://c.ymcdn.com/sites/www.clma.org/resource/resmgr/>.
5. Laboratory Medicine: Challenges and Opportunities. Xavier Bossuyt, Kurt Verweir, Norbert Blankaert. <http://www.clinchem.org/content/53/10/1730.full>
6. The Impact of Medicine on Laboratory Costs with Ideas to Reduce Utilization Eleanor M. Travers, MD, MHA, FCAP. <http://c.ymcdn.com/sites/www.clma.org/resource/resmgr/>
7. Test Utilization and the Clinical Laboratory. Dr. Curtis Hanson and Elizabeth Plumhoff. Mayo Clinic. 2012 <http://www.mayomedicallaboratories.com/articles/communique/2012/05.html>

Conclusion

The clinical laboratory has an increasingly important role in ensuring appropriate test utilization in clinical practice. Laboratory professionals can add value to their work by positioning themselves as clinical consultants for physicians who are trying to deal with the increasingly complex world of laboratory testing, including genetic-driven diagnostics and therapeutics. There are literally thousands of laboratory tests that clinicians might request

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- Outline areas where laboratory errors most commonly occur
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LIVE Webinar with [John T. Daly, MD, FCAP, Chief Medical Officer, COLA](#)



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At the end of the session, participants will be able to:

- Summarize errors which can occur during the post-analytic phase of testing
- Employ preventive measures to avoid post-analytic errors
- Outline the role of informatics in the clinical laboratory
- Apply steps in informatics utilization to avoid laboratory errors

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Direct Access To Test Results

Background

Until last year, the traditional healthcare model in this country placed the physician (or appropriate ordering provider) in control of determining what diagnostic and therapeutic monitoring (including laboratory tests) were to be performed on a patient. In addition, all results of tests and procedures were reported to the physician who assumed the responsibility of communicating the information to the patient. This model was reinforced by Medicare and Medicaid regulations and the laws of a number of states. The general public, however, was introduced to the concept of being directly involved in their own laboratory testing as early as the 1950's with the availability of over-the-counter urine glucose and ketone tests. As the number of individuals with diabetes continued to increase, these patients were encouraged to closely monitor their glycemic status in an attempt to decrease the incidence of complications. With diabetes mellitus leading the way, an expansion of over-the-counter testing technology, and a movement for more empowerment of consumers to take responsibility for their own healthcare, a major paradigm shift in healthcare has occurred, moving from a physician focus to a consumer focus¹.

The Institute of Medicine, in its 2001 publication "Crossing the Quality Chasm: A New Health System for the 21st Century", suggested a redesign of the system which would include (a) the patient as the source of control, (b) unfettered access for patients to their own medical information and to clinical knowledge, and (c) evidence-based decision making. Television, the print media and the internet, coupled with an aging, more educated and informed population of healthcare consumers, has produced consumers with access to a great deal of medical information.

A representative of the People's Medical Society, a medical consumer advocacy organization, provided a perspective at a March 2003 meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAAC). He described

today's healthcare consumer as "empowered, educated, demanding, critical of the healthcare system and providers, and the driving force for changes in healthcare."²

Physicians recognized that patients have a right to their medical information. There is also hope that by providing the information (directly) will allow patients to be more engaged, to be better partners, to be more compliant in their healthcare.

These generational and societal changes, focused on individual empowerment and personalized medical care, created the momentum for revisions to the traditional way that laboratory results were made available to patients. Direct access by patients to their own test results was made official policy in 2014.

The New Rule

On February 6, 2014, the Department of Health and Human Services (HHS), announced a [final rule](#) amending the Department's Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations, and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, to give patients direct access to laboratory test results. Until then, CLIA and CLIA-exempt laboratories were reporting results only to an "authorized person," defined as a person authorized under state law to either order, or receive, test results. In most states, that limited reporting of test results to the treating physician or the laboratory that initially requested the test. However, the HHS final rule now requires laboratories to also report those results directly to the patient, or his or her personal representative, upon request. It preempts state laws to the contrary³.

While patients can continue to get access to their laboratory test reports from their doctors, these changes give patients a new option to obtain their test reports directly from the laboratory while maintaining strong protections for patients' privacy.

“The right to access personal health information is a cornerstone of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule,” said HHS Secretary Kathleen Sebelius. “Information like lab results can empower patients to track their health progress, make decisions with their health care professionals, and adhere to important treatment plans.” Indeed, the final rule states that patients’ right to access test reports “is crucial to provide individuals with vital information to empower them to better manage their health and take action to prevent and control disease.”⁴

This final rule was issued jointly by CMS, which is generally responsible for laboratory regulation under CLIA, and two other agencies within HHS: the Centers for Disease Control and Prevention (CDC), which provides scientific and technical advice to CMS related to CLIA, and the Office for Civil Rights (OCR), which is responsible for enforcing the HIPAA Privacy Rule.

Under the HIPAA Privacy Rule, patients, patient’s designees and patient’s personal representatives can see or be given a copy of the patient’s protected health information, including an electronic copy, with limited exceptions. The laboratory will have to have an authentication process to verify the identity of the person making the request. The patient or the personal representative may have to put their request in writing and pay for the cost of copying, mailing, or electronic media on which the information is provided, such as a CD or flash drive. In most cases, copies must be given to the patient within 30 days of his or her request⁵.

Key Implementation Questions and Answers To Assist Your Laboratory⁶

1. What do the changes to the CLIA regulations at §493.1291 mean for laboratories?

The changes to §493.1291 allow an individual or an

individual’s personal representative to receive completed test reports directly from the laboratories upon request. Laboratories will need to identify the test reports as belonging to the individual by using their authentication processes.

2. Since laboratories vary greatly in terms of how they interact with individuals that request access to their laboratory test reports, is there any flexibility in how requests for access to test reports can be submitted, processed and responded to by laboratories?

This rule provides laboratories with flexibility as to how to set up systems to receive, process, and respond to access requests. These processes must comply with the requirements for access in 45 CFR § 164.524 of the HIPAA Privacy Rule, which addresses HIPAA-covered laboratories.

3. Will laboratories be permitted to charge individuals who request copies of test reports a fee for providing access?

Laboratories can charge individuals a reasonable, cost-based fee that includes only the cost of labor and supplies for creating the paper or electronic copy; postage, if the results are mailed; and if requested, the preparation of an explanation or summary of the individual’s protected health information. HIPAA-covered laboratories can’t charge fees to reflect the costs they incur in searching for and retrieving the information related to the individual’s request.

4. Do the new rules have any impact on the Medicare and Medicaid EHR Incentive Program meaningful use program?

Under meaningful use, many EHR systems include patient portals which allow patients direct access to their health information, including laboratory results.

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In addition, state, local, regional, and payer-based health information exchanges (HIEs) allow providers, including laboratories, to securely share patient information both between providers and, in some cases, with patients. If a laboratory shares a patient's lab results with a provider's EHR through an HIE, or directly, that information can be incorporated automatically into the patient record and, usually with physician approval, made available on the (Providers Health Records)PHR or sent to a patient's secure email address. Providers (or PHR systems automatically) may also send patients email notifications that there is new data available in the PHR/portal, reminding them to log in and review their lab results. These technologies not only facilitate patient access to lab information, but can make it easier for lab providers to share that information securely and at little or no cost. The changes preempt any contrary State laws that prohibit the HIPAA-covered laboratory from directly providing access to the individual.

5. Must a laboratory have an electronic health record (EHR) system, patient portal or be a part of a health information exchange (HIE) to meet this new requirement for patient access to test results?

A laboratory does not need to have an EHR system, patient portal or be a part of an HIE to meet the requirement for patient access to test results. However, we would anticipate that as EHRs, portals and HIEs become more commonplace, laboratories will develop processes to handle patient requests via these systems.

6. There are concerns regarding the laboratory giving individuals their laboratory test reports without the individual having the benefit of health care provider interpretation. Patients will not necessarily have the contextual knowledge to read and understand the reports they receive. Laboratories feel they may be required to interpret test reports for patients.

This rule does not diminish the role of the health care provider in interpreting the laboratory test reports for

his/her patient in the context of the patient's medical condition. We expect that individuals will continue to obtain their test reports and the interpretation of those test reports from their health care provider. Laboratories are required to provide individuals with access to their completed test reports. The rule does not require laboratories to interpret test reports. Laboratories can refer an individual back to their health care provider for this information.

7. Who can have access to an individual's sensitive laboratory test reports? An individual may not want a parent, spouse, partner or other person to see their test reports.

An individual has generally been granted an absolute right to access his or her own completed laboratory test reports when those reports are held by a HIPAA-covered laboratory. The only persons other than the individual that have a right to access such test reports directly from a HIPAA-covered laboratory are those persons who qualify as a person designated by the individual in accordance with the HIPAA Privacy Rule at §164.524(c)(3)(ii) or a "personal representative" of the individual. For the purposes of the Privacy Rule, a "personal representative" is defined at 45 CFR § 164.502(g) and, in certain contexts, includes a person who has authority under applicable law to make health care decisions for the individual. Such authority is generally determined under state law. HIPAA-covered laboratories are required under 45 CFR § 164.514(h) of the Privacy Rule to verify both the identity and authority of the person requesting an individual's protected health information.

These are only part of the Frequently Asked Questions that laboratories have about the new Direct Access Test Results rule. A more complete compendium of questions and answers is available at :

<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-11.pdf>

RESOURCES:

1. ASCLS Position Paper: Consumer Access to Laboratory Testing and Information. July 2012 <http://www.ascls.org/about-us/voice-your-opinion/position-papers/177-direct-access-testing/139-direct-access-testing>.
2. ASCLS Position Paper: Consumer Access to Laboratory Testing and Information. July 2012 <http://www.ascls.org/about-us/voice-your-opinion/position-papers/177-direct-access-testing/139-direct-access-testing>.
3. FDA Law Blog. Hyman, Phelps & McNamara, P.C. February 4, 2014. HHS Wants to Empower Patients by Providing Direct Access to Test Results- Except When It Doesn't. by Jeffrey N. Wasserstein & Jennifer M. Thomas http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/02/hhs-wants-to-empower-patients-by-providing-direct-access-to-test-results-except-when-it-doesnt.html
4. FDA Law Blog. Hyman, Phelps & McNamara, P.C. February 4, 2014. HHS Wants to Empower Patients by Providing Direct Access to Test Results- Except When It Doesn't. by Jeffrey N. Wasserstein & Jennifer M. Thomas http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/02/hhs-wants-to-empower-patients-by-providing-direct-access-to-test-results-except-when-it-doesnt.html
5. Patients, Caregivers Will Have Direct Access to Lab Test Results Due to New Rule by HHS Agencies. Senior Journal. February 3, 2014. http://seniorjournal.com/NEWS/Health/2014/20140203_Patients,_Caregivers_Will_Have_Direct_Access_to_Lab_Test_Results_Due_to_New_Rule_by_HHS_Agencies.htm
6. CMS Memorandum Publication of Final Rule "CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports. February 7, 2014 <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-11.pdf>

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GREEN CLINIC LABORATORY

RUSTON, LA

Laboratory Director:
Nancy V. Smith, MD

Laboratory Manager:
Tammy H. Singleton, MLS (ASCP)

Green Clinic Laboratory is housed within the greater Green Clinic facility located in Ruston, LA. We service 52 in-house multi-specialty health care providers as well as numerous non-Green Clinic health care providers.

Our services include hematology, chemistry, immunoassay, urinalysis, coagulation, microbiology, serology, and immunology. Our current test volume is approaching 500,000 tests per year.

We employ four full-time Phlebotomists, two full-time Clerical/Specimen Receptionists, and eight full-time Medical Laboratory Scientists.



Stories from the Front Line of Labs

Name: Jane Metko, MT (ASCP), MS-OLQ

Title: Director of Ancillary Services

Employer: Primary Care Associates of Appleton, LTD., Appleton, WI

I head up laboratory and radiology services for an independent, 21-doctor family and internal medicine practice. Our lab is staffed by five laboratory technicians and four phlebotomists. We offer an extensive in-house test menu, including testing in chemistry, immunoassay, coagulation, hematology, and urinalysis.

We see a lot of patients on a monthly basis who are taking the anticoagulant drug warfarin and need to have their PT/INR (Prothrombin Time and International Normalized Ratio) levels tested regularly to ensure that their blood is clotting appropriately.

On one Friday afternoon, Barbara Vanderaa, one of our laboratory technicians, was placing a PT/INR sample on our coag analyzer. We visually inspect each sample prior to testing, and Barbara noticed that this sample had a significantly low ratio of blood cells to plasma. Barbara immediately contacted the patient's physician to recommend the patient return for a complete blood count. The patient returned and the subsequent test showed that the patient's hemoglobin was critically low at 4.8 g/dL. The provider immediately admitted the patient to a local hospital where he was treated for a GI bleed and given a transfusion.

I was very proud of Barbara. Her initiative, attention to detail and commitment to providing quality care had a significant impact on this patient's health and overall medical outcome.

We always strive to work as a team with our practitioners to give them the information they need to make the right diagnosis. Patients may not know what we do behind the scenes, but an example like this illustrates the critical role the lab plays in effective healthcare.

Visit LabTestingMatters.org to read more Stories from the Front Line of the Lab and join us as we build a community to support quality laboratory medicine. If you are interested in sharing your story with the Lab Testing Matters Community you can contact Victoria Farrell at vfarrell@cola.org or [submit your story online](#).



Jane Metko and Barbara Vanderaa