

Clinical Laboratory Technology Advisory Committee

Minutes of the June 13, 2008 Meeting

Meeting held by videoconference from CDPH Richmond Campus and North Hollywood Kaiser Permanente Regional Laboratory.

[CLTAC Members Participating:](#) Laurie Armour, Michael Borok, Tony Butch, Lorri Dean-Yoakum, Leonard David, Elizabeth Dequinia, Vickie Finson, Tim Hamill, Lin Kassouni, Donna Kirven, Carmen Maldonado, Michael Terry, Peggy O'Toole, Salim Rafidii, Les Revier, Fred Ung, David Yong, Mary York.

[Former CLTAC Members Participating:](#) Vickie Bello, Terry Bryant, Sam Chafin, Morton Field, Imre Fischer, Robert Footlik, Deanna Iverson, Sol Notrica, Jim Ottosen,

[DPH Staff Participating:](#) Zahwa Amad, Frank Barnes, Norma Barocio, Grace Byers, Ron Harkey, Robert Hunter, Nema Lintag, Howard Manipis, Victoria Maxwell, Donna McCallum, Don Miyamoto, Karen Nickel, Bea O'Keefe, Shahrzad Radahd, Judy Schlosser, Joanne Sparhawk, Tom Tempske, Robert Thomas, Pat Toomer, Clint Venable, Kathy Williams, Ellen Yasumura.

[Welcome and General Announcements:](#) The meeting was called to order by Chairman Dr. Tim Hamill. He welcomed the participants and asked persons to identify themselves at both videoconference sites and on the telephone bridge. He noted that there was a quorum of CLTAC members present.

[Approval of the March 7, 2008 meeting minutes:](#) The minutes of the previous meeting were reviewed and approved.

[Department news:](#) Karen Nickel introduced Kathleen Billingsley, Deputy Director of Healthcare Quality. Ms. Billingsley reminded the CLTAC that the Ortiz bill created the new DPH and an advisory committee. The new CDPH was working on a strategic plan with a number of initiatives. A recent budget hearing was held that made General Fund reductions and the budget is a concern. Licensing and Certification in the Center has done a number of complaint investigations against hospitals and hospitals are taking this seriously. They are required to self report adverse events, and penalties are being assessed. Ms. Billingsley said a heparin recall the end of March impacted 480 dialysis clinics around the state.

[Laboratory Field Services Update:](#) Karen Nickel welcomed the participants and thanked Kaiser Permanente for providing the videoconference site in North Hollywood and for providing the telephone bridge. Dr. Nickel introduced Leonard David, a newly appointed member of the CLTAC. Leonard was nominated by the Engineers & Scientists of California Local 20. He is QA/QC supervisor in microbiology at the Kaiser Permanente Regional Lab in Berkeley.

Dr. Nickel said that LFS wanted to highlight a couple of issues with the CLTAC this time. The new LFS website would be introduced. An online demonstration in Richmond and North Hollywood is planned, and persons on the telephone bridge may want to follow along at their locations at www.cdph.ca.gov/programs/laboratory_field_services. LFS

will also discuss compliance problems with phlebotomy certification, the ongoing Bureau of State Audits that is underway now in LFS and finally, genetic testing concerns, especially direct-to-consumer genetic testing. Last time LFS related its concerns about this and the program has done lots of work since we met in March.

Dr. Nickel said the impact of the budget impasse was close scrutiny of expenses, no ordering of supplies, vendors not getting paid. This is always a difficult time for state government.

LFS has gotten approval to conduct civil service examinations. New job bulletins for both Examiner I and II are under development and an examination shall be given late summer. Anyone hired must be on a civil service list, so the exam is necessary. She encouraged interested persons to apply.

LFS continues its work to approve certification exams for licensure purposes. Since the last meeting, LFS has approved the National Registry for Clinical Chemistry (NRCC) exams for BS and PhD-level toxicologists and clinical chemists. LFS is planning on conducting exams in immunohematology and hematology in November as LFS doesn't have exams approved for those categories yet.

Dr. Nickel said LFS has some concerns about personnel licensing issues. First, the MLT licensing program is off to a slow start and asked the audience whether they knew why. The CLTAC offered some suggestions including union representation concerns, misunderstanding about work scope by labs, impact of autoverification and competition with lab aides. The second concern is the finding that many phlebotomists are not renewing, and third, CLSs that have failed the state exam several times are passing a certification exam. The CLTAC discussed these issues.

[Report of the CLIA 2003 Subcommittee](#): Robert Footlik said his committee, which is charged with preparing a crosswalk between CLIA as incorporated in state law in 1996, has been temporarily suspended for lack of staff support by LFS. It will reconvene when resources become available.

[Medicare Competitive Bidding Update](#): Donna McCallum updated the CLTAC on this federal project for the San Diego area. Implementation was put on hold because of an injunction filed by Sharp Healthcare and others. Federal legislation is proposed to repeal the project. LFS will follow this issue.

[Legislation Impacting Clinical Laboratories:](#)

- [SB 1184 \(Kuehl\)](#): Kathy Williams reported that this bill would require clinical labs to report all CD4 results to the county health officer. This is required for federal funding by the Ryan White Grant. The purpose is to assure completeness of HIV reporting.
- [AB 2658 \(Horton\)](#): Kathy Williams reported on this bill which would require electronic reporting of infectious diseases after the electronic system has been set up. Reporting by labs outside California would be voluntary.

Regulations Impacting Clinical Laboratories:

- DPH-07-010: HIV Screening Testing (CCR 1230): Dr. Nickel said the public would soon see these regulations. The need for these regulations was discussed last time. The CLTAC is encouraged to review and comment during the comment period.
- DPH-08-01: Clinical Lab Personnel Standards (CCR 1030-1061).
- DPH-08-02: Clinical Lab Standards (CCR 1050).
- DPH-08-XX: Washed Sperm Donor Standards (SB 443, Migden)

Karen Nickel said these would remain on the CLTAC agenda and input shall be sought as they are being developed, but not today.

LFS Website Update: Dr. Nickel introduced Maria DeSousa who has taken on the special assignment, along with Kathy William and Dona Lynch, of converting the former LFS website to a new website. All programs in the state are working to establish consolidated, user friendly websites with links to related issues. Ms. DeSousa reviewed the various online screens and links with the CLTAC and Fred Ung had the screening set up in North Hollywood for the participants there. Ms. DeSousa answered questions and said the work would be ongoing.

BSA Audit of LFS: Bea O'Keefe reported on a legislatively-mandated Bureau of State Audits investigation ongoing in LFS. Four auditors have been resident in Richmond since February 2008 until the end of June. They are auditing LFS' effectiveness in enforcing state laboratory law including conducting biennial inspections, complaint investigations, imposing appropriate sanctions, enforcing proficiency testing failure. The audit report shall be given to the legislature in August 2008. LFS will be required to prepare responses to their recommendations. LFS is already making changes in response to the auditor's findings.

Laboratory Licensure Project: Bea O'Keefe said LFS started registering and licensing laboratories that wanted to be reimbursed for MediCal testing in 2004 after passage of the Speier bill (SB 857 in 2003). This resulted in about 6500 newly registered laboratories and about 220 newly licensed laboratories. However, there are many other laboratories that should be licensed or registered. LFS did a data base sort between the CLIA and state data bases to identify these laboratories and is starting to issue license or registration invoices. The CLTAC asked why these were not already licensed. Ms. O'Keefe said short staff and lack of inspectors was the cause. Dr. Borok asked about accredited laboratories and Bob Footlik asked about POLs operating before January 1, 1996. Those operating after that date are required to be licensed or registered. This new project would be managed by one new Examiner that LFS had hired in Los Angeles.

Phlebotomy Complaints and Compliance Issues: Tom Tempske said that LFS was experiencing compliance problems with phlebotomy, as follows. (1) CPTs are being asked to do non-phlebotomy activities as lab aide duties, waived tests, (2) LFS is receiving false CPT application documents, falsifying high school graduation, experience, SSN, criminal convictions, (3) applicants are using phlebotomy work experience after 1/1/07, the date that certification was required, (4) falsified CPT

certificates. A CPT with a falsified certificate does not get a renewal invoice so labs contact LFS and find the certificate is not legitimate, (5) high volume of criminal convictions requires labor intensive Live Scan review, (6) some phlebotomy training programs are overly expensive and don't deliver on promises. The CLTAC asked questions about this. Why so many LiveScans for phlebotomists? Maria DeSousa said since the volume of applicants was so high, there was more exposure. LiveScans are required now for all license categories and the others are not so high. Donna Kirven criticized the certificate paper being used for phlebotomy certificates. Bob Thomas said LFS was working to correct problems with a new vendor. Jim Ottosen asked if it was permissible to photocopy a certificate since there were no longer any cards. Bob Thomas said that since the wallet sized card can no longer be produced, he and Dr. Nickel have approved photocopying the official certificate under certain conditions. The copy must be marked as a copy. It can only be used by the employee at multiple locations of the same employer. If the CPT is employed by more than one employer, the phlebotomist must request and pay a \$13 dollar fee for a duplicate. Mr. Thomas noted that this procedure may change if LFS is able to re-issue the wallet sized cards along with certificates with the new vendor.

Increase in Healthcare Providers Using Tissue Products: Ron Harkey said the number of providers using tissue bank products is going up very fast. The tissue bank industry includes those facilities collecting, processing, distributing or storing tissues, as surgical centers, hospitals and now, dentists. A wide variety of tissue is being recovered from cadaveric tissue and donations for use by these practitioners. Michael Borok asked about synthetic skin and allografts, not subject to tissue bank law. Bob Footlik asked when LFS would develop standards for tissue banks by regulation. Ron Harkey said it was impossible for LFS to do this since the area is so broad and technical.

Genetic Testing Concerns: Dr. Nickel said genetic testing was becoming an increasingly important component of healthcare. DNA-based tests can involve gene products, expressed proteins, metabolites, chromosomes, acquired somatic cell mutations. Genetic tests can be used to diagnose existing disease, predict future of disease, identify carriers of mutations, predict response to therapy, identify traits prenatally. It is said there are genetic tests for >1400 diseases already. Today, the CLTAC meeting is going to look at genetic tests from several perspectives. Dr. Nickel introduced Dr. Valerie Ng to give a federal perspective of genetic testing. Dr. Ng is pathologist and laboratory director, Alameda County Medical Center and member of the federal CLIAC committee.

Federal Perspective. Dr Valerie Ng said *the opinions expressed were her own and did not represent those of any federal or professional organization.* She said the organizations studying genetic testing include the CLIAC, SACGHS, CLSI, FDA and CAP.

- CLIAC recommends treating genetic testing like any other high complexity test, but should include issues like counseling and privacy concerns.
- SACGHS says genetic testing is unique since it can predict, it does not change in a lifetime, can be used to discriminate. They don't recommend genetics as a specialty. They are concerned about clinical validity, want web-based registry, education on use of genetic tests.
- CLSI not taking a stand now, but is waiting to develop standards.

- FDA put out notice about IVD MIA and LDT, discussed later.
- CAP is interested in proficiency testing of genetics tests.

Dr Ng discussed IVD MIAs (In Vitro Diagnostic Multivariate Index Assay) and LDTs (Lab Developed Tests “Home Brew”).

- LDTs are developed by a lab which establishes clinical validity, utility.
- IVD MIA uses multiple variables from multiple sources to diagnose a disease or dysfunction.
- FDA wishes to exert enforcement discretion over LDTs and IVD MIAs.
- FDA says labs performing IVD MIAs meet the definition of a laboratory.
- CLIA regulations only cover testing, apparently not IVD MIAs done apart from a laboratory.

The CLTAC had questions. When does a SNP (mutation) have diagnostic value? Dr Ng said only 5% of genetic diseases have a 1:1 correlation between dysfunction and mutation. Probably 95% are multi-gene, so this can get complicated. Will IVD MIAs were reviewed on inspection or by the FDA? The FDA is not involved yet. Bea OKeefe said the challenge was, the labs want to do genetics and LFS must be able to evaluate the validations.

State Perspective: Dr. Nickel said genetic testing in state and federal law is “just another type of clinical lab test”. However, state law established the specialty of genetics in 1996 with SB 113, but CLIA does not have the specialty designation. Genetics testing is high complexity and should be ordered by a physician in California. The test must be performed at a licensed and CLIA-certified laboratory. Genetic test results must be reported back to the ordering physician with the lab performing the test identified. The report must clearly state the reference range and allow interpretation of results. The reporting lab is responsible for accuracy of results. Any LDT must be validated by the laboratory performing the test. Any IVD MIA must also be validated before use.

What about direct-to-consumer genetic testing? Dr. Nickel said genetic tests could not be self-ordered in California and some internet businesses were offering tests directly to the consumer. These businesses were making interpretations of genetic tests done elsewhere and were not identifying where the tests were done. She said LFS had investigated 25+ genetic businesses and had sent cease and desist notices to 13 for violating state laboratory law. This was an ongoing investigation. LFS hopes that federal action on genetic testing would not require individual state action. Clarification was needed for genetic counseling, diagnostic versus predictive reports, risk assessment, and public concerns about cost and accuracy of results.

SNPS and Predisposition to Disorders: Dr. Nickel gave a brief description of SNPS and disease risk. SNPS are single nucleotide polymorphisms which involve a mutation of a single nucleotide (ATCG). The greatest interest in SNPs is matching cohorts with or without a disease. SNP maps help identify multiple genes with disease association. The impact is that SNP data is being used to predict predisposition to dysfunction. This is being offered on the internet to the public who can afford this testing. There is high interest in personalized medicine and many people want access. Many want to circumvent a physician to get genetic information. How should the physician be involved? Is he/she prepared to provide genetic counseling?

Validation of genetic diagnostic algorithms: There was not enough time for Bea O'Keefe to address this topic, so it was deferred to the next meeting of the CLTAC.

New Business:

- Infectious Disease Reporting: Dr. Borok asked when a private physician would be required to report a patient with MRSA. MRSA reporting has been required since February 2008. Kathy Williams said only reporting severely ill patients would be appropriate.
- Dr. Hamill said that LFS was creating a barrier for licensure of cytogenetic PhDs in California. Bob Thomas said that the regulations needed to be amended, and LFS was working on that now. He said PhD cytogeneticists needed 4 years experience to be licensed at the lab director level, but could not get that experience without a BS-level license. There is currently no trainee license for doctoral level cytogeneticists.
- Dr. Hamill asked for clarification regarding frequency of oral licensing examinations. Bob Thomas said that LFS would be moving from an annual/semi-annual schedule to a quarterly schedule for conducting these examinations to shorten the time-line to licensure for applicants.
- Referral of PT samples within a medical complex, does this violate the law? This question shall be held over to the next meeting.

Meeting Adjourned: The meeting was adjourned by Tim Hamill at 12:40 PM.

Next Meeting Date: September 5, 2008. Be prepared to set meeting dates for 2009.