COMMISION TO STUDY TESTING ON LYME AND OTHER TICK BORNE DISEASES

January 11,2011

Meeting minutes.

I. Call to order 9:02

II. Rep. Marsh opened the meeting with the required 91-A script.

III. Roll call. Present: Rep. Marsh, , M.D., Ben Chan, M.D., Carl Tuttle, Kathie Fife, Michelle Wagner, Lynn Durand, M.D, Tricia Aiston , Mark Pearson,
Rex Carr, M.D. (alternate for Lynn Durand, M.D.)
Absent: Apara Dave, Frank Hubbell, M.D, Sen. Jeb Bradley
Guest: Dr. Sam Donta

IV. Presentation by Dr Sam Donta,

a. Dr Donta was Head of ID at UConn in 1983 during onset of recognition of the Lyme Disease outbreak
b. Originally UConn helped to develop ELISA/ EIA testing for Lyme disease
c. They then developed Western Blot testing for Borrelia burgdorferi (Bb)
    i. They noted that the Western Blot was sometime unreliable
    ii. Found poor lab to lab reliability – operator dependent
    iii. But they found no other testing that reliably indicate exposure to Bb
d. Dr. Donta participated in a national conference that decided on
    i. Using 3 IgM bands and 10 IgG bands which "created at least some controversy and difficulty"
    ii. Using the Western Blot only if the ELISA was positive
    iii. He stated the 23 kDa band is very specific for Lyme disease
    iv. Also the 39 kDa band is specific for Lyme disease
    v. But the 41 kDa band is non-specific for Lyme disease (flagella antigen)
    vi. But the problem is there is not direct detection test for Bb
    vii. "it seems logical that a patient with continued symptoms is probably persistently infected."
    viii. He notes that patients specifically with Lyme arthritis have a robust antibody response
    ix. But patients without an antibody response are a difficult case, specifically a weak immune system may both cause negative serology and persistent disease
    x. He states there is corroboration in animal studies of persistence of Bb despite negative serology
    xi. Studies show sometimes IgM does not progress to IgG
e. Conclusion that Lyme Disease is basically a clinical diagnosis: that statutory agencies should be cautious with statements of the validity of testing – specifically "positive is helpful, negative is not"
f. Question from Rep Marsh: what is the predictive value of the testing? Answer: He does not have the exact numbers but noted "very high in arthritis patients, very low in other persistent cases, low in early cases"

g. Question from Dr. Durand: why were the 31kDa and 34 kDa bands not included in the result algorithms? Answer: Dr. Donta would have preferred if 31 and 34 kDa bands were included.
h. Statement from Dr. Carr: noted that the Dearborn conference specifically recommended the two tier testing to decrease the false positive rate in *Non Endemic* areas but that New Hampshire is an endemic area.
i. Question from Dr. Chan: Did Dr. Donta know of ways that labs have decreased user variability? Dr. Donta is aware of the lab test methodologies to decrease variability.
j. Dr. Chan noted that a test sensitivity and specificity is a characteristic of the test but that positive and negative predictive values are influenced by the incidence of the disease: that a lower incidence will result in a lower positive predictive value and higher incidence will result in lower negative predictive value.
k. Dr Chan noted that there is a decreased sensitivity early on in the disease (< 4 weeks) but that after 4-6 weeks the testing is very accurate.
l. Dr. Chan noted that the decision on which bands to include in the test methodology was not arbitrary but based on ROC curves
m. Dr. Donta noted that the PCR is disappointing in its' poor rate of demonstrating present infection; and that there really is no good antigen testing.
n. Question of Dr. Carr: to what degree should test results be used to decide on treatment? Answer: "negative antibody tests should not rule out treatment"
o. Mr. Tuttle noted that the testing is based just on the B31 strain of Bb so would the western blot pick up other strains of Bb? Answer; pretty well.
p. Mr Tuttle asked about other species of Borrelia like Borrelia myomotoi and would the Western Blot pick up those? This was not directly answered.
q. Dr. Donta noted that the decision of which bands to included was for population surveillance purposes; not clinical purposes. Dr. Chan questioned the difference between surveillance and clinical purposes.
r. Kathy Fife noted that it is important that the physician look at the whole patient and not just the tests.
s. Mr. Tuttle noted that in the document that he has distributed to the group by Dr Parent regarding the Lymrix vaccine trial, that 36% of the patients in that trial who were culture positive and PCR positive were seronegative.

Discussion ensued regarding need for a disclaimer on tests and regarding the role of clinical judgment when predictive value is low.

V. December 9 , 2020 meeting minutes were approved unanimously.
VI. Discussion by Dr. Chan of incidence of lyme disease in NH: discussion put off till next meeting, followed by an article Dr. Durand will provide about sensitivity and specificity.
VII. Discussion of different testing protocols deferred till a later date.
VIII. Suggestion of presentation of new antigen testing from Galaxy Lab; put off till a later date till after we conclude discussion of the presently recommended Two-tier ELISA/ Western Blot test methodology since that is the present CDC recommendation

IX. Planning for educational programs to disseminate this committee's findings: deferred to a later date.

X. Public Comments
   a. Sandy Picard, APRN, also a Lyme disease patient stated that she was shown to have multiple strains of lyme disease , mostly not detected by routine testing. She has started a Not for Profit in Maine asking the same questions as our NH committee and she suggested coordination.

XI. Next meeting;
   a. First choice Monday Feb. 8
   b. Second choice Friday Feb. 12
   c. 9:00 AM – 10:30 AM

XII. The meeting was adjourned at 10:26 AM