

Clinical Laboratory Technology Advisory Committee

Minutes of the September 5, 2008 Meeting

Meeting held by videoconference from KP Regional Clinical Technology Bldg, Berkeley,
KP Regional Laboratory, North Hollywood and
Telephone Bridge Line

CLTAC Members Participating: Laurie Armour, Michael Borok, Tony Butch, Leonard David, Lorri Dean-Yoakum, Elizabeth Dequinia, Tim Hamill, Lin Kassouni, Carmen Maldonado, Peggy OToole, Salim Rafidi, Les Revier, Michael Terry, Fred Ung, Mary York.

Former CLTAC Members Participating: Vickie Bello, Morton Field, Imre Fischer, Robert Footlik, Sol Notrica, Jim Ottosen, Curtis Johnson.

DPH Staff Participating: Zahwa Amad, Alan Ankerstar, Frank Barnes, Norma Barocio, Maria DeSousa, Pam Dickfoss, Pam Farrell, Ron Harkey, Robert Hunter, Nema Lintag, Victoria Maxwell, Donna McCallum, Don Miyamoto, Howard Manipis, Karen Nickel, Bea O'Keefe, Jan Otey, Shahrzad Radahd, Bonnie Sorensen, Joanne Sparhawk, Genie Tang, Tom Tempske, Robert Thomas, 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, amended and approved.

Department news: Karen Nickel introduced Dr. Bonita Sorensen, Chief Deputy Director of Policy and Programs for CDPH. Dr. Sorensen said CDPH appreciates the work and participation of the CLTAC. She discussed the state budget situation, saying all programs shall continue operating and some will be affected more than others. The activities of LFS are exempted from budget cuts. Dr. Sorensen mentioned the Bureau of State Audits report about LFS just posted on the BSA website. This was the result of many months of reviewing files and information by the auditors in LFS. The audit report cites shortcomings in inspections, proficiency testing, enforcement, complaint investigations and sanctions. CDPH welcomes these hard findings and will adopt an aggressive action plan to correct these deficiencies, short term and long term. LFS needs to maximize its resources to impose sanctions and collect fees. It has its marching orders! Dr. Sorensen said the new CDPH has new management and is working to improve processes and efficiency. For example, a consultant analyzed the regulation development process to improve time of implementation.

Laboratory Field Services Update: Karen Nickel welcomed the participants and thanked Kaiser Permanente for providing the videoconference site in Berkeley as well as the one in North Hollywood. Because of the lack of state budget, the contract for use of the site at the Richmond Lab was cancelled and there was no northern California meeting videoconference site. Kaiser Permanente kindly volunteered their Berkeley conference

center at the last minute. Dr. Nickel asked if the email list for the CLTAC and meeting participants was current as LFS was no longer mailing meeting notices. She noted that the CLTAC needed to nominate a chair for 2009. She said Dr. Hamill has been chair for over a year and may need a respite. Also, Dr. Nickel said the CLTAC would select the meeting dates for 2009 at this meeting.

Dr. Nickel said that LFS wanted to highlight a couple of issues with the CLTAC this time.

- Impact of budget impasse. There is still no budget and it is becoming more and more difficult for our vendors and for state workers. After the Governor's Executive Order, LFS was successful in retaining all of its part-time retired staff, but travel is restricted and LFS cannot order supplies.
- Recruitment of Examiner staff. LFS has been working hard to recruit qualified Examiner staff to fill vacancies. About 10,000 recruitment postcards were sent out this summer, about 120 people responded, 23 applications were received and about 14 took the civil service examination. She encouraged experienced laboratorians with an interest in quality laboratory standards to apply.
- BSA Audit of LFS. If you look at the BSA website (www.BSA.ca.gov) for Report 2007-040, you will see the audit report of LFS. Bea OKeefe will outline the audit findings and our response to their recommendations. LFS regrets their findings, but is taking immediate action for program improvements in the short term. Long term, LFS needs more staff and IT resources to do a better job.
- Approval of certification exams. LFS is continuing to work on approval of certification exam and will be conducting its (hopefully) last licensing exams (for hematology and immunohematology scientist applicants) in November.
- Genetic testing. Today we are going to continue our discussion of genetic testing and explain how we are licensing genetic laboratories and validating genetic diagnostic algorithms.

Report of the CLIA 2003 Subcommittee. Chairman Robert Footlik said that because of lack of staff liaison availability, this committee has no report.

MediCare competitive bidding contact update: Donna McCallum said that Congress had mandated CMS to conduct a demonstration project for competitive bidding for Medicare reimbursement of laboratory services. San Diego was selected as the first demonstration site. Because of laboratory protests about the project, Congress repealed the whole project.

Legislation impacting clinical laboratories

AB 1060 (Laird, urgency). Ron Harkey reported on this "spot bill", just recently introduced. It would allow dentists and oral surgeons to be exempt from tissue bank licensure requirements.

AB 682 (Berg, 2007). Karen Nickel reported on this bill which was enacted last year, but had unexpected consequences this year. The CLTAC had not discussed this bill last year as it only seemed to impact physicians, not laboratories. This bill repeals the requirement that physicians obtain written consent from their patients for an HIV test. However, a trailing part of this legislation was not repealed. This continues the requirement that a laboratory have written consent to perform HIV. Since the physician is not providing the consent, some laboratories are refusing to do HIV tests and that is

how LFS got involved. LFS met with the supporters of this bill and it was not their intent that laboratories would need consent. LFS was told that a notice in writing to that effect would be prepared for release to the CLTAC and posting on the LFS website.

Regulations impacting clinical laboratories: Dr. Nickel reported on regulations underway.

DPH-07-010 HIV Screening Testing Standards These regulations were released for public comment today. As proposed, they amend 17 CCR 1230. All the CLTAC members and many of the participants in this meeting are on the mailing list so LFS encourages everyone to review and comment before October 22, 2008. These will replace regulations enacted in 1986. They may need another comment period depending on comments received.

There has been no further work on the other regulations since the last meeting of the CLTAC:

DPH-08-01, (amendments to CCR 1030-1061),

DPH-08-02 (amendments to CCR 1050) and

DPH-08-xxx (regulations as mandated in AB 443, Migden, 2007.)

BSA Audit of LFS: Bea OKeefe discussed the purpose and findings of the recent Bureau of State Audits audit of LFS. The purpose of the audit was to assess LFS' ability to:

- Detect and investigate non-compliance,
- Investigate consumer complaints,
- Impose sanctions,
- Use authority to assess and collect fines,
- Limit participation in MediCal and Medicare.

The areas reviewed by the auditors included:

- Complaint processing and investigations,
- Proficiency testing oversight,
- Enforcement actions taken,
- Biennial inspections,
- Licensing of laboratories,
- Regulation writing,
- IT support,
- Legal support.

Summary of recommendations:

- LFS should perform all its mandated responsibilities, including inspection of every licensed lab every two years.
- LFS should review and investigate all complaints and bring to resolution.
- LFS should sanction labs as appropriate.
- LFS should improve proficiency testing monitoring of laboratories.
- LFS should review regulations and revise as needed.
- LFS should continue to license labs in CA and outside CA.
- CDPH should ensure LFS has sufficient resources to meet all oversight activities.

Bea OKeefe said LFS benefitted from the audit as it identified elements necessary for it to be a strong program, and drew attention to its resource needs.

The CLTAC asked many questions related to the audit. Q: Who authorized the audit? A: The state legislature. Q: The accrediting organizations review proficiency testing scores of accredited labs, so why isn't that good enough? A: The accrediting organizations have no enforcement authority except to deny accreditation. Q: If LFS has financial reserves, why isn't LFS allowed to spend them? A: LFS has not been able to justify use of the money. Q: Why is BSA so powerful? Why was the audit necessary? The CLTAC and the public already know that LFS has problems. A: No comment. Q: How would LFS monitor proficiency testing monthly when it is performed every 4 months? A: LFS gets the data electronically continually from the PT providers. Q: Why do labs pay yearly but get inspections every 2 years? Personnel licenses are every 2 years, CLIA every 2 years. Why not labs? A: Collection of lab fees is set up to be annually. This allows current data updates on lab operations. Q: What about regulations? How can you do them faster? A: This is a very labor intensive process with limited staff resources. Q: Isn't the bottom line money? A: LFS needs spending authority to add staff and IT. Q: LFS is fee supported so what is the problem? Q: What happens if LFS does not comply with audit recommendations? A: LFS has one year to make improvements. Not everything is possible until more resources. Q: Why has LFS had inadequate staffing for at least 10 years? A: LFS has been unable to fill its vacancies, and the vacant positions have been taken away over the years. LFS has been allowed to keep its retired annuitants to fill the gaps in staff. Q: The auditors do not respect the CLTAC. The CLTAC is not taken seriously. A: The auditors did not talk about the CLTAC with LFS.

[Genetic testing for diagnostic purposes](#): Dr. Nickel introduced a three-part discussion on genetic testing.

Overview of genetic testing. Dr. Nickel said the whole area of genetic testing is exploding now with lots of studies, publications, reports, public interest. These studies link genetic variants with diseases or dysfunctions, as Type 2 diabetes, breast cancer or colon cancer, or disorders, as lactose intolerance, baldness or taste. Some multi-variant analyses give relative risk of developing the disorder, a worrisome "predisposition". Much of these correlations are available in the scientific literature and are called "transparent". Others are kept a secret or even patented, and are "proprietary". Some businesses are taking the opportunity to contract with a lab performing genetic tests to market products as skin, hair or nutritional products. LFS is concerned when no physician is involved, the test interpretations are un-validated, and the consumer deals directly with the business, "DTC". This raises lots of concerns. This whole area is in a transition and LFS shall continue to be involved so as to protect public health and safety. Tom Tempske is going to discuss licensure of genetic labs.

Licensure of genetic laboratories. Tom Tempske said genetic risk analysis tests may not be traditional lab tests, but they meet the definition of a clinical lab test in state law. Therefore, they are subject to laboratory licensure law and standards in California, even if they are not subject to other state or even federal law. Applicable law for genetic labs includes laboratory director, supervisor and testing personnel requirements, and test requisition by a person licensed in the healing arts. In state law, genetics is recognized as a specialty, but not in CLIA. Mr. Tempske said there are 3 types of genetics labs: (1) the "traditional" lab that adds genetic testing to their full-service menu of tests or that

specializes in genetic tests. These labs notify LFS that they are adding genetic tests and provide analytical validation for any “homebrew” tests. They add “genetics” to their specialties on their license. (2) The second type of genetic lab is a business that offers genetic tests performed at licensed labs and pass the results off without further interpretation to the client. They may provide educational material and let the client figure out an interpretation. These businesses do not tend to need a license, but must disclose any markup of charge. (3) The third type of genetics lab is a business that offers genetic tests performed at licensed labs, but provides an interpretation using an algorithm to give a predisposition of dysfunction. LFS requires this type of business to be licensed and to validate their interpretation of the genetic tests done elsewhere.

Validation of genetic tests and diagnostic algorithms: Bea OKeefe followed up with a discussion on what LFS expects for documentation of validation of genetic tests and algorithms. Key issues that a laboratory must address are what are the intended use of the genes, sequences or mutations evaluated, the purpose of the testing and the patient population. The laboratory must give methodology and samples used to validate. Diagnostic genetic tests usually involve determination of the genetic profile of the patient and then using that to assess the risk or other parameters using a software algorithm. This should be validated by the traditional CLIA requirements for establishing accuracy, precision, reportable and reference ranges, analytical sensitivity and specificity. This may be challenging for a genetic test. Genetic tests also concern clinical and diagnostic sensitivity and specificity, positive and negative predictive values in a target population using peer-reviewed studies in recognized scientific literature and/or a retrospective epidemiological review. The validation of the software algorithm may also include using clinical data, randomized trials or banked samples and controlled variables. Ms OKeefe said that clinical efficacy may be required for reimbursement and some genetic risk assessments may be no better than standards methods.

The CLTAC had a number of questions about genetic testing. Q: California and other states are dealing with DTC genetic testing, why not the federal government? A: Federal law will have to be changed first. Q: In DTC genetic tests, who can order and who pays? A: A licensed healthcare provider must order and the consumer pays. Q: Does CLIA recognize genetic labs? A: They do not issue a CLIA certificate. CMS does not consider an “interpretation” a lab test, and certifies some genetic labs under chemistry or immunology. Q: How are DTC genetic businesses overcoming physician order and lab director requirements in state law? A: They would need to provide qualified persons to perform these duties.

Because of time constraints, Dr. Nickel closed the discussion.

Personnel licensing update: There was not time to cover this issue so Dr. Nickel asked that Bob Thomas defer this discussion on licensure of trainees and approval of training program to the next CLTAC meeting.

New business:

- Nominations for CLTAC chair were held. Elizabeth Dequinia nominated Tim Hamill, seconded by Donna Kirven. No further nominations were heard and Dr. Hamill accepted another term as Chair. This will start officially in 2009.

- Meeting dates for 2009 were set for March 6, June 12, September 11 and December 4, 2009.
- Referral of PT within a medical complex. Bea OKeefe said PT should be handled the same as a routine sample and when patient specimens are split between two laboratories (as protein electrophoresis), this would violate CMS' prohibition about referring PT samples. Ms OKeefe recommended that the lab contact CMS about how to handle this situation.
- When will the MediCal moratorium be lifted? Bea OKeefe said the moratorium had been in effect since April 2001, was renewed again in August 2008. A MediCal payment error study showed that labs billing for services had a higher error rate than the average of any other MediCal provider. There was concern about medical necessity for testing and as many as half of the errors were considered fraudulent.

Meeting Adjourned: The meeting was adjourned by Tim Hamill at 12:20 PM.

Next Meeting Date: December 5, 2008.