

The Present & Future of Laboratory Medicine

An Ongoing Analysis

A Life Saved

- Laboratory professionals making a difference
- The story of a nine year old, sick little boy
- How we helped
- His family's visit to the laboratory
 - His mother wanted to make something positive come out of her son's illness and
 - Help educate others about the about the "hidden spokes" (us) who should be seen and heard

CDC Impetus

- Concerns about cost of health care
- Need for improvement of quality and safety
- Call for systematic reviews of evidence on the effectiveness of health services
 - Needed to link evidence and clinical decision making, since individual studies rarely provide definitive answers to clinical questions

Laboratory Medicine: A National Status Report - 2007

- **Value of laboratory medicine to the U.S. health care system**
- **Market profile of the laboratory medicine sector**
- **Laboratory medicine workforce**
- **Quality and the total testing process in the clinical laboratory**
- **Quality systems and performance measurement**
- Laboratory information systems
- Federal regulatory oversight of laboratory medicine
- Reimbursement for laboratory medicine

Market Profile Of The Laboratory Medicine Sector

- Based on 2007 data from the Centers for Medicare and Medicaid (CMS) Online Survey, Certification, and Reporting (OSCAR) database, CDC estimates that:
 - Approximately 6.8 billion laboratory tests are performed annually in the U.S.
 - Laboratory testing revenues were a projected \$52 billion in 2007.

Market Profile Of The Laboratory Medicine Sector

- Clinical pathology comprises 66% of all laboratory tests and \$32 billion in revenue.
- Anatomic pathology and cytology account for 23% of laboratory tests and \$11 billion in revenue.
- Molecular and esoteric (e.g., low volume tests such as those for rare diseases) testing account for 8% of laboratory tests and \$4 billion in revenue.
- Drugs of abuse testing accounts for 3% of laboratory tests and \$1.5 billion in revenue.

Market Profile Of The Laboratory Medicine Sector

- More than 4,000 laboratory tests are available for clinical use. Of the 1,162 tests that are reimbursed by Medicare, about 500 are performed regularly.
- The number of genetic tests is growing. An estimated 1,430 diseases are now detectable using genetic testing; of these, an estimated 287 are tested only in research settings.

Market Profile Of The Laboratory Medicine Sector

- The number of Clinical Laboratory Improvement Amendment (CLIA)-certified laboratories has grown to exceed 200,000 in 2007.
 - Physician office laboratories represent 54% of clinical laboratories in this sector, four out of five of which are certified to perform only waived and/or provider-performed microscopy tests

- Hospital-based laboratories account for the largest proportion of total testing volume (55%) and generate the highest proportion of total testing revenue (54%), projected at \$28.4 billion for 2007.
- From 1999 to 2006, the average annual growth rate of both test volume and revenue was approximately 6-7%.
- In 2006, privately-owned laboratories generated revenues of \$15.5 billion (32% of total laboratory testing revenue that year).

Market Profile Of The Laboratory Medicine Sector

- Consumer directed testing is a key area for market growth. In 2004, 10-15% of hospital and commercial clinical laboratories offered some form of direct access testing.
- Laboratories should be prepared to assume a greater advisory role and provide other support to promote informed self care by consumers.

Value Of Laboratory Medicine To The U.S. Health Care System

- Laboratory testing has a major effect on clinical decisions,
 - provides physicians, nurses, etc. with information that aids in the prevention, diagnosis, treatment, and management of disease.
- Despite this scope of influence, spending on laboratory services accounts for only 2.3% of U.S. health care expenditures and 2% of Medicare expenditures.

Value Of Laboratory Medicine To The U.S. Health Care System

- Laboratory tests provide objective data about patient health that:
 - enable screening for risk factors,
 - accurate and early diagnosis,
 - determination of disease severity and likelihood of recovery,
 - selection and monitoring of treatment, and
 - evaluation of potential adverse outcomes.

Value Of Laboratory Medicine To The U.S. Health Care System

- Information provided by laboratory testing is critical for:
 - Maintaining quality and safety, including the prevention of adverse reactions.
 - Managing medication:
 - Provides information for maintaining optimum drug levels,
 - Helps to detect and recover from medication errors, and
 - Generates genetic information to guide personalized prescribing.

Value Of Laboratory Medicine To The U.S. Health Care System

- Some laboratory tests are vital to patient self management of chronic conditions.
- Laboratories protect the blood supply from pathogens and accurately match patients and blood products.

Value Of Laboratory Medicine To The U.S. Health Care System

- Services provided by clinical laboratories are critical to public health at the individual and population levels by identifying:
 - nosocomial infections,
 - antimicrobial resistance,
 - infectious disease outbreaks,
 - exposure to toxic substances, and
 - chemical and biological threats.

Value Of Laboratory Medicine To The U.S. Health Care System

- Laboratories also help to mitigate the effects of natural disasters by:
 - Enabling rapid turnaround of tests used during triage and emergency care
 - Providing tests to confirm the presence of communicable diseases that threaten the population.

Value Of Laboratory Medicine To The U.S. Health Care System

- Laboratory medicine supports the practice of evidence-based medicine
- Our services supply the evidence
- It is being incorporated into clinical practice guidelines, so practitioners and patients can make informed decisions about individuals' health care in specific circumstances.

Value Of Laboratory Medicine To The U.S. Health Care System

- Laboratory testing is one of several important indicators for assessing quality of care, particularly for national priority health conditions such as diabetes, heart failure, and colon cancer.
- Laboratory data can be used in support of value-based purchasing.

Value Of Laboratory Medicine To The U.S. Health Care System

- Greater attention by providers and payers to evidence-based medicine, practice guidelines, and quality indicators is contributing to more appropriate use of laboratory tests, and could diminish both overuse and underuse of tests.

Value Of Laboratory Medicine To The U.S. Health Care System

- There is a growing evidence base for the cost-effectiveness of laboratory tests
- This evidence is helping to inform appropriateness of test selection and sequencing, technology acquisition decisions, formulary design (including for pharmacogenomic-mediated therapies), and screening and other population-based interventions.

Laboratory Medicine Workforce

- The workforce is diverse and includes:
 - pathologists,
 - doctoral-level laboratory scientists,
 - technologists/scientists, and
 - technicians,
- Responsibilities include managing and applying evidence-based, scientific testing techniques to support patient care and protect against public health threats.

Laboratory Medicine Workforce

- However, there is growing concern regarding shortages in the number of laboratory professionals entering the workforce. The shortage could become pronounced with the forthcoming retirement of many laboratorians.
- At the same time, the demand for laboratory services continues to increase. Innovative technologies are changing the practice of laboratory medicine, educational requirements and staff qualifications.

Laboratory Medicine Workforce

- In 2005, there were an estimated 19,339 pathologists in the U.S., including 80% in community practice.
- Minorities are under-represented in the discipline of pathology, with 10% identified as Asian, 3% Hispanic, and 1% African American.
- Slightly more than half of pathology residents are female.

Laboratory Medicine Workforce

- An estimated 160,760 medical technologists/scientists (including cytotechnologists) and 144,710 technicians were employed in the U.S. in 2006.
- While nearly three-fourths of this workforce is female, it is more representative of the diverse ethnic makeup of the population, i.e., 12% Asian, 11% African American, and 7% Hispanic.
- By type of region, 58% of technologists/scientists work in an urban setting, 24% in suburban, and 18% in rural.

Laboratory Medicine Workforce

- The number of technologist/scientist and technician education programs has declined by more than 50% since 1970, with the most dramatic decline in technologist/scientist programs,
 - 71% closed between 1970 and 2007.
- In contrast, the number of phlebotomy training programs increased six-fold from 1987 to 2003.

Laboratory Medicine Workforce

- Current enrollment in specialized technologist/scientist and technician educational programs is lowest in blood banking and histotechnology.
- Recent recruiting efforts appear to be effective, specifically those targeted at recruiting minorities and males.

Laboratory Medicine Workforce

- The shortage of technologists/scientists and technicians is expected to worsen over the next decade with demographic changes and retirements.
- Although personnel vacancies were highest in 2000 (11-22%), they remained steady from 2002 to 2005 at an annual rate of 4-7%.
- Vacancies vary according to staff position, laboratory type and size, and geographic location.

Laboratory Medicine Workforce

- Technological advances will change the qualifications required of the next generation of laboratory professionals. The laboratory sector needs to clearly redefine staffing qualifications and workforce level requirements accordingly.
- ASCLS fully understands this
 - Impetus for Levels of Practice study and model
 - <http://www.ascls.org/currentevents/index1.asp>

Quality And The Total Testing Process In The Clinical Laboratory

- Chief issues affecting quality include poor communication and insufficient knowledge of tests that occur most often during test selection/ordering and interpretation of results.
- Common errors in clinical and anatomic pathology involve patient and/or specimen misidentification, specimen collection errors, and specimen contamination.

Quality And The Total Testing Process In The Clinical Laboratory

- Test turnaround time and notification of critical values are frequently cited for ratings of below-average to poor in customer satisfaction surveys.

Quality And The Total Testing Process In The Clinical Laboratory

- Lack of uniformity and standardization of clinical pathology test values among manufacturers hinders implementation of laboratory-based guidelines, which require method-dependent decision limits.

Quality And The Total Testing Process In The Clinical Laboratory

- Heterogeneity of test values also makes it difficult for clinicians to work in an integrated health system where more than one testing method is being used, or to address the needs of special patient populations.

Quality And The Total Testing Process In The Clinical Laboratory

- Laboratorian consultations are standard practice and reimbursed for anatomic pathology, but not as much for clinical and molecular pathology.
 - The primary barriers to interpretive consultations in clinical pathology reports are lack of reimbursement for such consultations and the shortage of subspecialty expertise.
- Expanded consultation services to clinicians would contribute to improved patient care and outcomes.

Quality And The Total Testing Process In The Clinical Laboratory

- Quality control (QC), performance evaluation, and test reproducibility standards to minimize diagnostic discrepancies and errors have been better defined and applied in clinical pathology than in anatomic pathology. Anatomic pathology needs to do the same.

Quality And The Total Testing Process In The Clinical Laboratory

- Standardization of data elements and report formats for all laboratory tests is necessary to improve physician comprehension and use of results as well as to integrate report data into clinical practice information technology applications.
- Better use of graphical displays in results reports may be especially important for new proteomic and genetic tests.

Quality And The Total Testing Process In The Clinical Laboratory

- Point-of-care testing (POCT) has the potential to significantly enhance the quality of care,
- Additional research is needed to identify the best methods for integrating POCT into daily clinical processes and improving its accuracy as needed.
- Operators of POCT devices must be trained appropriately in testing practices.

Quality Systems And Performance Measurement

- Achieving consistently high levels of quality in laboratory medicine calls for moving beyond stand-alone, analytic-focused, QC, quality assurance (QA), and proficiency testing (PT) activities.
- It requires more comprehensive quality management systems (QMS), such as those espoused in ISO 9001:2000 and ISO 15189:2003 standards.

Quality Systems And Performance Measurement

- Continuous quality improvement, Toyota “lean” production, Six Sigma, and failure mode and effects analysis are strategic tools for implementing QMS that are realizing benefits among early adopters, from small physician office laboratories to large reference laboratories.

Quality And The Total Testing Process In The Clinical Laboratory

- There are studies showing:
 - Use of continuous quality improvement and Six Sigma has contributed to financial savings and decreased turnaround time
 - Lean production has improved test quality and reduced errors,
 - Failure mode and effects analysis has decreased time to report critical laboratory values.

Quality Systems And Performance Measurement

- QMS has been most broadly adopted in transfusion medicine to meet Food and Drug Administration (FDA) requirements.
- However, adoption of QMS more broadly among laboratories should increase as CMS and accreditation organizations incorporate these standards into their requirements.
- Obstacles to implementation of QMS that must be addressed include resistance to culture change, lack of leadership and staff commitment to QMS, and insufficient funding of QMS activities.

Quality Systems And Performance Measurement

- Aside from PT, CLIA provisions have emphasized structural policies, procedures, and documentation requirements as a condition for accreditation and certification.
- Process measures to assess quality in the TTP remain relatively underdeveloped. Existing ones have not been uniformly defined or assessed for generalizability, and are subject to wide variation in their implementation.

Quality Systems And Performance Measurement

- Substantial work is needed to standardize indicators for pre- and postanalytic process related performance measures.
- Data collection, analysis, and reporting methods also need to be standardized.
- Research on laboratory performance has been limited by its focus on the larger, hospital based laboratories. Further research is needed examine the challenges faced by smaller laboratories and physician office laboratories when implementing process-related performance measurement and quality improvement programs.

Quality Systems And Performance Measurement

- A small body of evidence addresses the downstream clinical and economic impacts of particular tests.
- The lack of substantive research on the impact of laboratory testing restrains the demonstration of the value of laboratory medicine.

Other Initiatives

- Development of evidence-based methods to identify and evaluate Best Practices in Laboratory Medicine.
- Network of laboratories and partnerships with key stakeholders in laboratory medicine to support identification and foster adoption of evidence-based Best Practices.
- A report reviewing proficiency testing (PT) and the regulatory, educational, and quality improvement objectives of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)

- To learn more about participating in the pilot test network, click here:
<http://wwwn.cdc.gov/dls/bestpractices/participation.aspx>

Real Pros: Laboratory Techs Play Crucial Role

- By **JOHN HONG**
Published April 16, 2009 in issue 0815 of the Hook
- I like knowing the laboratory professionals personally. That way I can call when I have questions about ordering a test or when a result seems odd. Sometimes, a test needs to be re-run because the results just don't fit the clinical picture.



Real Pros

- Because my dad was a pathologist, I have always been around a microscope. (I lived under a microscope now that I think about it!)
- Because my dad was a pathologist, I have always been around a microscope. (I lived under a microscope now that I think about it!)
- Lab tests are often a vital part of a medical diagnosis.

Real Pros

- If lab professionals are not top-notch, well, it is likely the results will be incorrect, which could potentially be catastrophic.
- Could you imagine if your lab tests missed that you are iron-deficient anemic? You go about your business as your stomach ulcer continues to bleed, and then one day you die.
- Or suppose your blood cultures are incorrectly reported to have deadly bacteria, and your doctor (having been led astray) prescribes a ton of unnecessary antibiotics?

Real Pros

- Getting accurate results in the proper time frame is really important. Many times, I have a patient wait for the lab results before starting a new medication.
- For example, if a medicine can't be used with slow kidneys or liver problems, the lab is essential in the healthcare process.
- The doctor might have several possible diagnoses and need help from the lab.
- So lab folks play an important role in solving medical puzzles.

Real Pros

- Lab folks give doctors information to save lives, such as confirmation of bacterial meningitis or if a particular antibiotic will treat the particular strain of pneumonia.
- Laboratory professionals discover good news such as, "You are pregnant." Or bad news such as, "You are pregnant!"

Real Pros

- If someone has an important lab test like a new case of HIV, a lab professional calls the doctor to ensure good patient care. So lab pros do make a significant contribution to society and healthcare.
- If you have surgery, who do you think analyzes the removed organs and tissues?

Real Pros

- If there is a community outbreak, who do you think identifies the bug and finds out what can treat it?
- Who is involved in quality control of hospitals to prevent spreading disease?
- Don't call Ghostbusters. Call the lab professionals.

- My father, the retired pathologist, says the hospital is only as good as its laboratory professionals. And father... knows best.

Laboratory Information Systems

- The extent of LIS adoption and capabilities varies widely.
- While integrated delivery systems and large laboratories rely on LIS for many aspects of laboratory testing, physician office laboratories and smaller laboratories primarily use the LIS to facilitate compliance with CLIA requirements (e.g., QC, PT, QA, patient test management). (is this true?)

Laboratory Information Systems

- Further progress in integrating laboratory data more fully with clinical practice applications cannot be realized unless laboratories, health care organizations, vendors, and others stakeholders resolve differences in data interchange and terminology standards.

Laboratory Information Systems

- Enabling CPOE, decision support systems, and electronic health record applications with laboratory data in real time requires continued development of rule-based algorithms capable of generating and integrating accurate alerts, reminders, order sets, results reports, and a list of differential diagnoses based on patient signs, symptoms, and characteristics.

Federal Regulatory Oversight Of Laboratory Medicine

- Technological advances have made laboratory tests easier to use and less subject to user error, resulting in considerable growth in the number of waived tests from 9 tests in 1993 to more than 1,600 test systems and 76 analytes in 2007.
- CMS study found that some certificate of waiver facilities perform tests beyond the approved level of complexity.

Federal Regulatory Oversight Of Laboratory Medicine

- For non-waived testing, available evidence on the long-term impact of PT on laboratory performance is limited, and findings of existing studies are confounded by limited comparable data from CMS and survey organizations and other methodological shortcomings.
- Existing studies indicate generally improved performance in recent years, although some failure rates remain unacceptably high.

Federal Regulatory Oversight Of Laboratory Medicine

- While laboratories' flexibility to self-determine QC procedures is desirable, several factors may contribute to the inconsistencies in implementing this practice.
- CMS, the Clinical and Laboratory and Standards Institute, and other stakeholders are developing evaluation protocols that will outline principles for validation and provide laboratories with scientific guidance on the development of QC procedures for specific testing technologies and environments.

Federal Regulatory Oversight Of Laboratory Medicine

- Only a small number of genetic tests are regulated as in vitro diagnostics subject to FDA premarket review for safety and efficacy (via the 510(k) or pre-market approval routes).
- Most genetic tests are developed in-house by laboratories and are regulated under CLIA general provisions. This framework may be insufficient for the level of efficacy and protection sought for many tests by clinicians and patients, and creates incentives for genetic tests to be categorized as laboratory-developed tests and not be subject to the 510(k) or premarket approval routes associated with FDA-regulated tests.

Federal Regulatory Oversight Of Laboratory Medicine

- Recent guidance documents issued by FDA clarify its oversight of in vitro diagnostic multivariate index assays and analyte specific reagents (the active ingredients used in some laboratory-developed tests).
- This guidance indicates a noteworthy assertion of oversight that exposes the small but growing area of highly complex genetic testing to greater scrutiny usually associated with premarket review processes.

Reimbursement For Laboratory Medicine

- Difficulty in acquiring coverage, appropriate coding, and adequate payment can pose significant hurdles in the use of laboratory testing and decreased incentives for laboratories and test manufacturers to engage in further test development.

Reimbursement For Laboratory Medicine

- The Medicare program exerts the strongest influence on laboratory services payment for all U.S. payers.
- All public payers and approximately 67% of private payers use Medicare's payment methodologies as the basis for their own and as tools for negotiating discounts with providers.
- Suboptimal practices and other shortcomings in the Medicare reimbursement system for laboratory testing affect other public and private sector payers in the U.S. health system.
- Redesign of the current Medicare payment system for laboratory services is needed in order to meet the growing scientific, technical, clinical, and economic challenges of the U.S. health care system.

Reimbursement For Laboratory Medicine

- Continued use of 56 different fee schedules across the U.S. is inefficient and unnecessarily complex.
- For certain commonly ordered tests, the multiple schedules result in large regional variations, while for other tests, national limitation amounts results in inadequate Medicare payments.

Reimbursement For Laboratory Medicine

- Despite modest improvements in their transparency, the processes for establishing payment levels for new laboratory tests, including assignment of new and existing Current Procedural Terminology® codes to tests and related methods of cross-walking and gapfilling, remain archaic and inadequate.