

Update on State of Laboratory Medicine

Northeast Regional Conference & Exhibition
April 15, 2008
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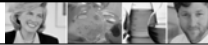


Management within the field of laboratory medicine requires more than attention to every day operations. Effective leadership dictates that we also keep a focus on the future in order to best prepare to manage the operations of tomorrow. This presentation will identify key trends impacting laboratory medicine including consumerism, technology, information systems and quality systems.

Session Objectives:

- Understand the importance of managing and leading for the future.
- Identify key trends which impact laboratory managers today.
- Learn some practical means to keep a pulse on the laboratory environment.

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KEY TRENDS

- Market Dynamics and Consumerism
- Technology
- Information Systems
- Quality Systems

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MARKET DYNAMICS & CONSUMERISM

- ❑ Consolidation, cost reduction and innovation
- ❑ Knowledge & public information
 - ✓ WebMD
 - ✓ Lab Tests Online
 - ✓ Labs are Vital
 - ✓ Results for Life
- ❑ Individuals as primary buyers of healthcare
- ❑ Home testing
 - ✓ Case of the DIY Liver Test
- ❑ Continued importance of local health care
- ❑ Personalized medicine

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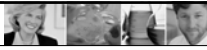
TECHNOLOGY

- ❑ Genetic based testing – not just research anymore
 - ✓ Infectious disease
 - ✓ Oncology
 - ✓ Predictive modeling
- ❑ Sophisticated automated systems
 - ✓ Tandem assay mass spec
 - ✓ Real time PCR
 - ✓ Fluorescence in situ hybridization
- ❑ Point-of-Care Testing

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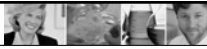
TECHNOLOGY

- ❑ Workstation Consolidation
- ❑ Anatomic Pathology
 - ✓ Proprietary test technology
 - ✓ Advances in imaging technology & links to the radiology department
 - ✓ Molecular diagnostics is blurring the lines between AP and CP
- ❑ Key influencers on growing IVD market
 - ✓ Mergers & acquisitions
 - ✓ Pricing pressures

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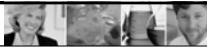
INFORMATION SYSTEMS

- Electronic Medical Record (EMR)
 - ✓ Growing commitments to development
 - ✓ Data integration
 - ✓ Provider spectrum – MD office to acute care hospital
 - ✓ More than just orders & results
- Data mining to impact diagnosis and treatment
- Medical decision making – linking auto-verification to electronic medical record

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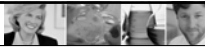
INFORMATION SYSTEMS

- Middleware – where does it fit
- Advances in acquisition and distribution of visual, imaging data
- Expanding functionality to meet molecular diagnostics needs
- Traditional LIS – what does all this mean

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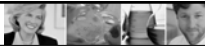
QUALITY SYSTEMS

- Focus on patient safety – not just traditional QC
- Increasing use of new tools
 - ✓ Six Sigma
 - ✓ LEAN
 - ✓ Other “manufacturing” best practices
- Evidence-based methodologies in the clinical lab

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QUALITY SYSTEMS

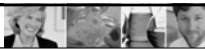
- National Agencies and Associations
 - ✓ Good Practice Sharing – CLMA’s GPS
 - ✓ JCAHO and CAP
 - ✓ National Quality Forum
 - ✓ Leapfrog Group
 - ✓ Agency for Healthcare Research and Quality
 - ✓ Institute for Healthcare Improvement

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JCAHO Lab Focus, Issue 1 2008

Top compliance issues for labs

- National Patient Safety Goal 2C and proficiency testing standards QC.1.20 and QC.1.30 were the most problematic requirements for labs in 2007. Each year, The Joint Commission collects data on organization compliance with its standards, National Patient Safety Goals, and other requirements to identify trends and focus education activities.
- “Labs can use this information to benchmark performance against all Joint Commission accredited labs and to determine if their processes meet the requirements,” says Margaret Peck, executive director, Laboratory Accreditation Program.
- The next slides list the areas that were most frequently identified as “not compliant” for clinical laboratories. The percentage of organizations that received Requirements for Improvement is provided in parentheses after the requirement number.

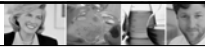
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JCAHO Lab Focus, Issue 1 2008

Goal 2 Requirement 2C (21%)

Measure, assess, and, if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values.

- **QC.1.20** (20%) Proficiency testing services used for specialty and subspecialty equal or exceed applicable laws and regulations with respect to variety and frequency of testing and satisfactory performance criteria.
- **QC.1.30** (18%) The laboratory maintains a cumulative record of participation in a proficiency testing program.
- **QC.5.300** (12%) The laboratory uses standardized procedures to acquire, receive, store, and issue tissues.
- **EC.6.20** (11%) Laboratory equipment is maintained, tested, and inspected.

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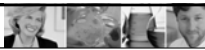
- ❑ **LD.2.60** (10%) The directorship of the laboratory is effective.
- ❑ **WT.1.60** (9%) Quality control and test result records are maintained.
- ❑ **QC.5.310** (7%) The laboratory's record keeping permits bi-directional traceability of all tissues.
- ❑ **QC.5.80** (6%) The laboratory uses written policies, procedures, and processes for administering blood and blood components and using infusion devices and ancillary equipment.

Goal 1, Requirement 1A (6%)
Use at least two patient identifiers when providing care, treatment, or services.

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IMPLICATIONS FOR TODAY'S LAB

- ❑ Staffing shortage
- ❑ New, complex technology will demand specialized skills
- ❑ Tension between generalist skills and specialized skills
- ❑ What will make your lab better than the competition
- ❑ Productivity, efficiency, service level
- ❑ Strategically planning your test menu
 - ✓ Traditional departments
 - ✓ Molecular diagnostics
 - ✓ Support for outreach efforts

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HOW CAN YOU BE PREPARED

- ❑ Be Informed – Devote Time to Learning

Knowledge management is ... "the systematic process of identifying, capturing, and transferring information and knowledge people can use to create, compete, and improve".
[American Productivity and Quality Center]
- ❑ Develop Skill Sets
- ❑ Participate in the Future
