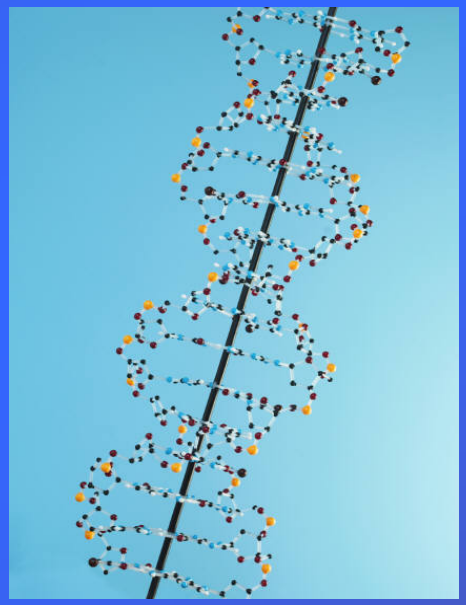
CLIA & Genetic Testing Oversight



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CLIA & Genetic Testing Oversight

Judith Yost
Director, Division of Laboratory Services

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CLIA & Genetic Testing (GT) Oversight

Topics for Discussion:

- Background & history of GT regulation
- What CLIA requires for GT in **yellow**
- Why no GT specific standards?
- CMS' plan to enhance GT oversight w/ existing authority
- Other quality & oversight efforts underway

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Background & History:

- Final CLIA regulations—1992
- NIH/DOE Task Force report—1997
- CLIAC/SACGT recs to HHS—1998, 1999, 2001
- CDC Notice of Intent—2000
- CMS CLIA Final QC regulations—2003
- SACGHS recs to the Secretary HHS----2008

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General CLIA Information:

- Impetus was deaths from incorrect Pap smears
- *Intent*--ensure accurate, reliable, timely testing
- Requirements minimal; based on test complexity
  - 3 categories: waived, moderate & high
  - More complex tests have more stringent standards
- **Most GT are high complexity***

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General CLIA Information:

- Program entirely funded by user fees; not gov't.
- Covers ***all testing*** on human specimens for health assessment--not just Medicare or FDA approved.
- >200,000 labs enrolled; **approx. 600-1K are GT***
- Excludes research, forensic, VA labs.
  - Research covered when patient-specific results are returned.
- Data indicates *improved performance* over time.

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What CLIA Already Covers

- **Quality control (QC)** — real time check of test quality
  - Monitors the performer, test & lab's environment
    - **Daily QC w/ some specific to GT;***
      - ***PCR, tests w/extraction & 2 levels of QC/day;**
    - **Test method (analytic) validation;**
    - **Calibration/calibration check;**
    - **Instruments, reagents, supplies;**
    - **Maintenance; Procedure manual;**
    - **Test results comparison;**
    - **Corrective actions; & Specialties.**

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What CLIA Already Covers

- **Proficiency testing** – accuracy measure (external QA)
  - Tests listed in regulations (83) – enroll in PT program
  - Tests not listed -- check test accuracy 2X/year
    - **Applies to GT***
- **Audit trail, confidentiality, specimen integrity & identification, complaints;**
- **Specimen collection, processing, test referral, test orders, result reporting;**
- **Facilities----Uni-directional workflow for GT***

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What CLIA Already Covers

- **Personnel**—Required positions w/ education, experience, training & **quality** responsibilities
  - *Laboratory Director — overall quality responsibility*
  - *Clinical Consultant*
  - *Technical Supervisor*
  - *General Supervisor*
  - *Testing Personnel*
- **Competency-** annual checks of personnel performance
- **Highest qualifications apply to GT labs***

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What CLIA Already Covers

- **Quality Assurance/Assessment**
  - Overall plan to monitor test systems & quality;
  - Encompasses all CLIA standards;
  - Correct problems/complaints effectively; &
  - Communicate with staff, clients.
- **Biennial surveys** look at outcomes (test results).
  - Assess ***All*** lab's systems & processes to assure quality
- Menu of **enforcement actions** for noncompliance
  - Sanctioned labs' Registry posted on CLIA web site

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Why no Genetic Testing Specialty?

- Survey data doesn't indicate a problem;
- GT specialty will not:
  - provide clinical validity;
  - solve PT/ QC sample paucity;
  - address ELSI or DTC issues.
- **No widely accepted definition** of a GT
- Dynamic GT area: prescriptive standards will be outdated; lock labs into outmoded compliance.
- Disruption to existing infrastructure & specialties

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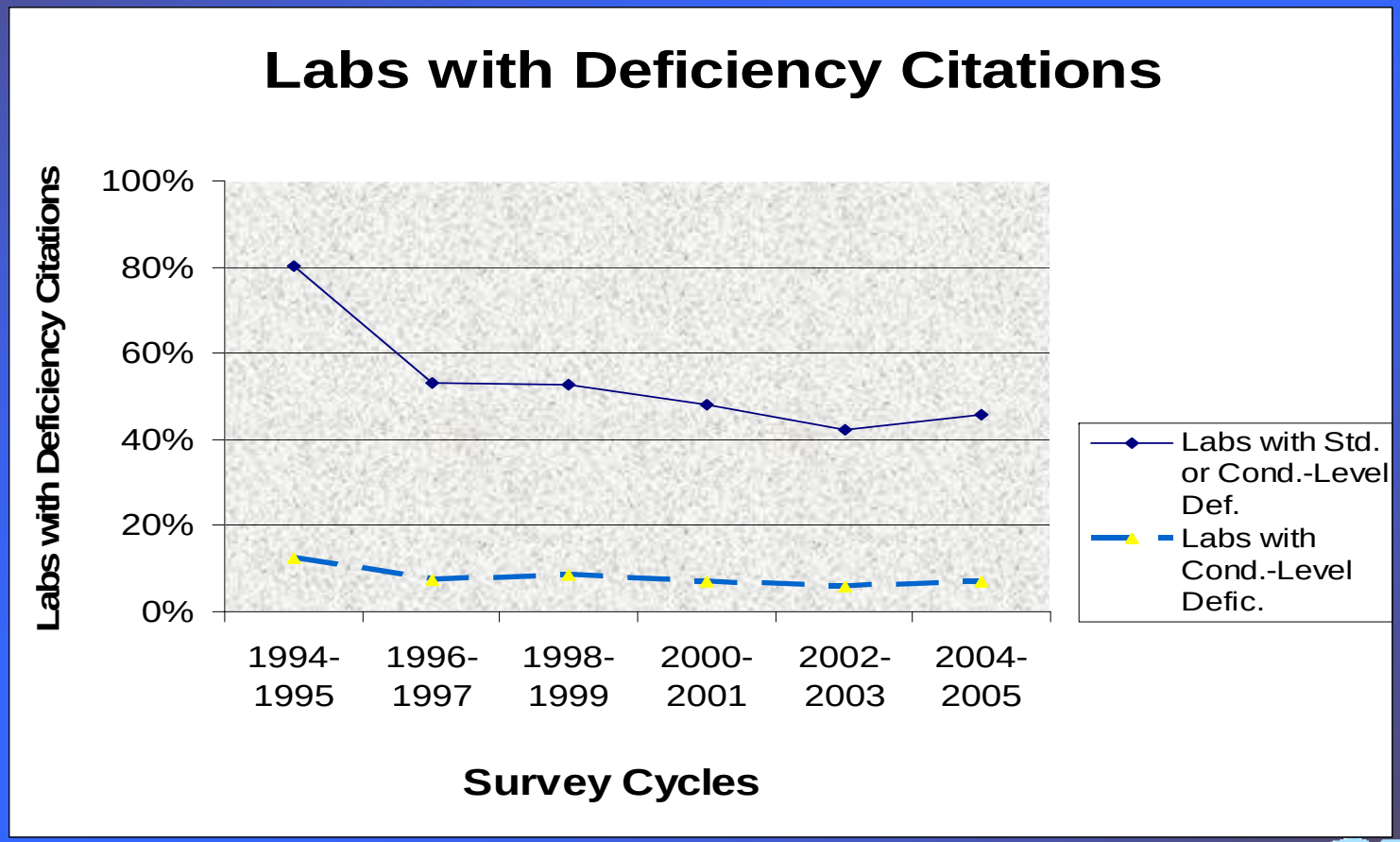

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Is There a Comparative Advantage to a Specialty?

- Labs already covered by CLIA;
- CMS can use *existing* regs to enhance outcomes;
- Professional & accred. orgs. have standards;
- Some advisory com. recommendations published in 2003 CLIA regulations;
- Lab community isn't unanimous;
- Rule = 3 yrs. & uses scarce CMS resources.

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Using Existing CLIA Rules Effectively

What is CMS doing to strengthen GT oversight?

- Transmit specific guidance to State surveyors
- Conducted surveyor technical & procedural training
- Publish educational MMWR for labs w/ CDC
- Explore survey alternatives w/ oversight agencies
- Partner to design alternative PT/QC
- Work w/ CLIAC, CDC, FTC, NIH & FDA

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Using Existing CLIA Rules Effectively

What is CMS doing to strengthen GT oversight?

- Collaborate with CLSI on professional standards
- Request FDA aid in complex test valid. reviews
- Collect data on GT laboratory performance
- Enhance CLIA web site for easy public access to lab certification info
  - Additional info on GeneTests & AMP web sites
- Monitoring DTC labs for certification

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Other Ongoing Efforts Underway:

- CDC, in partnership w/ GT community estab. GeT-RM:
  - Provide materials for QC, PT;
  - Facilitate test development;
  - Determine method validation;
  - Encourage research.
- CDC's further efforts:
  - Rare diseases; newborn screening pgm., CETT, EGAPP;
- CAP, JCAHO, NY have GT standards;
- CLSI/ACMG molecular guidance docs; more planned.

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Items CMS Will Augment:

- **QC**—partner to identify creative mechanisms & materials;
- **PT**— update '92 regulations w/ CDC to include some GT in existing specialties—if samples available;
  - Expand alternative GT PT mechanisms/approaches;
- **Personnel**— develop interpretive guidance w/ experts

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- **Issues Beyond the Scope of CLIA:**
  - Clinical validity;
  - DTC claims;
  - Informed consent;
  - Genetic counseling;
  - Tests that don't assess health (e.g., gender); &
  - ELSI.

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SACGHS Recommendations for CMS to Sec. HHS---2008

- Include all non-waived tests in PT regulations;
  - Promote further development of GT PT;
  - Identify more effective forms of alt. assessment;
- Train surveyors in GT technology; creative surveys;
- Develop a registry of GT w/ clinical validity information;
- Register uncertified labs;
  - Take approp. enforcement actions;
- Develop professional standards;
- Monitor DTC; Hire staff;
- Cover all health-related tests.

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- **Suggested Resolutions:**
  - Work with SACGHS & private sector to:
    - Study the best mechanisms for oversight & test quality.
      - Partner w/ other oversight agencies
    - Continue to develop & follow professional standards.
    - Continue to augment lab oversight & educate labs under current CLIA.

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Next Steps for CMS:

- Heighten surveyor awareness & train---complete;
- Initiate development of updated PT regs;
- Collaborate ongoing w/ advisory groups, experts, CDC, FDA, etc.;
- Encourage CLSI to develop more GT standards;
- Educate GT laboratories;
- Expand CMS/CLIA web site.

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An Offer You Can't Refuse!

- Assist HHS in GT oversight efforts to assure quality.
- Tell us your concerns, so we can address them using --
  - Existing CLIA infrastructure;
  - Current or updated mechanisms;
  - Your expertise;
  - Other programs/experts.

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Where to Find CLIA Info:

- CMS CLIA Web site:
  - www.cms.hhs.gov/clia
- CMS Central Office in Baltimore:
  - 410-786-3531
- Judy Yost's email:
  - Judith.yost@cms.hhs.gov

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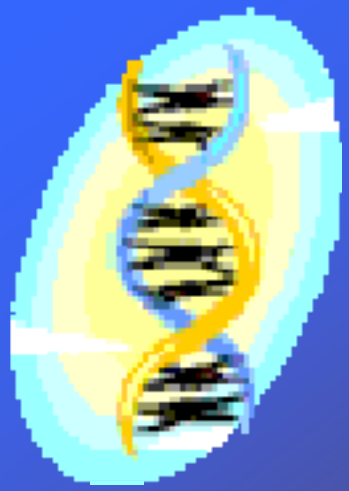
The End!

Thank You!!



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