Reflection and Reaction

Controversy brewing over Lyme disease testing

By objective criteria it is a moot point whether any diagnostic test on an individual patient is positive or negative when the tests are unreliable.1 In this position other forms of assessment of whether a patient has Lyme borreliosis or not are brought into action. Unfortunately, much of the other information available to assist in diagnosis relies on subjective assessment as to whether the patient was at risk or not. Subjective evidence, however, could turn out to be unreliable if unknown factors are at work.

The crux of the argument centres on the interpretation of laboratory tests—should they be regarded with suspicion as presenting too many false positives, or alternatively, are many of these cases true positives? If the former holds true, then perhaps many patients could be receiving unnecessary treatment with antibiotics, which for some may present a certain degree of risk. If the latter holds true, many patients are going untreated and left to progress into an illness not unlike syphilis in its later effects.

From the point of view of the patients, and those yet to find themselves with the disease, the latter is a far worse outcome. Who can blame anyone who insists on presumptive treatment when they are suffering typical symptoms? More humane acknowledgment of the awful predicament that patients find themselves in would be appropriate from those bodies whose duty it is to guard public health.

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In the October 2005 issue of The Lancet Infectious Diseases, Roxanne Nelson reported about the unreliability of standard testing for Lyme disease. Paul Mead, an epidemiologist at the US Centers for Disease Control and Prevention (CDC, Atlanta, GA, USA), expressed concern about newer Lyme disease assays “whose accuracy and clinical usefulness has not been adequately established”. Curiously, Mead seems totally unconcerned that the CDC’s reporting methods miss more than 90% of Lyme cases.2,3

Lyme disease, the most prevalent vector-borne illness in the USA, has become a major health-care problem, not because of laboratories that offer fully approved testing with increased sensitivity, nor because of physicians who are willing to treat Lyme patients based on clinical and laboratory evidence. The problem lies with government agencies like the CDC that sit on their hands in the face of a growing crisis, ignoring the undisputed need for better testing and taking pot shots at the messengers of Lyme awareness.

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Roxanne Nelson’s Newsdesk article contains the following misleading statements regarding the position of the US Centers for Disease Control and Prevention (CDC).

First, Nick Harris (IgeneX) is quoted as saying: “The CDC says the two tiered system works for Lyme victims... who have an erythema migrans rash”. The CDC does not recommend routine serological testing of patients with erythema migrans, in part because of low sensitivity at this early stage of illness.2 In the appropriate setting, such patients can be diagnosed and treated without the delay and expense of laboratory testing.3,5

Second, the article states that: “In chronic or late stage Lyme disease, the percentage of positive EIA is much lower [than 70%]”. This curious statement contradicts the preponderance of scientific literature as well as a...
basic understanding of immune responses.

Finally, Harris says: “The CDC claims that the PCR is not useful in the diagnosis of Lyme because of its low predictive value”. At issue is the testing of blood and urine by PCR.7 Although PCR can be highly specific, specificity alone does not determine the clinical utility of a test. Other factors include sensitivity, reproducibility, correlation with clinical illness, cost, and whether the same conclusions can be drawn based on clinical grounds or standard serological testing. A meta-analysis and recent evaluations have concluded that the scientific literature (not just the CDC) does not support the diagnostic utility of blood and urine PCR as a method for diagnosing Lyme disease.6,8,9

Paul Mead

Gates Foundation provide cash injection for malaria research

Pam Das’s December 2005 Newsdesk article1 highlights an unfortunate debate in the malaria prevention and control communities—the issue of expanding access to existing tools versus investing in innovation.

The devastating toll that malaria takes on families, communities, and nations cannot be reduced to an either/or discussion. To do so was clearly not our intent. We must scale-up use of existing tools as well as invest in research and development for future interventions. To overcome diseases affecting the industrialised world, we do both. We should do no less for diseases primarily affecting poor countries.

The Malaria Vaccine Initiative and Medicines for Malaria Venture operate from a conviction that, to defeat malaria, we need a comprehensive strategy. Current efforts to control malaria—especially drugs and drug combinations, insecticide-treated nets, and IRS

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