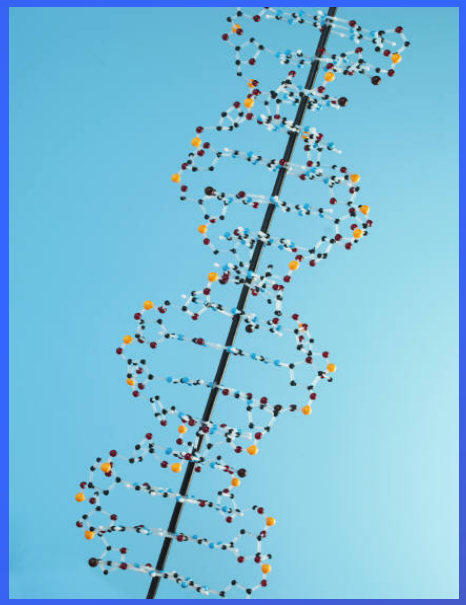
CLIA & Genetic Testing Oversight



CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

Judith Yost
Director Division of Laboratory Services

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

Topics for Discussion:

- Background & history of GT NPRM.
- What CLIA already requires for GT.
- Why no GT specific standards?
- CMS' plan to enhance GT laboratory oversight.
- Other quality & oversight efforts.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

Background & History:

- Final CLIA regulations—1992.
- NIH/DOE Task Force report—1997.
- CLIAC/SACGT recs to HHS—1998, 1999.
- CDC NOI—2000.
- Revised CLIAC recs to HHS—2001.
- CMS CLIA Final QC regulations—2003.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

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**.*

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

General CLIA Information:

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

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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.**

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

What CLIA Already Covers

- **Proficiency testing** – long term outcome accuracy measure.
  - Tests listed in regulations – 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**.*

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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.
- **Highest qualifications apply to GT labs.***

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

What CLIA Already Covers

- **Quality Assurance**
  - Overall plan to monitor test systems & quality;
  - Encompasses all CLIA standards;
  - Correct problems/complaints effectively; and
  - Communicate with staff, clients.
- **Biennial surveys** look at outcomes (test results).
- Menu of **enforcement actions** for noncompliance.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

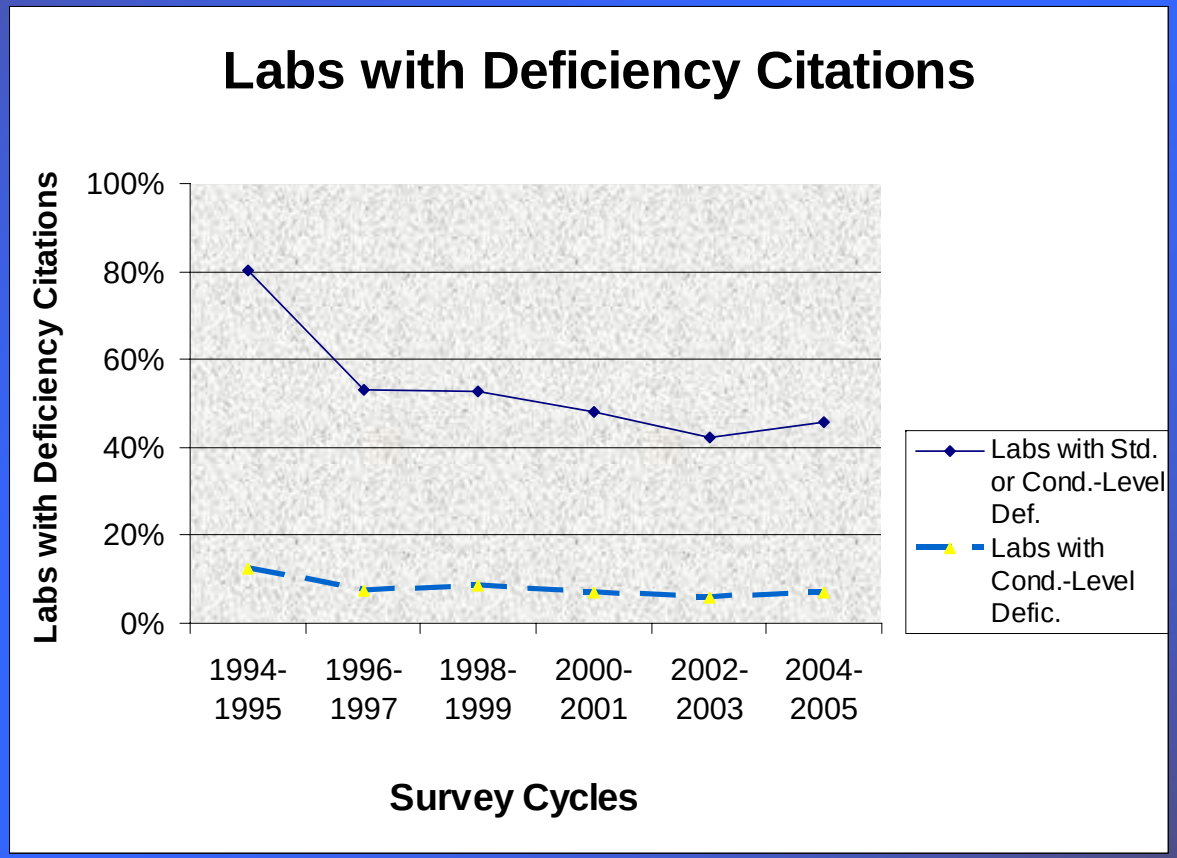
Why no Genetic Testing Specialty?

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

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight



CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Is There a Comparative Advantage to a Specialty?

- Labs already covered by CLIA;
- CMS will use *existing* regs to enhance outcomes;
- Professional standards exist;
- Several advisory com. recommendations published in 2003 CLIA regulations;
- Only a few organizations want a specialty;
- Affects approximately 600 entities; and
- Admin. rule = 3 yrs. & uses scarce CMS resources.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Using Existing CLIA Rules Effectively

What is CMS doing to strengthen GT oversight?

- Transmit specific guidance to State surveyors.
- Retain experts to conduct surveyor technical training.
- Publish educational materials for labs w/ CDC.
- Explore survey alternatives w/ oversight agencies.
- Design alternative PT/QC mechanisms.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Using Existing CLIA Rules Effectively

What is CMS doing to strengthen GT oversight?

- Work with CLIAC, CDC, FTC, NIH & FDA.
- Collaborate with CLSI on professional standards.
- Request FDA/CDC aid in complex test validation reviews.
- Collect data on GT laboratory performance.
- Enhance CLIA web site for easy public access to lab certification info.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

Other Ongoing CDC 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 has molecular guidance docs & more planned.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

Rebuttal to Hudson Study Findings:

- PT enrollment isn't required for GT, since there are few modules/samples available; so lack of enrollment has **no impact**.
  - Labs still subject to accuracy checks twice/yr.->1000tests;
  - PT required for only 83 tests in regs now.
- CLIA data confirms there are NO labs without a specialty.
  - CLIA fees based on the annual volume & types of tests.
  - Since there is no GT specialty, assume question was misunderstood.
- Most "potential" errors noted were not in test analysis, but pre or post test already covered by CLIA; documented in several publications & doesn't require a specialty.
- No. of CLIA specialties have actually been reduced over time.
  - Instead **QC was enhanced for ALL tests; technology improved**.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

Items we can consider in upcoming regs:

- **QC—** augment QC, if mechanisms & materials are identified;
- **PT—** intersperse GT PT in existing specialties—if available; or
  - Expand 1236 –unregulated analytes w/ alternative GT PT mechanisms:
- **Personnel—** expand cytogenetic TS to include GT?

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

- **Issues Beyond the Scope of CLIA:**
  - Clinical validity;
  - DTC;
  - Informed consent;
  - Genetic counseling;
  - Tests that don't assess health (e.g., gender); and
  - Ethical, Legal, Social Issues.
- **Suggested Resolution:**
  - Work with SACGHS to:
  - Pass legislation that covers all GT issues in a separate statute instead of CLIA ; or
  - Continue to develop & follow professional standards.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

Next Steps for CMS:

- Heighten surveyor awareness & train;
- Collect GT lab performance data;
- Collaborate ongoing with advisory groups, experts, CDC, FDA, etc.;
- Develop GT standards with CLSI; and
- Educate GT laboratories; expand web site.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

An Offer You Can't Refuse!

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

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

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

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA & Genetic Testing Oversight

The End!

Thank You!!

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES