

Measuring Value Initiative – Progress Report

Paul L. Epner, Taskforce Chair

The Coordinating Council for the Clinical Laboratory Workforce (CCCLW) is a coalition of more than a dozen laboratory organizations spanning the breadth of the field. Its primary mission is to increase the number of qualified clinical laboratory professionals. CCCLW's ability to fulfill its mission is being adversely impacted by the profession's lack of visibility to patients and providers, and by an almost singular focus on reducing laboratory costs, especially in clinical pathology. The emphasis on the clinical laboratory solely as a cost center is puzzling. Laboratory medicine accounts for less than 3% of national health expenditures in the United States, so even substantial cuts in laboratory-related expenditures would have little impact on the cost of health care nationally. However, the inappropriate ordering of tests, and the delay or misapplication of test results, can have significant and costly "downstream" impact on patient outcomes and the overall cost of health care.

This assertion is intuitive, yet largely unmeasured and unproven. A first step in assessing the value of laboratory medicine in patient care and outcomes would entail the development of corresponding measures. Accepted measures of value that laboratory medicine contributes, or could contribute, through its professionals and its technology, would be important to health system decision-makers in setting budgets and priorities. Data collected from appropriately validated measures would drive insights that could guide development of a balanced approach to the twin needs of operational efficiency, i.e. productivity and defect reduction, with clinical effectiveness, i.e. improved patient and system outcomes.

In 2014, the CCCLW began work on the development of such measures. A framework to assess the value of clinical laboratory professionals and technology is emerging, the result of a comprehensive literature search, a field survey of laboratory professionals, deliberation by an expert panel, and continued work by a small number of committed individuals following the conclusion of the expert panel. This report reviews the work that has been concluded thus far and describes the work that remains.

Literature Search

A 7-person subcommittee, led by Teresa Nadder, PhD, was charged with conducting a literature search to determine what potential measures of laboratory value could be found in peer-reviewed publications. The full report was delivered in December, 2015. An Executive Summary of that report is contained in Appendix 1. As expected, the peer-reviewed literature was sparse, although more than 70 publications were reviewed. The committee chose to describe its findings from the perspectives of key stakeholders or beneficiaries of the laboratories' results: clinicians, patients and families, the health system in which they operate, the national health system in aggregate, the public's health in their communities, pharmaceutical and device corporations and payers.

Benefits were derived that crossed many of the stakeholder groups. The value proposition was associated with the:

- information content of test results;
- consultative services on test utilization strategies;
- financial value associated with reduced costs of care or income generated for the health system from external activities of the laboratory;

September 4, 2016

- knowledge creation that improves the efficiency and effectiveness of care through the development of new technologies;
- strategic value as a contributor to decision-making on capital investments and the cost-effective, clinically appropriate use of new technologies; and
- improvements to the patient experience which increases their satisfaction with the health system.

The committee has begun preparation of a manuscript to be submitted to a peer-reviewed journal to support dissemination of their findings.

Survey

In January of 2016, a survey was developed and deployed to the members of several CCCLW organizations. The primary objective of the survey was to scan the landscape for evidence of value-driven initiatives or innovative thinking about laboratory value. As such, the goal was to obtain the greatest number of inputs as possible without regard to whether it was representative. The resultant convenience sample was used in entirety ($n=469$) with no attempt to identify and eliminate multiple respondents from the same institution.

Five questions were included in the survey to gather demographic information about the respondents. A broad range of laboratory sizes and settings were represented. Information about respondents is found in Appendix 2.

Respondents were asked to describe the context in which they operated by reacting to four statements about trends impacting the U.S. health system. This data is also shown in Appendix 2. Interestingly, the two statements that received the most consensus could be interpreted to conflict with each other. The statement "Our lab feels significant pressure to demonstrate our value to our institution's senior leadership" had a weighted average of 3.79/5.0 where 5 represents strongly agree and 1 represents strongly disagree. This suggests that laboratory professionals are not able to satisfy their systems with financial efficiency alone. However, the statement "Our lab feels significant pressure to cut costs" had an even higher weighted average of 3.92/5.0. This duality supports the anecdotal comments that the system asks for value, but looks primarily for cost reductions as its measure. The absence of broader measures of value seemingly contributes to the narrow perspective.

When asked if their institution had implemented some new process that clearly demonstrated the value of laboratory medicine to patients or the larger system, 239 responded. They indicated that the value delivered was, to varying degrees, associated with both the use of the technology, i.e. the test results, and the use of laboratory professionals. The replies could be aggregated into six categories:

- Appropriateness of Lab Testing, i.e. utilization management - 44 responses
- Infection Prevention and Therapy including Antibiotic Stewardship- 30 responses
- Operational/ Process Improvements- 22 responses
- Emergent Care: Diagnosis and Treatment and operations -20 responses
- Quality Assurance Systems -12 responses
- Patient Management and Support-5 responses

Respondents were also asked to describe measures they use to demonstrate value. Few new ideas emerged. The 164 responses fell into six groups, mirroring to a large degree the categories associated with their initiatives:

- Operational and process measures-57 responses

September 4, 2016

- Lab Test Utilization and Health Care Outcomes -37 responses
- Emergent Care: Diagnosis and Treatment and Operations-29 responses
- Infection Prevention and Therapy including Antibiotic Stewardship-27 responses
- Quality Assurance Systems -20 responses
- Patient and Health Care Staff Satisfaction Surveys- 7 responses
- Other miscellaneous - 7 responses

Finally, the survey provided participants an opportunity to imagine a program that would best demonstrate the value of laboratory medicine. Julie Gayken, retired Senior Director of Laboratory Services for Regions Hospital and HealthPartners in Minnesota, summarized the described attributes in the following seven statements:

1. Laboratory test orders would be appropriate for the purpose of use. Clinical appropriateness and associated clinical decision support would be defined and implemented collaboratively between laboratory and clinical professionals and patients.
2. Laboratory testing would be accurate and have proven clinical utility and effectiveness with safety nets for prevention of testing errors.
3. Laboratory Reports would be communicated to the ordering provider and patients as deemed necessary for effective and timely application in the care of the patient.
4. Laboratory results would be easy to access, read, interpret and document follow up. Co-ordination of care would be the goal, with real time access to laboratory professional clinical consultative support.
5. Safety nets with monitoring and support systems, whether manual or electronic, would be collaboratively developed and implemented. This would allow clinicians, laboratorians, healthcare staff and patients to easily do the correct process and make informed decisions.
6. All the needed actions and safety support would be appropriately funded with clear expectations for use and accountabilities. The balance measure of “cost effectiveness” would be applied to all initiatives.
7. Patients would be supported to allow easy engagement with the development of their care plans, setting expectations for quality of life and the “cause and effect” of their actions.

The full analysis of the open-ended questions by Julie can be found in Appendix 3.

Expert Panel

Following completion of the literature search and the survey analysis, an expert panel (EP) was convened. The participants can be found in Appendix 4. They represented multiple laboratory specialties, different settings, and a range of positions including administrators, scientists and physicians. Additionally, several non-laboratorians with expertise in measures, maturity models and general healthcare consulting joined the panel.

The agenda for the two-day meeting was ambitious:

- Introduction/Disclosures & Background
- Scope & Definitions
- Domains & Measures
- Framework & Model Development
- Deployment & Evaluation
- Wrap-up & Next steps

After a review of background information, the EP discussed and reached preliminary consensus to associate the output of their work with the label, *“High Value Laboratory Medicine.”* It was also decided that the final product

September 4, 2016

needed to map to both the National Quality Strategy and the Triple Aim to improve understanding with non-laboratorians.

The EP further determined that the profession's ability to describe its value is not sufficiently advanced to allow for the development of a robust set of discrete measures within the two days scheduled for this work. A decision to pursue development of a "maturity model." The work shifted to creating a framework with discrete domains and a hierarchy in which higher levels represented increased delivered value.

The meeting concluded with tentative domains (subsequently changed after the conclusion of the meeting):

1. Evidence-based Utilization Management
2. High Reliability & Patient Safety
3. Population Management
4. Leveraging Analytics
5. End-to-End Process Management
6. Generating/Disseminating Knowledge
7. Patient Engagement / Empowerment

For each domain, the EP defined five levels that were characterized by several attribute continuums:

1. Lab-centric to system-centric to patient-centric to patient/population-centric
2. Reactive to proactive
3. Silo'd to integrated
4. Performance evaluation derived from measuring internal processes to measuring outcomes

The EP adjourned with substantial work still needed. Descriptions of each hierarchical level for each domain were generated, but there was no sense that the work was finished. It was agreed that a smaller steering committee (shown in Appendix 4) would continue to meet and further develop the model. The incomplete tasks included finalizing domain names and developing operational descriptions of each level in each domain; creating a narrative that would explain the basis for the model and how it should be applied; and the development of a tool to aid an institution in assessing its current performance level with a visual read-out (spider diagram).

Current Status of Initiative

The steering committee has met several times and exchanged emails to further the work that remained to be done. No consensus has been achieved on the domains or the hierarchy, but progress continues to be made towards achieving the consensus.

Next Steps

The steering committee will continue to meet in order to complete the work product which was defined at the EP. This will include the following items:

1. Finalization of domain names
2. Development of domain definitions
3. Finalization of the descriptions of five hierarchical levels for each domain
4. Creation of an assessment tool with supporting narrative for laboratorians to use in determining their performance levels.
5. Development of a communications tool for laboratorians to use in communicating the results to the C-suite and non-laboratory healthcare professionals.

September 4, 2016

6. Develop of a plan for validating the framework
7. Preparation of a manuscript for an appropriate peer-reviewed publication to ensure review, debate and dissemination occurs.

Given the volunteer nature of the work without protected time, no timetable has been established, but it is hoped a draft of the manuscript and all work leading up to it can be completed in before the end of the year.

Appendix 1

Prepared for: Coordinating Council on the Clinical Laboratory
Workforce (CCCLW)

The Value of Laboratory Medicine: A Narrative Review of the Literature

Prepared by: Diane Davis, Denise Geiger, Roberta Madej, Teresa Nadder, Paramjit Sandu, Robert Schmidt, Steve Zibrat

TABLE OF CONTENTS

<u>EXECUTIVE SUMMARY</u>	<u>1</u>
<u>INTRODUCTION</u>	<u>4</u>
<u>VALUE OF LABORATORY MEDICINE TO THE CLINICIAN</u>	<u>6</u>
<u>VALUE OF LABORATORY MEDICINE TO THE PATIENT AND PATIENT'S FAMILY</u>	<u>22</u>
<u>VALUE OF LABORATORY MEDICINE TO THE PARENT ORGANIZATION</u>	<u>27</u>
<u>VALUE OF LABORATORY MEDICINE TO THE HEALTH CARE SYSTEM</u>	<u>32</u>
<u>VALUE OF LABORATORY MEDICINE AT PUBLIC HEALTH LEVEL</u>	<u>39</u>
<u>VALUE OF LABORATORY MEDICINE TO PHARMACEUTICAL INDUSTRY AND CMS</u>	<u>46</u>
<u>DISCUSSION</u>	<u>50</u>

EXECUTIVE SUMMARY

This report provides a narrative review of the current literature published from 2000 to 2015 on the value of laboratory medicine and presented to the CCCLW to contribute to their goal of identifying measures that would potentially tease apart the value of laboratory medicine from other health care services in achieving desired outcomes. The organization of the report is based on the perspectives of the following stakeholders of clinical laboratory services:

- Clinicians
- Patients and family members
- Parent organizations
- Healthcare systems
- Public health
- Pharmaceutical Industry
- Centers for Medicare & Medicaid Services

The working definition used in the development of this report for the value of laboratory medicine was patient health outcomes achieved per dollar spent. Laboratories affect value by making decisions that affect both outcomes and costs. Unfortunately, most studies on diagnostic tests focus on analytical or clinical performance. Very few studies produce data on patient outcomes except in very narrow situations such as the value of a particular test in a specific clinical situation. Though numerous publications addressed the need to identify strategies for defining the value of laboratory medicine, the literature is sparse with regards to the application of this definition. Common themes across the perspective of the stakeholders as determined by the literature are listed below.

Key Findings: Common Themes across Stakeholders' Perspectives

- Value through providing test results. The 2015 Institute of Medicine's report on Improving Diagnosis in Health Care notes that over the past 100 years, diagnostic testing has become a critical feature of standard medical practice. In addition to diagnostic information, the clinical laboratory test results indirectly affords value through providing management of and direction for therapy, prognoses, knowledge for research and development, and support for public health. Quality assurance and operational performance support the activity of providing test results.
 - Focusing on patient safety, healthcare professionals are showing increasing interest in the quality assurance of laboratory testing processes especially in the pre- and post-analytical phases of total testing phase (TTP) of laboratory testing. While the laboratory can and should contribute to minimizing these pre- and post-analytical delays, determination of laboratory value must be restricted to that which the laboratory can control.

- Laboratory medicine must take the lead in developing the studies of not just analytical accuracy but clinical utility that will provide the evidence that a test ordered in specific clinical situations will impact and improve patient outcomes.
 - Faster turnaround time (TAT) is often seen as desirable and has been a common theme in the literature for the past 30 years and cited as the preference that has driven much of the proliferation of point-of-care testing (POCT). Despite this ongoing “need for speed”, the evidence of improved outcomes that might result from a faster testing process has been contradictory.
- Value through consultation in test utilization strategies. Inclusion of laboratory services on diagnostic management teams (DMTs), tumor boards, and precision medicine consultations, improves patient outcomes and reduces the cost of health care. Studies designed to monitor requests for laboratory consultation and to use the information to identify opportunities for improvement are reported. Significant opportunities exist for laboratory professionals testing within molecular, genetic, and precision medicine to demonstrate value in assisting providers in diagnosing and treating patients with increasingly successful outcomes.
 - Financial value. Laboratories operate as a profit center when the hospital receives payments under a fee-for-service arrangement and operate as a cost center under prospective payment systems. In either case, efficient use of resources provides value to the organization. The value of the laboratory has been viewed in terms of the efficiency of the response to test requests.
 - Several different frameworks are available to evaluate laboratory performance and develop metrics for laboratory performance including financial perspective, the functional strategic perspective, the balanced scorecard, and the enterprise performance framework.
 - Ancillary services provide an opportunity for laboratories to escape commoditization and provide value by providing services to improve the effectiveness of testing. Much as manufacturers can increase value by providing services to help customers use their products effectively, laboratories can provide services to improve the effectiveness of testing and to be entrepreneurial with excess laboratory capacity and outreach.
 - Value through knowledge development.
 - The evolution of technology, molecular epidemiology, and bioinformatics, collectively, contributed to the rapid increase in value of laboratory services, especially in public health, since the 1960s. The impact on federal regulations from initiation of public health programs conveys value of laboratory medicine.
 - Advanced molecular testing has influenced health care associated infection rates, patient health outcomes, hospital length of stay, number of days in isolation, patient satisfaction, antibiotic stewardship, and health care economics, which can be used as

variables to measure the value of laboratory medicine and ultimately influence policy development affecting larger population units.

- The pharmaceutical industry is becoming increasingly dependent on laboratory tests (precision medicine) in the development of new drugs and the salvage or repurposing of therapeutics that had been abandoned prior to the pharmacogenomics developments. The FDA uses this data as a basis for regulatory determinations.
- Information generated from population-based surveillance programs enables the Centers for Disease Control and Prevention to develop practice guidelines for the prevention of antibiotic-resistant infections in healthcare settings, in the community, and in food. Dissemination of these guidelines resulted in decreases in health care associated infections. Data collected by laboratory medicine services have provided the impetus for the development of safe vaccines, standardization of methodologies, and providing an environment with less exposure to lead and second-hand smoking.
- Strategic value. Decisions on technology adoption, test menu choices, outsourcing, adoption of point-of-care testing, and design of a laboratory network have significant long-term effects on the organizations capabilities. Cost-saving testing management includes add-on tests, reflex testing/testing algorithms, discontinuing obsolete tests and preventing ordering without consultation. Laboratory services influence adjustments in hospital payments made by Center for Medicare and Medicaid Services for performance in the following quality domains: clinical process of care, patient experience of care, outcome domain, and efficiency domain.
- Value through patient satisfaction. Laboratories are important partners in improving the patient experience. Patient satisfaction is improved when services are offered in off-site convenient places and times. Further, patients are more satisfied when they can access their own lab results from anywhere electronically, and outcomes are likely improved because they become partners in their own health and compliance has been shown to improve when patients can directly access lab results. Clinical laboratory data is used in the Hospital Inpatient Quality Response Program which is intended to provide consumers with quality of care information to be used when making decisions about healthcare options.

Appendix 2

What best describes the laboratory/laboratories covered by these responses? (Choose all that apply)

Answered: 469 Skipped: 0

Answer Choices	Responses
▼ Core laboratory or other similar laboratory, i.e. multi-discipline centralized laboratory	50.75% 238
▼ Discipline specific laboratory - Chemistry	11.94% 56
▼ Discipline specific laboratory - Hematology	11.09% 52
▼ Discipline specific laboratory - Microbiology laboratory	16.42% 77
▼ Discipline specific laboratory - Cytology	9.17% 43
▼ Discipline specific laboratory - Molecular/Genetics	11.30% 53
▼ Discipline specific laboratory - Histology	6.61% 31
▼ Discipline specific laboratory - Blood Bank	13.22% 62
▼ Discipline specific laboratory - Public Health	7.46% 35
▼ Physician Office Laboratory	5.97% 28
▼ Clinic Laboratory	12.15% 57
▼ Other (please specify)	Responses 18.55% 87
Total Respondents: 469	

What is the best description of the setting where the respondent(s) work?

Answered: 469 Skipped: 0

Answer Choices	Responses
▼ Physician Office	4.05% 19
▼ Outpatient Clinic	2.13% 10
▼ Hospital under 200 beds	23.24% 109
▼ Hospital with 200-500 beds	18.98% 89
▼ Hospital over 500 beds	14.29% 67
▼ My responses are at a system level covering many or all of the above	7.25% 34
▼ Government (Veterans, State, Public Health, etc.) Facility	8.32% 39
▼ Reference lab, part of a large reference lab corporation or serving customers nationally	6.40% 30
▼ Independent lab serving a local region	6.82% 32
▼ Other (please specify)	Responses 8.53% 40
Total	469

How much do you agree or disagree with each of the following statements?

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree	Total	Weighted Average
The shift, FROM fee for service, e.g. "clinical laboratory fee schedule" reimbursed TO bundled, capitated or value-based reimbursement, is commanding significant attention from our parent organization.	18	27	131	142	84	402	3.61
Significant change in our laboratory will occur as a direct result of this reimbursement change.	18	29	135	146	74	402	3.57
Our lab feels significant pressure to demonstrate our value to our institution's senior leadership.	18	40	76	142	126	402	3.79
Our lab feels significant pressure to cut costs.	15	25	85	130	147	402	3.92

Appendix 3

Summary of CCCLW 2015 Lab Value Survey (Open-Ended Questions)

Review completed by Julie Gayken, MT(ASCP) CLC(AMT)

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Retired Senior Director of Lab Services, CLIAC member 2008 to 2012, LMBP Work group member, CLMA ICE program Assistant, CLMA Lab Compliance and Regulation Committee member.

February 27, 2016

Review and Summary Criteria:

- Responses coded per key categories
- Responses quantified per category
- Specific examples noted based on > 2 of same activity, measure or idea
- Inclusion of relevant information as determined by reviewer

Question	Responders	Activities/measures/Ideas
Value Initiatives- Q7	114	133
Performance Measures-Q10	112	184
Magic Wand Ideas-Q 11	183	305

VALUE INITIATIVES SUMMARY

Survey Question #7: We are seeking examples of initiatives where the value of laboratory medicine is readily apparent. The initiative could have originated in the laboratory, elsewhere in the institution or system, or with external partners such as outreach clients, however laboratory medicine value must have been acknowledged by non-laboratorians such as the senior leaders of your system. And the value must extend to patients or the system, i.e. it cannot be limited to measures of internal lab quality or department-specific cost effectiveness. Has your institution implemented a process that clearly demonstrated the value of laboratory medicine to patients or the larger system? If so, in just a few sentences, describe the initiative.

Reviewer's comment on question #7:

This question was intended to provide a snapshot of current and completed quality improvement initiatives that would enable the understanding of possible future eternal states that demonstrate the value of laboratory medicine in patient care and well-being.

It also gives a snapshot of the prioritization of lab leader's QI activities and demonstrates the transformation from lab-centric to collaborative patient-centric thinking. If you remove the traditional "Operational and Process Improvement" and "Quality Assurance Systems" sections,

74% of current state initiatives are focusing on collaborations between laboratorians and other health care professionals to jointly develop multi-disciplinary improvement initiatives.

It is somewhat surprising that there was not more patient involvement in these initiatives, but that should come with the push for shared decision making, involvement of patients in more satisfaction surveys and patient accountability for their own health and well-being.

The Infection prevention and therapy and antibiotic stewardship initiatives were most encouraging. The laboratory leaders appear to be dynamically partnering by researching and implementing new technologies for faster and more accurate information. The faster identification of microbes and the application of local antibiograms for targeted and more effective antimicrobial therapies was stated numerous times. This doesn't happen by chance, as the pathway to antibiotic stewardship is a new path which all stakeholders must travel together.

Even though there was only limited response about the use of genetic testing in diagnosis, prognosis and treatment, this new found knowledge and its application warrant mentioning. This is an evolving area that will require collaborative teams to understand and apply this new knowledge for better patient care and outcomes. Personalized medicine should also help to engage the patients at a more relevant level. We can only imagine where this path will take us.

Also encouraging is the perception that these initiatives did not just benefit from the laboratory data, but additionally from laboratorian participation.

▼ Data from laboratory test results was a significant factor in the initiative's success, but laboratory personnel were not very involved or their involvement was not very impactful.	11.72%	28
▼ Data from laboratory test results was not a significant factor in determining the change, but laboratory personnel contributed significant value.	5.02%	12
▼ Data from laboratory test results and laboratory personnel both served key roles in the initiative's success.	44.35%	106
▼ There were no major initiatives in the past two years that depended significantly on either data from laboratory test results or the involvement of laboratory personnel.	38.91%	93
Total		239

Aggregated Responses

Appropriateness of Lab Testing 44 responses-33%

- Utilization Focus
 - ✓ Diagnostic Teams Used to define appropriateness -13
 - ✓ Blood Transfusion Management -9
 - ✓ Evidence Based ordering algorithms used manually or electronically-8
 - ✓ Focus on send out (reference lab) testing orders -4

- ✓ Collaboration on outcomes for Diabetes management-3
- ✓ Consultation Services real-time or pre-order for genetic tests-2
- ✓ HPV and Cytology coordinated results reporting-2
- ✓ Consultation online and on demand for all testing-1
- ✓ Special transplant consultation-1
- ✓ Participation in public health and CDC sharing of info-1

Infection Prevention and Therapy including Antibiotic Stewardship- 30 responses -23%

- ✓ Positive blood culture rapid molecular testing to ID microbes added in lab -12 (verigene, Bio Fire)- Improved Turn-Around Time (TAT) and targeted antibiotic therapy
- ✓ Rapid microbe identification with Mass Spectrometry -4
- ✓ Improved TAT of microbes ID and targeted antibiotic therapy (MALDITOF, LC-MS/MS)
- ✓ MRSA Screen – pre op and on admission: less Hospital Acquired Infections(HAI)-4
- ✓ Blood Culture Contamination Rates reported and acted upon-3
- ✓ UTI prevention -1
- ✓ Use of Antibiotic Stewardship Teams for general Infection prevention and reduction in antibiotic effectiveness-2
- ✓ Viral sequencing technology added for viral therapy and bed management-2 (film array)
- ✓ Central Line infection prevention -1
- ✓ Use of 4th gen. of HIV test on Neg. rapid HIV test patients-1

Operational/ Process Improvements- 22 responses -17%

- ✓ Lab TATs reviewed and tracked per targets -4
- ✓ Promotion of lab's work to other Health care staff and organization -3
- ✓ Implemented outreach lab service to increase revenue -2
- ✓ IT integration between hospital and clinics -2
- ✓ Automation lines installed for specimen receipt/ prep/testing/ specimen retrieval-2 (decreased TAT)
- ✓ Decreased TAT for lab tests needed for patient discharge-2
- ✓ Centralized Value Analysis Committee to track costs/value -1
- ✓ Collaborated with Out Patient Cancer Center for on demand lab testing -1
- ✓ Non-punitive culture developed for error reporting and management-1
- ✓ Centralized lab service supports entire system -1
- ✓ Public Health lab provides free testing for targeted disease states to eliminate barriers-1
- ✓ Public Health labs partner with local hospital labs to provide Hepatitis and HCV testing-1
- ✓ Increased number of Point of Care coordinators to manage compliance to regulations-1

Emergent Care: Diagnosis and Treatment and operations -20 responses- 15%

- ✓ Chest pain biomarkers used to triage patients- Decreased TAT for Troponins-4

- ✓ Stroke diagnosis protocol with fast TAT INRs-6
- ✓ Sepsis Management with Lactic Acid, procalcitonin and rapid viral and microbe ID-8
- ✓ Over flow bed management with codes -1
- ✓ Lab testing in ED managed by lab and performed by lab staff-1

Quality Assurance Systems -12 responses 9 %

- ✓ LEAN, six sigma tools used for QI-3
- ✓ Sharing lab QA results with hospital Quality leaders and organization -3
- ✓ Public health labs certification-2
- ✓ Quality experts dedicated to lab-2
- ✓ QA “service recovery” program used for questionable lab results and delayed TATs-1
- ✓ Created new “Quality and Health Improvement Division of the Pathology Department-1

Patient Management and Support-5 responses -3%

- ✓ Shared patient stories of outcomes with organization-2
- ✓ Patient satisfaction survey used to direct support-1
- ✓ Lab results provided online, including POCT -1
- ✓ Patients made aware of drivers of their health per specific conditions -1

Reviewer's comment on question #7:

This question was intended to provide a snapshot of current and completed quality improvement initiatives that would enable the understanding of possible future eternal states that demonstrate the value of laboratory medicine in patient care and well-being.

It also gives a snapshot of the prioritization of lab leader's QI activities and demonstrates the transformation from lab-centric to collaborative patient-centric thinking. If you remove the traditional “Operational and Process Improvement” and “Quality Assurance Systems” sections, 74% of current state initiatives are focusing on collaborations between laboratorians and other health care professionals to jointly develop multi-disciplinary improvement initiatives.

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LIST OF PERFORMANCE MEASURES/METRICS AND SUMMARY

Survey Question #10: "List and provide a brief description of any qualitative or quantitative measures of impact on patient outcomes or system performance that has been used to determine your laboratory's performance with your organization's senior leadership."

Reviewer's comment on question #10:

Despite casting a wide net for existing innovations in measuring value, little new information emerged. Many responses were broadly stated with limited specific details. Measures were mostly qualitative based on the documented completion of the improvement activity and not necessarily the measurement of the effectiveness or efficacy of patient outcomes.

The blood transfusion management and the antibiotic stewardship measures are evolving to be relevant laboratory medicine measures. The transformational shift to laboratory information being considered a critical component of the diagnostic or treatment plan will need to addressed in order to establish its value in a measure or an outcome metric.

Of importance, many of the referenced activities were multi-disciplinary and collaborative. This indicates that lab does have a role in clinical outcomes that are being based on some form of standardized processes involving protocols and best practices for diagnosis of disease states.

Aggregated Responses

Operational and process measures-57 responses -31%

- Financials/ Economics/Efficiency/Justifications -28

- TAT reviews to target-18
(general lab tests-9, critical value tests-4, stats-2, AM rounding-1, Patient discharge-2)
- Pre-analytical Patient and specimen ID related-5
- Outpatient flow (e.g., wait times, queuing system) -6

Examples of Operational and process measures:

- ✓ TAT “in lab” per test with targeted goals: If variance is > 5 % increase in TAT, correction plan is done
- ✓ Reduction in Stat requests post implementation of auto validation of results
- ✓ Increased units of service and decreased costs
- ✓ Lab Total Cost of Care index comparison of area lab costs per patient, per specialty and per provider
- ✓ Billable tests per technical staff
- ✓ Gross contribution margin
- ✓ TAT of lab tests that contribute to faster discharge of patients impacting Length of Stay(LOS)
- ✓ TAT improvement after implementation of Outpatient clinic new testing
- ✓ Reports to Senior Leaders of impact to lab services and Patient care due to significant process changes
- ✓ # of lost or mislabeled specimens

Lab Test Utilization and Health Care Outcomes -37 responses- 20%

- Utilization based –total 24 responses
 - ✓ Blood Transfusion Management -9
 - ✓ General Statement of utilization review-7
 - ✓ Use of Diagnostic Teams -4
 - ✓ Other (e.g. genetic testing consultation for orders and cancer profiling)-4
- Health Outcome based – total 13 responses
 - ✓ Diabetes outcomes with glycemic control-2
 - ✓ General statements of better patient outcomes=11

Examples of Lab Utilization and Outcome measures:

- ✓ Lab staff representation of clinical teams (e.g., trauma, pulmonary, NICU, Stroke certification, Infection Prevention, Antibiotic Stewardship, Glycemic Control, Blood transfusions, Sepsis management)
- ✓ Units of Blood transfused per patient
- ✓ Blood product transfusion efficacy
- ✓ Cost effectiveness reports driving clinical focus on treatments directly related to specific lab results.
- ✓ Genetic Testing consultation for ordering decisions including clinical utility - tracking clinically significant interventions and cost reduction
- ✓ Community health project tracks changes in “basic health” for 1000 community members involved in life skills program.
- ✓ Patient Diabetes care status connected to # of lab test results in desired ranges.

Emergent Care: Diagnosis and Treatment and Operations-29 responses- 16%

- Emergency Department(ED) general TAT of lab results -9
- Sepsis management with Lactic Acid TAT -6
- Stroke management with INR TAT-7
- Chest Pain management with TAT for Troponins – 3
- Trauma support including Massive Transfusion Protocols (MTP)-4

Examples of Emergent Care Measures:

- ✓ Chest pain patient management with TAT for troponins: < 30 min
- ✓ Possible stroke patient management with TAT for INRs: <45 min (present to ED to result)
- ✓ MTPs TAT of products, appropriateness of transfusion, significant delays, effectiveness of communications and event.
- ✓ TAT of stat CSF gram stain

Infection Prevention and Therapy including Antibiotic Stewardship-27 responses-15%

- Faster and more directed therapy for infections and sepsis-13
 - ✓ Antibiotic stewardship(AS)
 - ✓ New rapid ID of microbes and effectiveness of drug use
 - ✓ Team approach to ID infections (UTI, Central line, pneumonia)
 - ✓ Decreased mortality for sepsis
 - ✓ Decreased LOS
 - ✓ Decreased Cost of care
- Decrease in colonization of microbes in hospital patients-(HAI) -6
 - ✓ New rapid molecular testing for surveillance of C. diff, MRSA, CRE, VRE
 - ✓ Decrease in mortality due to co- morbidities
 - ✓ Decrease in LOS
 - ✓ Decrease in cost of care
- Blood Culture Contamination Review and Management-4
- Other (hand hygiene)-4

Examples of Infection Prevention and Therapy including Antibiotic Stewardship Measures:

- ✓ Best practice and latest knowledge used for targeted antimicrobial therapy
- ✓ TAT of microbe ID reduced for better isolation management and decreased LOS
- ✓ # of interventions by pharmacy to correct antibiotic therapy
- ✓ Antimicrobial units /patient /day
- ✓ Cost of antimicrobial agents per patient episode
- ✓ Use of Antibiograms in suspect sepsis or pneumonia therapy decisions
- ✓ Sepsis mortality rates and associated LOS and cost
- ✓ Active surveillance for patient colonization of MRSA, VRE, ESBL producers, depressed Amp C producers, and CRE resulting in decreased patient to patient transmissions
- ✓ TAT of new rapid ID on positive blood cultures with direct communication to AS team reduces LOS and cost.

- ✓ Blood Culture contamination rate with associated reporting of possible contaminants allows management of under or over treatment.

Quality Assurance Systems -20 responses- 11%

- General Statements of use of quality measures

Examples of Quality System Measures:

- ✓ # of corrected reports and follow up with staff
- ✓ pre and post analytical quality parameters with specific targets
- ✓ Proficiency testing results and follow up
- ✓ Compliance to standards from accreditations and certifications

Patient and Health Care Staff Satisfaction Surveys- 7 responses 4%

- General statements of use

Other miscellaneous - 7 responses- 4%

MAGIC WAND IDEAS FOR VALUE AND SUMMARY

Survey question #11: If you could “wave a magic wand” and launch a program that would best demonstrate the potential value of laboratory medicine to improve patient outcomes, or healthsystem performance, what would it be? (Don’t worry about cost or feasibility.)

Reviewer’s comment on question #11:

This question was intended to help identify potential laboratory medicine domains that would impact patient health and well-being outcomes

The rich “wish list” that the responders provided have been aggregated according to the initial proposed domains and should help guide the definition of the aim/actions, so therefore, it is best, in this reviewer’s opinion, to provide a summary of possible broad and relevant aims/actions.

1. *Laboratory test orders should be appropriate for the purpose of use. Clinical appropriateness and associated clinical decision support should be defined and implemented collaboratively between laboratory and clinical professionals and patients.*
2. *Laboratory testing should be accurate and have proven clinical utility and effectiveness with safety nets for prevention of testing errors.*
3. *Laboratory Reports should be communicated to the ordering provider and patients as deemed necessary for effective and timely application in the care of the patient.*

4. *Laboratory results should be easy to access, read, interpret and document follow up. Co-ordination of care should be the outcome with real time access to laboratory professional clinical consultative support.*
5. *Safety nets with monitoring and support systems, whether manual or electronic, should be collaboratively developed and implemented. This will allow clinicians, laboratorians, healthcare staff and patients to easily do the correct process and make informed decisions.*
6. *All the needed actions and safety support should be appropriately funded with clear expectations for use and accountabilities. The balance measure of “cost effectiveness” should be applied to all initiatives.*
7. *Patients should be supported to allow easy engagement with the development of their care plans, setting expectations for quality of life and the “cause and effect” of their actions.*

Aggregated Responses

Appropriateness of test orders- diagnosis and treatment driven

The diagnostic process currently uses laboratory information as deemed necessary by the ordering clinician/provider. The challenge is in the support for the decision making by the ordering providers. The clinical significance of the information provided by the test result and its application for enhancing the diagnosis and treatment care plan is not always known or considered.

Ideas/ programs to support the link between diagnosis and treatment and the appropriate lab test orders:

- Clinical significance is needed for all tests with electronic alerts for orders
- Lab results linked to desired outcomes generate automatic guidelines for orders and use
- Ongoing education is needed for providers on best practices of use of lab information
- Electronic algorithm built by lab specialists should be based on clinical status, suspected or confirmed diagnosis, previous test results and expected health outcomes
- Clinician directed utilization programs should use best practices
- Decision support software, based on medical staff approved guidelines, protocols, can be used for test ordering
- Genomic profiling and use of this personalized information can be done on DNA extraction with cell transfer from patient's biopsy material
- Institute a respiratory virus panel for faster diagnosis
- Provide feedback to specialty based clinicians on lab tests ordered per diagnosis, per complaint and empower the specialties to set up specialty guidelines for lab use.
- Review board of laboratory medicine and medicine for review of lab utilization including focused event tracking of optimized care and proactive prevention of adverse events.
- Formulary for disease state use of lab tests
- Need disease specific designations to link to lab impact
- Collaborative clinical diagnostic teams set lab usage for challenging cases

- There needs to be help for development of clinical protocols which include the most efficient and effective lab test batteries
- Laboratory Medicine clinical staff should be represented in all clinical committees, (i.e., trauma, pulmonary, NICU, Stroke team, Infection prevention, Antibiotic Stewardship, Glycemic Management, Transfusion Committee, Order set development, Critical care, surgery, tumor boards)

Appropriateness of test orders- wellness and prevention driven

Wellness and well-being can be defined as the patient health status that provides reasonable freedom from chronic complaints, conditions and concerns that impact the patient's expected quality of life and risk for future disease states.

Ideas/programs to support the link between the chronic conditions, risk assessments and prevention of future disease states:

- Provide sexually transmitted disease screening for high risk patients
- Integrate public health labs to create a dynamic health information exchange to assess population risks
- Obtain health statistics and disease surveillance with lab tests included and track management of patients for significant changes in mortality and morbidity.
- Use regional anti-biograms and share MDRO data associated with colonized patients between acute care and long term care institutions.
- Meningitis/ Encephalitis PCR testing on one CSF per patient to improve outcomes and infection prevention.
- Ongoing education of clinicians and health care staff to know and understand the latest advances in diagnostic lab testing and clinical utility.
- Develop robust system of data analyses and data bases for lab testing to determine efficacy of lab test information for wellness screening and disease prevention
- Establish worldwide electronic health information service that can be accessed by anyone in regards to patient care and wellness per population
- Public health data needs to be integrated with private healthcare system data to determine the state of the environment and its population

Provide accurate, timely and cost effective test information

Laboratory leaders traditionally are focused on providing accurate, timely and cost effective test results.

Ideas/ programs to support the link to accurate, timely and cost effective results:

- Template for performance tracking in labs
- Online performance measure dashboard for labs with real time business intelligence
- Training for labs on key performance indicators and the importance of tracking quality measures
- Comprehensive quality program for pre-analytic, analytic and post analytic processes
- Continue to implement instrumentation that is more automated and state of the art to provide better technology and results
- Use Multiplex testing for more accuracy

- Ensure that non-lab testing staff are compliant to requirements for testing processes based on standardized operating policies and procedures
- Set TAT targets based on clinical process needs and monitor
- Routinely perform Return on Investment (ROI) on state of the art resources needed for instrumentation, work environment, personnel expertise and compensation.
- Install automation systems that improve test TAT

Communication of lab results for co-ordination of care

Co-ordination of patient care services, including lab information, is a high priority for patient safety. This co-ordination includes communication of results, easy access of lab results and effective and timely follow up.

Ideas/ programs to link effective and efficient communication of lab result follow up:

- Response system is needed that alerts when test results are read/ interpreted and deemed acceptable
- Provide lab results as quickly as possible
- Define a “quality lab result”
- Develop and use a computer program that tracks every time a health care worker looked at a lab result what interventions were then taken
- Integrate hospital and outpatient results
- Electronic medical record that is user friendly, searchable, easily customizable that can be used to order labs, and see lab results and act upon lab results
- Allow medical records to be integrated with multiple health care systems so that all involved in patient’s care can see the lab results and information in real time

Lab result follow up with interpretation and application support

Appropriate result interpretation starts with appropriate test orders. Therefore, the responses for lab test ordering from above also apply to result follow up. The difference in the following responses is the actual support for follow up.

Ideas/ programs to support enhanced result interpretation and application:

- IT solution for on demand lab consultation
- Tele medicine technology used for real time result interpretation
- Automated “lab result interpretation hotline” provided by clinical pathologists and technical staff specialists
- Team rounding including lab representatives
- Interpretive reports that guide the application of the information and suggest next steps
- Links to references of clinical significance and clinical utility
- Ongoing education provided to clinicians on changes that make lab results more sensitive, specific and better predictive values including harmonization of results

Patient involvement in their own care and well being

Patients have become more knowledgeable about their own health and well-being with access to the internet information.

Healthcare systems and clinicians are supporting shared decision making and payers and providers of care are encouraging patient accountability for health and well-being.

Ideas of programs from the survey to support and challenge the need to empower patients to become partners in their own care are as follows:

- More patient friendly communication of lab results
- Doctors should educate patients on why they are ordering lab tests
- Explain to patients the benefit of the lab testing and help patients learn how to ask for lab test information from their providers
- Patients should have choice of the lab services that they want
- Access to lab information and application to health care
- Ask the patient about concerns and questions

Patient Safety and Laboratory Medicine

Patient safety is a healthcare system and government goal. Adverse events are tracked with action plans for improvements as part of the accreditation status.

Ideas/ programs to support patient safety:

- Mandatory Root Cause Analysis (RCA) for moderate and high impact adverse events
- Demonstrate risk to systems/ processes/ outcomes from reduced funding for QA resources
- Calculate the liability and other impacts on patients due to wrong diagnosis
- Use ROI to measure prevention of patient or population adverse outcomes

Appendix 4

Expert Panelists

- **Erik Baldwin** MBA, MT(ASCP)DLM^{CM}, FACHE, CPHQ , Director of Accreditation, Regulation and Licensure for the Mid-Atlantic Region, Kaiser
- **Adam Birks** CLS, MLS (ASCP), Laboratory Director, Kalispell Regional Medical Center Laboratory
- **Michael Davis**, MS, MBA, Principal at Davis Business Advisory, LLC
- **Paul Epner**, MBA, M.Ed. Executive Vice President, Society to Improve Diagnosis in Medicine
- **Eleanor Herriman**, M.D., M.B.A., Chief Medical Informatics Officer, Viewics, Inc.
- **Chris Hubble**, MD, Consultant at Healthcare Performance Improvement (HPI)
- **Brian R. Jackson**, MD, MS, Vice President and Chief Medical Informatics Officer, ARUP Laboratories Assoc. Professor of Pathology (Clinical), University of Utah
- **David D. Koch**, Ph.D., DABCC, FACB, Professor of Pathology, Emory University and Director of Clinical Chemistry, Toxicology, and Point-of-Care Testing, Grady Memorial Hospital
- **Diana L. Kremitiske** MHA, MS, MT(ASCP), VP Laboratory Operations, Geisinger Health System
- **Bozena Labuda**, MT(ASCP), CHS(ABHI), Manager, Histocompatibility Laboratory, Histocompatibility & Immunogenetics Laboratory, Gift of Hope Organ & Tissue Donor Network
- **Andrew Lyzenga**, Senior Director, Quality Measurement, National Quality Forum
- **Susan Morris**, MPH, MLS(ASCP)^{CM}, Patient Safety Officer, St. Luke's Magic Valley Medical Center
- **Elissa Passiment**, M.Ed., Executive Vice President of the American Society for Clinical Laboratory Science (ASCLS)
- **Edward J. Peterson, Jr.**, MBA, MT(ASCP), Director of Laboratories, Barnes-Jewish Hospital
- **Khosrow Shobotani**, Chief Executive Officer, TriCore Reference Laboratories
- **Michele Smith**, MS, SCT(ASCP), Program Director, Cytotechnology Program; Manager, Cytology Services, University of Wisconsin-Madison, Wisconsin State Laboratory of Hygiene
- **Sam Terese**, MBA, MT(ASCP), Chief Executive Officer and President of PCL Alverno
- **Eva Wojcik**, MD, Chair of Pathology, Department of Pathology and Urology, Medical Director of Clinical Laboratories, Loyola University Medical Center

Steering Committee

- **Michael Davis**, MS, MBA, Principal at Davis Business Advisory, LLC
- **Paul Epner**, MBA, M.Ed. Executive Vice President, Society to Improve Diagnosis in Medicine
- **Julie Gayken**, MT(ASCP), CLC(AMT), Senior Director of Laboratory Services (retired), HealthPartners (Minnesota)
- **Chris Hubble**, MD, Consultant at Healthcare Performance Improvement (HPI)
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