

PHE recognises that patients and patient groups question the sensitivity of the diagnostic tests it and the NHS use to identify Lyme disease. This is in part because results from these national laboratories do not always agree with the results issued by private diagnostic laboratories. However, the European External Quality Assessment scheme results for PHE and NHS laboratories are comparable with accredited national laboratories across Europe and are a mandatory requirement for all laboratory testing in the NHS as part of best practice.

PHE is also participating in a side-by-side evaluation of all relevant commercial Lyme serology essays that are being led by the Australian government. PHE continuously evaluates new Lyme serology tests and will validate and implement new tests if appropriate. A study of several screening tests used by different NHS laboratories showed no significant difference between the different commercial products used in the UK. PHE has two PhD students at the University of Liverpool, who are investigating the diagnostic potential of new tests and novel testing approaches. It has also offered to work with scientists and patient groups to carry out robust side-by-side evaluation of its Lyme tests and those promoted by others.

The issues with diagnostic tests are not unique to Lyme disease and relate to biology rather than technology. The Lyme bacteria can be detected in the skin in the rash by a biopsy in around 50 per cent of cases, the sensitivity depending on hitting the right spot for the biopsy. The organism is present only transiently in human blood, and at very low levels, so blood tests are of little value to detect acute infection. Current tests therefore rely on detecting the antibody response to the infection, which in Lyme disease, as in most other infectious diseases, appears a few days after the symptoms. For this reason, GPs are advised to treat patients with the characteristic rash or with symptoms and a credible history of possible exposure to ticks without waiting for diagnostic tests, which are therefore not usually requested. The antibody response varies between individuals, but the most common antibody, which is consistent across virtually all cases, is covered by the C6 antibody screen. The blot adds additional information, and may be useful in early and late cases, so is used by PHE. PHE uses a C6 screen, with additional confirmatory testing with a blot, for this reason.

The challenge is to find tests that are sensitive, but specific for Lyme disease. The main issue with many of the methods put forward by different groups is that they

lack data on what other diseases or conditions would give a positive answer, or how many 'normal' people would also test positive. In order to improve diagnostics, PHE is investigating the use of improved scientific techniques to find the organism in blood and other samples. It is also studying possible targets for new antibody tests that may increase the chance of detecting a response. PHE is working with colleagues in the Czech Republic to obtain a wider range of samples, and clinical presentations to study, as the case incidence there is several times higher than in the UK. It is also working with Liverpool University and colleagues in the US looking into the disease. This work is likely to take several years to complete.

PHE has published and distributed a letter to GPs to raise awareness about Lyme disease, and has begun a series of GP training days, which will be expanded over the next few months. The patient charity Lyme Disease Action has an e-learning module for GPs, which is recommended by the Royal College of General Practitioners, and PHE also has a clinical helpline for doctors.

Both the Department and PHE are aware of an increase in concern about Lyme disease, which is reflected in an increasing number of media articles about the disease, celebrity campaigns and enquiries to PHE and the Department. PHE and Lyme Disease Action are increasingly concerned about the increase in misinformation that has accompanied some parts of this activity. As a result, PHE will work with NHS colleagues to increase awareness in the medical profession and to see how access to specialist services for Lyme disease patients could be further improved.

Finally, the Department has commissioned the National Institute for Health and Care Excellence to prepare national guidance for the recognition and management of Lyme disease, which will be available in 2018.