

COLA

Voluntary Standards and Non-Regulatory Approaches to Laboratory Improvement

CLIAC Committee

Atlanta, GA

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Presenter

Max Williams, MPA

Director, Policy and External Affairs
COLA



Standards Development

CLIAC wanted to know:

- How are areas identified for development
- Process of developing best practice standard or guideline
- Method used to evaluate use or utility of the standard



About COLA

- Physician directed
 - ACP, CAP, AMA, AAFP, AOA
- CMS approved -CLIA compliance
- Originally founded for physician office laboratories
- Integrated education throughout accreditation



About COLA

- 6700 laboratories
- Since 1992, >33,000 surveys
- Adding new specialties
- Adding QMS/ISO 15189 based program
- Currently renewing deeming authority
- Leadership in the promotion of quality and safety in laboratory medicine



Standards: What

- Guiding principles:
 - Is it practical and cost effective
 - Has impact on patient care/safety
 - Can be implemented
- What's required and what makes sense
- Needs of practicing physician and staff
- Global demand for quality and safety



Standards: How

- Utilize COLA Technical Expertise
 - Board of Directors (CAP- AAFP)
 - COLA Technical staff
- Evaluate laboratory practices
 - NCCLS, ISO, FDA, CLIA
 - Industry
- Benchmark national and international accrediting bodies

Standards: How

- Vetting
 - Is it practical and will the user understand
 - Does it make a difference- improve patient care, promote quality improvement, improve patient safety
- Future
 - Does it get to process
 - Can the process be improved

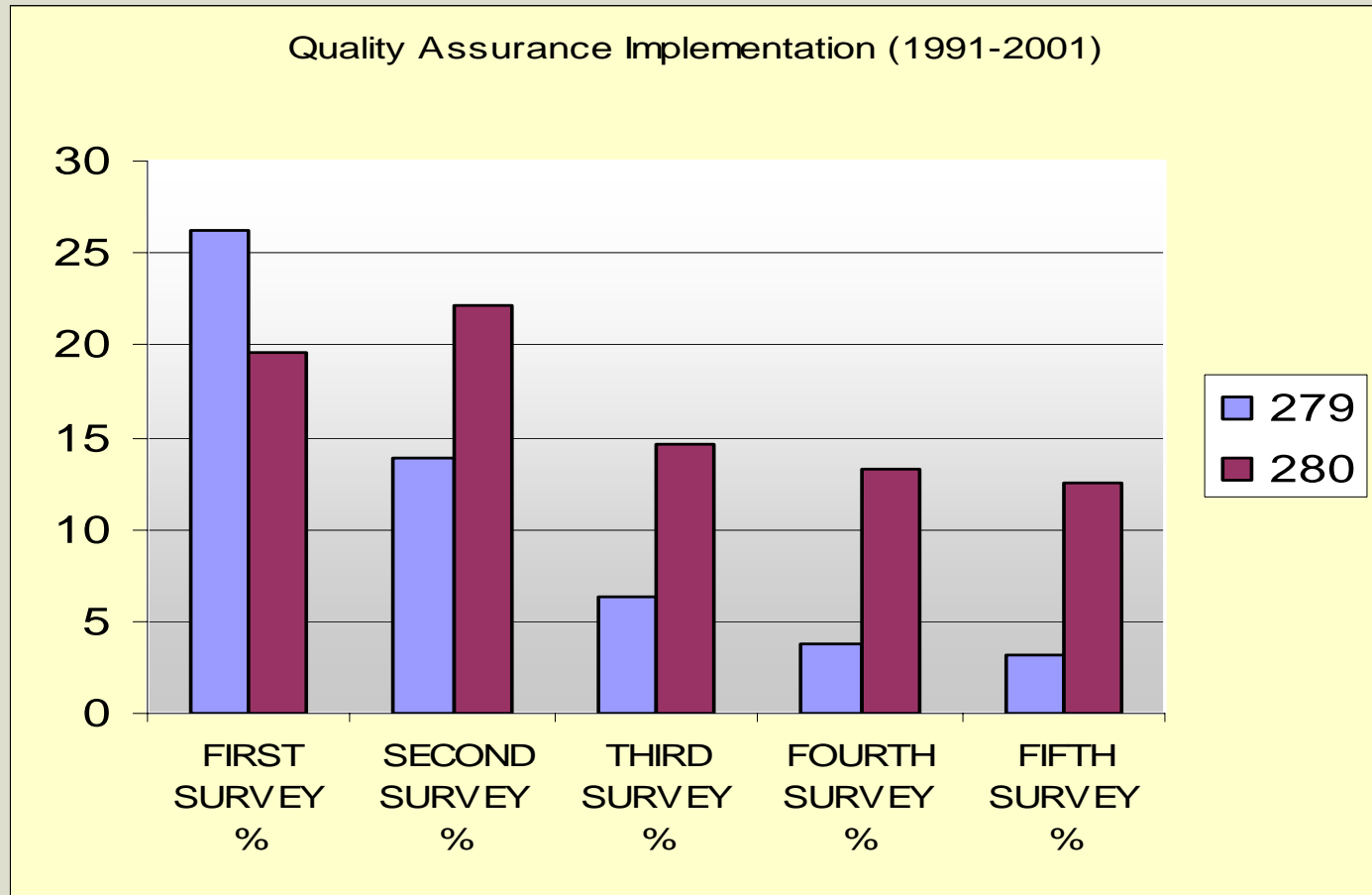
Standards: How

- Example: Incident Management (Q 285)
 - Accreditation Manual updates
 - *Insights* COLA newsletter articles in multiple issues prior to implementation
 - Educational “survey” period for 1 cycle
 - Surveyor training at time of on-site survey
 - COLA *LabGuide* #71 – Incident Management

Standards: Monitoring

- Are we improving quality and patient safety?
- “Lookback” and continuous monitoring
 - What’s working
 - Biggest compliance issues
 - CMS Validation issues
 - Customer feedback
 - Board of Directors

Example: QA in the POL



Standards: Monitoring and Improvement

- Standards are not frequently changed-
implementing criteria can be adjusted
- Look for ways to improve compliance
- Develop educational interventions
 - Quality Assurance Plan
 - e-Learning



September 22, 2004



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COLA
Working Together for Excellence in Healthcare

- Quality Control
- Quality Assurance
- Safety
- CLIA '88 Requirements
- Proficiency Testing
- Personnel Requirements
- Lab Director Responsibilities

September 22, 2004

Compliance Improvement and Performance Improvement

- Tough balance between requirements and best practices/recommendations
 - COLA criteria for waived testing
 - On-line - Best Practices for Waived Testing
- Drivers- what are they?
- Challenge to impart “habits of mind” of top performance



Current and Future Considerations

- Quality Management Systems
- ISO 15189
- On-line education and training
- Risk mitigation
- Improving waived test performance
- Drivers for performance improvement



Bottom Line

- Does it make sense?
- Does it make a difference?
- Does it work?
- Will the intervention be sustainable?

COLA

9881 Broken Land Parkway, Suite 200
Columbia, MD 21046

Information Resource Center

Phone: 800-981-9883 Fax: 410-381-8611

Web Site: www.cola.org

LabUniversity: www.labuniversity.org

Email: [info @ COLA.org](mailto:info@COLA.org)



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