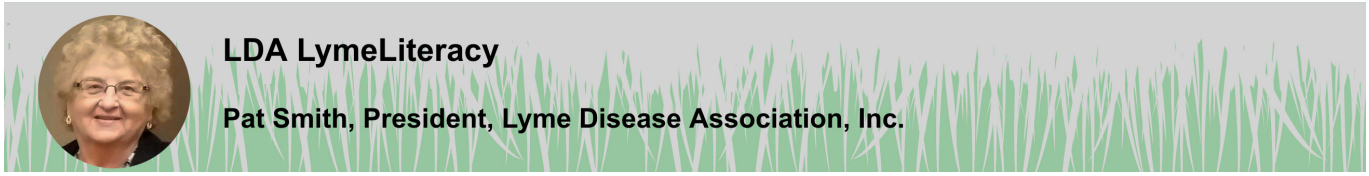
# President's Blog




# *LDA President's Blog* – CDC Doctor Webinar: Help or Hindrance for Patients?

**BACKGROUND** During May Lyme Disease Awareness Month, many Lyme groups across the country promote awareness with different projects, programs, and activities to focus on Lyme disease when the *Ixodes scapularis* poppy seed sized nymph ticks begin feeding in earnest.

When the CDC announced a webinar offering continuing education for health care providers for Lyme Awareness Month, some thought it would provide much needed education for doctors about the reality of Lyme disease for patients and what CDC could do to actually help. This assumption was a valid one. The 2nd HHS Tick-Borne Disease Working Group (WG) in its *2020 Report to Congress* had a recommendation that CDC should develop such a curriculum with patient involvement. Federal agency arguments at the WG table said patients could not really be present in the development of such programs– too difficult to get patients incorporated into that aspect. But certainly, as the unanimously adopted recommendation reflected, "the final curriculum shall incorporate feedback from patients, clinicians, and research scientists with expertise/experience that represents diverse scientific and clinical experiences on the full spectrum of Lyme disease and other tick-borne diseases/conditions." So did CDC solicit patient input for this online webinar? By its own admission when asked whether there was patient input at any level of

this webinar, the answer was no, because it was a clinical educational tool.

**MY ASSESSMENT** After watching this webinar, *Lyme Disease Update and New Educational Tools*, several times, I can honestly say any small benefit this conceivably could have had is clearly wiped out by the continued refusal of government to present the reality of Lyme disease. I saw no meaningful help for physicians nor for patients for their illness, and no information or new tools, only old, repackaged dogma. Read below for details.

**CDC WEBINAR PRESENTER** The webinar itself was presented by Grace Marx, MD, MPH, credentialed as a medical epidemiologist from Bacterial Branch, Division of Vector-Borne Diseases, CDC. No reflection on her personally, but further research online indicated she is board certified in internal medicine and infectious disease, and a member of the epidemiology intelligence service, credentials CDC did not seem inclined to mention in the webinar—despite bias in the latter two areas during the "Lyme Wars."

**TRANSMISSION TIME** Following CDC's standard rhetoric, the webinar opening discusses that disease transmission occurs after an infected tick has been attached for at least 24 hours and most transmission occurs after 36 hours. Instead of providing solid information that the longer a tick is attached, the greater the risk of infection, qualifiers were attached– often precluding doctors from making a timely Lyme diagnose and treatment. These qualifiers are not supported by all peer review, especially studies that indicate Lyme bacteria are sometimes found in tick salivary glands at time of attachment. So the time necessary to move from the midgut to those glands (which provides the basis for the 36 hr. estimate) is not a factor. No comment was made on attachment time for other tick-borne diseases—we know, however, there is no safe attachment time for a tick.

**DENYING LYME THROUGH GEOGRAPHY** Stating that ~500,000 people annually are diagnosed and treated for Lyme, Dr. Marx then showed the map of Lyme's geographic distribution, which only singles out 15 states in yellow – 95% of cases. The old adage, a picture is worth 1,000 words is often used in advertising to communicate ideas that in seconds convey the advertisers message which is, buy what I am selling, no time for the facts. Looking at this map quickly, a harried health care provider or anyone for that matter, can readily conclude Lyme is not a problem in other states. Tens of thousands of Lyme patients have been victims of that erroneous message and continue to be denied or have delayed diagnosis and treatment because of the false assumption that Lyme "doesn't exist" in their state.  As pointed out by *MyLymeData Patient Registry,* 72% of patients see four or more physicians before diagnosis and 35% see more than 10. Much of that undoubtedly relates to diagnosis by geography, since patients in low incidence states are often forced to search everywhere in-state to find a doctor not afraid and willing to diagnose and treat Lyme but often end up traveling cross country to get help for their disease.

The WG *Access to Care* 2020 Subcommittee, which I co-chaired, reported to the HHS WG that some of the states believed by CDC to be low incidence for Lyme have some of the highest numbers of insurance claims for Lyme. Citing a Wall Street Journal article featuring a Fair Health study which used a data base of 150 million privately insured individuals, the report indicated in 2016, North Carolina reported 32 Lyme cases to the CDC but made 88,539 health-care claims for a Lyme diagnosis. Also in the report, "…in California in 2016, there were only 90 CDC surveillance cases, while Quest Diagnostics (which is just one of the seven most-used Lyme disease testing labs) reported 483 positive tests, and FAIR Health Data showed insurance claims in the state at close to 47,000, making California one of the top five highest states for Lyme disease insurance claims in the U.S."

Dr. Marx pointed out there are case reports in other states but most are travel related. Several years ago I provided CDC with their own reported case numbers over time from the "other than 15 states." I asked CDC to provide me with data they had proving that most of these cases were travel related. The response: they did not have such data. On the 2nd Working Group, I tried to introduce a Recommendation to Congress that CDC go to the Council of State and Territorial Epidemiologists–who allegedly have control over surveillance criteria guidelines–and ask them to examine the validity of the "diagnosis by geography" portion of the Lyme surveillance criteria based on the inability of patients to get diagnosed due to it. CDC and other agencies at the WG table refused to agree to that reasonable request being put into a recommendation. The only conclusion I can come to is, government does not want Lyme disease to be found outside certain boundaries. They will do and have done everything in their power to prevent it from being found outside their proscriptive boundaries–turning their backs on patients who live there.

**ONE DOSE OF DOXY SOLUTION** Lyme disease prophylaxis was another topic included in the webinar. In order for a doctor to determine if prophylactic treatment should be used for a bite, 5 questions were listed:

1. Where the tick bite occurred, are ticks likely to be infected with *Borrelia burgdorferi*? (Geography)
2. Was tick removal within 72 hours?
3. Was the tick body flat or engorged?
4. Was it an *Ixodes* (blacklegged tick) tick?
5. Is doxy safe for the person?

Regarding the above questions, many people, including some physicians, do not know what a flat vs. engorged tick looks like. I have even heard stories of doctors telling patients you cannot get Lyme disease from a big tick, which at times, turned out to be a partially engorged tick. Many scientists

who work daily with ticks are reluctant to even identify a tick unless they see it physically, not from a picture, and now doctors are asked to identify ticks and determine engorgement. When I pointed out a fully engorged tick hanging from my mom's leg in the hospital years ago, the doctor told me it was a mole. I was certainly surprised to find moles had 8 legs…. As to attachment time, most people remove a tick immediately upon finding it and have no idea how long it has been attached.

The discussion of prophylaxis centered totally on one dose doxy. As I listened to this discussion, I could "see" the treating doctors and advocates cringing as I was at the CDC trying to justify using that protocol. Although they promote that protocol, Dr. Marx indicated CDC does not recommend tick testing for pathogens as a tool—results can lead to decisions about antibiotic treatment without conducive evidence of patient infection. Interesting statement, since arguments could be and have been made that current tests required by CDC don't provide that evidence either. Although there may be some downsides to tick testing, the only tool in CDC's toolbox is the one dose of doxy protocol—based on a single human trial that did not conclude that single dose doxy could prevent Lyme disease only that it prevented an EM rash in a small group of people. Prescribing one dose of doxy may also interfere with any later testing results.

One of the slides contained a link (I accessed after the webinar) entitled *Guidance for Clinicians: Recommendations for Patients after a Tick Bite.* There is a graphic for tick removal then a statement saying "Save the tick for species ID and degree of tick engorgement (important when determining eligibility for Lyme disease prophylaxis)." Under that is "Post- exposure prophylaxis for Lyme disease," the circumstances explaining when a single dose of doxy can lower the risk of Lyme disease— if:

- the bite occurred in a high incidence state [only map

with 15 states highlighted is shown] or in an area where >20% of ticks are infected with Bb—consult your local health department for details
- the tick can be identified based on adult or nymph blacklegged tick
- the estimated attachment time >36 hours based on degree of engorgement
- prophylaxis can be started within 72 hours
- the patient has no contraindication to doxycycline.

Additionally included in the pdf is a ruler, conceivably for the doctor to judge the  size of engorged ticks based on feed time. Almost sounded to me like CDC does not really want to promote one dose doxy as prophylaxis.

**VACCINES** Patients, advocates and doctors have been concerned that vaccine development has been the force behind refusal to develop safe and effective protocols to treat patients. It certainly has influenced Lyme disease testing protocols–almost the same protocols developed at the 1994 Dearborn conference exist today, with Western Blot banding requirements ("CDC bands") for Lyme disease influenced by the then upcoming vaccines, especially LYMErix. Bands never changed even after LYMErix was pulled from the market by its manufacturer, citing poor sales. The CDC webinar described LYMErix vaccine as both safe and effective, stating it was pulled from the market but no mention of why.  Dr. Marx indicated up and coming vaccines could be available in the future. No mention was made of the one in current FDA trials having an Osp A base, yet many felt and still feel that an Osp A base contributed to problems of vaccine recipients that led to the manufacturer withdrawing the LYMErix vaccine.

After 46 years of Lyme disease, the CDC and NIH do not yet know how to accurately diagnose Lyme or treat it successfully, especially when it has prolonged symptoms after 2 weeks of doxycycline.  Vaccines are certainly important tools when proven to be safe and effective and when they have been

developed by a transparent process not being run by the vested interests themselves. The CDC wants to have those vaccines at all costs—with billions made by manufacturers of new vaccines, even when there are potentially viable treatments in sight for Lyme but not being explored.  NIH is no different in that regard.

**RASH, TREATMENT, TESTING** You can listen to the webinar sections yourself about the EM rash issue, treatment, and testing. Most are too painful for discussion here by me, but I mention two issues. So much emphasis is placed upon the rash in diagnosis, so rashes should have been explained and pictures shown not just with a central clearing (bull's eye), but also without central clearing (not a bull's eye).  On one of the testing slides, it said, "should patients be tested for Lyme disease: look at pretest probability." Then, doctors should ask if patients have been in an area where Lyme is common, were likely exposed to ticks, and have symptoms characteristic of Lyme disease. If the answer to any of these questions is no, pretest probability is low, and testing is not advised. If all three answers are yes, moderate to high probability exists, and testing may be helpful depending on disease stage.  Based on that scenario, no testing for those in low incidence states for sure.

**COINFECTIONS**  Webinar co-infection advice is to talk to your local health department about them in your area. I personally ask that you please contact CDC if you do contact your health department and let CDC know how that advice works.  Since testing of ticks has not been undertaken in many states, and some coinfections are not known or even reportable, this advice can also be a deterrent to patients receiving proper diagnosis and treatment.

**NIH STUDIES** The CDC cites only NIH studies of long-term antibiotic treatment and their conclusions which do not show benefit but can be harmful. No mention of recent research which indicates otherwise or of rebuttals to those studies. At

the 2nd term HHS WG table, I fought tenaciously but successfully to keep in the *2020 Report to Congress* papers/opinions which contradicted those NIH findings, as NIH and CDC battled to keep them out.

**HOW TO CARE FOR THOSE ON NOT RECOMMENDED TREATMENTS** The slide 43 minutes in on "How I can care for my patients who are receiving treatments that are not recommended for Lyme disease," will most likely be the last straw for many. Not recommended by whom? Clearly there are published guidelines that meet National Academy of Medicine (formerly IOM) specs that support clinical judgement in treatment of Lyme disease. The first bullet of six is "to listen to the patient's story," the last bullet is to 'evaluate the risk of Lyme disease and consider an alternate diagnosis." This slide is accompanied by Dr. Marx's commentary not on the slide, "the goal is to demonstrate empathy and compassion…." In my 37 years of Lyme advocacy, I haven't seen that happen yet, and treatments are still withheld.

**BOTTOM LINE** The non-inclusion of patient input into this webinar is probably a good thing after all. No self-respecting patient or advocate would want their names tied to this webinar, especially when they read the slide below—a slap in the face to the hundreds of thousands of patients whose lives have been saved or vastly improved with long term-treatment and to the brave physicians who put their practices on the line to help patients get better.

**Post-Treatment Considerations** (slide)

- There is no proven treatment for post treatment symptoms:
    - Additional prolonged antibiotics have not been shown to improve long-term outcomes
- Long term antibiotic therapy has the potential to cause serious side effects, including:

- infectious diarrhea
- antibiotic resistance
- line associated infections

More than **two** courses of antibiotics are **NOT** recommended for the treatment of Lyme disease.

**RESPONSIBILITY** Who's responsible for this decades-long Lyme fiasco? The blame must be laid at the feet of an alliance of public health and some powerful medical "experts," who have allowed cases to go from 9,908 reported in 1992, to an estimated 500,000 cases annually. While actively seeking to build public trust with the LymeX public-private partnership, public health has not even lived up to its commitment to recommendations they supported on the WG, like CDC including patient input into educational programs. Yet they court the public/advocates so there will be funds allocated to government agencies to ostensibly provide help to patients. Then they use our public dollars to deny many patients the ability to get early diagnosis and appropriate treatment. Disingenuous? With so many lives at stake, that word seems too kind.

**Click here for CDC slides and for a video of the webinar**

**Click here for Tick-Borne Disease Working Group 2020 Report to Congress**

**Click here for Pat Smith's minority response: Effect of Geographic Restrictions on Lyme Diagnosis**