

inSights

INTO *Future Trends In Laboratory Medicine*

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FROM THE CHAIR



Richard S. Eisenstaedt, MD, FACP
Chair, COLA Board of Directors

Our focus in this issue of COLA Insights is on the increasingly central role of laboratory medicine in terms of disease prevention, diagnosis, management, and cure, as technological advances change the way healthcare is delivered.

Many of these advances are defined under the concept of *personalized medicine* i.e. the tailoring of medical treatment to the individual characteristics, needs and preferences of each patient during all stages of care. The basis for this revolutionary *pro-active* approach is *genomics*: the understanding that the genetic makeup of an individual is an important determinant of the effectiveness of specific drug therapies; as well as predictive of the potential for individuals to develop specific diseases and syndromes.

The determination of which drug therapies would be most effective for any particular individual rests on *pharmacogenomic* laboratory testing, known as *companion diagnostics*. These laboratory procedures help determine whether a patient should receive a particular drug therapy, or how much of the drug to give.

Our first two articles, “Personalized Medicine: the Future is Here!”, and “Pharmacogenomic Testing / Companion Diagnostics” provides you with the history, definitions, applications, and predictive potential of personalized medicine. Included are discussions about the core expertise of laboratories in genomic testing, data generation, results interpretation, and communication; and the developing new specialty of companion diagnostics. As a result, physician-laboratory communication and consultation continue to grow in importance.

Our next article, “Value-based Healthcare and the Enhanced Role of the Laboratory” discusses the new value proposition (designed to address the rising cost of healthcare) where value is determined not by fee for service compensation, but health outcomes achieved per dollar spent. We not only provide some history and background to explain this change in national health policy, but describe the various organizational models needed to achieve this, and why the laboratory has the expertise needed for outcome based, data driven treatment. These model requirements include multi-disciplinary, multi-organizational, team-based care with the capacity to collect and analyze performance and outcomes based measures; pathologists and laboratory professionals have the experience and expertise to identify significant trends, and medical outcomes from this data.

For a change of pace, we then discuss an issue that concerns many of our laboratories: how do you correctly apply IQCP to microbiology? This next article provides you with organized lists of microbiology tests that are good candidates for IQCP studies; as well as lists of those tests which do not need IQCP as long as regulatory requirements are met. Also provided is a compendium of frequently asked questions (FAQs) and responses provided directly by CLIA.

Finally, we complete this issue with a discussion of PAMA: the “Protecting Access to Medicare Act”, passed by Congress in 2014, and of COLA’s new leadership initiative to develop resources to educate policy makers and payers on the important role that “near patient testing” plays in physician office settings, and why it needs to be supported. This article is the first of our new “Trending” articles; with the goal of discussing the latest in legislative and regulatory activities occurring on the State and Federal levels, how they affect our profession, and other future trends in healthcare. This is brought to you by COLA’s new Innovation division, focused on COLA’s leadership in this area.

Richard S. Eisenstaedt



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COLA INSIGHTS

is published periodically by
CRI®, 9881 Broken Land Parkway,
Suite 215, Columbia, MD 21046-1195.

COLA INFORMATION
RESOURCE CENTER:
800.981.9883

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Personalized Medicine: The Future is Here!

Impacting the Role of Clinical Laboratories as it Impacts the Practice of Medicine

Introduction

Throughout human history, the practice of medicine has been primarily reactive. Even today, we usually wait until the onset of disease and then try to treat or cure it using standard, broad-based protocols. And because we have not fully understood the genetic and environmental factors that cause major diseases such as cancer, Alzheimer's and diabetes, our efforts to treat them have often been imprecise, unpredictable and ineffective. For example, on average, any given prescription drug now on the market only works optimally for half of those who take it.¹

However, within the last few years the field of personalized medicine has come into its own. Accompanied by major progress in knowledge and application, it is believed that personalized medicine is beginning to revolutionize medical and clinical care by utilizing genomics information specific to individual patients for their medical care. This allows the tailoring of medical treatment to the individual characteristics, needs and preferences of each patient during all stages of care, including prevention, diagnosis, treatment, and follow up.² It has also been described as providing "the right patient with the right drug at the right dose at the right time." In fact, personalized medicine has also been characterized as "precision" medicine.³

The more inclusive term 'P4 Medicine' is also gaining traction, for enabling a personalized, predictive, preventative and participatory method of treatment⁴.

Personalized medicine allows health care providers to⁵:

Shift the emphasis in medicine to prevention and prediction of disease rather than reaction to it;

- Focus on susceptibility to disease, improve disease detection, preempt disease progression;
- Make more informed medical decisions and earlier disease interventions than was possible in the past;
- Customize disease-prevention strategies;
- Prescribe more effective drugs and avoid prescribing drugs with predictable side effects;
- Have a higher probability of achieving desired outcomes thanks to better targeted therapies;
- Reduce the time, cost, and failure rate of

pharmaceutical clinical trials, and

- Eliminate trial-and-error inefficiencies that inflate health care costs and undermine patient care.

Personalized medicine is also about⁶

Risk Assessment: The use of genetic testing to reveal predisposition to disease.

- **Prevention:** Behavioral/lifestyle/treatment intervention to prevent disease
- **Detection:** Early detection of disease at the molecular level
- **Diagnosis:** Accurate disease diagnosis enabling effective disease strategy
- **Treatment:** Improved outcomes through targeted treatments and reduced side effects
- **Management:** Active monitoring of treatment response and disease progression.

While personalized medicine is the antithesis of the "one size fits all" protocols available for treating disease, it can, at the same time, be considered as parallel to the traditional approach in the treatment of disease but using more precise tools.

The Foundations of Personalized Medicine.....

Scientists advanced the cause of personalized medicine with the decoding of the human genome. In 2003, after more than a decade of research, the Human Genome Project was completed by the U.S. Department of Energy and the National Institutes of Health.

The goals of this project were to learn the order of the 3 billion units of DNA that go into making a human genome, as well as to identify all of the genes located in this vast amount of data. By 2003, almost all of the pairs of chemicals that make up the units had been put in the correct sequence. Current counts indicate that the human genome contains 22,000 to 23,000 genes.

One of the early hopes of the genomic project was to pinpoint specific genes that caused common diseases. Scientists now know that the answer is more complex, with many diseases the result of multiple genes interacting.⁷

.....and its great potential

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With the knowledge that an individual's genome influences his or her likelihood of developing (or not developing) a broad range of medical conditions, the focus of personalized medicine is also on wellness and disease prevention.

For example, if a person's genomic information indicates a higher-than-average risk of developing diabetes or a particular form of cancer, that person may choose a lifestyle, or sometimes be prescribed medications, to better regulate the aspects of health and wellness over which he or she has control. The person may benefit in the long run from making preventive lifestyle choices that will help counteract the biological risk.⁸

Genomic medicine may help determine a person's risk of developing several specific medical conditions, including:⁹

- Cancer
- Cardiovascular disease
- Neurodegenerative diseases
- Diabetes
- Obesity
- Neuropsychiatric disorders

Researchers are actively investigating the genomic information behind—and developing predictive testing for—such diverse medical conditions as:

- Infectious diseases, from HIV/AIDS to the common cold
- Ovarian cancer
- Cardiovascular disease
- Diabetes
- Metabolic abnormalities
- Neuropsychiatric conditions, such as epilepsy
- Adverse drug reactions
- Environmental exposure to toxins

The promise of personalized medicine is true patient-centered care

It is the recognition that each patient has a unique genetic makeup and is exposed to a set of environmental circumstances—and that treatments, particularly medicines, need to be more tailored to each individual's needs. The field of pharmacogenomics—an initial pillar of personalized medicine—has been built on the study of the interactions of medicines with one's complement of drug-metabolizing enzymes.

Today, we know that a subset of individuals with AIDS should not take the medicine Abacavir due to a potentially fatal side effect. Similarly, a subset of breast cancer patients should take the drug Herceptin because their tumor cells carry a receptor which helps mediate Herceptin's effectiveness. Tomorrow, we could have new medicines—developed through the efforts of identifying disease-causing genes, and specially tailored to interdict the protein products of these genes—which could help prevent heart attacks or osteoporotic fractures. Personalized medicine offers us the promise of more efficacious and safer therapies.¹⁰

The tools and technological advances enabling it encompass far more than the science of genetics. They include major advances in biomedical informatics, epidemiology, biostatistical insights, the world of “Big Data” and decision-support tools to help physicians deliver care more consistently and in line with the best evidence and the individual patient's needs. Advances also include smart phones and other instruments that measure patient glucoses, help titrate dosages of medicines according to one's needs and remind patients to take their medicines.

We are on the cusp of major breakthroughs for diseases that have reached epidemic proportions in the U.S. – cancer, diabetes, heart disease, obesity and Alzheimer's. If the promise of “personalization” is realized, we can help transform our health care system to be more effective and efficient, and most importantly, improve patients' lives by identifying disease earlier and treating it more effectively.

The Role of The Laboratory

Molecular Diagnostics encompassing both genomic and proteomic testing techniques, as well as the application of pharmacogenomics (the genetic prediction of which drugs will work best) has propelled intense interest in personalized medicine.

As part of this rapid change, laboratories are now actively evaluating and expanding their test menus to include the addition of genomic testing combined with traditional testing, for more personalized diagnostic services. Genomic testing has made it possible to detect diseases at earlier stages, and identify a person's susceptibility to diseases before symptoms occur.

An example is genetic testing for BRCA1 and BRCA2 mutations that can indicate individual risk for developing breast or ovarian cancer.

Pharmacogenomic diagnostic laboratory tests can also be

used to determine the benefits and harms for an individual of taking certain medications. These tests are known as *companion diagnostics*. Information on an individual's drug metabolism, for example, can yield information on who might benefit most from a drug and those at risk for atypical adverse reactions (through genetic variations influencing the rate and efficacy of drug metabolism, or other genetic variations related to drug response). Tests can also inform the optimal dose or treatment frequency needed to achieve a desired therapeutic effect in an individual patient.

The integration of traditional and genomic based testing brings with it new opportunities and challenges for the laboratory. The role of the laboratory is expanding to include interpreting the results of genomic testing within the context of personalized wellness management; the diagnosis, treatment and management of disease; as well as the monitoring of pharmacogenomic-based drug therapy. Laboratories also have significant challenges ahead related to organization, communication, capital investment, and staffing, as they attempt to fulfil these increased responsibilities and demands.

Challenges

The implementation of personalized medicine will imply a steep increase in the number of performed screening or diagnostic tests and a larger volume of data to be gathered, analyzed, and translated into information to serve as guidance for clinical decisions. Substantial upfront investments are furthermore needed for instrumentation, structural changes, education, and training efforts.¹¹

The need to join forces to achieve this aim is clearly represented by the joining of different competencies and technologies through the organization of a constructive collaboration between different professional personnel and working units. The first wave of molecular diagnostic testing was for treating infectious diseases, now cancer is the new frontier.

To better illustrate the nature of these challenges, we will discuss the three major challenges facing laboratories within the context of cancer diagnoses and treatment, through personalized medicine,¹²

1. The Adoption of Personalized Screening and Assessment Guidelines for Patients at Higher Risk of Cancer

A study of physicians' medical records for 741 patients, published by the *Journal of the American Board of Family Medicine*, noted that detailed family history information was insufficient to permit cancer risk assessment in more than two-thirds of patients. Individuals at moderate or high cancer risk were not identified as such in these medical

records. The study concluded that family physicians need to adopt explicit risk assessment criteria to identify, and to optimally care for, those at increased risk for cancer.

Laboratories can play an important role in supporting physicians in these risk assessment efforts. Panels of traditional tests and key clinical data can be offered to build a cancer risk profile that is easy for physicians to understand and explain to their patients. Patients who have been identified as being at a higher risk of cancer are clearly candidates for genomic-based blood tests prior to invasive biopsies or surgery. This new protocol can both reduce costs as well as improve quality of care.

"The future lab will play a much stronger role in identifying and staging cancer, which means labs will be more involved with interpretation and results reporting," said Heiner Dreismann, former president and CEO of Roche Molecular Systems. "This shift will not only change the role of the lab, but empower them to play a more vital role in healthcare outcomes than ever before. Labs must think beyond individual assays due to the heterogeneous nature of the over 2,000 types of cancer that have now been identified. Each type of cancer demands unique panels of assays."

2. Labs Add Value to Physician Practices Through Education

A major shift on the horizon is that personalized cancer care will begin in the primary care physician's office, not with cancer specialists. In addition to ordering traditional cancer diagnostic tests, primary care physicians (PCPs) will be ordering genomic-based tests that they are far less familiar with. Laboratories can add value to the physician's practice through education to physicians, nurse practitioners and physician assistants to:

- Identify patients and their families at increased risk for cancer and how to personalize cancer screening and assessment guidelines.
- Explain the clinical utility of new genomic-based tests and how they can help the PCP identify patients at higher risk of cancer.
- Explain non-invasive alternatives to biopsy procedures that pose their own risks of infection and complications.
- Allow PCPs to play a role in active surveillance now dominated by cancer specialists who may bring a bias toward aggressive treatment for all cancers.

3. Laboratories as Genomics Resource for Clinical Consults

One of the biggest challenges facing laboratories in the future will be shifting the lab's role from clinical service to providing relevant genomic information to assist clinical

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consultants to fulfill their role in this new age of genomic medicine. Most of the genomic tests for cancer require interpretation. The real value of the new genomic test menus can only be achieved by influencing the management of patients and related clinical outcomes. The challenges that labs will face in offering panels of new tests for early cancer detection are many. New offerings will likely affect every function of the lab, including staffing, processing, equipment purchases, results reporting, billing, validation and continuous education and training. While developing test menus, labs will not only have to evaluate pricing and ROI (Return on Investment), but they also will require more staff and new skill sets for interpreting test results and reporting results beyond entering results into laboratory information systems.

Labs will need to stay up to date with the latest advances in these technologies and their applications. Next-generation sequencing (NGS), for example, has been quickly adopted by major academic medical centers, but reimbursement reality is still limiting its acceptance in community healthcare systems. It is only a matter of time before labs will need to integrate NGS diagnostic tests as well.

In addition, there are regulatory and technical obstacles to overcome as well¹⁴.

Regulatory and reimbursement systems that were not designed to accommodate complex genomics-based diagnostics

- Absence of the electronic medical record-linked decision support tools needed to integrate the results of genomics-based diagnostic tests into routine clinical practice
- Intellectual property laws and practices that may present barriers to investment in genomics-based diagnostics

Conclusion

The approach to patient care in several areas of medicine is growing in complexity, and an integrated vision of all the aspects involving each illness in each individual is now possible. Most of these advances have come from the progress obtained from a better and more comprehensive knowledge of the human genome during the last years. This increasing understanding of human genes has allowed predictions of how some mutations could generate clinical entities with diverse behaviors concerning their aggressiveness and treatment responses.¹⁵ The application

of such tests is now available from clinical laboratories that have adopted the technology and vision of their role in facilitating the practice of personalized medicine.

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Pharmacogenomic Testing / Companion Diagnostics

Introduction

Modern medicine relies on the use of therapeutic drugs to treat disease, but one of the longstanding problems has been the documented variation in patient response to drug therapy. This variation in response can be due to the genetic makeup of the individual. Our unique genetic make-up and our individual response may mean that a drug that is effective for one person may be less effective for another or that a drug that is safe for one person may be less safe for another person—even at the same dosage.¹

In fact, every year in the USA alone, more than two million people experience adverse drug effects, and more than 100,000 die from those reactions. As such, adverse drug reactions are responsible for 5-7% of hospital admissions in the US and Europe, lead to the withdrawal of 4% of new medicines, and cost society an amount equal to the costs of drug treatment.² Another fact is that the drugs currently in use are only effective in 60% of the population³; and based on the patient's initial response, the dosage may then be increased, decreased, or discontinued.

This is illustrated for various drug therapies below:



Much of the current clinical interest in improving the effectiveness of drug therapy, and decreasing adverse effects is at the level of **pharmacogenomics**: the study of genetic variability that causes these individual responses to medications; as well as the application of genetic testing to patient care to improve prescribing safety and efficacy

Traditional Drug Therapy:⁴

When initiating drug therapy to treat a particular condition, healthcare practitioners typically prescribe one of several appropriate drugs. Dosages and timing of drugs are usually based upon the anticipated rate of metabolism and clearance from the body in the average person. They prescribe a “standard” dose based on factors such as weight, sex, and age. Clinically, however, each person responds uniquely to treatment and healthcare practitioners must make adjustments. For example, the healthcare practitioner may adjust the drug dose or switch to a different therapy, depending on whether or not the person's condition is responding to the medication and whether the individual is experiencing unpleasant or dangerous side effects. Sometimes a person may find that a treatment that has been working well suddenly causes a reaction when that person starts taking an additional drug.

The concentrations or effects of some drugs are monitored with blood tests and the drug dosages may be increased or decreased to maintain the drug level in an established therapeutic range, i.e. **therapeutic drug monitoring**. If changing the drug dose is not effective in treating or controlling the person's condition, or the person still has side effects, then the person may be given a different drug.

Utilizing Pharmacogenomics

This approach offers healthcare providers the opportunity to individualize drug therapy for people based on their genetic make-up. Testing people prior to initiating drug therapy to determine their likely response to different classes of drugs is a key emerging area of testing... known as **companion diagnostics**.

Companion Diagnostics⁵

Companion diagnostics are pharmacogenomics tests that help determine whether a patient should receive a particular drug therapy or how much of the drug to give, tailored specifically to the patient. These are an indispensable part of personalized medicine and will likely continue to rapidly increase in number and application to disease states. The first companion diagnostics were launched in the 1980s, and the commercial success of oncology drugs such as Herceptin® (trastuzumab) and Gleevec® (imatinib), which both require testing with companion diagnostics before they can be prescribed, has moved the entire companion diagnostic field forward.

From an initial start of a handful of oncology drugs with corresponding diagnostics, the field has expanded to include multiple therapeutic areas, and the number of combinations has grown by 12-fold.(from 5 to over 60). Based on drugs in clinical trials, the rapid growth will likely continue for the foreseeable future.⁶

Information on an individual's drug metabolism can yield information on who might benefit most from a drug and who would be at risk for atypical adverse reactions (through genetic variations influencing the rate and efficacy of drug metabolism, or other genetic variations related to drug response). Companion diagnostic testing can also guide the optimal dose or treatment frequency needed to achieve a desired therapeutic effect in an individual patient.⁷

Laboratory Partnership⁸

A healthcare practitioner may test a patient's genes for certain variations that are known to be involved in variable response to a medication at any time during treatment (for example, prior to treatment, during initial phase of treatment, or later in the treatment). The results of the testing may be combined with the individual's clinical information, including age, weight, health and other drugs that they are taking, to help tailor therapy. Sometimes, the healthcare practitioner may use this information to adjust the medication dose or sometimes to choose a different drug. Pharmacogenomic testing gives the healthcare practitioner additional information but may not necessarily replace the need for therapeutic drug monitoring.

Testing may be ordered prior to starting specific drug therapies or if a person who has started taking a drug is experiencing side effects or having trouble establishing and/or maintaining a stable dose. Sometimes a person may not experience such issues until other medications that affect the metabolism or action of the drug in question are added or discontinued.⁹

Laboratory consideration of initiating companion diagnostic testing includes (as for any new test specialty) the following:¹⁰

1. The clinical utility: i.e. evidence to support use of the test; and the importance of the test to patient management
2. The reliability of the companion diagnostic test
3. The cost of the companion diagnostic test
4. The logistics / investment needed to perform the testing
5. Specific regulatory requirements.

However, it is important to keep in mind that because the companion diagnostic test is designed to be paired with a specific drug, the development of both products required close collaboration between experts in both FDA's device center, which evaluated the test to determine whether it may be cleared or approved, and FDA's drug center, which evaluated the drug to determine whether it may be approved.¹¹

As a result, there are additional considerations by ordering physicians as well, before initiating companion testing by the laboratory:¹²

1. Clinical utility; how it helps manage patient disease and decision making
2. The intended use in association with the drug
3. The potential medical guideline changes
4. The reliability, availability and accessibility of Companion Diagnostic test
5. The cost and reimbursement for the testing.



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Patient counseling

To facilitate better understanding by patients, they may be referred for consultation with a genetic counselor prior to and after having a pharmacogenomics test performed. Genetic counseling and informed consent are recommended for all genetic testing.¹³

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Value-based Healthcare and The Enhanced Role of the Laboratory

Introduction

Over the last quarter of a century, despite tremendous advances in medical science and technology, there has been a growing realization that the healthcare delivery system has not been able to provide consistently high quality care for all Americans. In response to this, value-based healthcare has now become the focus of our national health policy, with value defined as the health outcomes achieved per dollar spent.

Value-based systems incorporate clinical outcomes in provider reimbursement, and generally provide differential payments based on measures of clinical quality and cost. Reimbursement may be associated with meeting specific performance criteria, with some systems grading reimbursement along the continuum of the patient's journey with their disease; i.e. higher reimbursement for care of a more complex disease.¹

In order to meet the demands of these payment reforms, medical practices are adopting a team-based approach to the delivery of those services providing proactive patient

care. This approach facilitates increased coordination between practitioners within the healthcare system, and connects patients to community-based resources and support. This requires providers to adopt the newer technologies for communication and monitoring.

The Department of Health and Human Services (HHS) announced in 2014 that by the end of 2018, half of Medicare payments will go to Alternative Payment Models (APMs) such as Accountable Care Organizations (ACOs), Patient-centered Medical Homes (PCMHs), and healthcare organizations that accept bundled payments.²

These models require a robust I.T. infrastructure across the continuum of lifetime care including:

- Health Information Exchanges (HIEs): which allow doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information electronically—improving the speed, quality, safety and cost of patient care.

- Electronic Health Records (EHRs)
- Hospital Information Systems (HIS)
- Laboratory Information Systems (LIS)
- E-prescribing
- Medical Device systems
- Diagnostic Imaging Systems

It also requires development of multi-disciplinary, multi-organizational, team-based care models to actively manage emerging care plans, care delivery, and compliance with evidence-based care practices across a variety of providers and care settings.³

In order to accomplish this, organizations are collecting and analyzing performance and outcomes measures. Pathologists and laboratory professionals have the expertise to identify significant trends and patterns and medical outcomes from this data. In turn, these analyses can be used to adjust the decision support and clinical pathways used to care for different disease states, and effectively reduce and control the cost of care.⁴

Indeed, laboratory clinical expertise, in combination with the lab's network of physician and patient touch points, make laboratories a central component of any integrated provider organization. By hosting the vast majority of centralized information, laboratories reaffirm the importance of highly functioning physician/laboratory relationships.⁵

Realizing the Potential for Laboratory Leadership

The value proposition for laboratory medicine is expressed in terms of its contributions to decision making in clinical care, how the care delivered, and the resources required to deliver that care. The key objective of laboratory medicine is to contribute to guiding this decision making to ensure the best health outcome for the individual patient, while minimizing risk and adverse outcomes, and maintaining reasonable cost.⁶

Through the deployment of a robust connectivity system, laboratories have the ability to streamline physician office work flow, receive test orders and return results to a variety of EHR systems in real time, and play an essential role in building physician relationships. Downstream benefits can include enhanced lab order accuracy, more complete patient and billing information, improved revenue collections, and better patient outcomes – all critical

differentiators in an era of quality improvement and cost reduction mandates.

Pathologists and laboratory professionals should be considered uniquely equipped to assist in the development of clinical pathways and clinical decision support software to guide physicians in test selection.⁷ The appropriate utilization of laboratory tests can create significant savings in laboratory expenses.



Operational Strategies⁸

Clinical laboratories must recognize the opportunities that value-based healthcare systems create, and respond with strategies that position the lab to reach its full potential. The following strategies are crucial for labs to meet the clinical information needs of physicians practicing within these organizations, and demonstrate their institutional value by facilitating decision support and coordinated care:

Align With Organizational Goals:

Laboratories have to review their operational assumptions, and align their goals with the organizational goals and actively pursue ways to increase the success of the group that they serve.

Extend and expand laboratory services

Reach out to all staff in physician offices, nursing facilities, clinics, and service centers. Create a network of integrated and coordinated laboratory services across the continuum of care. Develop the infrastructure and logistics required to serve chronically ill patients who need to access care periodically in different venues from a variety of providers, in an ambulatory environment. Expand the test menu to include preventive and chronic patient care testing and monitoring.

>> CONTINUED ON PAGE 12

Build electronic connectivity solutions to providers that effectively integrate data in and out of physician practice EHRs.

Laboratories can be instrumental in assisting physicians with the selection and implementation of EHRs, and with the meaningful use and interoperability of these systems. They also can demonstrate value to their physician clients by streamlining order and result processes within physician offices.

Improve the operational efficiency of the laboratory

One of the most important steps a laboratory can take to position its services for inclusion in a coordinated-care model is to improve every process, so as to eliminate waste, minimize variation, and reduce costs.

The focus now will change from savings based on individual reimbursements per CPT code, to reducing overall costs. The goal is to contribute to the larger organization-wide savings and to provide value in ways that best support the clinician in daily encounters with the patients.⁹

Careful analyses of staffing needs, workload distribution, and hours of operation, instrumentation and test menu must be implemented to ensure that redundancies have been addressed. However, laboratory operations are not static; these systemic studies should be carried out on a continuous basis to ensure adjustments are made to reflect changes in test demand, regulatory requirements and changes in technology.

Develop test utilization-management tools

There are currently more than 3,500 laboratory tests that physicians can order to diagnose patients and manage their treatment. Each test has its own strengths and limitations, and the nomenclature can be inconsistent between laboratories. The multiplicity of test names is a source of confusion for many physicians. For example, a physician ordering a test for Vitamin D could have 12 different options for selecting the same, similar, or related tests. Due to the complexity of modern laboratory testing, such as genetic testing and other esoteric tests, it would be unrealistic to expect physicians to be experts in laboratory medicine. Nearly 15 percent of physicians report that they are uncertain about what tests to order. Studies indicate that nearly 21 percent of all laboratory tests ordered are either unnecessary or unwarranted based on the patient's symptoms. Estimates show that hospitals could reduce their costs by perhaps \$5 billion annually by eliminating

redundant tests. Additional savings to the overall healthcare system could be realized through increased use of appropriate tests to diagnose diseases early, when treatment is more effective and less costly.

Laboratory professionals have the knowledge and expertise to help improve test utilization through a variety of methods, including the design of educational materials, development of disease-specific test ordering guidelines, and creation of computerized clinical decision support interventions that identify those tests not suitable for the condition being investigated.¹⁰

A proven strategy is to begin by monitoring test utilization with variation analyses to determine the disparity between provider orders within a facility or across multiple organizations for a specific diagnosis. This data can be analyzed and, combined with recommendations from professional societies for specific diagnoses or specialties, to develop internal guidelines that support optimal usage of the laboratory. Once this data has been communicated to the providers in a positive, informative format, a committee can be appointed to use the variation analysis to begin to establish best-practice ordering guidelines.¹¹

If the laboratory is part of the hospital organization, test utilization review can be performed by a multispecialty medical committee, such as a laboratory formulary committee, with the scope and authority to recommend the appropriate use or availability of lab tests, as well as review processes for referred test orders and protocols for lab workup for specific disease states. Laboratory experts are uniquely qualified to be involved in the development of computerized physician order entry (CPOE) with clinical decision support (CDS), test algorithms, and clinical pathways. Pathologists and Clinical Consultants have the medical training necessary to analyze aggregate clinical data for outcomes and quality.

Provide Detailed Test Interpretations

In conjunction with the need for guidance in test selection, there is also a need for automatic, patient-specific narrative interpretations from the laboratory that include information and recommendations about other lab testing options and relevant clinical details. There is a clear need to not only provide physicians with test selection assistance, but also with useful patient-specific interpretations of complex test results that lead to appropriate clinical decisions. In a study by J. Hickner and P.J. Thompson, et al.

titled “Primary Care Physicians’ Challenges in Ordering Clinical Laboratory Tests and Interpreting Results.”¹² Hickner found that clinicians were “uncertain how to interpret the diagnostic tests they ordered” in 8.3 percent of their patient encounters, translating to 13 million patients per year

The expertise of highly knowledgeable individuals can be utilized to create complex laboratory evaluations that can lead to improvement in the overall quality of care, reduction in medical errors, and reductions in the cost of care. Implementing patient-specific narrative interpretations can consistently reduce medical error.¹³

Educational Outreach¹⁴

Clinicians receive limited formal education and training in laboratory medicine. Few medical schools include a separate and distinct course on laboratory medicine in their curriculum, require training in a clinical laboratory setting, or assess the competency of the resident in laboratory medicine. As educators, laboratory professionals can develop the program curriculum and courses needed to inform residents about testing and how best to utilize it in patient care decisions. Clinical laboratorians also can teach the residency courses and develop the tools to assess competency in laboratory medicine. Laboratory professionals can also help clinicians with patient education.

Conclusion

As value-based healthcare becomes the prevailing model for healthcare delivery, laboratory testing will be focused on prevention, diagnosis, and the management of chronic diseases. The goal of preventive testing will be to diagnose an issue before it becomes a high-cost healthcare episode. In this scenario, the cost of the test versus reimbursement will not be the deciding factor on whether to perform the test. Instead the focus will be on what it can save the patient and the entire organization by enabling early detection.¹⁵

In addition, successful laboratories under the new challenges of healthcare reform will be the laboratories that are the most integrated within their health systems, leveraging outreach relationships, actively participating in the formative stages of organizational development, and preparing for upcoming reimbursement changes.

The paradigm shift in healthcare from episodic care to chronic-care management represents a once-in-a-generation opportunity for proactive laboratories to redefine their value in a new, much larger role as integrators of critical clinical information and decision support.

Laboratory professionals are ready to contribute their expertise in devising more effective and efficient diagnostic and therapeutic protocols.

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IQCP and Microbiology

Introduction

A year and a half ago, the Centers for Medicare and Medicaid Services (CMS) implemented the Individualized Quality Control Plan (IQCP), as a voluntary quality control option for tests and test systems that do not follow CLIA default quality control (QC) requirements. IQCP provides laboratories with flexibility in customizing quality control policies and procedures based on risk management assessments for the test systems in use and the unique aspects of each laboratory.¹ This is now the only alternative to CLIA default QC requirements.

IQCP replaced Equivalent Quality Control (EQC) which had been defined by CMS as the alternative QC option since 2004. This occurred because there were concerns expressed by representatives from accrediting organizations, professional organizations, industry, and governmental agencies about the rigidity and the limit of scope with EQC; that a “one-size-fits-all” requirement for QC would not work with all new technologies.

CLSI (Clinical and Laboratory Standards Institute) standards for streamlining quality control had been incorporated and accepted as part of the CMS interpretive guidelines since the 1990’s. But in October 2014, a memo notifying laboratories that all references to CLSI would be removed from the CMS interpretative guidelines (IG) was issued. The revised CMS IG released in May 2015 contained no references to CLSI. CMS stated that this action had nothing to do with the implementation of IQCP but was due to the fact that the CLSI documents must be purchased and are not freely available to the public.² These guidelines were utilized for all laboratory testing where appropriate, but were especially welcomed as guidance for the specialty of microbiology, where there are several exceptions to standard CLIA quality control requirements.

Thus, IQCP became the only acceptable quality control option for Microbiology testing, (with the **current** exception of COLA accredited laboratories).

CLIA/ CAP/JCAHO Laboratories: in order to continue using CLSI guidelines for Microbiology QC, IQCP must be implemented.

COLA Laboratories: may continue using CLSI guidelines for Microbiology QC; no IQCP required **at this time**. Note: COLA labs that undergo CLIA validation surveys must implement

IQCP OR revert to the regulatory QC requirements, if so directed in the CLIA survey report. COLA accredited laboratories using CLSI Microbiology QC guidelines should plan to complete IQCPs for these test systems by early 2018.

CLSI Documents Removed from the CMS Interpretive Guidance³:

- **CLSI M50 – Quality Control for Commercial Microbial Identification Systems**

Are you doing Stream-line QC? If so, to continue stream-line QC you will need to do an IQCP.

- **CLSI M22 – Quality Control for Commercially Prepared Microbiological Culture Media**

Exempt culture media will require IQCP (e.g. Blood agar, Thio broth, Urease agar, Blood culture media, CNA, MacConkey, etc.).

- **CLSI M100 – Performance Standards for Antimicrobial Susceptibility Testing**

All disk diffusion and MIC susceptibility testing with weekly QC will need IQCP Labs performing gradient MIC susceptibility testing with weekly QC will need IQCP.

- **M100 Sensitivity QC**
- **M22 Media QC**
- **M50 Microbial ID Systems – Streamline QC**

Manufacturer’s Instructions: (as in all specialties where the IQCP option is available):

- Laboratories must follow all manufacturer’s instructions.
- When the manufacturer’s instructions for QC are absent or less stringent than the “default” CMS/CLIA control procedures: the laboratory must choose to either:
 - Follow the CLIA default QC regulations OR
 - Implement IQCP.

Microbiology tests that are good candidates for IQCP⁴

Labs may do CMS/CLIA 'default' QC as listed below, or IQCP:

Test	QC Frequency (CMS/CLIA)
Direct Antigen Tests with an internal control (e.g. Rotavirus, RSV, Strep A, Legionella Urinary Antigen, Strep pneumoniae urinary antigen, Flu)	Each day of patient testing (for external controls (pos. and neg.)
Molecular-based Testing with an internal control (e.g. Illumigene, BioFire, Cepheid)	Each day of patient testing (for external controls (pos. and neg.)
Identification Systems (If currently doing CLSI M50 streamline QC), including Yeast ID systems	Each new lot # and shipment <u>Check (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity of each substrate (includes mycology ID systems)</u> <u>Each biochemical reaction used in the identification system must be verified for positive and negative reactivity with each new lot number and shipment</u>
Antimicrobial Susceptibility testing (e.g. Vitek, MicroScan, Disk diffusion testing)	Each day tests are performed, must use appropriate control organisms to check procedure Each batch of media AND each lot # and shipment of antimicrobial agents before, or concurrent with initial use
Antifungal susceptibility tests	Each day tests are performed, laboratory must use the appropriate control organism(s) to check the procedure <u>Each batch of media and each lot number and shipment of antifungal agent(s) before, or concurrent with, initial use, using an appropriate control organism(s)</u>
Media (*NOTE: IQCP would be for exempt media only) (Defined by CLSI M22) The laboratory has the following two options: follow all applicable CLIA QC regulations, OR implement IQCP. Laboratories may use the data obtained while following the CLSI microbiology guidelines as part of the risk assessment	The CLIA regulations for media [42 CFR 493.1256 (e)(4) (i-iii)] state the laboratory must do the following before, or concurrent with the initial use; <ol style="list-style-type: none"> 1. Check each batch of media for sterility if sterility is required for testing; 2. Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and 3. Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

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Testing that does NOT need an IQCP as long as regulatory requirements for these tests are met

Continue performing QC frequency as you are currently doing as outlined below:

Test	QC Frequency (CMS/CLIA)
Gram stain	Weekly
AFB Stain (eg Kinyoun)	Each day of use
Fluorescent stain (includes fluorochrome)	Each day of use
Beta Lactamase other than Cefinase	Each day of use
Bacitracin	Each new batch, lot # and shipment
Catalase	Each new batch, lot # and shipment
Cefinase	Each new batch, lot # and shipment
Coagulase Plasma	Each new batch, lot # and shipment
Staph latex	Each new batch, lot # and shipment
Germ Tube	Each new batch, lot # and shipment
ONPG	Each new batch, lot # and shipment
Optochin	Each new batch, lot # and shipment
Oxidase	Each new batch, lot # and shipment
Spot indole	Each new batch, lot # and shipment
X & V factor strips/disk	Each new batch, lot # and shipment
Other reagents, disks / strips/stains (e.g. PYR, Mcat disk and others)	Each new batch, lot # and shipment
Salmonella and Shigella antisera, streptococcal serotyping systems	Each lot # and shipment, and once every 6 months
LactoPhenol Cotton Blue	Each lot number (commercially prepared), and shipment
Special Stains used to detect Parasites (e.g. acid fast, fluorescent)	Each time of use
Parasitology permanent stain(s)	Each month of use, the laboratory must check permanent stains using a fecal sample control material that will demonstrate staining characteristics
Antimycobacterial susceptibility test	Each week tests are performed, laboratory must use the appropriate control organism(s) to check the procedure Each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s)

Summary of testing that does NOT need IQCP as long as manufacturer's instructions followed are more stringent than CLIA requirements

- EIA testing in 96 well format, or break away wells (Manufacturers recommended positive and negative controls run with each batch)
- Non-exempt culture media (chocolate agar, Campylobacter media, and media selective for Neisseria species) (as defined in CLSI M22-continue QC frequency as currently performing – no change)
- Anti-mycobacterial susceptibility test (continue QC frequency, each week tests are performed)
- Lactophenol Cotton Blue
- Parasitology permanent stains (monthly)
- Special stains to detect parasites (e.g. acid fast, fluorescent) (Each time of use)

Good candidates for IQCP in Microbiology:

- Tests that have an internal control (electronic/procedural/built-in) as it applies to direct antigen tests and rapid molecular tests
- Exempt culture media (as defined by CLSI M22)
- Antimicrobial susceptibility testing
- Identification Systems (for Streamline QC)

Additional Frequently Asked Questions (FAQs)

Recent informal feedback from COLA-surveyed laboratories indicates that there remains some uncertainty regarding the application of IQCP to Microbiology testing, even among laboratories that have been performing IQCP for over a year. In an effort to provide as much information as possible, below are some additional FAQs and responses from CMS directly:⁵

I. Many bacterial culture media have been exempt from QC based on data collected by CLSI. Therefore, laboratories do not have in-house data on these media. Would laboratories have to do daily QC on all these media until they had in-house data to implement IQCP?

CLIA is not prescriptive about the data/evidence to be considered for the laboratory's IQCP. It is the LD's responsibility to determine acceptable data. However, the laboratory must document that its Quality Control Plan (QCP) is based on evidence of the test system's accuracy and stability, and supports the QC type, number and frequency in the QCP. In-house data, established by the laboratory in its own environment and by its own personnel, must demonstrate that the stability of the test system supports the number and frequency of the QC documented in the QCP. This in-house data may include historical QC data while using the CLSI guidance and the CLSI documents to assist with the Risk Assessment (RA) as part of the IQCP data.

II. Is it acceptable to develop a master IQCP plan for culture media in the microbiology lab, with all the necessary elements covered, or does the lab need to develop an IQCP plan for each specific culture media type?

There is no specified way in which the laboratory must organize the risk assessment information for IQCP. For media, some laboratories have chosen to create a single IQCP that addresses all media used, while others might develop individual ones for each media type.

III. How is the QC for microbiology identification systems to be handled?

Microbiology identification systems (systems using two or more substrates or two or more reagents, or a combination), are subject to §493.1256(e)(1). The requirement at §493.1256(e)(1) states that the laboratory must check each batch/lot/shipment to verify positive and negative reactivity of each substrate. Laboratories that perform less QC than the regulations must develop an IQCP that supports their QC frequency.

IV. Do we need to do an IQCP for antimicrobial susceptibility tests (AST)?

IQCP is strictly voluntary. Laboratories may choose to develop an IQCP or follow the CLIA regulations. Since the CLSI exceptions for AST were removed from IGs, laboratories have two choices: follow all applicable CLIA QC regulations; or implement IQCP.

V. The manufacturer for our blood culture instrument does not require QC. Per manufacturer's instructions, we monitor the temperature and perform preventative maintenance. What are the CLIA regulatory quality control requirements? Do we need to implement an IQCP? If so, what data is acceptable for performing the risk assessment?

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All laboratories have decisions to make on the analytic control procedures they will employ for any test system and/or instrument. CLIA regulations for the analytic phase of testing can be found in § 493.1250. The choice to use manufacturer's instructions (if they meet or exceed CLIA's regulations), CLIA QC regulations as written or to develop an IQCP is the decision of the LD

VI. Does the laboratory need to perform the CLIA regulatory daily QC and micro specialty QC requirements (i.e. end-user QC) for a period of time to collect supporting data for its IQCP?

In general, CMS is not requiring that laboratories use the CLIA regulatory requirements as written to perform the IQCP. The LD is responsible for determining the most appropriate Quality Control Plan (QCP) for the test based on all of the data from the various sources available to him/her. Surveyors will continue to use the outcome oriented survey process to determine whether the laboratory is actually providing accurate and reliable test results and other related services, and is operating within the applicable CLIA regulations. It is the LD's responsibility to determine acceptable data. However, the laboratory must document that its Quality Control Plan (QCP) is based on evidence of the test system's accuracy and stability, and supports the QC type, number and frequency in the QCP.

Conclusion

Microbiology testing, including molecular infectious disease testing and direct antigen testing performed using non-waived instruments or devices that have internal control processes are good candidates for IQCP. In addition, microbiology testing performed using media, identification systems, and susceptibility test systems can benefit from IQCP. Laboratories must have an IQCP to define the use of reduced QC, even if following manufacturer's instructions or Clinical and Laboratory Standards Institute (CLSI) guidelines (with the current exception of COLA-accredited laboratories). Previous data collected by the laboratory and manufacturer certificates of analysis maybe used in the risk assessment. Without an IQCP, default CLIA QC requirements are applicable.⁶

The IQCP option, requiring the assessment of risk through all three phases of testing, rather than just the analytic phase, provides greater awareness of the entire microbiology testing process, broadens the scope of competency

assessments, and improves orientation and training. Microbiology is, by its very nature, a team effort, from specimen acquisition, handling and storage, to confirmatory testing and follow up. While a separate issue from the discontinuance of the CLSI guidelines, IQCP enables the maintenance of these QC protocols while taking into account changes in technology and organization of this discipline.

RESOURCES:

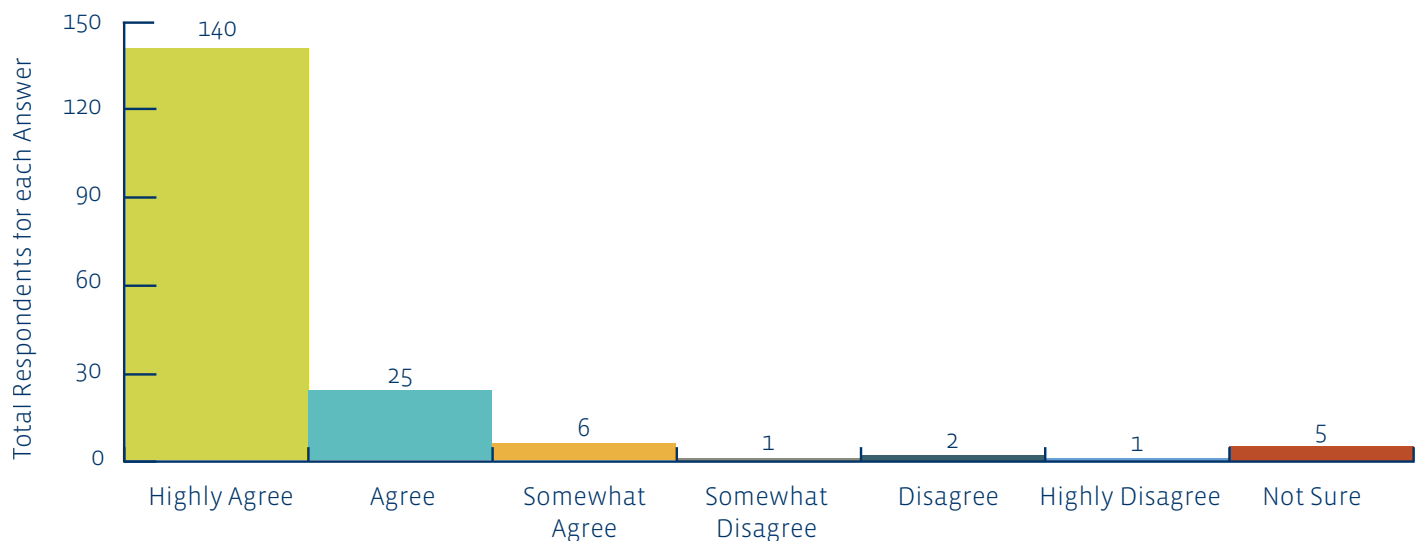
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COLA Leads the Charge to Protect Near Patient (In-Office) Testing

Near patient testing continues to be an important tool in the diagnosis and treatment of patients in the modern physician office.

Physicians Agree Near Patient Testing Has A Positive Impact On The Health of Elderly Patients

Figure: How much do you agree with this statement? Many of our elderly patients experience better outcomes because we provide clinical laboratory testing within our practice.



Ref: © 2017 COLA National Practice Survey

However, reimbursement cuts by public and private payers challenge access to rapid, near patient clinical laboratory services. For this reason, COLA has launched a multi-year, awareness and action campaign to educate policy makers and private payers on the importance of near patient testing to early diagnosis and treatment, chronic disease management and overall population and community health.

Current Challenge

In 2014, Congress passed the Protecting Access to Medicare Act (PAMA) to direct the Centers for Medicare and Medicaid Services (CMS) to develop a market-based methodology for determining the rates Medicare will pay for tests under the Clinical Laboratory Fee Schedule (CLFS). The intent of the law is to ensure that Medicare payment rates are based upon the weighed, median average of the private insurance market. This is an entirely new framework for Medicare rates under the Clinical Laboratory Fee Schedule.

A deeper analysis shows that the current data collection and evaluative pricing methodology, if fully implemented, will jeopardize patient access to laboratory testing. The issues stem, according to experts in the laboratory market, with

problems in the data that will be used to determine market-based pricing for the CLFS. First, in the final implementation rule, CMS defined a retrospective reporting period with no advance warning to providers of laboratory services of what, how and the time period (when) for which they would need to report data. This has made it difficult for providers to collect the proper data retrospectively. Second, there are several challenges to the reporting parameters that will distort the determination of final rates. Notably, most physicians with office laboratories did not meet the thresholds that would have required reporting, and hospitals performing (non-patient) outpatient laboratory services to their community were not required to report under the final rule. As such, a majority of the data CMS has received was provided by the two largest, national

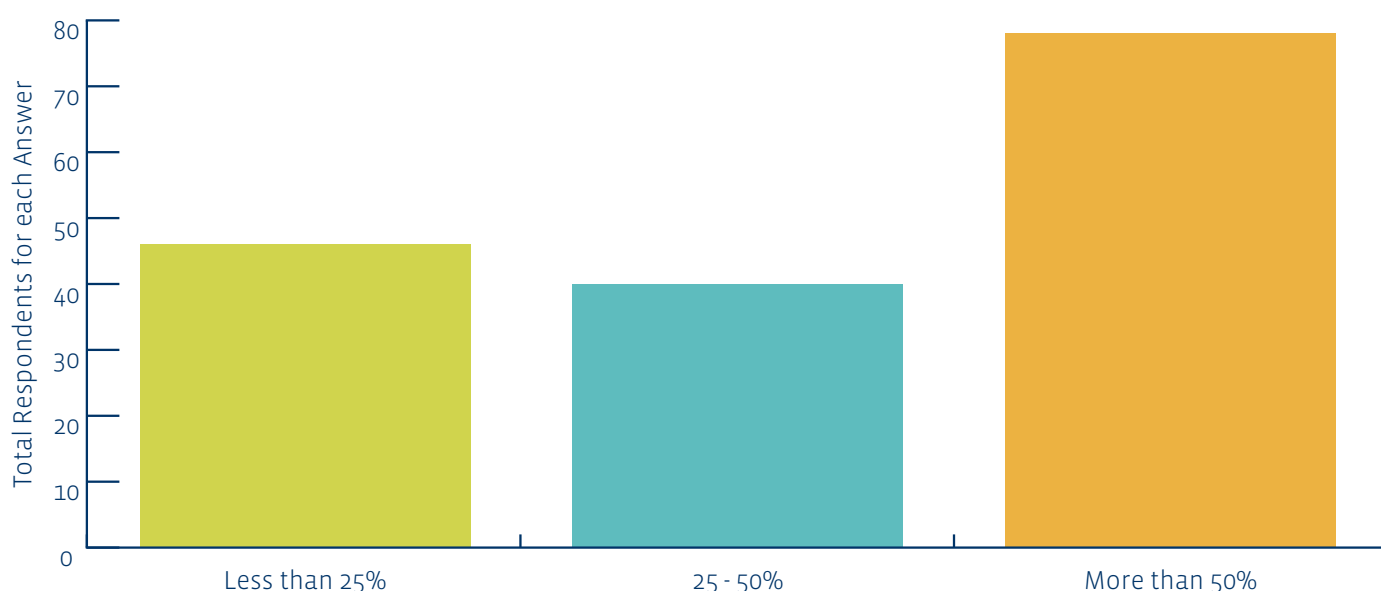
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commercial providers of lab services. It is well known that these two providers deeply discount the most common tests for the private market in exchange for exclusive or near exclusive contracts with insurers. As a result of these two influences, experts project that the new Medicare fee schedule for clinical laboratory services will not truly

represent the private market, with the greatest concern being how the law will impact the Medicare rates for tests used most commonly for early diagnosis and treatment. Furthermore, since managed care contracts are often tied to a percentage of Medicare payments, these reductions could have a cascading effect.

Physicians Report A Majority of Their Private Payer Contract Reimbursement Rates Are Tied To A Percentage of Medicare Rates

Figure: Regarding your provider contracts with private payers, what percentage of your contracts tie reimbursement rates for laboratory services to a percentage of Medicare rates?



Ref: © 2017 COLA National Practice Survey

Challenges Answered

At this time, stakeholders are active in lobbying Members of Congress and CMS to take another serious look at PAMA implementation. COLA is supporting the American Medical Association, American Academy of Family Physicians the American College of Physicians by providing impact data, which was gathered during a qualitative and quantitative research study, on the adverse impact of PAMA implementation on access to near patient testing.

In the coming weeks, COLA will be working with our partners as a subject matter expert to share what we found in our research and to convey the importance of near patient testing to early diagnosis, treatment and physician-patient communication. At this time, stakeholders are fully engaged in advocacy efforts to secure improvements to PAMA

implementation which will safeguard near patient testing.

To find out more about COLA's efforts you can visit the new website www.NearPatientTestingMatters.org.

NearPatientTestingMatters.org is the go to resource for the latest information on the value of near patient clinical laboratory testing. The website contains patient stories on the impact of near patient testing, a national survey on the impact of near patient testing on your practice and the latest news and information. COLA will continue to update this website as PAMA and new actions are taken in the public and private sector that may have the unintended or intended consequence of harming access to lab testing in your practice. Visit www.NearPatientTestingMatters.org for more information.

inSights SPOTLIGHT:

LABORATORY EXCELLENCE AWARD

DERBY FAMILY MEDCENTER DERBY, KS

LABORATORY DIRECTOR:
DR. DAVID W. NIEDEREE, MD

LABORATORY SUPERVISOR:
AMANDA KENNEDY, MLS (ASCP)CM

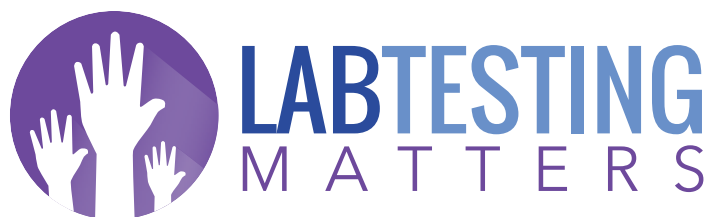
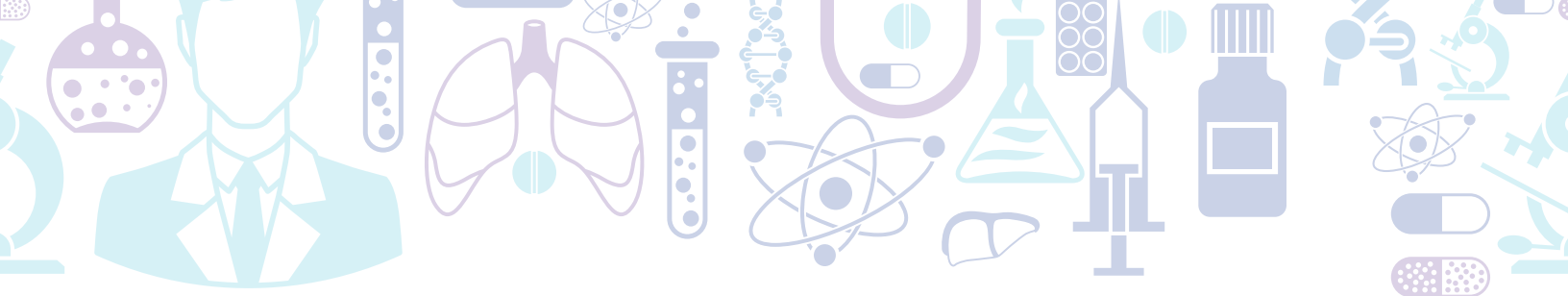
Derby Family Medcenter is one of the largest family physician offices in south central Kansas providing the most comprehensive diagnostic technology right in our office. Derby Family Medcenter laboratory is a physician office laboratory also serving as a central laboratory specializing in sample processing, and reporting quality and timely results for 15 health care providers. The providers are located in 6 different facilities and include 13 family physicians, 1 nurse practitioner, and 1 physician assistant. Derby Family Medcenter (DFMC) offers clinical hours 7 days a week including urgent care, staying open until 8 or 9pm.

All lab samples from the 6 Medcenter offices are collected and transported to the Derby site to be properly processed and evaluated for acceptability. Samples are then either ran in house, or sent to a reference lab. DFMC provides testing in the following specialties: chemistry, urinalysis, hematology, gonorrhea/chlamydia by PCR, BNP, microscopy for fungal exam, vaginal wet prep, scabies prep, and rapid testing for strep, influenza, RSV, mono, H. pylori, pregnancy, and hemocult.

Our team of skilled professionals including 4 medical assistants, 1 radiologic

technologist, and 1 Medical Laboratory Scientist work collaboratively to provide quality results of over 300,000 tests per year. We also provide skillful and safe sample collection for patients of all ages. We take pride in putting our patients at ease during phlebotomy procedures which may cause anxiety. With the help of COLA, the user friendly COLAcentral, and technical bulletins, we are able to stay current on changing regulatory requirements in order to provide the best care possible to our patients.





NEAR PATIENT TESTING CAN HELP QUICKLY IDENTIFY THE NEXT ZIKA



Our interconnected society makes it vital that our public health professionals get real-time access to diagnostic information for quick identification of the disease and treatment. However, potentially devastating cuts to the Medicare Clinical Lab Fee Schedule could hurt all laboratories but particularly hard hit will be rural and frontier communities.

COLA, a national laboratory accreditor and an advocate for quality in laboratory medicine and patient care, recently released a video highlighting the importance of near patient testing within our total network of laboratories and our ability to respond to a public health crisis.

"When someone becomes ill they tend to see their own local physician first," Dr. John Daly, Chief Medical Officer for COLA, said. "Local providers who utilize their own in-office lab can quickly rule out other infections. When an infection is not identified they can send the specimen to a more sophisticated laboratory. This expedites the identification process compared to sending initial testing out to a reference lab," Daly continued.

The loss of rapid diagnosis would make small communities more vulnerable to exotic infectious disease outbreaks if local community laboratories were to shut down.

Medicare may soon cut reimbursements for many laboratory tests under a new law. "If this law gets implemented as currently proposed, it would have very real and devastating consequences to our public health infrastructure and our capacity to respond expeditiously during an outbreak," Dr. Daly said.

COLA has launched a new webpage, NearPatientTestingMatters.org, to highlight the importance of near patient laboratory testing with interviews from the field of small laboratories and doctors, research and reports that show just how vital these labs are to the health of communities.

