Clinical and Laboratory Standards Institute: Addressing POCT Needs; The Good, The Bad, and The Risky

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Director, Education

3 Rivers POCT Network
June 7, 2012
Today’s Presentation

• Discuss who CLSI is by providing background, membership, and document information.
• Define the relationship CLSI has with the ISO, the College of American Pathologists, and The Joint Commission.
• Outline POCT growth for the past 20 years, and provide insight on POCT futures.
• Detail CLSI POCT documents and products how they can meet the many POCT needs.
• Discuss the new EP23 document on risk management
CLSI Background

- Established in 1968
- Nonprofit corporation based in the United States
- Accredited standards developing organization
- Volunteer-driven through our governance
  - Structure and technical operations
- An organization of organizations
  - No individual memberships
CLSI Today

- 45 employees
- 2000 member organizations
- Nearly 2300 active volunteers
- Consensus standards and guidelines
- > 75,000 documents each year distributed
Vision

To be the leader in clinical and laboratory standards to improve the **quality of medical care.**
Mission

To develop **best practices** in clinical and laboratory testing and **promote** their use throughout the world, using a **consensus**-driven process that balances the viewpoints of industry, government, and the health care professions.
CLSI Consensus Process

Government

Industry

Professions

Balance
CLSI Consensus Process

- Meetings are open to everyone.
- Meeting materials are fully available.
- Consensus committees contain a balance of interests.
- Conflicts of interest are fully disclosed.
- An appeals process is open to any individual or organization.
A consensus standard or guideline is a document developed to promote uniform products, materials, methods, or practices.
Member Organizations

- 1615 Hospitals and Laboratories
- 121 Industry Organizations
- 106 Educational Institutions
- 43 Start-up Companies and Consultants
- 49 Government Agencies
- 35 Professional Societies

TOTAL = 1969 Organizations
CLSI Members and Volunteers

Diverse representation from three constituencies

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<th>Industry</th>
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Abbreviations: IVD, in vitro diagnostics; LIS, laboratory information system.
Members and Volunteers

- Argentina
- Australia
- Belgium
- Brazil
- Bulgaria
- Canada
- France
- Germany
- Hong Kong
- India
- Iran
- Israel
- Italy
- Japan
- South Korea
- Mexico
- Netherlands
- PR China
- Saudi Arabia
- South Africa
- Spain
- Sweden
- Taiwan
- Trinidad/Tobago
- Turkey
- United Kingdom
- United States
CLSI Consensus Committees

- Automation and Informatics
- Clinical Chemistry and Toxicology
- Evaluation Protocols
- Hematology
- Immunology and Ligand Assay
- Microbiology
- Molecular Methods
- Point-of-Care Testing
- Quality Systems and Laboratory Practices
Committee Structure

- Chairholder
- Vice-Chairholder
- Members
- Advisors
- Contributors
- Reviewers
- Staff liaison (Executive Office staff)
The Document Development Process

Project Idea → Published Document
Two Timeline Tracks

Track 1 – 15-month timeline
Track 2 – 25-month timeline

Timeline determined by:
• Scope
• Complexity
• Comprehensiveness and depth
• Degree of controversy
## CLSI Publications

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Improving the Quality of Medical Care
CLSI’s Key Global Activities

International Organization for Standardization (ISO)

- CLSI is Secretariat for ISO Technical Committee (TC) 212
  “Clinical laboratory testing and *in vitro* diagnostic test systems” and its working groups (WGs):

  - WG 1: Quality and competence in the medical laboratory
  - WG 2: Reference systems
  - WG 3: *In vitro* diagnostic products
  - WG 4: Antimicrobial susceptibility testing

- CLSI is administrator of the ANSI-Accredited US Technical Advisory Group to ISO/TC 212.
### College of American Pathologists Crosswalk

#### CLSI REFERENCES IN THE CAP LABORATORY ACCREDITATION PROGRAM CHECKLISTS

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‡ Noted, not referenced.
†† Electronic only.
The Joint Commission Crosswalk

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CLSI Guidelines in StatisPro

- **EP05** – Evaluation of Precision
- **EP06** – Evaluation of Linearity
- **EP09** – Evaluation of Bias and Comparability Using Patient Samples
- **EP10** – Preliminary Evaluation
- **EP15** – Verification of Precision and Trueness
- **EP17** – Limits of Detection and Limits of Quantitation
- **C28** – Establishment or Verification of Reference Intervals
The consensus committee did not form until 2001 when the Connectivity Industry Consortium document was presented to CLSI.
Point-of-Care Testing Documents

- AST04-A2 Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline—Second Edition
- C30-A2 Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition
- C52-A2 Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline—Second Edition
- H49-A Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline
- HS02-A Provider-Performed Microscopy Testing; Approved Guideline
- HS03-A Pulse Oximetry; Approved Guideline
- POCT01-A2 Point-of-Care Connectivity; Approved Standard—Second Edition
- POCT02-A Implementation Guide of POCT01 for Health Care Providers; Approved Guideline
- POCT04-A2 Point-of-Care In Vitro Diagnostic (IVD) Testing; Approved Guideline—Second Edition
- POCT05-A Performance Metrics for Continuous Interstitial Glucose Monitoring; Approved Guideline
- POCT07-A Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline
- POCT08-A Quality Practices in Noninstrumented point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline
- POCT09-A Selection Criteria for Point-of-Care Testing Devices; Approved Guideline
- POCT11-A2 Pulse Oximetry; Approved Guideline - Second Edition
Growth 1990-2000

- Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88)
- CLSI document C30-A2: *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition*
- Reduction in turnaround times (TAT), errors, and paper
- Smaller sample size
Growth 2000-mid 2008

- Creation of more waived testing
- Handheld devices with more choices
- Data management
- Connectivity and getting results into the Electronic Medical Record
- Greater acceptance of POCT
Growth mid-2008-2011

- Information technology (IT) done instantly (wirelessly)
- Open IT platforms with security systems in place
- Hospitals and vendors under extreme pressure
- Decrease in inpatient numbers
Growth for the Future

- Increase in outpatient care/Physician office laboratory (POL) market
- Growth of self care through the Internet and drug store accessibility
- Focus on efficient and cost-effective tests
- Information management as opposed to data management
Timeline

1990 - 2000
Data Collection

2000 - 2008
Data Management

2008 - 2012
Information Management

- Open IT
- Wireless
- Growth outpatient testing
- Efficient tests

- More choices
- More acceptance

- Data management
- Connectivity

- CLIA 88
- CLSI

- Reduced TAT
- Small sample

- Efficient tests

2008 - 2012
Information Management
Internal Factors

• Hospitals are more focused on critical care (e.g., increase in patient age, increase in heart disease)
• Intensive insulin therapy initiatives
• Clinical effectiveness
• Workforce issues: technologist shortage
  • 12,200 new technologists needed/year but only 4,000 – 6,000 new graduates/year
  • Projected need for 710,000 technologists by 2013
External Factors

• Significant growth in number of waived tests

• Significant growth in number of nonglucose POC tests in hospital setting

• Clarity on reimbursement (Centers for Medicare and Medicaid Services is committed to this)
External Factors

• Shifts in the IVD sector. Growth in POCT market of 10% to 15%. Traditional IVD is flat.
• Disasters:
  ➢ Emergency preparedness
  ➢ Epidemics/pandemics
• POCT is more entrepreneurial—Big players such as Alere, Roche, and Siemens, but also many of the little players
Data Management

• Each device has its own data management capabilities.

• New devices communicate more information to existing applications.

• Wireless connectivity

• Paperless patient charts
Informatics and Middleware

- Outside vendor choices have grown.
- Large databases contain information of which other hospital areas may not be aware.
- Information sharing, Computers on Wheels
- On-demand patient outcomes and information to connect various department data
Technologies

• Minimal to noninvasive sampling
  ➢ Transcutaneous bilirubin
  ➢ Pulse oximetry
  ➢ Continuous glucose monitoring

• Broader range of immunoassay tests, hematology testing, and nucleic acid-based tests (DNA/RNA) and tests for infectious diseases

• Sepsis disease markers and stroke markers

• Lab-on-a-chip
Outpatient Areas-Physician Office Laboratories

- Increase in:
  - Number of CLIA-waived licenses
  - Use of POCT devices
  - Patient satisfaction
  - Therapy adjustments
  - Time and money saved by POLs
- Health care cost controls (fewer hospital admissions by using POCT to triage patients)
Outpatient Areas-Clinics

- Disease management clinics
- Sexually transmitted disease clinics
- Coagulation clinics help with patient compliance
  - Clinical efficiencies through frequent and timely laboratory measurements (e.g., INR)
  - Continuum of care
Outpatient Areas - Patient Self Testing

• Internet access and number of sites has increased.
  ➢ Labtestsonline.org
  ➢ Physician laboratories, privatemdlabs.com
• More over-the-counter drugs
  ➢ Number of choices and information about these choices grows.
• Simpler health care solutions to the growing cost of care
  ➢ Lack of health care insurance
  ➢ Increasing insurance co-pays
Outpatient Areas-
Patient Self-Testing (cont’d)

• Direct Access Testing
  – Certain states allow this type of testing.
  – Online laboratory kit ordering sites have grown.
  – Typically a lab draw site is within 10 miles of one’s home.
  – Walgreens, Walmart, and other are taking part of this testing.
Limitations

• Cost of testing
• Analytical accuracy of POCT solutions
• Data management and the lack thereof in manual testing.
• Evidence for improved patient care outcomes
How Can You Help

• Be a champion for laboratory medicine in general.
  – http://www.clsi.org view Committees and Volunteer areas
• Get involved with a number of laboratory and legislative organizations (eg, American Society for Clinical Laboratory Science or Clinical Laboratory Management Association).
• American Association of Clinical Chemistry POC specialist certificate program
  – http://www.aacc.org/development/certification
• Get involved with teaching in nursing programs.
• Market and promote the POCT field.
Certificate Program

- Regulations
- Policies and Procedures
- Connectivity and IT
- Quality Management
- Administration
- Instrument Selection and Validation
- Education and Training
- Communication

- Courses must be taken within a 12 month period.
- After completing all eight online courses, you must take a multiple choice comprehensive examination to receive your POC Specialist Certificate.
Point-of-Care Specialist Certificate

Betsy Garman

Has successfully completed the AACC Point-of-Care Specialist Certificate Program, an online education program which covers administration, communication, connectivity and information technology, education and training, instrument selection and validation, policies and procedures, quality management, and regulations associated with the practice of point-of-care testing.

Given this 29th day of October, 2008

Larry Broussard, PhD
President
AACC

Kent Lewandrowski, MD
Chair, Critical and Point-of-Care Testing
A Division of AACC

Point-of-Care Testing Documents

• **POCT07-A** Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline

• **POCT08-A** Quality Practices in Noninstrumented point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline

• **POCT09-A** Selection Criteria for Point-of-Care Testing Devices; Approved Guideline
Future Documents

- **POCT06-A** Guidelines on the Impact on Glucose Measurements When Different Sample Types are Used; Approved Guideline
- **POCT12-A3** Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline - Third Edition
- **POCT13-A3** Point-of-Care Glucose without Laboratory Support; Approved Guideline - Third Edition
Companion Products

- Addressing Errors in Point-of-Care Testing Reference Guide
- Instrument Selection Worksheet
- Quality Control Troubleshooting Flow Chart
- Corrective Action Report Quick Guide
- Quality Control Log Sheet Quick Guide
- Nasal Smears for Inflammatory Cells Quick Guide
- Proficiency Testing Exception Response Form Quick Guide
- Urine Sediment Examinations Quick Guide
- Wet Mount Preparations and KOH Preparations Quick Guide
EP23

Laboratory Quality Control Based on Risk Management; Approved Guideline

• Provides guidance for laboratories to develop a customized quality control (QC) plan based on risk management.
• Assists laboratories by describing the multiple factors that must be considered when developing laboratory-specific QC protocols.
Developing a Quality Control Plan

MEASURING SYSTEM INFORMATION

- Medical Requirements for the Test Results
- Regulatory and Accreditation Requirements
- Test System Information
  - Provided by the Manufacturer
  - Obtained by the Laboratory
- Information About Health Care and Test Site Setting

PROCESS

Risk Assessment

OUTPUT

Quality Control Plan

PROCESS

Post-implementation Monitoring
Process Map

Start

- Startup/maintenance/calibration
  - Reagents/calibrators/parts procurement and storage
    - Yes – First error or malfunction. Perform step 1 time
      - Troubleshooting performed and corrective action taken
        - Repeat examination
    - No
      - Measuring system error message or malfunction?
        - Yes – Second error or malfunction, or Results don’t match Clinical picture after Repeat examination
          - STOP Collect sample to send to core lab
            - Yes
              - Results are reported
            - No
              - Does result match clinical picture?
                - Yes
                  - Results are evaluated
                - No
                  - Results are reported
  - Operator training and competency
    - Laboratory Environment
# Risk Acceptability Matrix

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<th>Probability of Harm</th>
<th>Negligible</th>
<th>Minor</th>
<th>Serious</th>
<th>Critical</th>
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EP23 Companion Products

Implementation Workbook

Risk Assessment Worksheet

Plus – More fully worked examples coming soon

www.clsi.org