Controversy brewing over Lyme disease testing

In the October 2005 issue of *The Lancet Infectious Diseases*, Roxanne Nelson reported[1] 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.

Steven E Phillips, Joseph J Burrascano, Richard Horowitz, Virginia R Savely, Raphael B Stricker

SEP is president of the International Lyme and Associated Diseases Society, Bethesda, MD, USA. JJB, RH, VRS, RBS are also at the International Lyme and Associated Diseases Society.

Correspondence to: Dr Raphael B Stricker, International Lyme and Associated Diseases Society, PO box 341461, Bethesda, MD 20827-1461, USA. rstricker@usmamed.com

1 Nelson R. Controversy brewing over Lyme disease testing. *Lancet Infect Dis* 2005; **5:** 605.

2 Meek JI, Roberts CL, Smith EV, Cartter ML. Underreporting of Lyme disease by Connecticut physicians, 1992. *J Public Health Manag Pract* 1996; **2:** 61–65.

3 Boltri JM, Hash RB, Vogel RL. Patterns of Lyme disease diagnosis and treatment by family physicians in a southeastern state. *J Community Health* 2002; **27:** 395–402.

Roxanne Nelson's Newsdesk article[1] 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[6] as well as a 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.

Stephanie Woodcock

SW is Chairperson, Lyme Disease Action, Registered Charity number 1100448.

Correspondence to: Mrs Stephanie Woodcock, Lyme Disease Action, PO Box 235, Penryn, TR10 8WZ, UK. woodcocks@lymeuk.eclipse.co.uk

1 Nelson R. Controversy brewing over Lyme disease testing. *Lancet Infect Dis* 2005; **5:** 605.

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

Correspondence to: Dr Paul Mead, Centers for Disease Control and Prevention, **[Au: street address?]** Ft Collins, CO **[Au: zip code?]**, USA. **[Au: tel/fax numbers?]** pmead@cdc.gov

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2 Centers for Disease Control and Prevention. Lyme disease diagnosis. http://www.cdc.gov/ncidod/dvbid/lyme/ld_humandisease_diagnosis.htm (accessed Jan 20, 2006).
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6 Aguero-Rosenfeld ME, Wang G, Schwartz I, Wormser GP. Diagnosis of lyme borreliosis. *Clin Microbiol Rev* 2005; **18:** 484–509.
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Gates Foundation provide cash injection for malaria research

Pam Das's December 2005 Newsdesk article[1] 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 **[Au: please define]**—have been substantially bolstered over the past few years. The international community must further increase funding for current interventions to prevent death and suffering from malaria now.

Malaria has eluded efforts to control it in Africa for millennia, so a comprehensive strategy must also include innovation—eg, better drugs, better insecticides, and a vaccine—to defeat this scourge on poor countries.

New tools or existing tools? Clearly, we need both.

Jeff N Haskins, Chris Hentschel, Melinda Moree

JNH is at Burness Communications; CH is CEO, Medicines for Malaria Venture; MM is Director, PATH Malaria Vaccine Initiative. Correspondence to: Jeff N Haskins, Burness Communications, **[Au: street address?]** Bethesda, MD **[Au: zip code?]**, USA. **[Au: tel/fax numbers?]** jeff@burnesscommunications.com

1 Das P. Gates Foundation provide cash injection for malaria research. *Lancet Infect Dis* 2005; **5:** 743.