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CLMR manuscripts include identification to the CLMA Body of Knowledge for Medical Laboratory Management.
Labs Play a Crucial Role; And We Will Deliver

It is with great enthusiasm and optimism that I greet you in my first message as president of the Clinical Laboratory Management Association. When I joined my first international committee nearly a decade ago, I had no idea that I would one day lead this organization, particularly in such exciting times. The clinical laboratory is taking on ever greater importance within the healthcare system and with regard to patient outcomes.

In my keynote address at G2's Volume to Value 2013 conference, I stressed the crucial role of laboratory medicine in enabling clinicians to arrive at timely and accurate diagnoses, as well as providing key information that supports treatment selection and efficacy assessment. I also stressed that the value we deliver is hampered by the IT systems that distribute our information and the skills of clinicians who order tests and interpret results. In too many cases, such factors harm patients. People die because lab tests are not retrieved. They go through unnecessary pain and suffering from diagnostic journeys that could be shortened by the right test. During my tenure as president, I will look for ways to engage our membership to make a positive difference in these areas.

In addition, we must build on the positive momentum achieved during KnowledgeLab 2013, where attendees and vendors alike responded with extraordinary praise. It is clear that CLMA has a vital role to play in shaping laboratory leaders today and in the future. Our members need ongoing training, networks of colleagues, and a common voice that reaches from their institution to Washington, D.C.

A very high priority for me will be expanding the training CLMA offers on the skills, competencies, and the art of leadership and strengthening the links between training and CLMA's Body of Knowledge. Another high priority is the development of strategies to advocate more effectively for our members and the profession.

I hope you will find opportunities for involvement in CLMA; a new, board-approved governance structure will provide one avenue for engagement, but there will be others. I'm confident at least one of them is sure to interest you. Although change takes time, consider my style to be one of constructive impatience. Please send me thoughts about your vision for CLMA; I'm in a hurry to incorporate them into our strategy.

Looking forward to the progress we will make together,

Paul L. Epner
A Strategic Partnership: Your Diagnostic Information System Vendor
The future of healthcare requires more than just an LIS. To effectively perform their role, laboratories will need a strategic, long-term informatics partner, focused on the laboratory and the structure of the diagnostic data it provides. Orchard’s success comes from our commitment and focus on the laboratory and the changes in healthcare to partner with our customers to develop, deliver, integrate, and support the very best laboratory information systems on the market.

One System for Integrated Diagnostics
The dividing lines between laboratory disciplines are blurring. Molecular and genetic testing are driving much of this change. The Orchard® Pathology diagnostic information system is an all-inclusive system for clinical, cytology, molecular, and anatomic pathology. Orchard Pathology utilizes a single database—no need for multiple systems or modules.

Structured Data for Synoptic Reporting, EMR Integration, Data Mining, and Analytics
Structured diagnostic data, discrete and codified, is essential to the future of healthcare and the development and utilization of personalized medicine. Unlike legacy text-based systems, Orchard Pathology uses a configurable worksheet with established templates, drop-down menus, protocols, diagnoses, and coding for data standardization and structure, synoptic reporting, integration, and analytics. Report information is stored in discrete data fields that enable EMR integration and enhance data mining for evaluations, correlation studies, and analytics.

An Integration Engine Bringing Locations and Diagnostic Data Together
A major objective of HITECH/Meaningful Use is to enable the electronic transfer of medical data. IDNs, ACOs, and other organizations will need to bring multiple healthcare delivery and testing sites together, providing a centralized repository of data and access from anywhere. Orchard® Copia® is a robust SQL Lab/EMR integration engine designed to link multiple lab sites, provide EMR connectivity, and serve as a central hub and result repository.

Learn More About how Orchard Can Be Your Diagnostic Informatics Partner
We celebrate our 20th anniversary this year, and our commitment to and focus on the laboratory has not wavered. Since that first installation in 1993, more than 1,200 laboratories across the country have turned to Orchard Software. Our long-term success, continuous growth, and breadth of expertise are testimony to our lab focus and our ability to deliver.
KnowledgeLab 2013 Redefines CLMA’s Annual Event

CLMA’s KnowledgeLab 2013, held in April at the Caribe Royale All-Suite Hotel and Convention Center in Orlando, Fla., exceeded all expectations. In addition to attracting nearly 650 lab managers related lab professionals and vendors KnowledgeLab redefined CLMA’s annual event and completed the transition from the association’s former ThinkLab conferences.

The transition was more than a name change. CLMA leadership started from the ground up to build an event that could meet the needs of new lab leaders as well engage and challenge seasoned veterans. The foundation of the event was its clearly defined purpose — KnowledgeLab is a place where:

- Knowledge is gained
- Knowledge is shared
- Knowledge is valued

Every aspect of the conference, including engaging educational sessions, key industry vendors, exciting speakers, and remarkable networking events tied back to KnowledgeLab’s three key principles, and the results speak for themselves. The event’s total attendance was a 12 percent increase from ThinkLab ’12. Attendee feedback was overwhelmingly positive, with 96 percent of respondents to the attendee survey indicating they would recommend KnowledgeLab to their colleagues. Nearly 95 percent said the value of attending KnowledgeLab outweighed or was equal to the cost of attending. More than 96 percent responded that KnowledgeLab met or exceeded their expectations.

When it came to education, the evaluation scores reflected the quality and value of the conference. Attendee evaluations indicated that 97 percent of the sessions were rated good or excellent in terms of relevance to the laboratory management profession, and 98 percent of attendees indicated that sessions were presented by experts in the session topic. Similarly, more than 95 percent of attendees rated the overall quality and value of the conference, general sessions, and breakout sessions as good or excellent.

Although the event is over and planning for 2014 is underway, CLMA members can relive the KnowledgeLab 2013 experience by viewing photos on the CLMA Facebook page. If you missed the conference, many KnowledgeLab 2013 educational sessions are available for purchase as Education on Demand sessions on the CLMA website. To ensure that you don’t miss the education, networking, and vendors in 2014, mark your calendars for KnowledgeLab 2014, which will be held May 4-7, 2014, at the Rio All Suite Hotel and Casino in Las Vegas. For more information, visit www.clma.org.
KnowledgeLab Exhibitors and Sponsors

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KnowledgeLab 2013 Sessions now Available Via Education on Demand

Recordings for select KnowledgeLab 2013 sessions are now available for purchase at the CLMA member price of $49 or nonmember price of $79. CEUs will be awarded.

Education on Demand offers pre-recorded sessions available 24/7 at a fraction of the price of live-streamed and in-person events. If you attended KnowledgeLab 2013, you now can easily share learnings with your entire staff team for one low price. And if you missed this year’s conference, Education on Demand is a prime opportunity to expand your knowledge base and gain cutting-edge insights.

For more information, visit CLMA’s Education on Demand webpage or contact CLMA Headquarters at 312.321.5111 or email info@clma.org.
KnowledgeLab 2013 Highlights
1. On day 2, attendees relax and have fun at the Poolside Attendee Dinner.
2. Attendees consult with vendors at the exhibit hall throughout the conference.
3. An attendee is surprised by the “Exhibit Hall Prize Patrol.”
4. The main stage and education sessions were full throughout the four-day event.
5. Members of the 2012-13 and 2013-14 Board of Directors include (front row, left to right) Carla Orner, Deborah Wells, Kathy Inglis, Edna Parker, Deb Garton, (back row) Mary Jo Bonifas, Kevin O’Connell, Patty Eschliman, Rodney W. Forsman, Paul L. Epner, Paul Labbe, Jane Hermansen, and Dennis Winsten. Missing: Belinda Vanatta.
6. Attendees took advantage of the lab tour at Orlando Regional Medical Center.
7. A poster presenter and attendee discuss poster findings in exhibit hall.
8. Education continues to be one of the most important aspects of CLMA’s annual event.
9. Two attendees have a little fun with the Body of Knowledge picture board.
ICQP – the ‘Right’ QC for Your Laboratory
Presented by Judy Yost, MA, MT(ASCP), Director, Division of Laboratory Services, CMS

Body of Knowledge domain:
8. Compliance and Risk Management

The Clinical Laboratory Improvement Amendments (CLIA) and EP-23 Individualized Quality Control Plan (IQCP) session gave a history of the Quality Control (QC) requirements since the Clinical Laboratory Improvement Amendments of 1988 (CLIA) went into effect in September 1991, provided rationale for updating the CLIA QC rules, and previewed CLIA’s current approach to QC for laboratories.

CLIA is the law that governs the operations of clinical laboratories in the United States. Regulations define how laboratories comply with the law. The Centers for Medicare and Medicaid Services (CMS) provides oversight of the regulations and is responsible for writing the updates that keep the rules current to reflect changes in technologies and standards of practice in clinical laboratories.

CLIA’s QC history includes updates to the original CLIA rules in 2003 by incorporating the QC section into a new comprehensive Quality System regulation. The inception of Equivalent Quality Control (EQC) came in 2004 and allowed laboratories to customize their QC for certain systems. A new provision for alternative QC was written into CMS’ Interpretive Guidelines in lieu of changing regulations. This allowed laboratories to implement “equivalent quality testing.”

In 2005, the Clinical and Laboratory Standards Institute (CLSI) convened a well-attended laboratory stakeholders’ meeting titled “QC for the Future.” It was sponsored by accrediting organizations, industry representatives, professional organizations, and government agencies.

The Clinical and Laboratory Standards Institute (CLSI) directed the development of their Evaluation Protocol (EP)-23—Laboratory Quality Control Based on Risk Management. The group that developed the document was chaired by James Nichols, Ph.D., Vanderbilt University School of Medicine. He assembled a large group of experts to complete the document that was published in October 2011.

CMS will incorporate key EP-23 concepts into CLIA Interpretive Guidelines (IG) as an acceptable QC policy called Individualized Quality Control Plan (IQCP). IQCP permits a laboratory to implement the “right” QC that is appropriate for each test.

The IQCP approach applies to CMS-certified non-waived labs. It covers all phases of the testing process and it may or may not reduce QC amount or frequency. The implementation of IQCP is optional but the default is the CLIA regulation 493.1256(d)(3). The current IQCP can be used for existing and new analytes/test systems and specialties, except for cytology and histopathology.

Once effective, IQCP will supersede the current EQC policy. Existing CLIA QC and quality system concepts won’t change via regulations. CMS will give approximately two years from the effective date for laboratories to get IQCP into place.

CMS’ outcome-oriented survey process will continue. Inspectors will require as a minimum that laboratories follow manufacturer’s instructions. As always, the laboratory director has overall responsibility for QC.

Before CMS permits IQCP, all surveyors must be trained on principles of risk management and principles of IQCP. IQCP must go through clearance through the agency before it will be made effective. There will be an education and transition period for labs before IQCP is fully effective.

Information and guidance will be provided to laboratories via CMS’ website. Questions can be directed to IQCP@cms.hhs.gov.

Laboratories can start now by downloading information as it becomes available. Until the effective date of IQCP, laboratories should continue to follow existing QC protocols; learn about EP-23 concepts and IQCP; plan and complete their transition accordingly by phasing out EQC (if using it); and determine whether to implement the default QC or IQCP.
SESSION SNAPSHOTS  

SESSION 4B

Benchmarking: Your Laboratory by the Numbers

Presented by Jane Hermansen, MBA, MT(ASCP), Outreach Program Coordinator, Mayo Medical Laboratories

Body of Knowledge domains:

2. Business and Clinical Operations
9. Medical Decision Support

The Institute for Healthcare Improvement is a non-profit organization dedicated to advancing care and health worldwide. Their intent is to work with healthcare providers to achieve overall improvements in healthcare by way of the Triple Aim initiative. Overall, this initiative calls for the improvement of the patient experience, to better the health of patient populations, and to reduce the cost per capita for healthcare. Because the laboratory plays a major role in the diagnosis, treatment and in disease prevention, attention to quality practices must be evident. In part, this is addressed through benchmarking these actions.

The ability to accurately benchmark laboratory activities has been a moving target for years due to the complexities of modern clinical laboratories. With significant advances in technology—methodologies, instrumentation, quality practices, and internal policies and procedures—the need to compare oneself to industry standards has become an ever-increasing challenge and is oftentimes unattainable. With advances in technology, test menus today are extensive yet reasonably adaptable and accessible to most modestly equipped laboratories. Thus with the vast numbers of different instruments and associated techniques, intralaboratory comparisons have become a greater challenge as these testing modalities expand.

Accepting these limitations, a practical and easy approach to improving benchmark productivity is to look within your own laboratory. That is, compare yourself to yourself. Comparing yourself over time, regardless of the metrics used, can provide valuable information that will guide a laboratory manager to enhance productivity, improve quality, placate employee morale, and be cost-effective. Metrics that can be useful for these comparisons can include:

- Revenue;
- Expenses;
- Test volumes;
- Tests per discharge;
- Cost per diagnosis; and
- Relative Value Units (RVUs).

Critical to this process is consistency (e.g., using the same parameters for the time periods to be compared—month to month, quarter to quarter and year to year). Defining those parameters is essential and among the first steps to be taken: What are you comparing?

- The number of orderable tests?
- Single tests within a panel?
- Reflex tests?
- By CPT code?
- By reportable value?

Once these specifics are determined, consistency in compiling the same data over time must be maintained in order to accurately show changes that otherwise become irrelevant.

Once collected, sharing the data with those concerned is important. Use of the Balanced Scorecard process can be helpful by showing how improvements (or lack of) can impact finances, customer services, internal business processes, and the learning and growth associated with the entities mission and vision. The goal(s) may include any of the following:

- Profitability;
- Quality management;
- Decreased turnaround times;
- Improved test utilization;
- Enhanced productivity;
- Opportunity for new test development; and
- Research and education.

If external benchmarking is unavailable, internal benchmarking can be easily achieved. But to do so, data collection must be consistent throughout the period of review. Apply simple statistical methods to evaluate the information and then communicate the successes (or failures) to the appropriate personnel, and it will provide direction that will lead the laboratory to achieving their goals.
SESSION 1B
Digital Pathology
Presented by Robert J. Corona, DO, MBA, CPE, FCAP, FASCP, John B. Henry professor of pathology and chairman, Department of Pathology and Laboratory Medicine Medical Director, Upstate University Hospital Laboratories Director of Neuropathology

Body of Knowledge domain:

7. Information Management and Technology

Though digital pathology has been around for several decades, it has not been rapidly accepted due to technical limitations. Just as advancements in computer hardware have enhanced our everyday lives through better and faster processing systems, computing abilities, image resolution, and information storage, so has it had an impact on digital imaging. Digital pathology has the potential of redefining how surgical pathology is performed.

Traditional, manual processing of tissues for pathologic evaluation has been fragmented and inefficient, subject to numerous opportunities for mishandling, misidentifying, and potentially misdiagnosing due to human limitations. Digital scanning of glass slides provides greater opportunities by acquiring and distributing patient information in an effective and potentially cost-saving manner. Digital pathology can provide enhancements in laboratory techniques (special stains, immunohistochemistry, etc.), diagnostic consultations, intraoperative (frozen section) diagnoses, medical student and resident education, diagnostic decision support, peer review, and tumor boards.

Whole slide images that are barcoded can reduce misidentification errors, can be electronically delivered off-site, integrated into various information systems (LIS, HIS), and tracked through the entire histology process. The ability to share information long distance can be invaluable and can greatly improve patient care. Storage of digital images can be compressed and kept electronically on any large-volume server. Scanner technology has vastly improved over the last decade and provides exceptionally clear and resolute images. With appropriate software, difficult to identify cell types can be researched by hovering over the cell and accessing various reference libraries to aid the pathologist in rendering an accurate diagnosis.

Yet, there remain some concerns regarding the routine use of digital pathology. The biggest hurdle is the final approval by the Food and Drug Administration (FDA). While the FDA does not directly regulate laboratories, it does regulate use of medical devices, which includes scanners, monitors, software, and other related pieces of medical imaging equipment. The main issue is assurance that whole-slide scans truly reflect an accurate reflection of the pathology seen under a microscope compared to computer images. Many expert witnesses have testified that these concerns are unfounded. Other countries have embraced digital pathology and have shown that it has been of great value, especially in areas where the availability of pathologists may be limited.

In addition, CLIA has yet to address digital pathology with regard to regulations, especially concerning performance standards, calibration, controls, and test reporting. However, the College of American Pathologists (CAP) added a digital image analysis section in 2010 to the anatomic pathology checklist that covers DNA analysis, morphometric analysis, and fluorescence in situ hybridization (FISH). In 2011, CAP created 13 guidelines for the validation of digital pathology for clinical use. Final rules are expected soon.

Storage of digital images can be from 100 MB to 1 GB of data, thus requiring high-capacity storage devices. Dr. Corona pointed out that 30,000 surgical pathology cases (with an average five slides per case) would consume up to 75 terabytes in a year! Fortunately, technology has kept pace with this need and can provide the needed storage space that only a few years ago would have been unachievable.

Despite the current perceived limitations, digital pathology, like digital radiology, will enhance diagnostic capabilities and provide a level of patient care not seen in the past. The idea of a virtual autopsy using these technologies can replace outdated traditional methods and offer a more complete examination. As modern medicine embraces the convergence of digital imaging, medical informatics, and molecular testing will be the near future in caring for patients.
SESSION SNAPSHOT  By Martha Casassa, CLD(ASCP), MT(ASCP)

SESSION 2A

The 10 Cs of Employee Engagement

Presented by Joseph Keary, MS, MBA, Irwin Army Community Hospital

Body of Knowledge domains:
1. Governance and Organizational Dynamics
2. Human Resource Management

Joe Keary, MS, MBA, Irwin Army Community Hospital, presented “The 10 Cs of Employee Engagement” and addressed the Body of Knowledge domains of Governance and Organizational Dynamics and Human Resource Management. His presentation described how employee engagement is a superior means to meet the needs of both management and staff and create a successful environment while improving employee retention and recruitment as a bonus benefit. Engaged employees are fully involved in and enthusiastic about their work, care about the future of the laboratory and the larger organization, and are willing to put in extra effort to ensure success. These are the employees who are committed to the vision and mission of their team and the organization. They are involved in committees and activities beyond the lab. They also are the ones likely to recruit other engaged employees. In today’s workforce, only about 17 to 29 percent of employees are engaged. Keary noted this is like having only two to three players on a Superbowl team engaged to play. No one wins that way!

Keary made sure his audience also heard that the 10 Cs are not about the employee, but about them as leaders. Engaging your employees makes your lab life easier and more successful. Good things happen in a department with engaged employees. What leader doesn’t want that? And Keary’s emphasis was on the term leader—not just those with a management title. The 10 Cs matter to all leaders whether emerging, new or seasoned. Engagement is a means to leadership success.

Keary also noted that employee satisfaction does not necessarily equal employee engagement. They are not mutually inclusive. Satisfaction tends to measure short-term, transitory perception while engagement is longer-lasting. However, one can facilitate the other.

What are the 10 Cs that Keary presented? The 10 Cs are activities or traits leaders need to be aware of and utilize to promote teamwork, efficiency, effectiveness, and retention among their team members. The list includes:

1. Connect;  
2. Career;  
3. Clarity;  
4. Convey;  
5. Congratulate;  
6. Contribute  
7. Control;  
8. Collaborate;  
9. Credibility; and  
10. Confidence.

Keary covered each C by providing fact followed by no-nonsense, down-to-earth, practical examples from his own lab and how he applies each C in his own workplace. A recurring theme on a number of slides was that:

• Leaders must show that they value employees;  
• Engagement is a direct reflection of the relationship between leaders and employees; and  
• Maintain a friendly and open attitude to all employees.

Keary provided a bonus, tongue-in-cheek C—coffee. According to him, it makes everything better!

In parting, Keary left the audience with his story about an important motto he has posted in his lab. It demonstrates the value of each and every staff member and reflects his attitude about his staff and the work they do: Sine nobis… sunt divinare. (Translation: without us, they are guessing.) It was clear from his presentation that he actively puts into practice all 10 Cs at his lab and provided the means for those attending to do the same.

All Suite Hotel and Casino, Rio is indeed one of the top choices when it comes to Las Vegas accommodations. Owned and maintained by one of the leading public gaming entities in the United States—Caesars Entertainment Inc.—Rio All Suite Hotel and Casino was the pioneering Las Vegas resort under the all-suite hotel category. It was inspired by the colorful and flavorful city of Rio de Janeiro, hence its name. Moreover, the Rio perfectly captures the fun and dynamic Brazilian culture; therefore, visitors are treated to an experience amplified by all things dazzling, exciting, and beautiful.
SESSION 6C
How to Develop an Excellent Presentation and Make Your Meeting Work
Presented by Anthony S. Kurec, MS, H(ASCP)DLM

Body of Knowledge domain:
10. Professional Development

“Meetings: The Practical Alternative to Work”

While this statement was made tongue-in-cheek, as laboratorians, we understand the necessity of time management. Often our days seem to be comprised of meeting after meeting, and so many of them, due to poor planning, seem to be a waste of time. While we can’t control the content of the meetings we attend, Anthony S. Kurec, MS, H(ASCP)DLM, presented a blueprint for attendees to use so they are not being guilty of wasting other people’s time. Kurec explained how to execute a well-planned, organized, and interesting presentation when it is our turn to present.

The goals of this session were to explain adult learning, how to effectively prepare before meetings, how to manage team members, how to manage facilities, how to use different facilitation techniques, and how to establish credibility as a leader and facilitator.

Kurec cautioned his audience that before scheduling a meeting, the most important thing to consider is whether a meeting is actually necessary, because time spent on a meeting consists of a lot more time than the time spent in the meeting itself.

Once it has been determined that calling a meeting is justified, meeting preparation is paramount. Considerations include:

Where should the meeting be held? What type of space will you need? What type of seating, writing space, and equipment will be required? What about refreshments, temperature, name tags? Will you need flip charts, an overhead, or use PowerPoint? Kurec offered many useful tips for the use of printed materials, especially when using PowerPoint, to give them optimum effect with the meeting participants.

What type of meeting should be called? Will it be a taskforce, an ad hoc meeting, a standing meeting, or a board meeting? Will this be a one-time meeting or will it require several meetings? How long will each meeting last? It is important to let invited members know what kind of time commitment will be expected.

Who will come to your meeting? If a meeting is called, it is vital that to consider the composition of the group. If selecting a committee, consider carefully who will be invited to participate. The most effective committee will be comprised of a mix of committed people with the right skill sets and positive attitudes. If the group composition is not up to you, consider the diversity and group dynamics. Is it a homogenous group of professionals, or a mix of people of all backgrounds and ages? Kurec also described the learning style of adults and how it differs from that of students.

Prior to the meeting, Kurec recommends developing an agenda. Each item should be listed and a time frame allotted. This agenda should be sent out in advance of the meeting so that members can prepare as needed.

When the meeting begins, the leader should welcome the group, introduce the members, and set the ground rules, for instance, “leaving titles at the door.” Once the meeting begins, it is the leader’s role to observe the group and keep the group on topic. He or she facilitates the meeting by paraphrasing for poor communicators, reinforcing correct or helpful comments, and minimizing embarrassment of the members. It is important to stick to the agenda and the allotted time. If it appears that an agenda item is taking longer than expected, it may become necessary for the item to be tabled for discussion at a later date. If other items come up that are important, but were not on the agenda, Kurec recommended putting these in a “parking lot” for future consideration. The leader is also responsible for controlling the speed of the meeting, the tone and civility of the meeting, and making sure the group sticks to the mission.

Minutes are extremely important, so a scribe should be appointed. It is important that they be sufficiently detailed, but remember, they will be discoverable, so be mindful of this when putting them together. Minutes should include date, start and finish time, place, attendees, purpose, topics discussed, results, outcomes, action items, and the next meeting date.

In conclusion, Kurec gave a very useful and informative presentation that illustrated by example how good planning, preparation, and effective management can make your next presentation a great one and your next meeting a success.

Don’t Forget to Submit Your CE Credit by July 15

If you attended KnowledgeLab 2013, be sure to enter your CE codes and print certificates by July 15. Attendees must have been registered for sessions in order to receive credit. Visit the certificate center for more information.
Before we can address what is unique about laboratory leadership, we must first consider key attributes of leadership that transcend specific fields or departments: having a clear vision, being self-aware, and managing effectively.

Managers get things done, but leaders define what needs to be done. They start with clarity about “true north,” the unchanging and absolute reference point by which a leader makes judgments. In all aspects of healthcare, this should be the welfare of the patient. It’s not the payer; it’s not the hospital; it’s not the government. It doesn’t change if you’re an administrator, a physician,

What’s Unique About Laboratory Leadership?
By Paul L. Epner

CLMA Fundamentals of Laboratory Leadership Course Overview
The CLMA Fundamentals of Laboratory Leadership course is designed to address the fundamental communication, decision-making and critical thinking skills necessary for laboratory leadership. The ultimate goal of the program is to accelerate the competency and skill development of new laboratory managers and supervisors and in doing so, cultivate a cadre of future laboratory leaders.

The inaugural offering of this course kicked off with two webinars in March and continued in conjunction with CLMA’s KnowledgeLab 2013 held in April.

Through webinars before the conference, a full-day pre-conference workshop, a program of specially selected sessions at KnowledgeLab, and a mentored project, the course provides the opportunity for new managers to assess their own leadership style, understand and practice effective communication within the laboratory and external to the laboratory, and develop critical thinking and decision-making skills. Real world case studies introduced participants to the science and the art of leadership. Faculty included Michael J. Hostetler from Cornell University and Dr. Michael Astion, Division Chief, Laboratory Medicine at Seattle Children’s Hospital.

After the on-site coursework, participants will continue working with a mentor to complete a personally designed, six-month project that reinforces their knowledge and brings direct benefit to their institution. Following the wrap-up of the course, they will continue their leadership journey with a network of other new leaders.

Visit the Fundamentals of Laboratory Leadership webpage for more information.
a nurse, or a laboratory professional. With true north in sight, a leader establishes a clear vision of what their organization can and should become. Their vision arises from the value needed by the larger enterprise of which their organization is a part, but the direction is always true north.

Just as important, leaders communicate their vision in a way that resonates with employees such that they adopt that vision as their own. When an organization acts with a common vision, it’s an indication of good leadership. Maintaining alignment requires more than merely articulating the vision; leaders have to demonstrate their commitment to it through their actions and decision making. This means considering decisions for their impact on organizational alignment as well as other operational considerations. This added perspective requires careful reflection by the leader and encouragement of diverse points of view from the organization. It means seeking disconfirmation of decisions as much as expecting confirmation. It means building consensus not demanding obedience.

The second most important attribute is self-awareness. In my experience, the most common reason why individuals fail as leaders is their own blind spot. People don’t want to follow leaders who have hidden agendas or who put their ego or personal needs ahead of the organization. Yet many unsuccessful leaders do just that without realizing it. A self-aware leader recognizes when their own behavior is sabotaging the vision that they have established, but it is no easy task. One has to understand one’s own biases. For example, when employees say something that conflicts with a stated direction, a bad leader tends to assume the worst of intentions while a good leader considers the possibility there is a simple misunderstanding or valid differences in assumptions.

Stephen Covey says, “seek first to understand and then to be understood.” A good leader is a good listener. However, limiting biases and being a good listener is not enough. A leader must also understand that the perceptions of others drive their behaviors and ultimately their trust in the leader. Inevitably, there will be times when a leader’s actions will conflict with the vision, and some of their innermost feelings will conflict with their outward statements. Employees recognize these conflicts, which undermine trust. Self-awareness helps the leader recognize those conflicts as well and accept accountability for them, enabling actions that will bring back harmony with the vision.

Finally, a good leader must also be an effective manager. Effective management involves many characteristics, but a few, in particular, are worth mentioning because of their strong association with leadership. Effective managers delegate; they don’t abdicate. Employees don’t like being set up for failure or abandoned to a difficult task. They want to know that their manager will support them and share accountability without micromanaging. An effective manager also seeks to “coach, not catch.” Assuming that every employee is doing the best they can, shortfalls in performance are opportunities to counsel an employee so they can learn and do better. Most people want to do well and are willing to work on improvement in a supportive environment that is grounded in assuming the best about people.

Finally, effective managers expect employees to be accountable in the same way that good leaders hold themselves accountable. Delivering on commitments is part of building trust. Ignoring performance problems helps no one, but it must be done objectively and with consideration for the assumed good intent of the employee. In those situations, where the person just isn’t buying into the vision or the culture or isn’t trying to address issues, they need to be helped out of the organization so that they can find their right place.

What’s unique?

There is very little that is unique about leadership in the laboratory. Certainly, the context and specific problems are different, but the principles are not. It is still necessary to define “true north” and establish a vision. The most frequent challenge facing laboratory leaders is their focus on factory-like measures, such as productivity and lower cost per test, while they fail to drive for the true north of healthcare (e.g., improved patient outcomes).

Some people lead solely by the authority that is associated with their position. Others lead with the support of those that are led. For most, it is a combination of the two. However, the enthusiastic support of those you lead is an exhilarating proposition. By defining and driving toward true north; by setting an aspirational vision that resonates with employees; by avoiding the landmines that are common with individuals who are not self-aware; and by providing effective management, the goal of being a successful leader can be within reach.

Paul L. Epner is a healthcare consultant focused on defining the optimum role for laboratory professionals in maximizing patient outcomes. He spent 31 years in industry in various leadership positions and is the president of CLMA and course director of CLMA’s new Fundamentals of Laboratory Leadership course.
The Body of Knowledge (BOK) is a roadmap that helps individuals identify their personal path toward competency as a laboratory leader. The BOK identifies 10 areas of management responsibility (domains) and the necessary skills to master (competencies) to become an exceptional laboratory leader. Each competency is broken into three levels, including Level I (emerging), Level II (developed), and Level III (advanced).

How to Use the BOK

Use the self-assessment tool that comes with the BOK to identify your own areas of strength and weakness and then browse the CLMA educational offerings to find courses and resources that will help you progress toward improved competency in those areas of weakness.

Who Should Use the BOK

All laboratory leaders at any stage in their career can benefit from the self-assessment tool and professional development opportunities that are identified through the self-assessment as areas for growth.

- New and aspiring laboratory leaders: Understand the skills needed to advance your career and use the BOK assessment as a management competency tool in preparation for laboratory inspections
- Senior laboratory leaders: Guide your preparation for the Diplomate in Laboratory Management (DLM) exam
- Hospital administrators and people managers: Identify opportunities for professional growth for laboratory staff

CLMA encourages members to access this free member benefit, and the new self-assessment tool through the BOK webpage. Members can also purchase a printed copy of the BOK. If you have any questions about the BOK, please contact CLMA Headquarters at 312.321.5111.
The clinical laboratory profession descended on Washington, D.C., and Capitol Hill in March to attend the 24th annual Legislative Symposium, a collaborative effort by CLMA, the American Society for Clinical Laboratory Science (ASCLS), American Medical Technologies (AMT), American Society of Clinical Pathology (ASCP), and Association of Genetic Technologists (AGT).

More than 150 professionals, representing clinical laboratory interests and their respective associations, spent the first day in sessions on effective lobbying efforts and the information of topical interest to present at the Congressional offices the following day.

CLMA had more than 30 representatives, along with four CLMA scholarship-sponsored attendees, and met with 35 Capitol Hill offices. CLMA Immediate Past President Rod Forsman, board of director member Paul Labbe and board of director member and advocacy committee coordinator Mary Jo Bonifas met with the new CLMA members in attendance to walk them through the process.

The scholarship winners were first-time attendees and also represented key states with congressional representation on the House and Senate committees. Diana Chestnut from Montana, Mike Hiltunen from Michigan, and Greg Lane from West Virginia all had a great experience and plan to return in future years. CLMA also sponsored the attendance of Martha Casassa, chair of CLMA’s Health Systems Advocacy Committee.

“This was an exceptional opportunity to learn more about the legislative process and more detail about the topics that clinical laboratories are facing on the national level, such as funding cuts and workforce shortages,” Hiltunen said. “The valuable take away that I gained was the need...
for advocacy at the state and national levels. We, as labora-
torians, need to be the knowledge source to make sure that
our elected officials fully understand the issues affecting our
industry and act in the best interest of patients”

Another first-time CLMA attendee, Ed Nartowicz, from
Kentucky, was impressed with his experience on Capitol
Hill. “While I was initially a bit hesitant in attending, I found
the day of preparation was exactly what I needed to feel a
little more relaxed, and once I was at the Capitol, I knew I
belonged there and had something important to say. It gave
me a feeling that we could be part of the solution. I hope
that more CLMA members can attend in the future, as it
helps to give us a voice with our legislators.”

Key messages at this Legislative Symposium were two-fold:
• The Workforce Reinvestment Act (WIA) – Statistics
show that with the closing of many medical lab
science schools, the profession is facing a shortage
of personnel. There is a demand for 11,000 medical
laboratory scientists each year, yet the remaining
accredited schools are graduating only 5,000. The
House recently passed HR 803, and the Senate
needs a companion bill to release funds to support
the remaining schools, which would allow current
unemployed workers to be retrained for jobs in the
clinical lab science field.
• Recognize the value of clinical lab sciences by re-
directing further cuts scheduled to hit our industry.
Laboratories have demonstrated excellent cost sav-
ings and efficiency over the past 25 years, repre-
senting only 1.6 percent of the Medicare budget
but positively impacting the healthcare of more
than 90 percent of the Medicare beneficiaries. The
clinical lab fee schedule, which was established in
1984, has been cut over the years. Today, clinical
labs are paid only 75 percent of that level when
adjusted for inflation. In addition, due to health
reform and sequestration on the federal budget,
laboratories are facing an additional 20 percent cut
in reimbursement over the next 10 years. The pur-
pose while at Capitol Hill was to convey that labo-
atory testing is a service and not a commodity.

The legislative health aides had insightful questions dur-
ing the individual office visits. They inquired about educa-
tional background of the scientists performing tests, their edu-
cational levels, and whether laboratorians see patients directly.
Examples were shared of laboratorian's participation in the
healthcare team toward direct patient care, diagnosis and treat-
ment, and many personal relationships were formed. Congress
is moving from a fee-for-service reimbursement model toward
a focused accountability of care based on quality and value.

The key takeaways from the Legislative Symposium
and our Capitol Hill visits were that before anyone is going
to listen to our plea to not apply any further cuts to the
Medicare fee schedule, they need to be convinced of the
value we provide. The way to do that is with specific,
patient-focused examples. As laboratorians, we need to
ensure our voice is consistently heard with our federal
regulators on the value we have in healthcare. The CLMA
Advocacy Committee is actively working on ways CLMA
members can accomplish this goal.

Figure 1 demonstrates the rate of inflation (CPI) that the reimbursement
of lab tests were to follow, the actual reimbursement with the fees
frozen or reduced over the years, and the additional reductions in
payments on the Medicare Lab fee scheduled starting this year.
Source: Mayo Clinic

It is very important to keep a
dialogue going with our elected
officials, so please utilize the
following links to find your local
Congressmen and write them an
email telling them about the great
things our laboratory profession
offers to the healthcare field.

Online resources:
FIND YOUR REPRESENTATIVE
FIND YOUR SENATOR
Important advances in HIV diagnostics and treatment have been made in the last two decades. Studies suggest that early therapeutic intervention in the form of antiretroviral therapy (ART) can significantly reduce disease transmission and increase life expectancy in certain settings. However, undiagnosed individuals cannot benefit from treatment and continue to contribute to HIV transmission.

Attitudes toward HIV screening have also changed, and many regulatory and logistical barriers for routine HIV testing have been overcome. Most recently, the U.S. Preventive Services Task Force (USPSTF) released new guidelines assigning a grade A recommendation for routine HIV screening of adults and adolescents, 15 to 65 years of age, in the United States (www.uspreventiveservicestaskforce.org). In 2005, when the USTPSF last considered the matter, the decision was made that there was insufficient evidence to support anything other than a grade C recommendation for HIV screening of the general population. However, less than a year later, in 2006, the Centers for Disease Control and Prevention (CDC) published a landmark set of recommendations shifting HIV screening strategy from targeting high risk populations to routine opt-out screening for persons 13 to 64 years of age in all healthcare settings. The CDC cited evidence that targeted screening had limited success with 25 percent of individuals infected with HIV remaining unaware of their HIV status.1

This profound disagreement between public health and clinical practice direction has been in effect for seven years, although there has been increasing support by many professional organizations for routine opt-out screening.2 The USTPF policy change, however, is not just an overdue alignment with the CDC position; it has important practical implications for clinical practice. The USTPF recommendations...
are used as a standard by many professional societies and health organizations and can directly affect reimbursement by healthcare plans, in effect dictating local HIV testing practices. Importantly, under the New Affordable Care Act (ACA), a grade A recommendation for preventive services mandates that health plans, both private and public, will provide coverage without out-of-pocket expenses to the consumer.

In addition to the evolution of government policies regarding who should be tested, there are also new recommendations for laboratory diagnosis of HIV. For more than two decades, the gold standard for HIV diagnosis has been immunoassay (IA)/rapid test followed by Western blot for confirmation. In 2010, the CDC/APHL proposed an alternative HIV diagnostic algorithm that was subsequently endorsed by the Clinical and Laboratory Standards Institute (CLSI). The new algorithm is a three-step process that incorporates the most recent technological developments, eliminates the Western blot altogether, and, for the first time, formally includes nucleic acid amplification tests (NAAT). The first step is screening with an immunoassay, preferably an antigen/antibody (Ag/Ab) assay, followed by a supplemental assay that can differentiate between HIV-1 and HIV-2 antibodies, and concludes with nucleic acid amplification test (NAAT) for resolution of samples that are discrepant between the screen and supplemental test results. The algorithm is predicated on the use of Food and Drug Administration (FDA)-approved assays, which improve detection of acute HIV infection and accurate differentiation between HIV-1 and HIV-2 infection.

The initial test recommended is an HIV Ag/Ab combination assay that simultaneously detects HIV-1 and HIV-2 antibodies, as well as p24 antigen. The advantage to this assay format is improved detection of acute HIV infection (AHI) prior to seroconversion. Studies have demonstrated that antigen/antibody combination immunoassays, also referred to as fourth-generation HIV screening assays, can detect HIV infection five to seven days earlier than third-generation HIV antibody only tests. In the United States, there are only two FDA-approved fourth-generation assays: the ARCHITECT HIV Ag/Ab Combo (Abbott Laboratories, Abbott Park, Ill.) and the GS HIV Combo Ag/Ab EIA (Bio-Rad Laboratories, Redmond, Wash.). The use of an antigen/antibody assay is preferred for screening because it can identify individuals with acute HIV infection, who are highly infectious and more likely to transmit HIV.

Any repeatedly reactive sample on the screening test must be followed up with an HIV-1/HIV-2 Ab differentiation assay. At the moment, the only assay that is FDA approved for both detection and discrimination between HIV-1 and HIV-2 antibodies is the Multispot (Bio-Rad Laboratories, Redmond, Wash.) rapid test. Originally FDA-cleared as a screening assay for use only in multitest algorithms, and as of April 2013, it is now FDA approved for use as a supplemental test in conjunction with the new CDC algorithm. Although the manufacturer states the sensitivity and specificity of Multispot are 100 percent and 99.9 percent, respectively, lower specificity performance has been reported in some studies. In fact, the use of the Multispot as a supplemental test is accompanied by new interpretation instructions. The Multispot has a total of four spots—one for HIV-2, two that are specific for HIV-1 antigens, a gp41 recombinant, and a gp41 peptide. Prior interpretation guidelines allowed for reaction at either of the spots to be reported as positive for HIV-1. Both HIV-1 spots must be present for the samples to be considered positive for HIV-1. Any samples that are discordant between the two HIV-1 antigen spots must be reported as indeterminate and proceed to nucleic acid amplification tests (NAAT) for resolution. Any specimens that are positive for HIV-2 and negative for HIV-1 can be considered positive for HIV-2 infection.

Although the Multispot is reportedly more sensitive than the Western blot by approximately seven to nine days, it still detects only IgG antibodies. Therefore, any specimens that are negative for both HIV-1 and HIV-2 by Multispot, and are discordant between the antigen/antibody combination screening assay and the Multispot supplemental test, necessitate follow-up with NAAT to rule out acute HIV infection. However, the vast majority of diagnoses are established HIV infections and will be resolved at this step.

One attribute of the Multispot is that it is superior to Western blot in accurately detecting and classifying HIV-2 infections. The Western blot was designed for confirmation of HIV-1 infection, and there is evidence that known HIV-2 samples tested by Western blot can be misclassified as HIV-1 or missed altogether. Misclassification is important because certain first line of therapeutic drugs used for HIV-1 treatment are ineffective for HIV-2. HIV-2 infections remain rare in the United States, with only 166 cases identified in
between 1988 and 2010. Notably, the Western blot remains highly specific for HIV-1 infection and will continue to have a role in HIV diagnostics.

The primary advantage of the Multispot is that, unlike the Western blot, it does not require specialized testing or expertise, and it can be easily performed by clinical laboratories currently providing HIV screening. In essence, HIV screening and confirmation can now be performed in the same primary care institution, reducing turnaround time and expediting diagnosis.

Although the new HIV screening guidelines will simplify serologic testing, the inclusion of NAAT testing in the final resolution arm will present significant new challenges for laboratories. By far, the most readily available HIV-1 NAAT resource for hospitals and clinics is viral load (VL) tests, which are currently approved only for therapeutic drug monitoring, not diagnosis. There is only one assay, the Gen-Probe Aptima HIV Test (Gen-Probe, San Diego, Calif.), that is approved for diagnosis of acute HIV infection or for confirmation of repeatedly reactive immunoassay results. Aptima, however, is a manual test and is offered by a relatively small number of laboratories. Though the number of samples requiring NAAT testing in the new diagnostic algorithm is projected to be small, the barrier of uneven access to FDA-approved confirmatory testing does not favor timely reporting of resolved test results, which is the intention of the guidelines. The inclusion of HIV Aptima on automated platforms that perform other non-HIV Aptima tests would contribute to better access, since these instruments are widely placed in U.S. laboratories. Pursuit of a diagnostic claim by manufacturers of HIV VL tests would provide even greater test access. Current versions of these assays have very similar detection capabilities to Aptima and are widely available. At this time, there may be little incentive for companies to pursue diagnostic claims for VL tests given the small anticipated volumes of diagnostic testing. In the absence of a diagnostic claim, utilizing VL as diagnostic assays would constitute “off-label” use. Laboratories recommending such use should have validation studies that satisfy Clinical Laboratory Improvement Amendments (CLIA) regulatory requirements.

Although laboratories are restricted from promoting HIV VL tests for diagnostic applications, physician ordering these tests in various settings of potential acute infection is not restricted and is likely widespread. Test options for HIV-2 NAAT resolution are much more limited and problematic. Currently, no approved HIV-2 NAAT assay is available in the United States. and none are likely to be developed in the foreseeable future. HIV-2 testing is performed by a limited number of research and specialty laboratories, and information regarding the analytic and clinical validation of these tests is limited. In addition, the pathway for HIV-2 test development is more difficult than for HIV-1 due to the much more limited number of available viral genomic sequences and less robust global sequence monitoring programs.

The CDC/APHL algorithm is an important option for laboratories to consider, but the limited availability of FDA-cleared assays at each step in the new algorithm may present a challenge for some institutions. In an era when increased demand for HIV screening and diagnosis is expected, having multiple diagnostic algorithms and testing platforms is generally desirable. Ultimately, the choice of algorithm and assays employed will be guided by the needs of the population served by the laboratory and clinician preferences. Practical considerations such as need for automation, cost, and access to specific FDA-cleared platforms will also have a significant impact on laboratory testing strategy. However, all laboratories benefit from proliferation of diagnostic assays that are specific and sensitive, enhancing early detection of HIV infection, and reducing false positive results that necessitate follow-up. An accurate and prompt HIV laboratory diagnosis will be critical to mainstream HIV testing and in achieving the National HIV/AIDS Strategy goal of reducing the number of HIV infected persons who are unaware of their HIV status from 21 percent to 10 percent.

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Healthcare payors are implementing a new reimbursement model called pay-for-performance (P4P). P4P programs are being designed by the Centers for Medicare and Medicaid Services (CMS) to improve the effectiveness and safety of patient care so that they may serve as a positive force in our nation’s healthcare system.1

Reimbursement for medical services has long been based on a fee-for-service model whereby physicians are reimbursed for the quantity of services performed with little regard to quality, efficiency, or outcomes.2 The P4P model rewards healthcare providers for meeting predetermined performance measures. There is a demonstrated need for the clinical laboratory to identify standardized quality measures that are both useful and evidence based.3 The question posed in this survey of clinical laboratory leaders was: As federal payors move toward P4P from pay-for-service, what standardized quality indicators should be standardized nationally as part of clinical laboratory quality management plans and which should be linked to reimbursement?

Methods

The methodology employed for this study was a quantitative electronic survey of clinical laboratory leaders. A survey methodology was chosen because it provides an excellent way to gather information about a certain group of individuals at a national level.4 Nominal data were collected in this survey. It was estimated that it took respondents approximately five minutes to complete. A letter of consent was provided to each participant. The survey was administered in a natural, non-manipulative setting at the convenience of those who wished to participate. The survey is stored anonymously and electronically on www.surveymonkey.com.

The sampling strategy used for this study was convenience sampling. The participants were leaders in the clinical laboratory industry, defined as supervisor level or higher. Google and LinkedIn were utilized to identify such individuals through searches using job titles. A limited number of internationally recognized laboratory quality experts were also identified through Google searches utilizing professional organization email listings. There was no limit placed on the number of requests sent or participants. The survey was administered on a voluntary basis utilizing email to request participation in the study.

Collected data were tallied by simple manual tabulation and recorded in Microsoft Excel spreadsheets. Results were reported in actual numbers of respondents for each possible answer to each question, percentages, and in graphs. The data were analyzed for trends, such as the majority of respondents perceiving that a specific metric should be linked to reimbursement.

Limitations

The major limitation of this study was the scarcity of email contact information for clinical laboratory leaders. Email addresses were painstakingly identified through time-consuming Google and LinkedIn searches over six weeks in order to achieve the 224 respondents. Another limitation of this study was the generalized nature of the questions. This was done purposefully to obtain a general overview of the areas clinical laboratory leaders think should be standardized and/or linked to reimbursement. However, this proved to be a limitation, as respondents commented that there was not enough information in some cases for them to answer in a way that reflected their beliefs on each topic.

Results

The survey was sent to 1,051 leaders in the clinical lab industry. This study received 224 responses with respondents representing 43 states and six foreign countries. This represents a 21.3 percent response rate. Figures 1 through 4 provide a summary of the data.
Discussion

The results of this survey were quite decisive. Despite a range of just less than 30 percentage points of responses in favor of standardization of the quality metrics presented in the survey, the results of this survey show that lab leaders are overwhelmingly in favor of nationally standardizing metrics.

The majority of respondents were in favor of nationally standardizing all quality metrics presented. Additional suggestions were made to standardize metrics in the areas of personnel qualifications/certification, training/continuing education, productivity/efficiency data, and transfusion data. Proficiency testing performance was the metric that the most respondents agreed should be standardized across all clinical labs nationally. This is not surprising, as this is the measure by which clinical labs currently benchmark their performance as it is required by Clinical Laboratory Improvement Amendments (CLIA) regulations.

Respondents were also in favor of standardizing specimen identification error rate metrics. This was also expected, as specimen identification errors are the most prevalent and costly types of errors that occur in the laboratory. Critical value reporting was the third most agreed upon quality metric for standardization. This was also predictable, as hospitals already monitor this key performance indicator. Completion of competency assessments was the quality metric that received the fourth most favorable responses. Competency assessments of technical staff are a requirement for CLIA certification and for subsequent accreditation, so this is not a surprise.

The most surprising of the responses to quality metrics for standardization was the fifth-ranked metric—pre-analytical data entry error rates. Drawing from personal experience and the literature, the pre-analytical phase is the phase in which most errors occur and also receives the least amount of attention in the lab. It was surprising that more than 80 percent of respondents recognized the importance of this metric.

The least favored quality metrics for standardization were also quite predictable. The metric with the least responses in favor of standardization was report transmission metrics. This is not a metric that laboratories typically track, as it is perceived to be outside of the control of the lab. Customer satisfaction came in close to last for standardization. Comments received indicate that laboratory leaders view this information as too subjective and biased.
to standardize. Standardization of specimen rejection rates received the third least favorable responses due to the perceived lack of control that the laboratory has over this metric. Several respondents commented about how they did not feel that it is appropriate for the laboratory to be accountable for metrics over which they have no control. While this sentiment may be valid, it is helpful to look at this from a global perspective. The patient does not care where the error occurred. It is the responsibility of everyone involved in the total testing process to track metrics that establish a baseline for quality improvement, regardless of whether or not they “own” the entire process. Labs have a responsibility to provide this critical feedback to providers, who otherwise would not be aware of these errors. Quality lab services do not begin and end inside the confines of the laboratory.

The responses to the questions regarding linking quality metrics to reimbursement in a P4P reimbursement model were quite similar to the results of the standardization questions. Proficiency testing, critical results reporting, specimen identification errors, and completion of competency assessments were the four metrics receiving the most favorable responses. The only other quality metric receiving favorable responses from more than half the respondents was interpretation error rates. This is not consistent with the responses to the standardization section. This metric is critical to patient safety as interpretation errors can have serious implications. These metrics received markedly less favorable responses overall than the metrics for standardization. This reflects a general reluctance of lab leaders to accept P4P reimbursement as a viable payment model for clinical laboratory services. This sentiment was reflected many times in respondents’ comments at the end of the survey.

Not surprisingly, the metrics that received the least favorable responses for linking to reimbursement were those that the laboratory has the least amount of control

The majority of respondents were in favor of nationally standardizing all quality metrics presented.
over. As noted above, these include rejection rates, report transmission metrics, specimen collection, and handling metrics and customer satisfaction scores.

**Conclusion**

Three major conclusions can be drawn from the results of this study, including:

1. Clinical laboratory leaders recognize the need for standardized quality metrics for laboratory services. Historically, laboratory management has focused on analytical metrics. The results of this survey show that laboratory leaders feel that metrics across all phases of testing should be incorporated into quality management plans standardized nationally.

2. Clinical laboratory leaders are largely not in favor of the clinical laboratory becoming subject to pay-for-performance reimbursement. This is evidenced by significantly less favorable responses across all quality metrics for linking to reimbursement as compared to the responses for standardization. The metrics that received the most favorable responses are those that the laboratory has the most control over.

3. Clinical laboratory leaders recognize the importance of quality in the clinical lab as evidenced by the responses received. Feedback provided in the comments section of the survey was thoughtful and passionate.

It is currently very difficult to compare laboratory performance between institutions because of a lack of standardized quality metrics. However, each clinical laboratory must comply with federal CLIA regulations for quality as well as implement and maintain a mandatory quality management plan for ongoing quality management. Because quality indicators should already be tracked, all that is needed for external comparison of quality amongst these labs is a consensus within the industry on what quality indicators to include. By establishing standardized pre-analytic, analytic, post-analytic, and total testing process quality metrics through consensus of clinical laboratory leaders, the clinical laboratory can take ownership of quality and patient safety in the lab.

If lab services become subject to P4P reimbursement, the results of this study will provide a voice for leaders in the clinical laboratory industry to educate government leaders and legislators as they determine the metrics that will become subject to pay for performance reimbursement.

**Future Research**

This study has been successful in providing a consensus on what general metrics clinical laboratory leaders feel should be nationally standardized and which of those metrics should be linked to reimbursement if clinical laboratory services become subject to pay for performance. A recommendation for future research is to further explore this issue in a more granular manner. This could be achieved by developing and administering a survey for each laboratory specialty that provides specific examples of quality metrics and how each metric is defined. This survey would then be administered to clinical laboratory leaders in each respective specialty.

**References**


Jennifer Dawson, MHA, DLM(ASCP)SLS, QIHC, is the manager of quality management for National Jewish Health’s Advanced Diagnostic Laboratories, one of only 22 laboratories in the United States with the CAP 15189 accreditation. Dawson is responsible for overseeing regulatory affairs and the quality management system for all lab services, including phlebotomy, pre-analytical, client services, microbiology, immunology, complement, molecular, mycobacteriology, microbiology, pharmacokinetics, histology, and point-of-care testing. She successfully led the laboratory through CAP 15189 surveillance in March.
How compliant are you with all your equipment validation per Clinical Laboratory Improvement Amendments (CLIA) and your accreditation requirements? Equipment validation process is a crucial component in assuring patient safety, which has been escalated by clinical regulators since 2007.

To keep up with the needs of diagnostic testing and the advancements in technology, many clinical laboratories require a number of analyzers and point-of-care testing devices to maintain that level of quality. In addition, many involve computer software and hardware that may need a separate validation process.

To be compliant, your laboratory equipment validation must meet all requirements pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA’88; revised in April 2003) and implemented Dec. 31, 2007. The standards also require laboratories to develop, implement, evaluate, and maintain an effective, ongoing and data-driven quality assessment and performance improvement program. The self-assessment and performance improvement programs must be appropriate for the complexity of the organization and services provided. They should focus on maximizing outcomes by improving patient safety, quality of care, and patient satisfaction.

A strategic and simple approach to equipment validation starts with a validation master plan (VMP). This foundation provides a structured approach to equipment validation that will allow many problems to be addressed before they become crises. It also assures equipment needs (functional, business and technical) are met. It should also assess and mitigate any potential hazards, all equipment data reviews and establish policies and procedures that are available to all users, and, most of all, to comply with all patient safety requirements.

Definition

Validation is defined as “establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.” The system shall provide a high degree of assurance that every step, process, and change has been properly evaluated prior to its implementation. The VMP is a document that describes how and when the validation program will be executed in an institution for the specific equipment/project.

Background

The concept of validation was first proposed by two Food and Drug Administration (FDA) officials, Ted Byers and Bud Loftus, in the mid-1970s, in order to improve the quality of pharmaceuticals (Agalloco, 1995). It was proposed in direct response to several problems in ensuring sterility of large volume parenteral products.

CLIA regulations set standards on test systems, equipment, instruments, reagents, materials, and supplies for clinical laboratories. Laboratories must properly qualify, monitor, and, after April 2004, verify or establish performance specifications for any test systems used.

Each laboratory that modifies an FDA-cleared or approved test system, introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as textbook procedures, Gram Stain, or potassium hydroxide preparation), or a test system in which performance specifications are not provided by the manufacturer, must establish performance characteristics before reporting patient test results.

Characteristics include: 1) accuracy 2) precision, 3) reportable range of results, and 4) appropriate normal values. Some provisions of the above requirements were introduced during an educational period in April 2004, whereby adverse findings would result in deficiencies.

Effective December 2007, the following CLIA-specific requirements are formally in effect and laboratories must comply. As of December 2007, unmet requirements were compiled in a “statement of deficiencies” (Form CMS-2567) and shared with the institution giving them 10 calendar days to respond with a plan of correction (PoC).
Requirements as published in the CLIA regulations include the following provisions:

- 42 CFR 493.1253, Establishment and verification of performance specifications;
- 42 CFR 493.1254, Maintenance and function checks; and
- 42 CFR 493.1255, Calibration and calibration verification procedures.

**Examples and Templates:**

The author provided several examples for validation deliverables, which serve as templates for the process per accreditation and CLIA requirements. Download the PDF now.

**Start With a Validation Master Plan**

Develop a VMP that will have at least the following components:

1. Equipment master file (EMF) – Lists all equipment, the equipment identity-serial number(s), manufacturers, specific functionalities, etc.
2. Validation protocol (VP) – A procedure for each type of equipment that outlines the principles and methodology involved, specifically including:
   A. Defined areas and systems to be validated (i.e., selection qualification that includes confirmation that the appropriate equipment was chosen);
   B. Installation qualifications (IQ) conform to all manufacturer requirements;
   C. Operational qualifications (OQ) include the training and competency assessments of all equipment operators;
   D. Performance qualifications (PQ) confirm results through other comparative methodologies by referring to accuracy, precision, and linearity studies; and
   E. Final approval identifies the approval process for each step throughout the validation procedure and includes the approval of the licensed director for the laboratory.
3. Validation master timeline (VMT) – A written projected timeline for the entire validation processes.

The entire validation processes shall embrace the basic principle of quality assurance in that any clinical diagnostic instrument should only be utilized for its intended use and incorporates the understanding that quality, safety, and efficacy are built into the equipment design. Furthermore, quality must be continuously monitored throughout the useful life of the equipment.

Equipment validation in clinical practice shall always incorporate the following good laboratory practice (GLP) and good clinical practice (GCP) premises:

1. Validate equipment prior to clinical use of patient testing – Each laboratory diagnostic instrument used to test or measure patient clinical specimens must be qualified and validated appropriately prior to its clinical use in patient care.
2. Complete approved deliverables for validation processes – The equipment qualification and validation process shall produce the following deliverables and approved accordingly:
   A. Selection qualification (SQ) – These are procedures that outline a process to ensure that the correct equipment has been selected and will be used as the manufacturer had intended it to be used. This is often a collaborative process that not only involves senior laboratory leadership but also others from the organization’s executive management team, materials management office, information technology personnel, and the finance/medical contracts office. The protocol should address the appropriate utilization and integration of the equipment, ensure that maintenance and technical support procedures are established, confirm the instrument’s specifications for functionality are met, and business requirements, including service contracts and instrument upgrades, are in place. And, as directed by CLIA guidelines, approval by the laboratory director is required.
   B. Operational qualification (OQ) – These procedures are performed by the vendor’s technical representative. They address environmental issues, instruction on equipment operation and backup, interfacing with the laboratory information system, preventive maintenance schedule(s), and presentation of any other pertinent information relevant to the equipment. This documents that vendor-specified procedures have been appropriately shared with the end users and assures proper use of the equipment as designated by the manufacturer.
   C. Performance qualification (PQ) – These procedures are performed by the equipment opera-
tors in collaboration with the technical service representative. This assures that the equipment performs as specified by demonstrating the accuracy, precision, and linearity of the tests involved. By using comparative methodologies, studies should show agreement of greater than 99.9 percent for both accuracy and precision. Linearity should demonstrate a correlation coefficient (r^2) of greater than 0.90 with a coefficient of variation (CV) of less than 5 percent.

D. Equipment master file (EMF) – This master file tracks all equipment and the placement of equipment. It is maintained by the laboratory and shared with the appropriate departments within the institution (biomedical facility, physical plant, facilities planning, and/or institutional engineering department). This assures that the equipment has been properly tagged, identified, and recorded for the institution. It also shows a maintenance schedule has been established as well as where and when an instrument is physically relocated and when/what equipment has been retired or is no longer operational.

E. Hazard analysis (HA) – This assessment is performed when new equipment is brought into the laboratory to ensure personnel and environmental safety pursuant to Occupational Safety and Health Administration (OSHA) requirements. Manufacturers are obligated to identify any potential equipment’s hazards (i.e., electrical shock, fire, explosion, and/ or radiation, etc.) label them appropriately to alert end users. Personnel training programs need to identify these hazards so that appropriate safety precautions are established and implemented as part of the operational protocols. Any hazardous waste products (biological, chemical, or radiation) must be identified with appropriate guidelines for handling and disposal. Any personal protective equipment (PPE) that might be required for operator protection should be clearly identified.

F. Equipment traceability matrix (ETM) – This procedure outlines what personnel/departments are required to be involved in the equipment acquisition process. This provides a clear audit trail for each step thus ensuring that the required deliverables are completed and signed off by the responsible parties and approved by the laboratory director.

All Medical Equipment including clinical laboratory analyzers will affect patient care or medical treatments if not validated appropriately. A structured and clear implementation plan will ensure success in meeting the objectives and compliant to the regulation requirements. By developing the Validation Master Plan (VMP), institutions will be able to leverage and simplify the tasks involved that ultimately assuring quality results and patient safety as well as managing risks that might affect the business operations thus impacting patient care at the institutions.

References
4. Clinical and Laboratory Standard Institute: GP 37 APPROVED Equipment Validation

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