

Clinical Laboratory Technology Advisory Committee
Minutes of the June 8, 2007 Meeting
Meeting held by videoconference from CDPH Richmond Campus and
North Hollywood Kaiser Permanente, and by telephone bridge

CLTAC members participating: Laurie Armour, Michael Borok, Elizabeth Dequinia, Vicki Finson, Tim Hamill, Lin Kassouni, Donna Kirven, Carmen Maldonado, Peggy OToole, Salim Rafidi, Michael Terry, Fred Ung, Lorri Dean Yoakum, Mary York.

Former CLTAC members participating: Morton Field, Imre Fischer, Robert Footlik, Jim Ottosen.

CDPH staff participating: Michael DiBartolamis, Ron Harkey, Paul Kimsey, Ray Meister, Don Miyamoto, Karen Nickel, Bea Okeefe, Jan Otey, Haynes Sheppard, Robert Thomas, Pat Toomer, Clint Venable, Barbara Wieskamp, Kathy Williams.

Public members participating: 17 public members attended in Richmond, 18, in North Hollywood and 23 persons were on the telephone bridge.

Introduction and general announcements: Chairman Tim Hamill opened the meeting in Richmond at 9:03AM. He welcomed the participants and asked persons to identify themselves at both videoconference sites and on the telephone bridge. He noted that election of the new CLTAC chair would be held during new business, at the end.

Approval of the March 2, 2007 meeting minutes: Dr. Hamill noted that there was a quorum of the CLTAC. The minutes of the March 2, 2007 meeting were reviewed, amended and approved.

Department news: Dr. Paul Kimsey, Division of Laboratory Science, noted that this would be his last meeting with the CLTAC, as the reorganization of the Department of Health Services would remove his involvement. He said SB 162 had created the new Department of Public Health of which LFS shall become part. Dr. Mark Horton, the new director, is experienced in public health. LFS shall become part of the Center for Healthcare Quality, along with Licensing and Certification which oversees hospitals and nursing homes. This is a large organization and should be a good fit for LFS. Dr. Kimsey said there was concern in Sacramento about the delay in initiation of MLT licensing. Several public participants voiced similar concerns. Dr. Borok asked if Dr. Horton had been confirmed by the senate (not yet), what the cost of the reorganization is (supposed to be neutral) and the mandate for budgetary responsibility (legislative hearings underway).

LFS update: Dr. Karen Nickel thanked Kaiser Permanente for their ongoing support of the CLTAC. She also thanked Dr. Kimsey and Laboratory Science for his loyal support of the advisory committee for 10 years and wished him well on his new assignment.

Dr. Nickel introduced and welcomed the new members of the CLTAC as follows:

Laurie B. Armour, cytotechnologist, Palo Alto Medical Foundation, nominated by CA Association of Cytotechnologists, replacing Patrick Manou.

Anthony (Tony) Butch, clinical chemist, UCLA, nominated by American Association of Clinical Chemistry, Southern CA Section, replacing Paul Fu.

Vicki Finson, CLS, blood bank specialist, nominated by Blood Centers of California, replacing Cherie Evans.

Jan Schwarz, RN, Kaiser Permanente, nominated by the CA Healthcare Association, replacing Carolyn Days.

Fred Ung, CLS, Laboratory QC manager, Kaiser Permanente, nominated by CA Coalition of Clinical Lab Professionals.

Lorri Dean Yoakum, CLS, Laboratory compliance and safety, nominated by the CA Clinical Lab Association, replacing Terri Bryant.

One remaining vacancy, non-voting member, no nomination received from Advanced Medical Technology Association (AdvaMed), formerly Healthcare Instrument Manufacturer's Association (HIMA).

Dr. Nickel said LFS started a recruitment campaign for Examiner staff in December. About 8,300 recruitment postcards were mailed to licensed persons in metro Bay Area, Los Angeles and Sacramento. About 100 responses were received, about 30 submitted applications, and about 20 took the exam. To date, those that passed will have to be interviewed in an effort to fill some of the 17 examiner vacancies in LFS. Lack of staff has prevented startup of MLT licensing and has continued backlogs in most activities. Dr. Nickel encouraged meeting attendees to consider a job with LFS! The CLTAC asked if salaries and location have changed. (No)

Blood lead reporting. Dr. Nickel introduced Dr. Ray Meister of DHS' Occupational Lead Poisoning Prevention Program. That agency investigates lead poisoning, registers laboratories that test for lead, and oversees employee lead testing for CalOSHA and CDHS. The program was created by legislation in 1986 and tracks lead poisoning cases in children and adults. All labs are required to report electronically all blood lead levels >10mcg/dl within 3 working days and <10mcg/dl within 30 calendar days. Dr. Michael DiBartolemeis said 50,000 blood lead tests are done each year, 8,000 requested through employers. This section tracks exposure and poisoning and relies on labs to comply with reporting requirements. The CLTAC asked what reporting information was needed, the difference between acute and long term exposure, what information is required for reports on children, and why must every blood lead be reported, even <10.

Legislation impacting clinical labs.

AB 185 (Dymally) Robert Thomas said this bill was a follow up to AB 1161 of last session that explained duties and supervision of unlicensed laboratory aides. Because the author was receiving opposition to this bill, it was pulled back. It may be re-introduced next year if there is consensus.

AB 1175 (Niello) Mr. Thomas said this bill was a follow up with AB 2156 (Niello) last year which authorized autoverification. This bill would make the delegation of autoverification voluntary for the Technical Supervisor.

AB 1442 (Feuer) Bea Okeefe said this bill would eliminate DHS approval of labs doing HIV testing but would retain licensure or registration requirements.

SB 661 (Maldonado) Dr. Nickel said this bill dealt with billing for anatomical pathology and would prohibit billing for pathology performed at another laboratory unless part of the testing was done at the primary location.

SB 366 (Aanestad) Karen Nickel reminded the CLTAC that an earlier Aanestad bill (SB 1355) in 2004 authorized cytotechs to perform up to the limit recommended by instrument manufacturers of automated devices as approved by the FDA. That meant the California cytotechs could perform up to 200 Pap tests per day using automated Pap devices. The DHS was charged with doing a literature review to see if this caused any negative patient outcome. Dr. Nickel said the literature search had been done, thanks to Lynn Sandweis, retired cytotech from UCLA who did the search. A total of 21 journal articles were reviewed. Five of these articles did extensive correlations between manual and automated Paps. All reported significantly higher specificity for high grade lesions, improved sensitivity for low grade, and decreased false negative rate. SB 366 would authorize DHS to change the limit for cytotechs using automated devices, but this will not be necessary since there was no report of negative patient outcome.

Report of CLIA 2003 subcommittee: Robert Footlik, chair of the subcommittee, reported that the group plus a number of interested persons, continue to meet, reviewing CLIA 2003 and CLIA as published in 1994 (current state law). They are spending lots of time on quality systems, working on microbiology that afternoon. There would be no report until the review is completed. The CLTAC will then be presented a crosswalk of differences for considerations.

Update on CLIA exemption: Karen Nickel said that Governor Schwarzenegger has directed DHS to again seek CLIA exemption for California laboratories, removing duplicate fees and oversight. LFS was approved for a 3-year track to get ready for CLIA exemption and 2006-07 was the first year. LFS was authorized to hire 10 positions to start staffing up for laboratory inspections, complaint investigations, proficiency testing, etc. LFS was not able to fill the examiner positions in 2006-07 and was denied more staff in 2007-08, so this will delay the 3-year effort by at least one year. LFS is now shooting for CLIA exemption in 2009-10. To conduct the full CLIA exempt laboratory program, LFS estimates it will need about 47 people, but currently only has 17, including clerical staff.

Progress on “continuous personnel licensing”: Robert Thomas reported on the new concept, continuous personnel licensing. He calls it this because eventually applicants can apply throughout the year without specific deadlines. This would be possible with certification examinations rather than a single state licensing exam and with online applications. As of June 6, a total of 480 persons had applied online for CLS licensure with 167 already qualified for the state exam, 139 for certification exam, 32 temporary licenses issued and 146 files pending review. The CLS application deadline for the state exam in November is July 15 with all documents complete by August 15. Those taking an approved certification can apply after that and take those exams any time. CLTAC questions included, who got temporary licenses (only those training in CA and taking state exam in November 2007), what is the timeline for persons applying once they pass the ASCP or AMT exams? (4 weeks?), does ASCP or AAB give specific scores of applicants (AAB = yes, ASCP = no).

Status of phlebotomy and MLT licensure: Robert Thomas said phlebotomy certification remains a strong program with lots of interest. To date, there are 104 programs approved to train phlebotomists, 22,726 persons certified with 1,042 pending review in LFS. Quite a number of phlebotomy applications have been abandoned (519) for failure to meet certification standards.

LFS has been unable to start MLT licensure because we have been unable to hire examiner staff needed. This has caused great consternation among colleges, hospitals and laboratories. LFS is holding fast that it cannot start the program without staff. CLTAC questions, a CPT's performance must be reviewed monthly. How is this done? (onsite observation, review of blood draws), what happens if an applicant exceeds the 4 year look back (they must retake the certification exam), If an MLT program is NACCLS-approved, can the MLT do high complexity tests in CA (No), Can a CPT competency be judged by their ability to collect sterile blood culture? (don't rely on that), Has ASM applied for approval of their exam yet (no), the 26 weeks required for MLT training, can some be student labs? (general student labs not acceptable, must be lab with actual testing going on)

CDC HIV screening and confirmation protocols: Bea Okeefe reported that in September 2006, the CDC had released guidelines advocating routine voluntary HIV testing of all adults. LFS has seen an upsurge of applications for rapid HIV testing locations, perhaps in response. There are currently 6 "rapid" HIV tests on the market, OraSure, Reveal, Unigold Recombigen, Multispot, Clearview Stat Pak and Clearview Complete. These tests utilize a variety of specimens including oral fluid, whole blood, serum or plasma. Most of the tests that use whole blood or oral fluid are waived. Tests that use serum or plasma are generally moderate complexity. Some are either waived or moderate depending on specimen used. Waived tests are single use and therefore do not lend themselves to high volume testing. Some give results immediately, some require up to 40 minutes.

California regulations (title 17 CCR 1230) require any reactive screened HIV to be confirmed by a more specific test prior to reporting as positive. The CDC studied one of the rapid HIV tests and found a number of false positive reports when confirmed with EIA. The CDC recommends that any reactive HIV screened test be confirmed with Western Blot or IFA, even if a follow up EIA test is negative. Further, the CDC recommends that if a rapid HIV test is reactive and the Western blot or IFA is negative or indeterminate, that retesting be done 43 weeks later. Questions from the CLTAC, when does the army use waived HIV tests to confirm waived HIV? (only in developed countries), Should HIV-1 or -2 be tested? (US tests for HIV-1 only.) How can an oral fluid test be used with serum? (test modification would have to be fully validated, but modification of FDA kit is not currently allowed). What about proficiency testing of waived HIV? (a number of PT providers supply samples) , the CDC protocol should be enforceable, not a recommendation, a comment.

Prenatal testing for hepatitis B—a reminder: Carol Sparks of DHS Division of Communicable Disease Control said that all pregnant women should be tested for HBsAg as it can be transmitted to the baby. The woman can be administered a vaccine which gives baby some immunity. Labs must report HBsAg to local health officer. There is a problem that labs fail to confirm positive hepatitis or fail to report. There are 9 different HbsAg tests with varying confirmation procedures. In pregnant women a neutralization procedure may be required. Often a lab may not know a woman is pregnant and may not do the supplemental test.

Validation of multivariant index analysis (MVIA): Bea Okeefe updated the CLTAC on MVIA, sometimes called *in vitro* MVIA. LFS is dealing with this more and more as labs combine data from multiple assays or multiple labs, using demographic information and an empirical algorithm to make diagnosis. There are 3 components, individual test results, the calculation and the patient-specific result. The problems include, how to validate the multiple test results, unwillingness of labs to share data, no proficiency testing, source of algorithm is proprietary, and

labs claim MVIA is not a test. Because of concern, the FDA has announced that MVIA will be regulated like any other test, based on risk, Class 1 = low risk, Class 2 = moderate, Class 3 = high risk. Ms Okeefe urged the CLTAC to get more information on MVIA and stay informed. Observation, the “test system” of CLIA should include the complete algorithm (Footlik).

Scope of work concerns in genetic testing, histotechs and PAs: Robert Thomas reported that LFS continues to get many questions about work scope of these persons. Regarding genetic testing, “genetics” refers to the specialty of genetic testing. This includes clinical cytogenetic testing and clinical genetic molecular biology (17CCR 1029.52 and 1029.53). Clinical genetic molecular biology means the determination of all aspects of the nucleic acids of the human genome with respect to genotype and phenotype. Genetics means molecular biology related to the diagnosis of human genetic abnormalities whether acquired or birth defects. Molecular biology in state law refers to a subspecialty for diagnosis of infectious diseases.

The questions that LFS gets basically are who can do what testing? Persons qualified to perform high complexity genetic testing include, physician/surgeon, clinical genetic molecular biologist, clinical laboratory bioanalyst or clinical lab scientist. Persons qualified to perform high complexity molecular biology tests include a physician/surgeon, bioanalyst, clinical lab scientist, clinical microbiologist scientist, clinical microbiologist, or clinical chemist scientist. The problem is, persons want to cross over between genetic testing and molecular biology testing because they share some technology. Questions from CLTAC, so many of the duties in genetic testing are repetitive, can’t lab aides do them (BPC 1269 is not clear where pre-analytical ends and analytical steps begin), CLIA has no genetics specialty so labs are forced to be certified in chemistry or toxicology (this is a CLIA issue, not state).

Histotechs are authorized in California law to prepare human surgical specimens for gross description and dissection under the direct supervision of a qualified pathologist. They must have a HS diploma or equivalent. The pathologist must be physically present onsite. For tissue processing that does not involve dissection, the pathologist must be available, not necessarily on site.

Pathologists’ Assistants who are certified by the AAPA or the ASCP BOR may prepare human specimens for gross description and dissection without direct supervision, but they must be competent and accountable to a pathologist supervisor. Uncertified PAs need to work under direct supervision as histotechs are. Questions from CLTAC, what about deeners, autopsy techs, what are they allowed to do? (look at their job description, competency and certification).

Election of new CLTAC chair: Chairman Tim Hamill opened the floor for nominations for Chair for 2007-08. Mary York nominated Dr. Hamill, seconded by Vicki Finson. Hearing no further nominations, Dr. Hamill was re-elected as chair.

New business:

What kind of supervision do histotechs need if they only stain tissue? Robert Thomas said they did not need direct supervision only general supervision.

Can we talk about the 3 lab limit for lab directors? Bea Okeefe said the issue had been revisited since the last CLTAC meeting and upheld. The limit includes co-directors, waived labs, and

hospitals with multiple sites. What about blood banks? They is not included unless they are dual licensed as a clinical lab.

Hearing no further new business, Mary York moved that the meeting be adjourned, the CLTAC agreed and the meeting closed at 12:30. It was announced that the CLIA 2003 subcommittee would meet again at 1:30 that day.