

PE1662/A

Lyme Disease UK submission of 24 October 2017

Thank you for your request for our response to the above petition. As the co-founder of Lyme Disease UK, we are fully in support of the petition and urge the Scottish Parliament to ensure all of the suggested actions are implemented as quickly as possible.

Lyme Disease UK is a not-for-profit organisation founded with the aim of supporting patients. We:

- actively promote awareness of prevention measures, tick removal, and early symptoms by website information, leaflet distribution, hosting stands at events and conferences and other public awareness measures
- provide a support mechanism to assist the general public to help identify the early symptoms and the progression of symptoms that may occur with Lyme disease and co-infections that may be transmitted by a tick bite.
- are in contact with many of the leading researchers and doctors with a strong interest in Lyme disease.

With respect to the actions suggested in the petition:

Improve Testing

As part of our efforts, we run a patient support Facebook group for those that are struggling to get a diagnosis for their symptoms. We now have almost 8,000 members and the number is rising. There has been an alarming rise in the numbers of chronically ill members who have either been undiagnosed, diagnosed with other non-specific illnesses such as CFS/ME, or diagnosed with Lyme disease and given inadequate treatment or worse, no treatment.

Patients are caught in the middle as many receive negative test results with current UK two-tier testing using ELISA and Western blot. However, they then go on to get positive results from tests from European or US laboratories which are dismissed by the NHS. It then becomes extremely difficult for patients to know which results to believe, especially when they are displaying symptoms of Lyme disease and in many cases, have a history of tick exposure and in some cases, an EM rash for which they never received timely treatment.

Foreign tests which are identifying infections are either covering more strains of borrelia, more strains of co-infections, or are less reliant on immune response than the UK test.

- As stated by the International Lyme and Associated Disease Society, "There are 5 subspecies of *Borrelia Burgdorferi*, over 100 strains in the USA, and 300 strains worldwide." Only 3 of these are classed as more common European strains. Patients may be infected with other strains which current UK testing does not identify.

- Members are also finding they are co-infected with strains of infections such as babesia (parasite), bartonella or ehrlichia, for which testing is not available in the UK. For example, Dr. Richard Horowitz has stated that many of his European patients who remain sick after treatment are found to be infected with babesia duncani, for which there is no UK test. We have a list of some of the co-infections on our website at: <https://lymediseaseuk.com/co-infections/>
- Lyme disease and multiple co-infections can suppress the immune system, especially in patients co-infected with infections. In such cases, a test which does not rely on immune response has the potential to pick up more cases than the current UK test.

The patients who are getting different test results abroad compared to the UK are perhaps amongst the sickest with an extremely alarming collection of debilitating symptoms. We therefore believe that improved testing is an important factor in allowing patients to receive treatment within the UK.

Testing should be extended to include all known strains of borrelia found in the UK, e.g., borrelia miyamotoi, which is not included in current testing. Alternative tests should be evaluated. These include the MELISA test (<http://www.melisa.org/>), the ELISpot test (<https://www.arminlabs.com/en/tests/elispot>), the Nanotrap Lyme Antigen test (<http://www.ceresnano.com/nanotrap-lyme-test>), and biomarkers such as CXCL13 (<http://www.euroimmunblog.com/cxcl13-novel-biomarker-for-neuroborreliosis/>).

Testing should also include multiple strains of co-infections such as babesia, e.g., babesia duncani. A recent veterinary study (<https://www.ncbi.nlm.nih.gov/pubmed/28917304>) found a range of species of borrelia and babesia in ticks infesting cats in the UK. Babesia testing can be unreliable but we would like to see the babesia FISH assay (<https://www.igenex.com/testing/diagnostic-tests-for-babesiosis/>) evaluated for use in the UK.

A first step which could be taken very easily is to provide the resources to give Raigmore Testing Laboratory the status of Reference Laboratory and to extend its remit to cover all tick-borne infections, particularly babesia.

Improve Treatment

We agree that guidelines are needed which cover all tick-borne infections and which acknowledge the persistent nature of the Lyme bacteria. We are strongly in support of the point of view of the International Lyme and Associated Diseases Society. They state (<http://www.ilads.org/lyme/about-lyme.php>) that "Many patients with chronic Lyme disease require prolonged treatment until the patient is symptom-free. Relapses occur and retreatment may be required."

Patients who get diagnosed early and given adequate treatment are often treated successfully. However, we find that patients in which early diagnosis is missed go on to develop debilitating chronic symptoms which are not

relieved by the standard treatment. Guidelines should ensure that patients are not abandoned by the system, an experience all too common amongst our members.

NICE have recently issued draft guidelines on Lyme disease. However, the scope was narrow and they do not address patients who may be infected with multiple co-infections or who may have persistent infection. The draft guidelines also reveal just how much research is needed to develop treatment protocols and how poor the current evidence is.

In the absence of a truly reliable test and given that new species of borrelia and co-infections are being identified regularly, Lyme disease should be a clinical diagnosis based on patient symptoms, signs and history. It is our experience that doctors are not confident in making a clinical diagnosis of Lyme disease, and yet are quick to dismiss the possibility of a borrelia infection. Patients are not being informed about the issues with testing or the fact that there is no known cure for Lyme disease. Doctors are not given the flexibility to extend treatment protocols and patients are not given the option to undergo experimental treatment unless they pay for it privately and consult doctors with clinical experience in successfully treating the illness.

The suggestion of a specialist treatment centre would be very useful to patients. Many patients are also suffering from mitochondrial issues, immune suppression, multiple chemical sensitivities, and a host of other complications. A team of specialists who could address all such issues and log patterns seen in Lyme disease patients would be of great benefit.

Research will be key to achieving better outcomes for patients. The NICE draft guidelines authors have stated “There is currently insufficient quality evidence on the most effective drug and dose, and the effectiveness of extended treatment or retreatment regimens in those with continuing symptoms remains uncertain.” It would greatly benefit patients with continuing symptoms if such research was to take place urgently. Persistence of borrelia has been demonstrated in vitro and in animal studies (<https://www.nature.com/emi/journal/v4/n8/full/emi201551a.html>). Many private Lyme disease practitioners believe that persistence is the reason for patients' continued symptoms, despite treatment. Research into the mechanisms of persistence would greatly help in finding a cure.

Improve Education

Lyme Disease UK and its members are actively involved in public awareness. However, sick volunteers cannot be expected to provide sufficient nationwide awareness. Public resources need to be put into educating the public. Ensuring appropriate information is available at visitor centres, etc., would ensure that the awareness is extended to tourists who may not have access to other forms of education.

GPs need to be educated to ensure they recognise the wide range of non-specific symptoms which often fluctuate and rotate in Lyme disease. Dr. Richard Horowitz has written a book “How Can I Get Better?” which addressed the issues he faces in treating patient with tick-borne infections. In

it, he provides a MSIDS (Multiple-Systemic Infectious Disease Syndrome) questionnaire (<http://docs.google.com/viewer?a=v&pid=sites&srcid=ZGVmYXVsdGRvbWFpbnxjYW5nZXRiZXR0ZXlyfGd4OjViM2FhOTFjYWVviY2RmNzI>). Basing education on this questionnaire would give GPs a framework to use for diagnosis and treatment.

We urge you to develop a Scottish National Plan for Tick-borne Infections, similar to the French National Plan for Lyme (<http://solidarites-sante.gouv.fr/archives/archives-presse/archives-communiques-de-presse/article/marisol-touraine-lance-le-plan-national-de-lutte-contre-la-maladie-de-lyme-et>) and to include co-infections. The French plan includes many of the measures suggested in the petition: information panels at the entrance to forests; training of health professionals on tick-borne diseases; providing doctors with a standardized assessment describing the list of examinations allowing a complete diagnosis in anyone with evocative symptoms; implementation of a national diagnostic and care protocol to ensure standardized care for patients throughout the country; specialized treatment centres opening in 2017, bringing together all the specialties involved (these centres will also be a place of training for professionals); development of diagnostic research; and in-depth research to better understand all the diseases transmitted to humans by ticks, to identify the clinical symptoms and to provide tools for a better management of patients.

The French Plan goes further by including implementation of a "smartphone" application to report the presence of ticks and the establishment of a cohort of patients attending specialized treatment centres, to improve scientific knowledge of the disease. Lyme Disease UK would support the use of patients to help improve scientific knowledge and would be happy to help facilitate this.

Many of our members with late-stage Lyme Disease are unable to work, not to mention the strain it has had on family life, careers, and social life. These patients are seriously ill and left to fall through the cracks of the system. The burden on the society is very large. Many patients have seen over 20 different consultants, taking up significant NHS resources but without a resolution of their symptoms. They are often claiming disability and unemployment benefits and do not contribute to tax revenues. Some have had to close down or reduce the scope of their businesses, resulting in the loss of employment for others. By tackling this problem correctly, they could become active, contributing members of society and the economic burden could be significantly eased.

We are happy to answer any further questions you may have and we thank you for allowing us the opportunity to respond.