QUICK CLIA 101 & CLIA COMPLIANCE

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Quick CLIA 101

- Impetus for Clinical Laboratory Improvement Amendment (CLIA):
  - Deaths from inaccurately read Pap smears.
  - Proliferation of “blackbox” technology w/ no oversight in physicians’ offices.

Quick CLIA 101

- Congress passed the Law in 1988.
  - Regulates all testing on humans for health purposes using minimum quality standards.
  - To ensure accurate, reliable testing regardless of location.
  - Includes research when results returned & specimens have unique ID.

Quick CLIA 101 Cont'd.

- Final Regulations published Feb. 1992
  - 5 Quality standards based on test complexity.
    - The more complex the test, the more stringent the standards.
    - Most Genetic tests are high complexity.
  - CLIA Certificate for highest test level; one per site.
    - Exceptions for hospitals/universities.
  - Entirely user fee funded by certificate & survey fees.
    - Based on annual test volume.
  - Program administered by CDC, FDA & CMS.
  - Detailed, specific standards for Cytology.

Quick CLIA 101 Cont'd.

- Test Complexities:
  - **Waived--** simple, accurate tests w/o routine oversight; lab must follow mfgrs.' instructions.
  - **Moderate—**most tests here; automated; lab must meet quality standards & be surveyed.
  - **PPM—**provider performed microscopy-sub-category of mod.; done w/ microscope during patient visit; lab must meet quality stds.; no routine oversight.
  - **High—**manual; require more training, technique & result interpretation; most stringent stds.; surveyed.

Quick CLIA 101 Cont'd.

- **Quality Standards**:
  - Personnel qualifications & responsibilities--lab director has overall responsibility; required positions.
  - Quality Control (QC)—mechanism to ensure test is working that day.
  - Patient Test Management (PTM)—record keeping system; patient ID, confidentiality, test referral, etc.
  - Proficiency Testing (PT)--external test for accuracy by private org. or lab checks accuracy 2X/yr.
  - Quality Assurance (QA)—now called Quality Assessment--ongoing, plan to monitor & ensure quality results; communicate & solve problems.

Quick CLIA 101 Cont'd.

- **<u>CLIA Surveys</u>**:
  - Biennial, announced.
  - Routine surveys include *only* moderate & high labs.
    - Others based on alleged complaints.
  - Performed by CMS trained State Agency Med. Techs. or
  - By approved accrediting orgs. with equivalent standards; e.g. CAP.
  - Educational, outcome-oriented with QA focus.
- Data indicates improved lab performance over time & more labs than ever enrolled in CLIA.

CLIA Compliance for G.T. Labs

GENERAL INFORMATION:

- Labs must enroll & meet all 5 major CLIA quality requirements:
  - Personnel, QC, PT, PTM, QA.
- Flexibility in how & when lab meets standards.
- Priority depends on test quality impact.
- No penalties for non-enrollment; unless intentional after notification or refusal to comply.
- CMS will provide technical assistance to labs.

CLIA Compliance for G.T. Labs

SURVEY FACTS:

- The first survey is information-sharing unless risk to patient safety is found.
- Survey process looks at outcomes—results.
- Problems found that affect test quality are cited on lab's survey report, but the surveyor will:
  - Offer customized guidance to correct problems,
  - Set priorities,
  - Suggest resources & timeframes for correction &
  - Provide verbal ideas to improve minor problems.
- Lab is given credit for what they do right.

CLIA Compliance for G.T. Labs

SURVEY PROCESS:

- Perform entrance Interview.
- Tour lab.
- Observe testing.
- Interview personnel.
- Review records, data/information.
- Assess outcomes & determine compliance.
- Conduct exit conference & generate survey rept.
- Lab develops plan of correction if problems found.

CLIA Compliance for G.T. Labs

CLIA STATE SURVEYORS:

- Are professional & knowledgeable about CLIA, laboratory practices & quality assurance.
- Evaluate lab's overall ability to provide accurate results rather than individual standards.
- Receive periodic training by CMS &/or experts.
- Will receive specific, detailed training with new CLIA G.T. regs.
  - CMS will enlist nationally recognized G.T. experts.

CLIA Compliance for G.T.

- **Without specific G.T. training a CLIA surveyor can:**
  - Review lab director's qualifications & responsibilities.
  - Evaluate QC, instrument maintenance & analytical test validation & PT data.
  - Interview testing personnel: observe test procedures.
  - Verify specimen integrity, identification, handling, audit trail, confidentiality, etc.
  - Assess lab's plan to assure accuracy internally & externally and solve problems;check turnaround time.
  - Assist the lab to meet applicable CLIA requirements.

CLIA Compliance for G.T.

- **CLIA experience with G.T. research labs:**
  - Much of what lab does to verify test works & results are correct facilitates meeting CLIA.
  - Existing documentation & data are useful.
  - Organizational materials are acceptable: e.g. job descriptions, safety plans, etc.
  - THERE ARE G.T.RESEARCH LABS IN COMPLIANCE WITH CLIA!!!

CLIA Compliance for G.T. Labs

- CMS considers every lab unique, but a possible priority order to meet CLIA might be:
  - **Personnel qualif. & responsibilities**-- esp. lab director & testing persons; i.e., edu., experience, competency & training.
  - **Quality Control—**correlation with a “gold standard”; re-testing known specimens; clinical information.
  - **Proficiency testing—**external mechanism to ensure accuracy 2X yr.;e.g., splitting specimens if no priv. co.
  - **Quality Assurance—**lab’s assessment of all CLIA requirements & quality practices.

CLIA Compliance -- G.T. Labs

QUESTIONS???????????